Welcome!!

The VA, and Research in general, is full of rules, regulations, guidance, policies, acronyms, etc. We will never be able to keep up with the constant changes nor we will be able to include everything in this document. We will, however, try our best and remind you that there is no such thing as a thoughtless question if you don't know the answer.

Let's start with the basics:

Clinical Trials Unit & the Veterans Research and Education Foundation

WHAT IS THE VETERANS RESEARCH and EDUCATION FOUNDATION?

The Veterans Research & Education Foundation (VREF) is a Nonprofit Research and Education Corporation (NPC). NPCs are VA-affiliated non-profit corporations that provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. This means VREF administers all money for medical research and education projects done in the VA that is NOT VA money. For example, money that comes from pharmaceutical companies (Novartis, Pfizer), private foundations (Michael J. Fox Foundation), Universities, or from other federal entities (Department of Defense).

More information about the Veterans Research and Education Foundation can be found at https://www.vrefstl.org/

VHA Research Overview: Office of Research & Development (ORD), Office of Research Oversight (ORO), & Types of Research Funding

The Office of Research and Development is part of the Veterans Health Administration (VHA) and currently includes four Research Services with the primary responsibilities of handling the reviews of projects and programs submitted for funding consideration, as well as items specifically related to investigator needs. These include:

- **Biomedical Laboratory R&D**: Supports pre-clinical research to understand life processes from the molecular, genomic, and physiological level regarding diseases affecting Veterans
- **Clinical Sciences R&D:** Supports clinical trials and other research to determine the feasibility or effectiveness of new treatments (e.g., drugs and devices), compare existing therapies, and improve clinical practice and care
- **Rehabilitation R&D:** Supports research to develop novel approaches to restore Veterans with traumatic amputation, central nervous system injuries, loss of sight or hearing, or other physical and cognitive impairment to full and productive lives
- **Health Services R&D**: Supports research at the interface of health care systems, patients, and outcomes examining all aspects of VA health care (e.g., quality, access, patient outcomes, and costs)
- ORD Enterprise-level programs that support scientific work:

- The **Cooperative Studies Program (CSP)** is ORD's flagship clinical research enterprise division specializing in multisite clinical trials and epidemiological research on health issues of vital importance to Veterans.
- The **Million Veteran Program (MVP**) is ORD's most recent group that focuses on genomic research and maintains a national infrastructure for biospecimens, data and analysis. Both programs work with the ORD services on conducting highly innovative approaches to addressing problems for the VA healthcare system and nation.
- The **Office of Research Protections, Policy, and Education (ORPP&E)** was created to protect participants in VA human research. ORPP&E is responsible for:
  - All policy development and guidance for human research protection in the VA
  - All training and education in human research protection throughout the VA
  - Creating and implementing the VA Central IRB

The **Office of Research Oversight (ORO**) is dedicated to promoting the responsible conduct of Department of Veterans Affairs (VA) research for the protection of Veterans and others who volunteer in VA research, and for the benefit of all Veterans whose health and well-being are improved by the discoveries made through a sound and ethically grounded VA research program.

ORO monitors, reviews, and investigates matters of research compliance that involve VA research. Specifically, ORO provides oversight of compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct.

The VA St. Louis HCS Medical Center Director submits a report to ORO every year.

ORO also provides training to facility Research Compliance Officers (RCO) and oversight of RCO auditing programs.

- When the Research Compliance Officer (RCO) reveals a compliance issue he or she may take it up with the AO, ACOS/R&D, or other administrative sections in Research Service to correct the problem. There may be reporting requirements.
- The RCO reports to the MCD and research compliance works best when the RCO and the Research Office work together to identify and correct problems, as they arise and educate investigators how to do the right thing.

Types of Research Funding

- **VA Funds** (Issued by VA Office of Research and Development directly to and administered by the VA facility. For example, VA grants)
  - For all VA services: Must be a US citizen eligible for VA employment
  - Must have a 5/8ths VA appointment (or approved waiver) to accept the award

- For BLR&D: Clinicians are automatically eligible to submit; Non-clinicals must apply for eligibility

- **Federal Funds** (Issued by agencies such as NIH, DoD, CDC, NCI and administered by the Veterans Research and Education Foundation)
- **Educational Grants** (Issued by various entities, such as the Missouri Foundation for Health, Washington University Grants, etc., and administered by the Veterans Research and Education Foundation)
- **Private Grants** (Nonprofit Corporations (NPC), private industry, pharmaceutical companies, etc., and administered by the Veterans Research and Education Foundation)

VA Directives, Handbooks, & Policies

The mission of VA Research is fourfold:

- to improve Veterans' health and well-being via basic, translational, clinical, health services, and rehabilitative research
- to apply scientific knowledge to develop effective individualized care solutions for Veterans
- to attract, train, and retain the highest-caliber investigators, and nurture their development as leaders in their fields
- to assure a culture of professionalism, collaboration, accountability, and the highest regard for research volunteers' safety and privacy

Whether you work for the Foundation or the VA, use a commercial or local IRB, VA Directive 1200.05 (Requirements for the Protection of Human Subjects in Research) and 1605.01 (Privacy and Release of Information) are the overarching set of rules that we abide by.

Every Policy, Form, Guidance and SOP that we refer to are derived from VHA Directives.

Link to VHA Directives: https://www.va.gov/vhapublications/publications.cfm?pub=1

- VHA Directive 1200.05: Requirements for the Protection of Human Subjects in Research
- VHA Directive 1605.01 Privacy and the Release of Information

Link to VHA Handbooks: https://www.va.gov/vhapublications/publications.cfm?pub=2

Local SOP's: \\vhastlfpcres01\Research2\Research_Folders\SOP\Standard Operating Procedures SOPs

WHAT IS NEEDED TO GET STARTED?

All personnel (VA paid or WOC) will work with the Research Training Coordinator to complete all required annual research trainings, a current Scope of Research Practice, and CV/resume/bio sketch.

Training & Personnel Documents:

- TMS Training (Privacy & HIPAA, Information Security Awareness, Government Ethics, etc.)
- CITI Training (Human subjects protection)

- PIs and all project staff must complete CITI training requirements for VA.
- The courses required depend on the type of project you will be working on, for example:
  - CITI courses include human research, species specific animal trainings, post procedure care of rodents, biosafety training, biosecurity training, waste anesthetic gas training, Department of Transportation shipping training, radiation safety training, and Conflict of Interest training (required for all PIs and staff).
- Additional trainings may be required:
  - TMS SRS Training Modules
  - Sponsor Study specific trainings (to be completed once study personnel is added to the study)
- Scope of Research Practice
  - Please see the templated Scopes of Research Practices for new employees, located in the Appendix
- CV
  - Required for all research personnel
- Medical/Nursing License (Required yearly)
  - Current CV/Resume

Access to VA Infrastructure

- **Physical accesses:**
  - Keys to employee Office, CTU, etc.
  - Parking lots
    - Parking References located in the Appendix
  - Employee Phone, Computer, Printer, etc.
  - Employee provided with day-to-day office supplies, such as pens, stapler, highlighters, tape, binders, binder sheets, etc.
  - List of current Research Staff/personnel, job title, and contact information will be provided by the Research AO or CTU Manager

- **Technological accesses:**
  - Computer/PIV badge/VA log in
  - Research ADPAC to assign access codes & E-pass for new research employees
  - Network Printers *(Please refer to Section 7 for Guidance on how to Map a Network Printer to your PC & additional information on Shared and Personal Drives)*
  - Access to CPRS, JLV, VistA, Microsoft Office 365, & Adobe Prov privileges
  - Access to One Drive (for personal use only; Ex: saving current personal CV/training certificates, etc.; All study related documents should only be stored on the Research Drive)
  - Access to ClinCard (Issued/granted by the VREF Executive Director as needed) Set up account in IRBNet Registration Instructions (Please refer to Section 22 of the manual as well as the IRBNet registration instructions located in the Appendix)
  - Set up account with Commercial IRBs (ADVARRA, Sterling; as needed)

WHAT IS THE ROLE OF THE CLINICAL RESEARCH COORDINATOR (CRC)/NURSE?

Working for the St. Louis VA Department of Research and Education allows the Clinical Research Coordinator/Nurse (CRC/CRN) to focus on patient specific duties as designated by the Principal Investigator(s) (PI). Every study protocol is different however, all Research demands the following:

- Adherence to research ethical and regulatory standards.
- Maintenance of records of studies as per VA & FDA guidelines. *(Please see section 20 of the manual regarding storage of research records)*
- Protection of study subjects' Protected Health Information (PHI) and Personally Identifiable Information (PII).

Although the Principal Investigator (PI) is ultimately responsible for the conduct of the study at the site, the CRC/CRN:

- Has full understanding of the protocols that are assigned to the CRC/CRN as the Lead and working knowledge of those that the CRC/CRN are assigned as back-up.
- Develops, completes, and collects accurate source materials.
- Manages subject recruitment and schedules all research related visits.
- Prescreens/screens subjects for eligibility based on protocol inclusion/exclusion criteria.
- Participates in/conducts the informed consent process.
- Maintains a patient specific study binder
- Maintains study specific regulatory binder
- Is the primary contact for study subjects, outside laboratories regarding findings, and study Sponsor/CRO.
- Accurately collect and enter data into the study's eDC (electronic data capture) as required by protocol.
- Ensures that all study subjects are appropriately documented and compensated (if applicable) after each study visit
- Reports AEs, SAEs and protocol deviations as required by the VA Research Department/VREF, IRB of Record and study protocol.
- Ensures that the necessary supplies and equipment for a study are in stock, in date and in working order.
- Works collaboratively with the Regulatory Staff to support the maintenance of accurate regulatory documents.
- Conduct in-services for Service Line, Nursing Unit or Department Staff if a study will impact their daily workflow.

- Collection, shipment and processing of specimens
- Collection and documentation of vitals
- ECG collection
- Ordering and stocking of CTU supplies
- Maintenance of CTU equipment
- May also serve the role of Coordinator on Minimal Risk trials

In addition to completing all study related clinical tasks as assigned by the PI and the study protocol, the CRC/RN is also responsible for the following:

- Prepares documents including but not limited to drug applications, initial protocols, amendments, renewals, progress reports for submission to applicable government agencies and IRBs for obtaining approvals required to initiate and conduct clinical trials
- Interact with the Primary Investigator (PI) and IRB to facilitate submissions, modifications, renewals, end of study reports, etc. for the research protocol.
- Coordinates and participates in all site selection, initiation, interim monitoring and close-out site visits.
- Participate in all research, staff, and multi-disciplinary meetings as applicable to assigned trials.
- Maintains accurate and essential documents per study as required by the VA, FDA, IRB, sponsor and other regulatory bodies or funding agencies.
- Submits and maintains any applicable ancillary committee approvals.
- Maintain and store essential staff documents including CV, license, training and site laboratory certifications
- Develop appropriate regulatory reports and associated documentation in accordance with standard operating procedures (SOP) and study specific processes.
- Compile and submit reports, documents, and correspondence as necessary to the IRB, sponsor and CRO.
- Utilize IRBNet for submission of all regulatory documents

WHAT KINDS OF CLINICAL TRIALS DOES THE VA ST. LOUIS DEPARTMENT OF RESEARCH AND EDUCATION & VREF ADMINISTER?

Clinical trials can be classified in multiple ways. Following are some of the different categories and general descriptions:

Treatment Research

Involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.

Prevention Research

Looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.

Diagnostic Research

Looks for better ways to identify a particular disorder or condition.

Industry Sponsored Trials (Sponsor)

Manufacturers of test articles (pharmaceuticals, devices or tests) fund and run these clinical trials which are opened at multiple sites/countries functioning independently of one another. Protocols are written, data collected, and the study analyzed by the sponsor/CRO. Test articles are provided by the sponsor when they are being used "investigationally". The sponsor is responsible for filing of new drug applications, label changes and device approvals with the FDA.

Multi-Center Trials

Involves the implementation of the same clinical trial at two or more independent investigational sites where participants are seen for an intervention and/or outcomes assessment. These studies have multiple PIs and each is responsible for the conduct of research at their own site.

Investigator Initiated Trials (IIT)

A clinical trial in which the investigator conceives the research, develops the protocol, and serves as sponsor investigator. The sponsor investigator initiates and conducts the clinical trial – alone or with a team. It's under the sponsor investigator's immediate direction that the investigational product (if any) is administrated, dispensed to or used by a subject. Can be funded through pharmaceutical companies or grants received by the investigator.

Phases of clinical trials

- Phase I trials
  Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
- Phase II trials
  The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

- Phase III trials
  The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- Phase IV trials
  Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.
- Other kinds of clinical research: Chart review studies, sample collection/analysis, etc.

Randomized Control Trial

A study design that randomly assigns participants into an experimental group or a control group. One of the interventions may be a standard of care medication, an investigational drug, a placebo, or no intervention at all.

Prospective Cohort

A type of longitudinal study where researchers will follow and observe a group of subjects over a certain period of time to gather information and record the development of outcomes.

Retrospective Cohort

A type of longitudinal study in which researchers look back to a certain point in time to analyze a particular group of subjects who have already experienced an outcome of interest.

Pilot Study

Help identify design issues and evaluate feasibility, practicality, resources, time, and cost of a study before the main research is conducted. It involves selecting a small number of patients and trying out the study on them.

Blinded Study

A type of study in which the patients (single-blinded) or the patients and their doctors (double-blinded) do not know which drug or treatment is being given

Double Blinded

Double blinded is a method of blinding where both treatment groups may receive placebo. For example, one group may receive Treatment A and the placebo of Treatment B; the other group would receive Treatment B and the placebo of Treatment A.

All studies fall into one of the following categories and require R&D and IRB review/approval:

- Exempt (retrospective data analysis, minimal risk)
- Expedited (minimal risk) review studies (don't require full board IRB review)
- Non-exempt (greater than minimal risk) and require full board IRB review

HOW DO WE DECIDE IF A CLINICAL TRIAL IS FEASIBLE AT OUR SITE?

Clinical trial feasibility is a process to evaluate the possibility of conducting a clinical trial in a particular region, specific medical centers/site with an objective of optimum project completion in terms of timelines, targets, and cost.

In most cases, the CTU/Foundation or an experienced PI will be approached by a study sponsor/CRO to assess their interest in being a site for a specific clinical trial. Other times, a physician will "hear" about a study and contact the sponsor directly to express his/her interest in being a local PI.

Prior to release of information by the sponsor/CRO to our site, a Confidentiality Disclosure Agreement (CDA) is executed. A CDA is a legal agreement between the VA and the sponsor which outlines information the parties wish to share with one another and are considering a relationship/collaboration together and need to understand the other's processes, methods, or technology solely for the purpose of evaluating the potential for a future relationship. Upon execution of the CDA, the sponsor/CRO may send us a protocol outline or a final protocol. They may also send additional information depending on their disclosure SOPs. In most cases, they will also send a feasibility questionnaire. This process is completed by the VREF Program Support Specialist.

Feasibility questionnaires are a set of questions prepared by a sponsor/CRO to identify the potential and interest of a site/investigator to run the clinical trial successfully. The questions generally are all encompassing, from potential enrollment numbers to personnel and storage space and everything in between. Once site questionnaires are received from the sponsor/CRO and completed by the PI and CTU Manager, a Pre-Site Selection Visit (PSSV) or Site Selection Visit (SSV) will be scheduled to offer both the sponsor/CRO and the Study Team an opportunity to discuss the protocol prior to making a final decision regarding feasibility for both parties.

Should we be selected as a site, a Cooperative Research and Development Agreement (CRADA) is negotiated. A CRADA is an agreement between the VA and one or more non-Federal parties under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other partner. In exchange, VA may provide personnel, services, facilities, intellectual property, equipment, or other resources, excluding funds, for research and development efforts that are consistent with VA's mission. In other words, a contract. Some sponsors have already established master CDAs and CRADAs with the VA Central Office which allows all local VAs to work with these sponsors without having to re-sign or re-negotiate these agreements.

When a project is funded by a federal entity other than the VA (ex. DOD, NIH, etc.) a prime or subaward agreement is executed rather than a CRADA. Prime and subaward agreements are also contracts under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other partner. In exchange, VA may provide personnel, services, facilities, intellectual property, equipment, or other resources, excluding funds, for research and development efforts that are consistent with VA's mission.

ONCE WE HAVE BEEN CHOSEN AS A SITE, WHAT HAPPENS?

Industry Sponsored Trials (Sponsor)

The sponsor of the Clinical Trial will determine if they be utilizing a commercial IRB (Ex: Advarra) as the IRB of record, not the VA, and is also responsible for paying the commercial IRB directly for the review of our VA site. The VA and VREF cannot pay the commercial IRB for their services. If a sponsor decides that they will not be using a commercial IRB, then the study will be submitted to our local IRB for review and oversight.

The St. Louis VA currently has reliance agreements to work with the following commercial IRBs:

- **Advarra**
- **Sterling**
- **WCG (Submissions through gov.IRBNet; not Connexus)**

The sponsor may also choose to outsource a Clinical Research Organization (CRO) (ex. IQVIA) to assist in the planning, coordination, execution, and supervision of all processes involved in the development of a clinical trial, while being a central contact point between the sponsor and other trial participants (i.e., ethics committees, regulatory agencies, vendors, and hospitals, participating sites, etc.

There are three main steps for project approval when using a commercial IRB:

1. Local VA IRB Acknowledgement and preliminary PO and ISSO review
2. Commercial IRB Approval
3. Local VA RDC Approval

Local VA IRB Acknowledgement and Preliminary PO & ISSO Review

Prior to a new Industry sponsored clinical trial being submitted to a commercial IRB (e.g: Advarra, Sterling, or WCG IRB) for site approval, the VA requires that a local IRB review to be completed. If a Research Coordinator is assigned to the study at start up, they are responsible for preparing the regulatory documents for this review. However, if there is not a Research Coordinator assigned to the study, the Prep Team can assist the PI with this process.

The initial Local VA IRB Acknowledgement and preliminary PO and ISSO review package will be submitted to the "Research Submission" Board in IRBNet to ensure visibility to both the IRB/RDC Administrators.

- The following regulatory documents are typically included in the IRBNet package for review:
    - H-PO Checklist (VA Form 10-250)
    - H-ISSO ERDSP Checklist
    - Sponsor Approved Protocol
    - Sponsor Approved ICF(s) with added VA language in tracked changes

- HIPAA (either combined with ICF or separate VA Form 10-0493)
- VA 10-9012 (is study has an investigational drug)
- Application for partial HIPAA Waiver of Authorization (if applicable for recruitment purposes)
- Copy of Commercial/External IRB Application
- Copy of the Investigator Brochure (if applicable)

Once the IRB administrative Acknowledgement & Preliminary ISSO/PO review have been completed, the PI/CRC will send the ACOS of Research and Education the "VA Facility Endorsement Letter for Commercial IRB Review" for ACOS review and signature.

> *The purpose of the letter is to ensure that the local VA Facility is aware that the VA Investigator is submitting a cooperative study to the ORD-approved commercial IRB and confirmed that neither the VA nor the VREF is contracting directly for the IRB review services provided by the commercial IRB. The commercial IRBs have requested this institutional documentation as part of standard processing of investigator applications.*

Local SRS Submission

Simultaneously, if the Sponsor Protocol also includes any safety components, for example, biological hazards, human cells/tissues (blood, cultures, bodily fluids), rDNA, chemicals, ionizing/nonionizing radiation, etc., it will also need to be reviewed by our Local Safety Research Committee. The PI/CRC will complete Form AA-PRPSS at initial study start up to assist in determining if the study will require review by our Local SRS Committee. Once the PI/CRC fills out the form, it will be emailed to the SRS Administrator (stl.srs.admin@va.gov) for review & signature.

- The following documents are typically included in a separate SRS submission package in IRBNet:
  - Sponsor Protocol
  - Staff Documents
    - Scopes of Research Practice
    - CVs
    - Form M-Financial Conflicts of Interest for Investigators (COIs)
    - Training Checklists
  - Form L-Study Personnel Log
  - Financial Conflict of Interest Determination
  - Form AA-PRPSS (Signed by SRS Administrator)
  - SRS Project Safety and Hazard Assessment Form-For Initial Review of New Projects
  - VA Form 10-0398 Research Protocol Safety Survey
  - SRS – Chemical Inventory Form
  - Annual PPE Form - Hazard Assessment and Personal Protective Equipment Selection
  - Radiation Safety Committee (RSC) Approval (If applicable; any radiation including Standard of Care requires Radiation Safety approval)
  - Institutional Biosafety Committee (IBC) Approval Letter (If applicable)

Commercial IRB Submission

Once the PI/CRC receive the ACOS signed VA Facility Endorsement Letter, they can submit the project for Commercial IRB review and approval. The Study Sponsor and/or CRO will provide the PI/Study Team with a list of documents that will be required for submission.

Local RDC Submission

After the study receives Local IRB Acknowledgment, Local SRS approval (if applicable), & Commercial IRB approval, the PI/CRC, will need to submit the project for Local RDC review. The CRC/PI will create a new package in IRBNet for RDC review. The package will be submitted to the "Research Submission" Board in IRBNet to ensure visibility to both the IRB/RDC Administrators.

- The following documents will be included in the RDC submission package:
    - Sponsor/Commercial IRB approved ICFs/HIPAA with VA language
    - Sponsor/Commercial IRB approved Protocol
    - Sponsor/Commercial IRB approval memo/letter
    - Form AA-PRPSS (if applicable, Signed by the SRS Administrator)
    - Form L-Study Personnel Log
    - Local Research Staff Documents
        - Scopes of Research Practice
        - Current CVs
        - Training Certificates
        - Local Form M-Financial Conflict of Interest Form (PI and Co-I's)

It is recommended that the CRC/CRN wait until all approvals are received prior to scheduling the Study Initiation Visit (SIV).

Investigator Initiated Trials (IIT)

An IIT is a clinical trial in which the investigator conceives the research, develops the protocol, and serves as sponsor investigator. In a standard industry sponsored study, the roles of the sponsor are usually separate from those of the investigator. In an IIT, the same individual usually fills both roles. This person is therefore responsible for the initiation, funding, and conduct of the clinical investigation. Funding for IITs is often competitive via grant applications but can also be supported by pharmaceutical companies.

Although IITs follow, and must comply with, all the same Regulatory rules as an Industry Sponsored Trial, they are essentially a DIY project. All the above referenced documents are necessary and are generally a collaboration between the PI, and CRC/CRN. IITs are reviewed and approved by the VASTL (Local) IRB but may also require FDA or other government agency oversight depending on the funding source, the use of an "investigational" product and/or the intention of the study.

During the IRB review process, the IRB/Reviewer may submit questions and/or comments to the Regulatory Coordinator which must be addressed prior to issuance of an Approval Letter.

Regardless of whether the study is approved by a commercial or the local IRB approved the study, it will then go to the RDC Committee for final approval.

RESPONSIBILITY BREAKDOWN	
Feasibility	CTUCTU Manager, PI, ACOS/AO of Resarch
CRC/CRN	
Delegation/Study Personnel Log	Source Data Agreement
Training Checklists	Recruitment Plan/Agreement
Site Information Forms	Scheduling Site Initiation/Interim Monitoring Visits
Financial Disclosures (COI)	Protocol/Investigation Brochure Signatures
Form 1572	Medical License for PI/Study Team (PRN)

IN THE INTERIM…

Each protocol will have a CRC/CRN and potentially a backup CRC/CRN designated to the study. The CRC/CRN may be designated at the time of study acceptance. However, if there is not a CRC/CRN assigned at the time of study acceptance, the Prep Team can assist the PI with the initial study startup of the project. While the Lead CRC/CRN waits for the final approvals, the sponsor/CRO will be in touch to begin preparing the site to open to enrollment. Most of the work assigned to the CRCs/CRNs by the sponsor/CRO will be in the form of web-based trainings that are specific to the study (eDC/IWRS systems, the technologies such as tablets, laptops, wearables, study portals, etc.). It is the CRC/CRN's responsibility to ensure that the sponsor/CRO is aware of all study staff that need access to the trainings.

Other responsibilities for the CRC/CRN are:

- Preparation of Source Documents ("Docs"), if necessary

  It is important that all information that is collected during a patient visit can be traced back to when and by whom it was first captured. Source data will come primarily through your visit with the study patient but can come directly from medical records, lab tests, study logs, and subject diaries. Source docs help to ensure that all necessary data is captured correctly for proper entry into the eDC and review by monitors and auditors.

  CTU

In some cases, Source docs are supplied by the sponsor/CROs. It is also possible that as technologies are developed, Source docs will become entirely electronic.

Source docs serve multiple purposes:

- Collect data for transfer to the eDC
- Guide to ensure that the CRCs/CRNs collect the appropriate data at each visit
- Provides an auditable link from the eDC back to the original source
- Provides information necessary to answer data queries

Sources for Source Docs preparation:

- eCRF completion guidelines/layouts
- The Protocol Schedule of Events/Assessments which gives a visit-by-visit overview of the study
- The Protocol describes what, how and when to collect data

Information to be included on Source Docs:

- Study number and/or short name, subject initials, study number and visit date
- Enough room to write the data collected legibly
- Units of measure, any instructions regarding timing, confirmation of fasting status, space for writing notes and signature of person collecting the data
- Protocol version that Source Docs are based on
- Page numbers (e.g. Page 2 of 4)

Once done and whenever possible, get a second set of eyes to review the Source Docs and continue to work with the sponsor/CRO to ensure that all study accesses have been granted to the appropriate study staff

WHAT HAPPENS ONCE A STUDY IS APPROVED?

Industry Sponsored Trials (Sponsor)

The PI & CRC/CRN is responsible for working with the sponsor/CRO to schedule a Site Initiation Visit (SIV) which can be on-site or virtual. If on-site, CRC/PI's can reserve Room STL VA-JC, Building 2, basement floor) or /(large conference room). Regardless of location/modality, Calendar invites with agenda are to be sent to the PI, Co-Is, all CTU Staff and Research Pharmacist (if investigational drug to be used). A PI may also specify a certain individual may only perform certain tasks, as noted on the Form L-Study personnel log or the sponsor's delegation log.

This visit is conducted to assure that the site and all affected departments are prepared to initiate and implement the research and that appropriate training is completed and documented. All greater than minimal risk protocols are required to conduct an SIV prior to the conduct of any study related activities.

The Sponsor's Delegation of Authority Log (DOA), documentation of attendance and study specific trainings should be completed during the visit. Studies which impact a particular Service Line, nursing unit or department may require an in-service.

Once completed and the sponsor/CRO issues an Activation Letter, enrollment can begin.

Investigator Initiated Trials (IIT) Site Implementation

While waiting for receipt of the IRB and RDC approvals, it is the responsibility of the CRC/CRN to prepare the following items for study start up:

- Overview of study objectives
- Time and events schedule for the protocol.
- Subject recruitment/screening including inclusion/exclusion criteria
- Review & familiarization of the informed consent
- Procedures for dispensing the test article (investigational agent/device)
- Test article storage and records
- Protocol-specific forms and procedures
- Development and/or organization of source documentation and regulatory binders
- Review both local & sponsor guidelines & process for Adverse event reporting

PRE-SCREENING, HIPAA WAIVERS AND STUDY RECRUITMENT

In most cases, you will be working with a PI that will be referring patients to you for pre-screening primarily from their specialty clinic and/or through their contacts with other clinics. You may also need to scan clinics on your own. During the preparation of regulatory documents for submission to the IRB of record and RDC, the PI/CRC/CRN/Study Team/Prep Team will complete a portion of the application that describes how and where potential participants will be recruited from and request a HIPAA Waiver (Form E-HIPAA Waiver) which allows pre-screening.

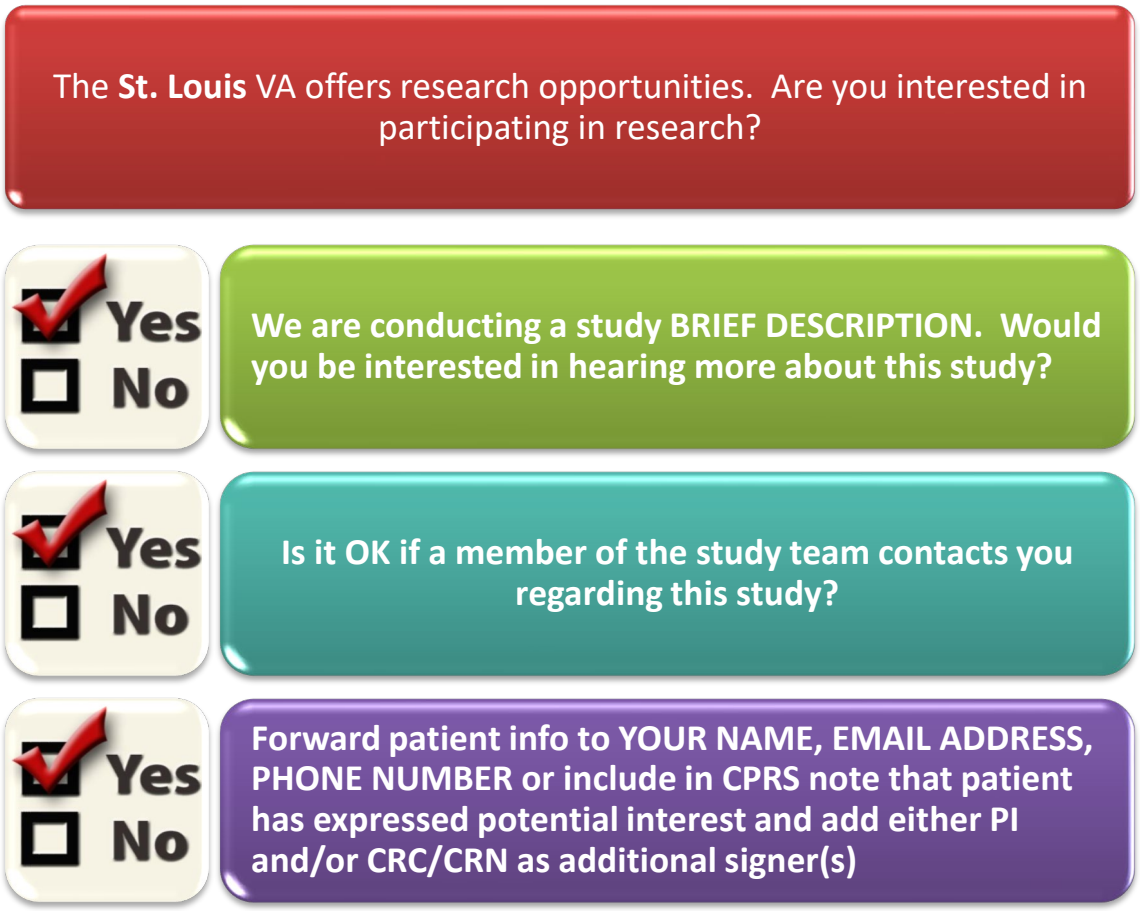
Pre-screening potential study participants helps to determine initial eligibility for study participation. Pre-screening can be done prior to obtaining Informed Consent as it does not include any study specific research procedures. At this stage, based on existing information in the patient's medical record, you can address some things in addition to general inclusion/exclusion, such as the ability to attend on-site visits and past history of appointment and medication compliance.

Example of a Recruitment Plan for a Cardiology study:

The cardiology clinic and cath lab schedule will be reviewed daily by both the PI and study coordinator to identify potential patients. Subjects will be identified by the Principal Investigator, Co-Investigators, CRC/CRN or may be referred by clinical staff in the cardiology Clinic or cath lab. For potential participants who are not under the clinical care of one of the study team investigators, a study team member will inform the patient's clinical team of the patient's possible eligibility for this study and to request that the clinical team approach the patient to introduce the study and assess the patient's interest in hearing more about the study. If the patient is interested, the clinical team will ask permission for approach by the research study team and will pass along the potential participant's name and contact information to the research study team by phone or encrypted email if permission is provided. Subjects may also be identified by these staff from the units they cover. Those that appear to meet inclusion/exclusion criteria will be approached by the study team.

For potential participants who are not under the clinical care of one of the study team investigators, a study team member will inform the patient's clinical team of the patient's possible eligibility for this study and to request that the clinical team approach the patient to introduce the study and assess the patient's interest in hearing more about the study. If the patient is interested, the clinical team will ask permission for approach by the research study team and will pass along the potential participant's name to the research study team if permission is provided.

If a potential study participant is identified by the PI or other member of the patient's clinical care team, the CRC/CRN will be advised that a potential study participant has been informed about the study and has expressed interest in participating in research. If the CRC/CRN finds a potentially eligible patient, the CRC/CRN will advise a member of the patient's clinical care team. The patient will then be approached by a member of their clinical care team to see if they are interested in participating in research opportunities. Only after it has been confirmed by either the PI/CO-I or member of the patient's clinical care team that the patient is potentially interested, may the CRC/CRN approach the patient with additional information.



Initial contact with the potential study participant can be either face to face or via telephone. A brief discussion regarding the study can take place to introduce yourself and confirm their interest in research and the study in question. If interest continues, you may either provide the potential participant with the ICF to take home or send it to them via US Mail or UPS to give them time to review on their own or with family/friends. You can set up a day and time to call him/her to discuss the IFC and/or study further. Always include your contact information so that s/he can call at any time with questions to help aid in the decision. If the IRB has approved additional information about the study that, too, may be provided to the patient.

If the patient is interested, you will schedule the potential participant for their Screening/Baseline visit, at which time ICF completion will occur.

The PI/CRC/CRN/Prep Team will request a Waiver of HIPAA Authorization for all studies that will be prescreening potential patients prior to the patient signing a informed consent form during the regulatory startup process. The Form E-HIPAA Waiver will provide detailed information about the prescreening methods to allow the IRB and/or RDC to make the required determination. PHI obtained

in research for which the IRB of Record has waived the requirements to obtain a HIPAA authorization may not be disclosed outside.

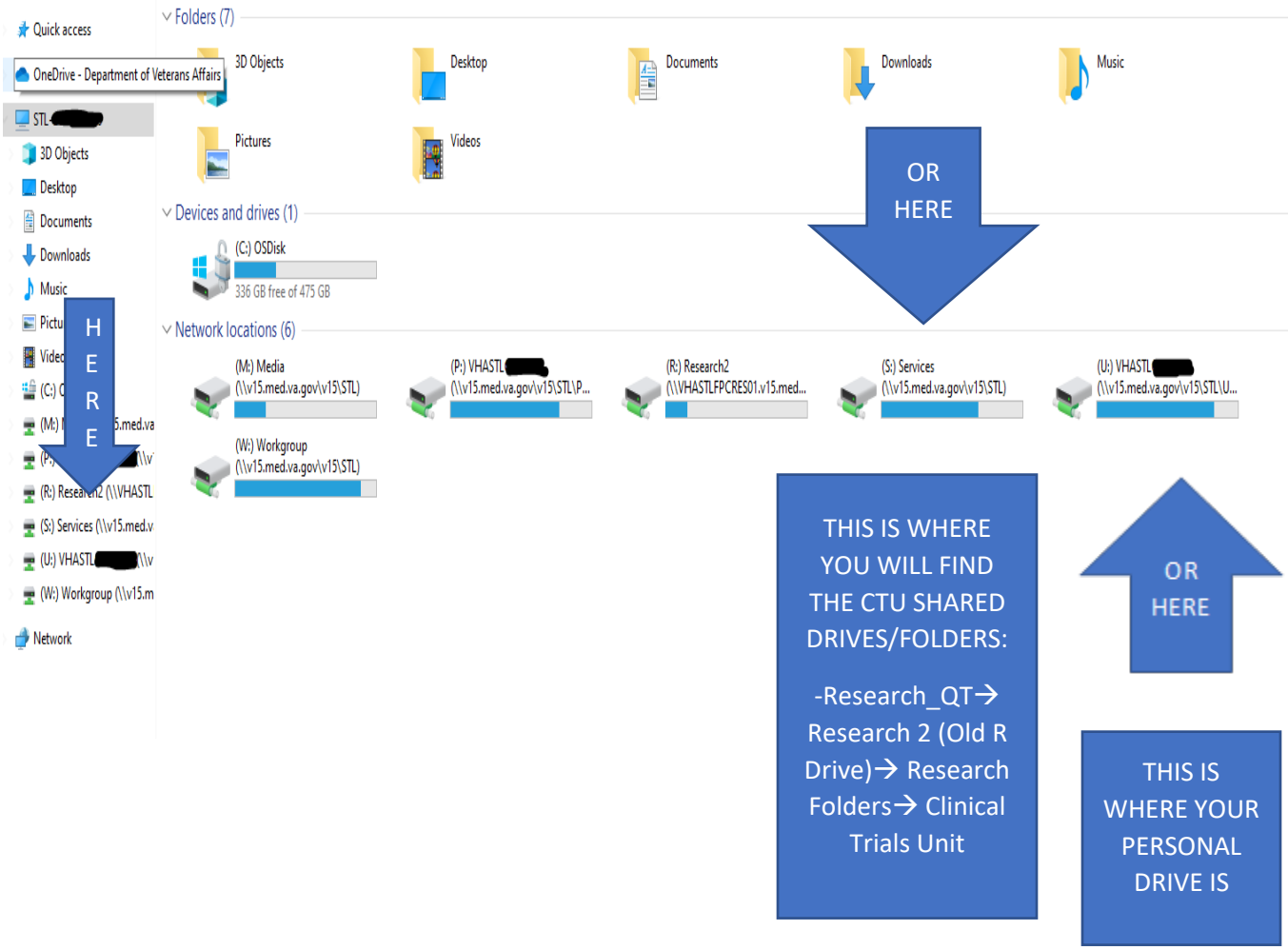
Example of a request for a HIPAA Waiver:

A waiver is requested for pre-screening CPRS records of individuals possibly eligible for this research study. For pre- screening, we will assess whether the patient is enrolled in any other studies, review medical history, and review the remaining inclusion/exclusion criteria. *(Please see the appendix for an example of a completed HIPAA Waiver)*

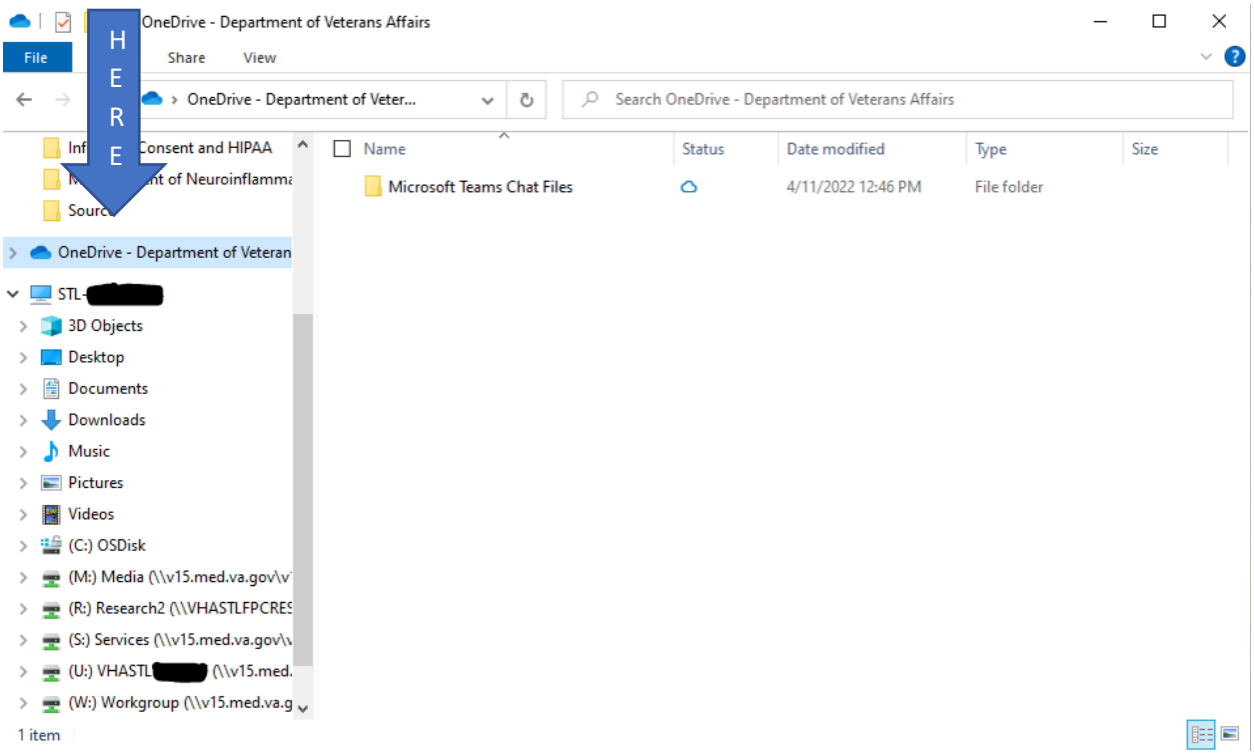
EXAMPLE ONLY

WHERE THE CTU SHARED DRIVE AND YOUR PERSONAL DRIVES ARE LOCATED

How to Access the S Drive (Research2 Drive) & U Drive (recently replaced with One Drive for new employees)



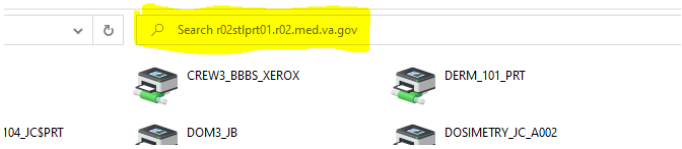
How to Access to your OneDrive



How to Map Network Printers

1. First, identify the network printer name, which should be labeled on the front/top of the printer (Example: STL-DPRESEARCH_BBBS)
2. Next select the STL_GUI Executables Folder from your desktop

3. Then select the STL Shortcuts Folder
4. Then select Network Printers
5. Next you can search for the Network Printer Name by entering the network printer name in the search field located in the top corner. Once the network printer has been identified, double click on the printer name to add it your user profile.



Note: Please keep in mind that you will need to follow the same instructions for all desktops that you will be working on (For example, research employee office desk computer, CTU exam room computer, etc.)

WHAT IS THE INFORMED CONSENT PROCESS?

Informed consent is a process, not just a signature on the ICF. The study team has a duty to the potential participant to provide relevant information about the research and ensure that the potential participant understands the study, does not withhold relevant information, express undue influence, or coercion, and makes certain that the potential participant has been given sufficient opportunity and time to consider whether to participate.

The person obtaining informed consent must be knowledgeable about the study and capable of answering any questions from potential participants. It is important that the PIs/Co-Is make themselves available to answer questions at the request of participants both before and throughout the duration of the study. There are instances where the study sponsor insists that a PI/Co-I be the site signatory on the ICF. In most cases, however, the CRC/CRN will be authorized to sign consent if designated by the PI to do so.

Following are excerpts from the April, 2013 ACRP White Paper: "The Process of Informed Consent":
(A copy of the ACRP White Paper-The Process of Informed Consent is located in the Appendix for your reference)

Environment
The environment where the process of consent is conducted should be determined by the type of research being conducted but there should always be a period where a private, confidential, and "safe" setting is afforded to facilitate a constructive dialogue between the prospective subject and the person(s) involved in obtaining consent. A physician's office or an examination room would likely be an appropriate location whereas a patient waiting room or a pre-op area would be examples of locations which may not be conducive to the obtainment of legally effective informed consent. Patients in these latter environments may exhibit stress associated with illness or procedural related anxieties (e.g., fear of pending surgery, cardiac catheterization, chemotherapy) which could compromise the process of consent.

Assessment of Capacity to Consent
All prospective subjects must have the cognitive ability to provide legally effective informed consent. If there is any concern about an individual's cognitive ability an appropriate assessment should be performed by a qualified individual.

Presentation of the Elements of Informed Consent
The required elements of informed consent should be presented and discussed with the prospective subject in a sequential manner utilizing the approved ICF as a guide. The presentation should be structured to facilitate a dialogue with reinforcement and elaboration of important information (e.g., the risks of the research). The person(s) involved in obtaining the subject's consent should constantly evaluate whether the process is achieving the goal which is obtainment of legally effective informed consent from the subject. In addition to paying attention to general signs of information receptivity, it is often helpful to ask open-ended questions in order to identify points of confusion which require clarification.

- During discussion, make every attempt to confirm that the patient understands all aspects of the study:
    - Number and timing of study visits
    - Labs – Routine and optional
    - Questionnaires
    - Technology to be used
    - Length of study
    - Who and How to contact Study Staff both during and off hours

Use of a Delayed Consent Procedure

The amount of time allotted to the process of consent is dependent upon the nature and complexity of the research and the need to minimize the possibility of coercion or undue influence. In some research (e.g., complex or risky research) a delayed consent procedure should be used in order to afford the subject the opportunity to discuss participation in the research with family, friends, counselors, or other confidants before they sign the ICF. If the individual is uncomfortable or anxious about participating in the research they should be instructed to take the ICF home for further review and consideration before deciding whether or not to participate in the research.

- A copy of the ICF can be hand delivered or mailed to the potential study subject. If mailing, an IRB Approved cover letter should be used in addition to a copy of the ICF.

Documentation of Informed Consent

Documentation of informed consent is the conclusion of the initial consent process. Whoever documents the obtainment of informed consent (i.e., signs the ICF) must be qualified to attest to the fact that the subject has provided legally effective informed consent. While a number of qualified research personnel can, and should, be involved in the process of consent, it should be remembered that the PI is ultimately responsible for all aspects of the research including informed consent. The individual who assumes responsibility for documentation of informed consent and the consenting subject should sign and date the ICF.

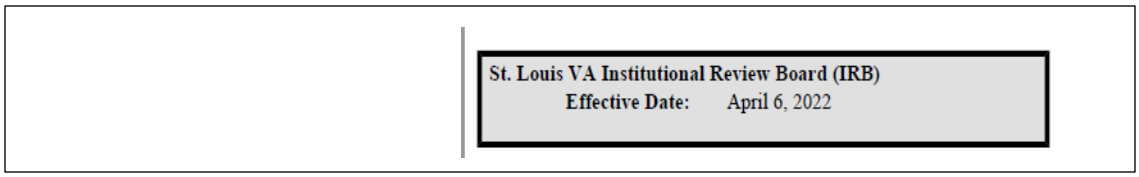
Once the consent is signed, the PI/Co-I will make the final determination of eligibility of potential participants. A potential participant can sign the ICF but the potential participant may be declared ineligible after physician review or failure of testing during screening.

- The current IRB approved ICF template is located: in the CTU Shared Drive (R:) → Research_Folders→ Forms→ Mater Forms Folder IRB-RDC→ User Forms→ G- Informed Consent Template
    - You can also access a copy of the ICF template in IRBNet: Forms and Templates→ St. Louis VA Research Submissions, St. Louis, MO-Documents for Researchers G-Informed Consent Template

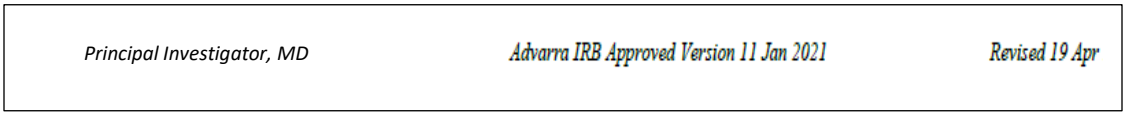
- Only print copies of the ICF on an "as needed" basis. DO NOT print copies in advance as ICFs, can and do, change.

- Ensure that IRB footer is present on the printed ICF. This will include the approval date of the ICF.

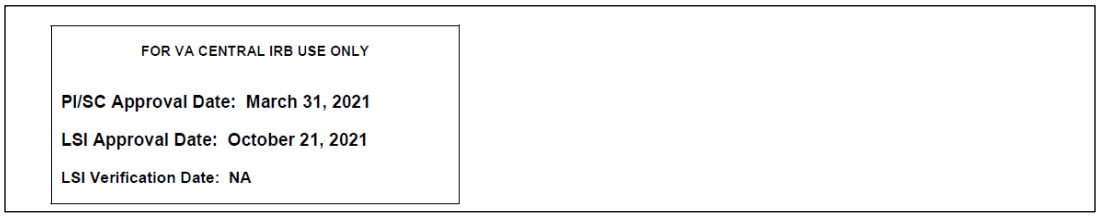
EXAMPLE #1: IRB Approval Stamp from Local St. Louis VA IRB via IRBNet



EXAMPLE #2: IRB Approval Stamp from Commercial IRB (Example: Advarra IRB)



EXAMPLE #3: IRB Approval Stamp from VA Central IRB ICF



- Prior to signing consent, review and note all locations where either a signature or initials are needed. In most instances, the consent document will require at least two places to sign:
    - Main Informed Consent
    - HIPAA (Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research)

- Do not make any notations of any kind on the ICF.
- Give copy of signed consent to the subject and file/distribute internally (or as dictated by protocol or ICF):
    - Original included in the Research patient study binder
    - Scan original copy and save to study folder on the Research Drive
    - If study drug will be dispensed - Email copy to IDS along with a copy of the completed 10-9012
        - A copy of the ICF and hard copy of the VA 10-9012 will be given to the Research Pharmacist prior to the administration/distribution of the drug.
        - A copy of the VA 10-9012 should also be included in the participant study binder
- **Reconsent** as needed throughout the trial.
    - New information/changes to the study protocol/consent can happen and may affect the subject's decision whether to continue in the research. Every change to the protocol and/or consent may not require reconsent.
    - If either the study sponsor or the IRB require that the study participant be reconsented, all above steps must be repeated.
    - Depending on the information/change, required reconsent may be determined to occur:
        - Immediately
        - Before the next scheduled visit
        - Before a specific study procedure
        -

REGARDLESS OF WHETHER YOU ARE INITIALLY CONSENTING THE PATIENT OR RECONSENTING THEM, ALL THE ABOVE STEPS ARE TO BE FOLLOWED.

NO STUDY PROCEDURES MAY BE CONDUCTED UNTIL CONSENT IS SIGNED!!!

Documentation of Informed Consent in CPRS

You must document the informed consent process in CPRS once a patient has signed a consent. This is done by opening the chart of the patient who has signed the consent and going to the note section in CPRS. At the bottom of the note section, click on "new note". This will open a window where you can select the location of the visit. Type in "JC-Gen Med Research" and select it. This will then open another window where you can select the note template. In the "Progress Note Title" section, type in "research informed consent" and the template for "Research Informed Consent Documentation" will be displayed. This is the template you will need to select. Fill in the highlighted sections of the note (Name of study, PI, PI contact number, date of ICF and HIPAA signature, and your name as the person who obtained consent and HIPAA). Once you save your note, it will not display in the note section until it is signed. Right click on your note and select "sign note now". You will need to enter your CPRS access code to sign the note. Note that you cannot edit your note once it is signed.

PATIENT BINDER/ACCOUNTING OF DISCLOSURES OR…WHAT GOES IN/WHAT GOES OUT

Patient Binder

You will make a patient binder for every patient that is enrolled into a study. This binder is your "bible" for each patient. We all use the same numbered tab format so that those that cover for us and study monitors, can find information quickly and efficiently. Regardless of the number of sections that follow, the first three sections are:

1. Consent(s) (ICF & HIPAA Authorization) – Initial and Reconsent(s), as necessary
2. Con Meds
3. AEs/SAEs
4. Copy of Participant Compensation method (copy of study voucher, check, Clincard, etc.)

Table of Contents templates can be found in: CTC Drive → Templates → Binder Templates.

Examples of Information that should be collected and placed in a patient binder, per study visit, includes:

- Completed/signed source docs and all handwritten notes made during study visits
- CPRS Notes that support data collected for entry to eDC:
    - Eligibility
    - Test results (ECG, CT/MRI, etc.)
    - Demographic info
    - Medical/Surgical history
    - Lab results
    - Progress notes from SOC providers between visits (as needed)
    - ER Visits
    - Hospital admission/discharge summaries
- Study related central lab reports
- Patient diaries
- Research notes

A rule of thumb – If the FDA/ORO were to come in tomorrow for a "surprise" audit, would your patient binders be up to the scrutiny?

STUDY NAME

1	**CONSENT** (Original signed ICF, HIPAA Authorization, 10-9012 [if applicable], Copy of Initial Consent Note)
2	**CON MEDS** (Why here? Con Meds are commonly collected/reviewed at each study visit. Easier accessibility)
3	**AEs/SAEs** (Why here? AEs are commonly collected/reviewed at each study visit. SAEs and associated directions, forms and details. Easier accessibility)
4	**VISIT 1**
5	**VISIT 2**
6	**VISIT 3**
7	**VISIT 4**
8	**VISIT 5**
9	**VISIT 6**
10	**VISIT 7**
11	**VISIT 8**
12	**VISIT 9**
13	**VISIT 10**
14	**UNSCHEDULED VISIT(S)**
15	**MISCELLANEOUS FORMS INFORMATION**

COMPLETING SOURCE DOCUMENTS:

All documentation must be done in permanent ink, preferably black or blue.

Source docs are completed during the patient visit or immediately after.

ALWAYS REMEMBER ALCOAC+:

Attributable – It should be clear who has documented the data.

Legible – Readable and signatures identifiable

Contemporaneous – Data is recorded when the work was performed

Original – The first record made by the appropriate person. The investigator should have the original source document.

Accurate – Consistent and real representation of facts.

Complete – Ensures everything is included and nothing is missing

Consistent – Data in sequential manner with a sign and date

Enduring – Using media that mains and protects records

Available – Available for review at any time

MAKING CORRECTIONS:

NEVER use White Out™, scribbles, X-outs, erasures in Source Documents.

Corrections should be:

- Stricken through with a single line (Do not obscure the original entry)
- Initialed and dated so there is a record of who made the change and when

WHAT IS ELECTRONIC DATA CAPTURE (eDC)?

An electronic data capture (eDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials. eDCs allow for data to be reported in real-time, ensuring data is always available for review, especially when used for high-risk trials. eDC queries can be instantly delivered allowing for reduced turnaround times for clarification and provides real-time audit trails which helps to ensure the validity of the data entered.

There are many ways that eDCs are used in clinical research:

- Data can first be recorded on paper (source documents) and then transcribed into the system and saved in an electronic case report form (eCRF).

- Data can also come directly from patients using ePROs (electronic Patient Reported Outcomes). ePROs is a survey of the status of a patient's health that comes directly from the patient, i.e. the patient reports the data directly. These surveys can include pain intensity diagrams, visual analog scales, psychological symptoms, and general quality of life measures, such as how the condition impacts a patient's daily life.

- Data collected using eCOAs (Electronic Clinical Outcomes Assessments), allow clinicians and caregivers to use phones, tablets, computers, and other electronic devices to report data.

There are multiple companies that provide these systems, and their number is growing as technology progresses. Some names that you will become familiar with are Medidata Rave, REDCap, InForm, IBM Clinical, ERT and the list goes on. Training for each system is managed by the sponsor/CRO. Each system will require training within the system itself.

When entering information into the eDC, make sure that you have information in the patient binder to verify the information you are entering. To save both you and the Monitor time during a Monitoring Visit, highlight or flag the information as you enter it into the system.

Do not use medical abbreviations in the eDC. It is invitation for a query. If a patient has CHF, enter Congestive Heart Failure.

When entering concomitant medications, enter the **generic** NOT the brand name.

REPORTABLE EVENTS

SEE: Listing of Reportable Events – Best source of what and when to report

ADVERSE EVENTS (AE)

An Adverse Event is any untoward medical occurrence associated with the use of a drug in humans, *whether or not considered related*. Simply, it is **any** (labs, symptoms, etc.) change in the subject's health status since the Baseline Visit for which there is a reasonable possibility that the study drug may have caused the event.

Example:

> At the Baseline Visit, the patient reports that s/he has hypertension that is controlled by a diuretic. All the information you have regarding the patient's medical history and concomitant medications verify this to be true. The patient is dispensed study medication, takes the first dose during the visit and is scheduled to return for a study visit in four weeks. The next week, s/he has a PCP appointment and his/her blood pressure is outside of their normal. The patient states that s/he has been taking his/her diuretic as directed. The PCP asks the patient to monitor his/her blood pressure at home and call back in two weeks with the readings which the patient does. His/Her readings remain outside of his/her normal and the PCP prescribes an ACE Inhibitor. At the study visit, the patient reports the addition of the ACE Inhibitor.
>
> This is an Adverse Event as this was a change in the subject's health status (worsening of hypertension) which is an untoward medical occurrence associated with the use of a drug in humans, whether or not considered related.

This event should be documented:

- On the source doc for that visit
- In the eDC
- On an AE Log located in the patient binder which must be reviewed and signed by the PI/Co-I
  (If the PI/CoI is not physically available to review the AE and sign the log at the study visit, email him/her the information and request a decision on causality and severity.)
- In the CPRS Research Note

If documentation of the event is needed from a non-VA facility/outside hospital (OSH), information will need to be requested from the location. A Release of Information will be be signed by the patient. Most hospitals have a Release of Information form on their websites. If not, an all-purpose form is available in IRBNet.

SEE: FORM: Authorization to Release RHI – VA Form FL 10-212

UNEXPECTED ADVERSE EVENT (UAE)

An Unexpected Adverse Event is any event that is not listed in the investigator brochure, product package insert, or is not listed at the specificity or severity that has been observed or the event is not consistent with the risk information described in the protocol and/or informed consent.

Examples:

Hepatic necrosis would be unexpected (by virtue of greater severity) if the investigator brochure referred only to elevated hepatic enzymes or hepatitis

Cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the investigator brochure listed only cerebral vascular accidents.

Adverse events or suspected adverse reactions that are mentioned in the investigator brochure as occurring with a class of drugs or as anticipated from the pharmacological properties of the drug but are not specifically mentioned as occurring with the particular drug under investigation.

Keep in mind that an AE can become an SAE so when in doubt, document the AE. Some protocols only require specific events within a specific timeframe to be AEs. If the Sponsor/Monitor determines that what you have recorded does not fit the protocol definition of an AE, they will advise to strike it from the record which provides an audit trail should any questions arise. It is always better to be ahead of the data instead of behind it.

This event should be documented:

- On the source doc for that visit
- In the eDC
- On an AE Log located in the patient binder which must be reviewed and signed by the PI/Co-I
  (If the PI/Co-I is not physically available to review the AE and sign the log at the study visit, email him/her the information and request a decision on causality and severity.)

AE Log template can be found in: CTC Drive → Templates → Binder Templates.

- In the CPRS Research Note

If documentation of the event is needed from a non-VA facility/outside hospital (OSH), information will need to be requested from the location. A Release of Information will be to be signed by the patient. Most hospitals have a Release of Information form on their websites. If not, an all-purpose form is available in IRBNet.

SEE: FORM: Authorization to Release RHI – VA Form FL 10-212

SERIOUS ADVERSE EVENT (SAE)

A Serious Adverse Event is an adverse event or suspected adverse reaction that if, in the view of either the investigator or sponsor, results in any of the following outcomes:

1. Death
2. Life-threatening adverse event
3. Inpatient hospitalization or prolongation of existing hospitalization
4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
5. Congenital anomaly/birth defect

For reporting purposes, notify the following as soon as you are made aware:

- PI/Co-I
- Sponsor or CRA via eDC or fax
- Regulatory staff

This event should be documented:

- If notified during a study visit, on the source doc for that visit
- In the eDC
- On an AE Log located in the patient binder which must be reviewed and signed by the PI/Co-I
  (If the PI/Co-I is not physically available to review the SAE, email him/her the information ASAP)
- On the study specific SAE Log
- If notified during a study visit, in the CPRS Research Note

Not all Sponsors use the eDC as the first method of SAE notification. The "how" of reporting should be ascertained prior to enrolling the first patient in the study. It is important to have paper documents available in the patient binder should someone other than the lead CRC/CRN need to report the event.

Against everything that is research, it is more important to the Sponsor for you to enter/fax an incomplete SAE report immediately upon notification than to wait until you have all the details. You can always amend your information; you can never get back time.

SEE: SOP 151-209 – Local Deaths and Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Other

FORM: Reportable Event – DEATH/UPIRTSO form (Form U-Adverse Events Form) *(Located in Appendix for your reference)*

If documentation of the event is needed from a non-VA facility/outside hospital (OSH), information will need to be requested from the location. A Release of Information will be to be signed by the patient. Most hospitals have a Release of Information form on their websites. If not, an all-purpose form is available in IRBNet.

SEE: FORM: Authorization to Release RHI – VA Form FL 10-212

RESEARCH INFORMATION PROTECTION INCIDENTS (RIPP)

Any information security incident related to VA research including, inappropriate access, loss or theft of PHI; noncompliant storage, transmission, removal or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI must be reported. This must be reported to the ISSO and/or PO within 1 hour of becoming aware of the incident.

Examples:

- Inappropriate access, loss or theft of documents containing PHI (e.g., informed consent forms, HIPAA Authorization forms, case report forms)
- Unauthorized destruction (accidentally or intentionally) of research records
- Loss, theft or unauthorized destruction of equipment (e.g., laptops, other mobile devices, external storage media) containing VA research-related PHI
- Transmission of VA research-related PHI not encrypted according to VA standards
- Use or connection of unauthorized equipment (e.g., non-VA thumb drive, unauthorized personally owned equipment) to store, process, or transmit VA research-related PHI

PROTOCOL EXCEPTIONS AND DEVIATIONS

A **Protocol Exception** is a temporary protocol deviation that is approved by the Sponsor and the IRB, prior to its implementation. Protocol exceptions are generally for a single subject and/or visit.

It is the CRC/CRN's responsibility to request approval from the Sponsor. Regulatory staff will submit to the IRB for approval.

Forms: T-Protocol Deviation Forms

Examples:

> Patient will be out of town during the protocol specified visit window and has made you aware. The visit is to be conducted on-site as central labs are to be drawn. Patient will be able to attend a visit upon his/her return the following week.
>
> Patient is already enrolled in a Minimal Risk Study and is eligible and willing to participate in a Greater than Minimal Risk Study

A **Protocol Deviation** is any unplanned departure from the study protocol that is not approved by the Sponsor/IRB, and does not harm the participant's safety, rights, or welfare and the completeness, accuracy, and integrity of the study data.

These events must be documented on the study specific Deviation Log.

Examples:

> Physical exam was not completed as the PI was unexpectantly unavailable.
>
> CK lab was not drawn at baseline.

CPRS AND JLV

CPRS is an acronym for Computerized Patient Record System. CPRS is used exclusive by the VA and is the electronic health record for patients receiving treatment at a local VA.

CPRS enables you to enter, review, and continuously update all information connected with any patient. With CPRS, you can order lab tests, medications, diets, radiology tests and procedures, record a patient's allergies or adverse reactions to medications, request, and track consults, enter progress notes, diagnoses, and treatments for each encounter, and enter discharge summaries.

CPRS organizes and presents all relevant data on a patient in a way that directly supports clinical decision-making. The comprehensive cover sheet displays timely, patient-centric information, including active problems, allergies, current medications, recent laboratory results, vital signs, hospitalization, and outpatient clinic history. This information is displayed immediately when a patient is selected and provides an accurate overview of the patient's status before clinical interventions are ordered.

JLV is an acronym for Joint Longitudinal Viewer. JLV is a read-only, web-based application for viewing patient electronic health records from other VAs, Department of Defense (DoD), and Community Partners.

JLV TRAINING RESOURCES

TMS JLV Introductory Training (VA 131003505) - This training covers JLV A to Z. It takes about 45 minutes start to finish. **Log into TMS and search JLV.**

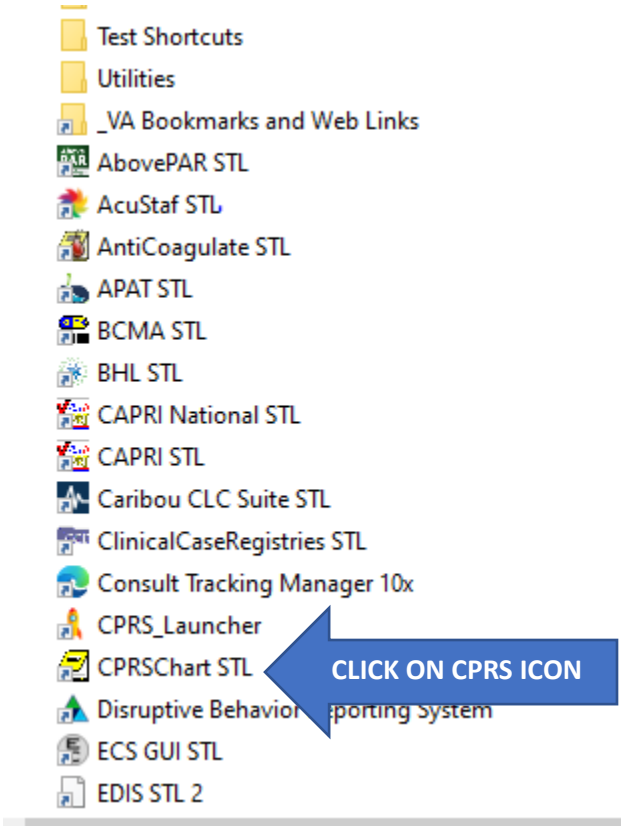
JLV Resources – Videos, PowerPoint and other materials are located in the appendix of this training manual.

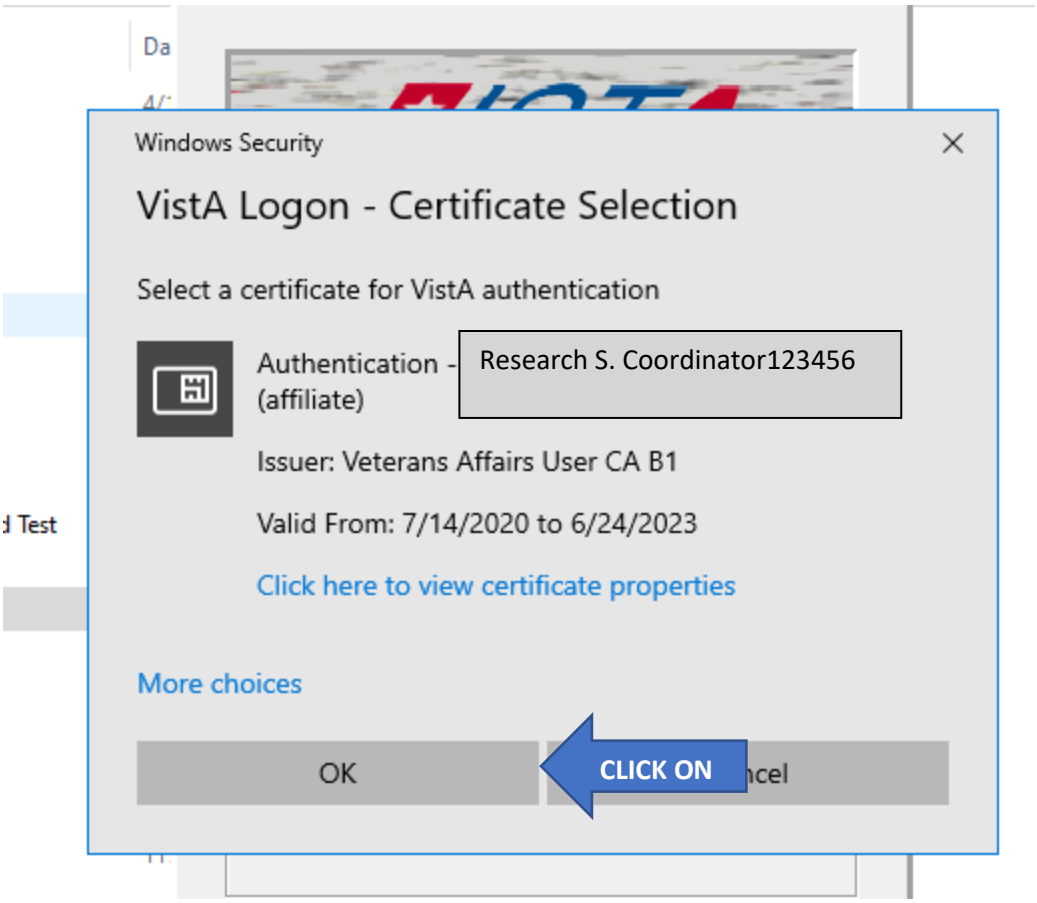
JLV Training Exercises Guided practice using JLV in a Provider, Nursing, Ancillary or Administrative role!

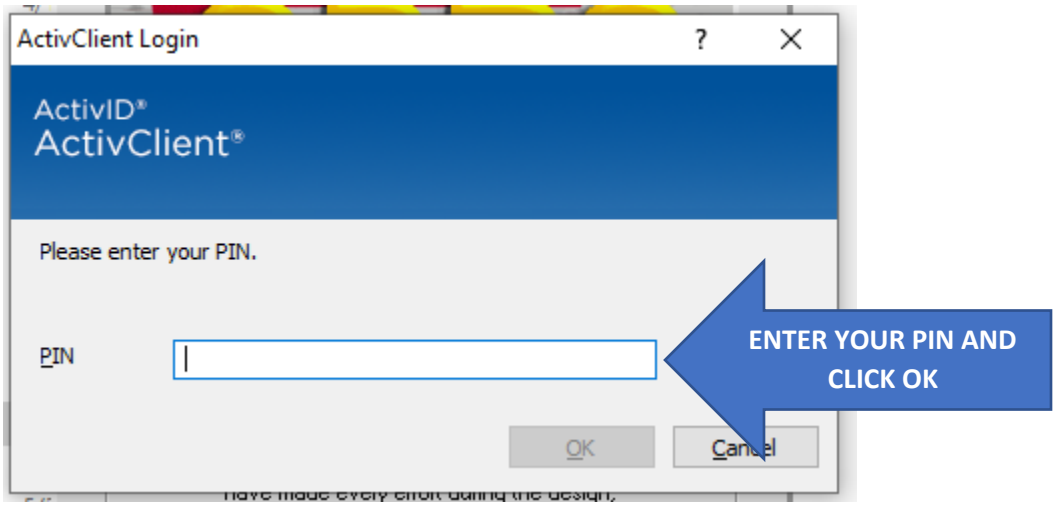
JLV Quick Tips –1-page How-To-Guides for the most common things you need to do or data you need to find in JLV

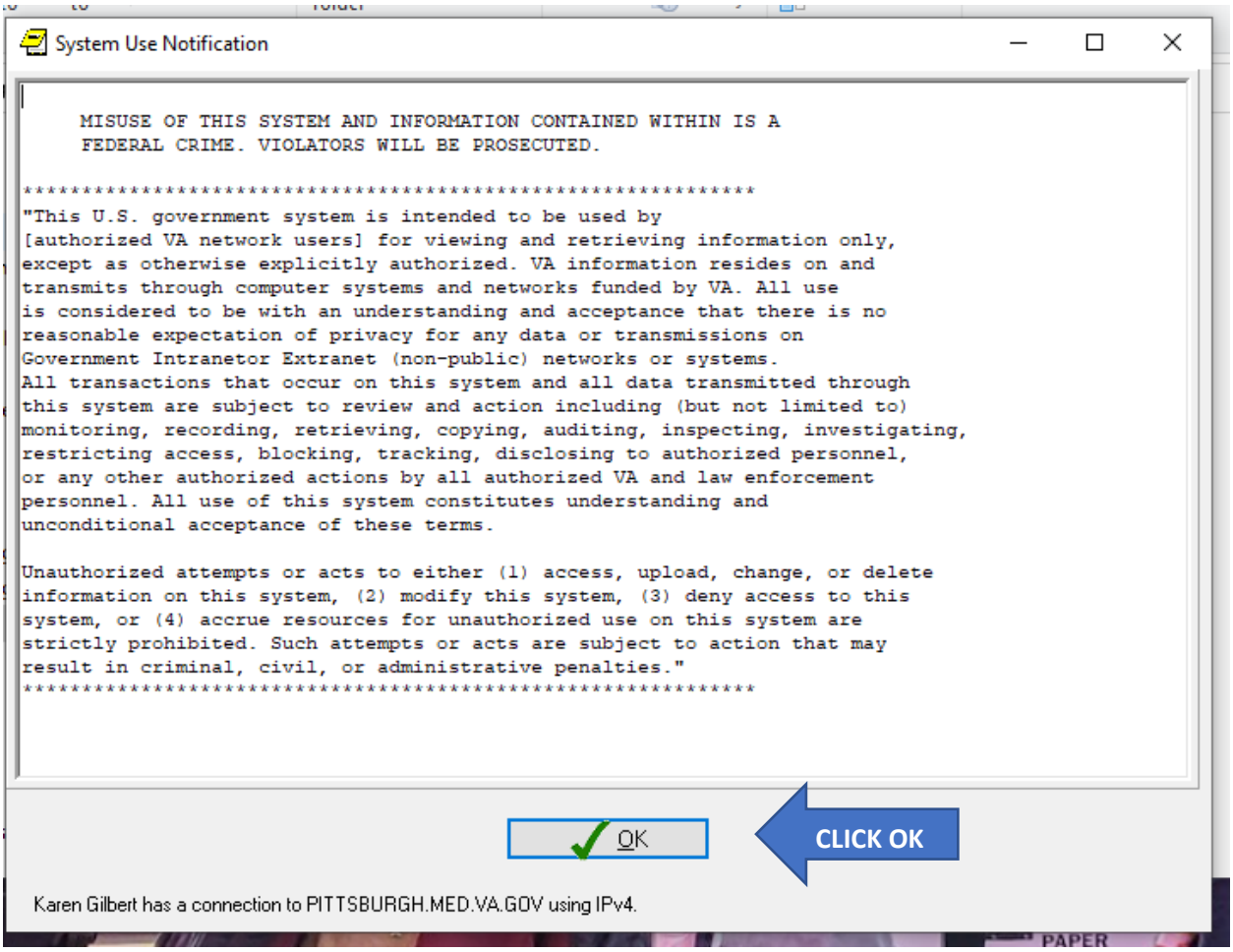
SIGNING INTO CPRS

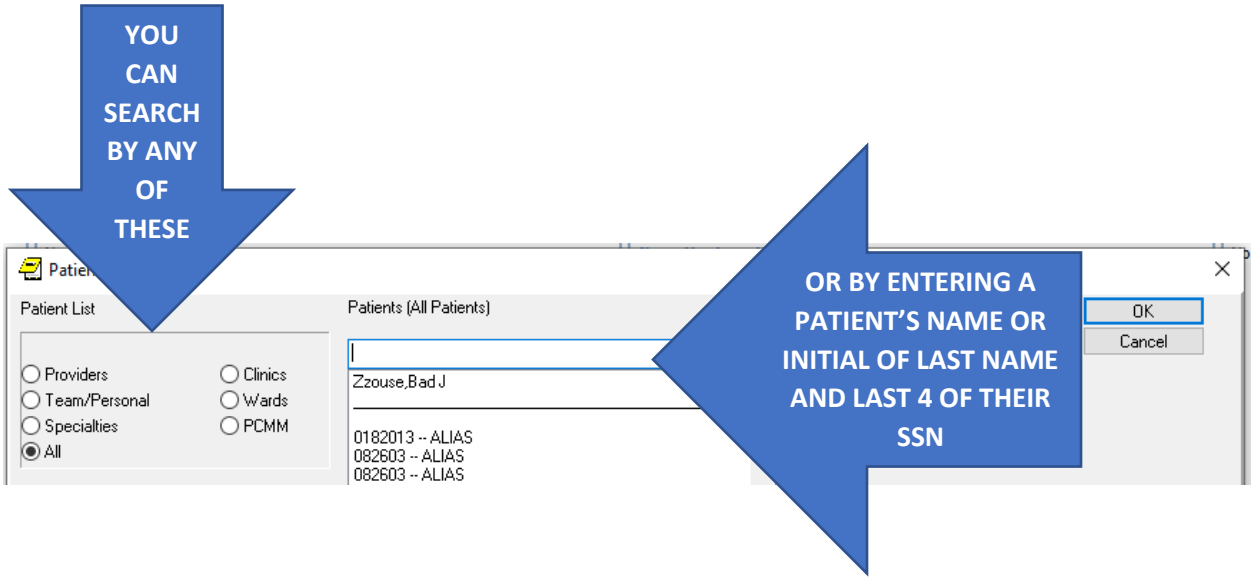
Your PIV Card must be inserted in your computer to sign in.



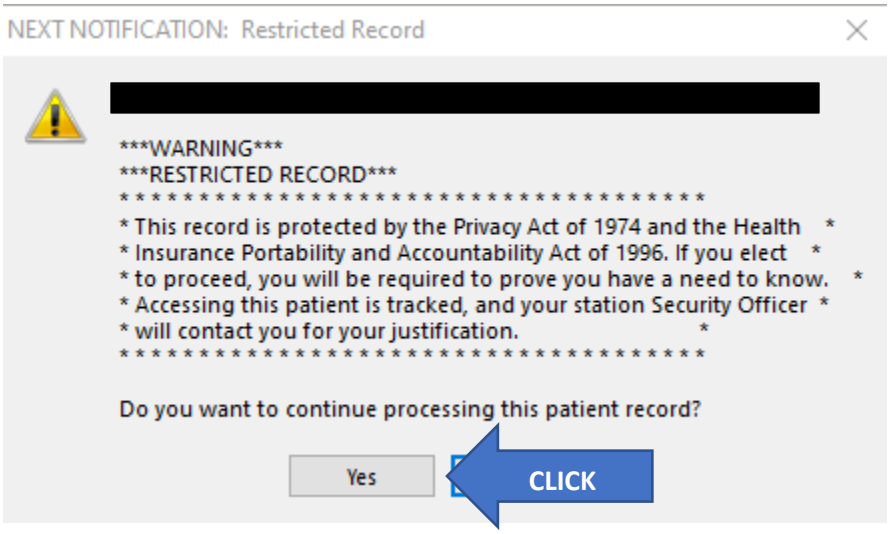

Windows Security
VistA Logon - Certificate Selection
Select a certificate for VistA authentication
Authentication - (affiliate)
Research S. Coordinator123456
Issuer: Veterans Affairs User CA B1
Valid From: 7/14/2020 to 6/24/2023
Click here to view certificate properties
More choices
OK
CLICK ON


ActivClient Login
ActivID®
ActivClient®
Please enter your PIN.
PIN
ENTER YOUR PIN AND CLICK OK
OK
Cancel

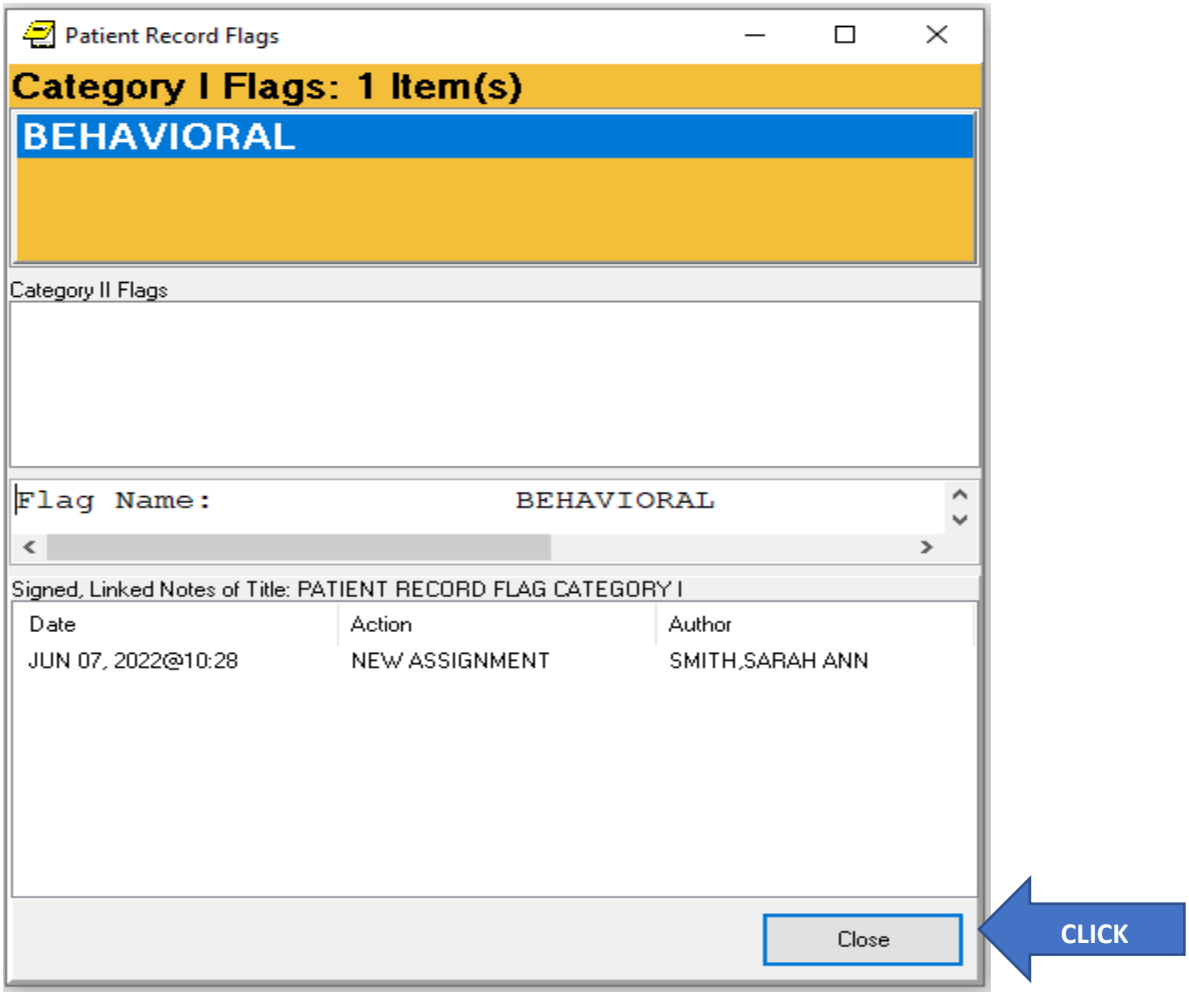

System Use Notification
MISUSE OF THIS SYSTEM AND INFORMATION CONTAINED WITHIN IS A
FEDERAL CRIME. VIOLATORS WILL BE PROSECUTED.
****
"This U.S. government system is intended to be used by
[authorized VA network users] for viewing and retrieving information only,
except as otherwise explicitly authorized. VA information resides on and
transmits through computer systems and networks funded by VA. All use
is considered to be with an understanding and acceptance that there is no
reasonable expectation of privacy for any data or transmissions on
Government Intranetor Extranet (non-public) networks or systems.
All transactions that occur on this system and all data transmitted through
this system are subject to review and action including (but not limited to)
monitoring, recording, retrieving, copying, auditing, inspecting, investigating,
restricting access, blocking, tracking, disclosing to authorized personnel,
or any other authorized actions by all authorized VA and law enforcement
personnel. All use of this system constitutes understanding and
unconditional acceptance of these terms.
Unauthorized attempts or acts to either (1) access, upload, change, or delete
information on this system, (2) modify this system, (3) deny access to this
system, or (4) accrue resources for unauthorized use on this system are
strictly prohibited. Such attempts or acts are subject to action that may
result in criminal, civil, or administrative penalties."
****
OK
CLICK OK
Karen Gilbert has a connection to PITTSBURGH.MED.VA.GOV using IPv4.


YOU CAN SEARCH BY ANY OF THESE
Patient List
Providers
Clinics
Team/Personal
Wards
Specialties
PCMM
All
Patients (All Patients)
Zzouse,Bad J
0182013 -- ALIAS
082603 -- ALIAS
082603 -- ALIAS
OK
Cancel
OR BY ENTERING A PATIENT'S NAME OR INITIAL OF LAST NAME AND LAST 4 OF THEIR SSN

If this Warning appears, you will need to click "Yes" before you can continue to the patient record.

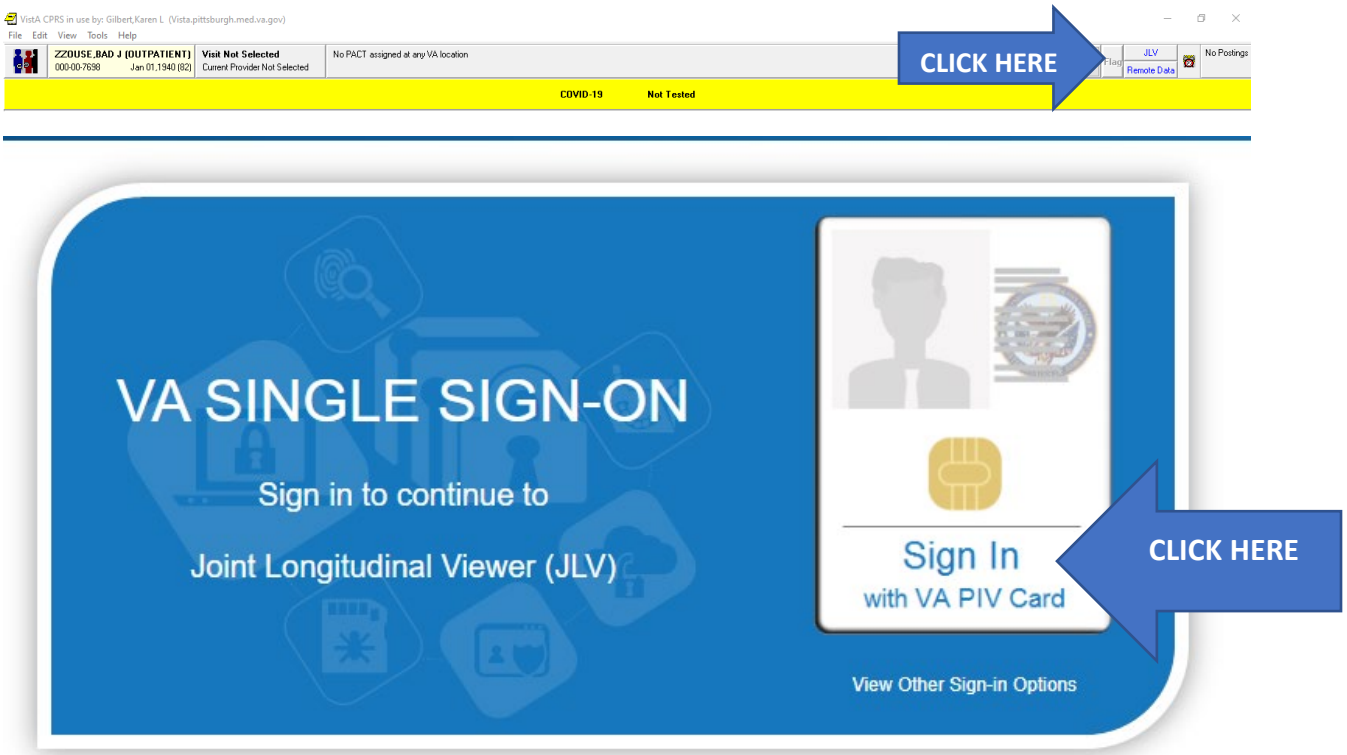


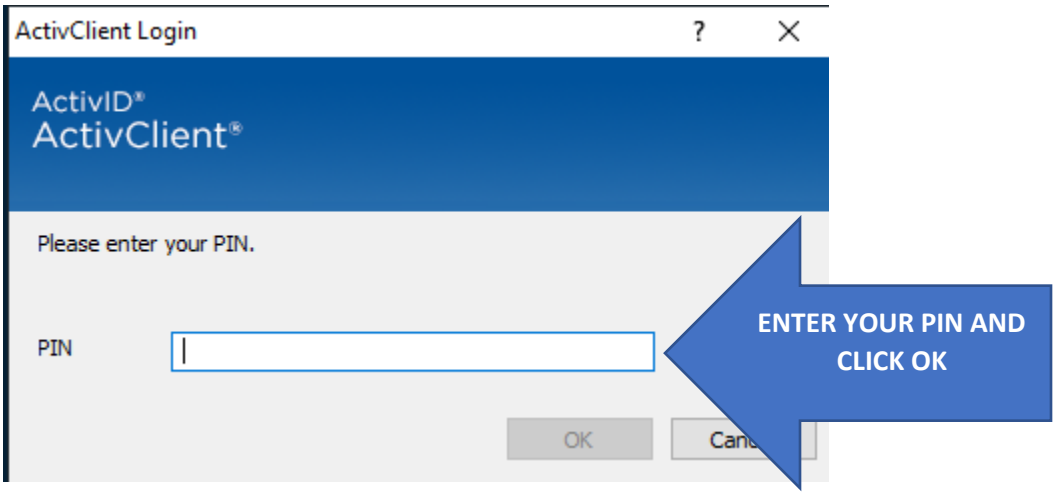
If any Patient Record Flag appears, you will need to click "Close" before you can continue to the patient record. There are flags that may influence your decision regarding study eligibility.

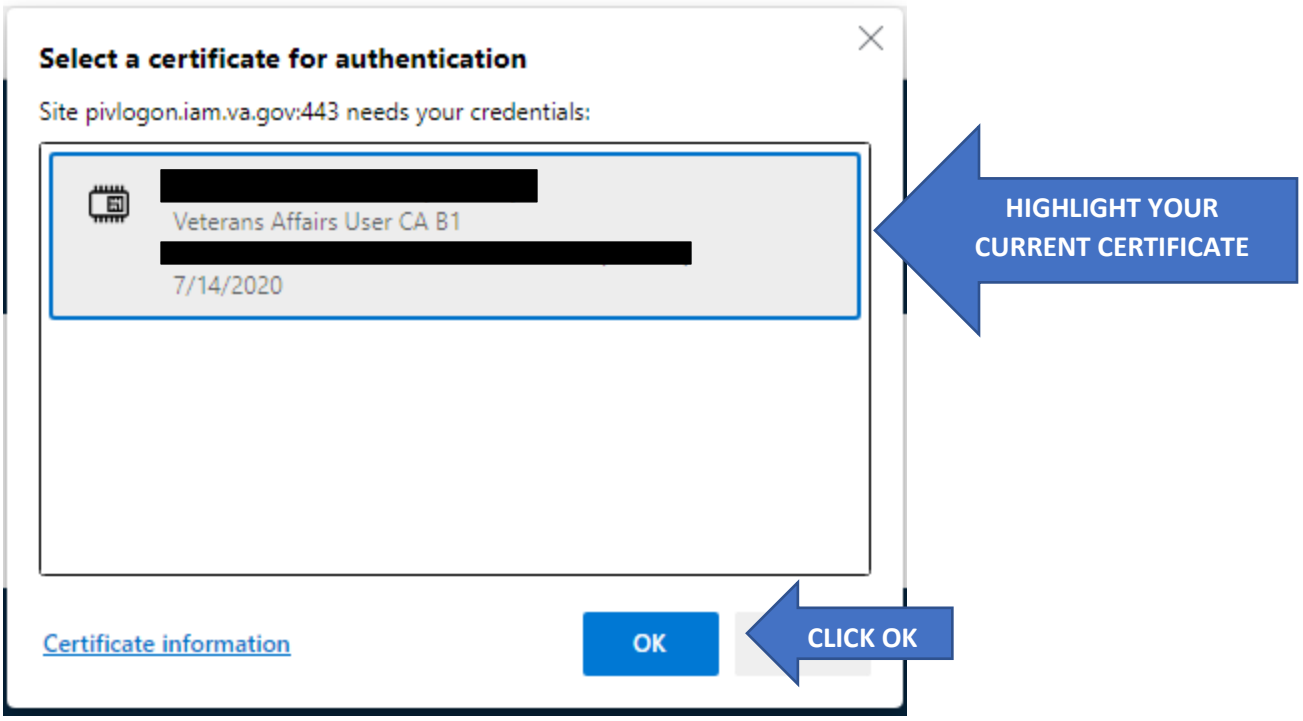


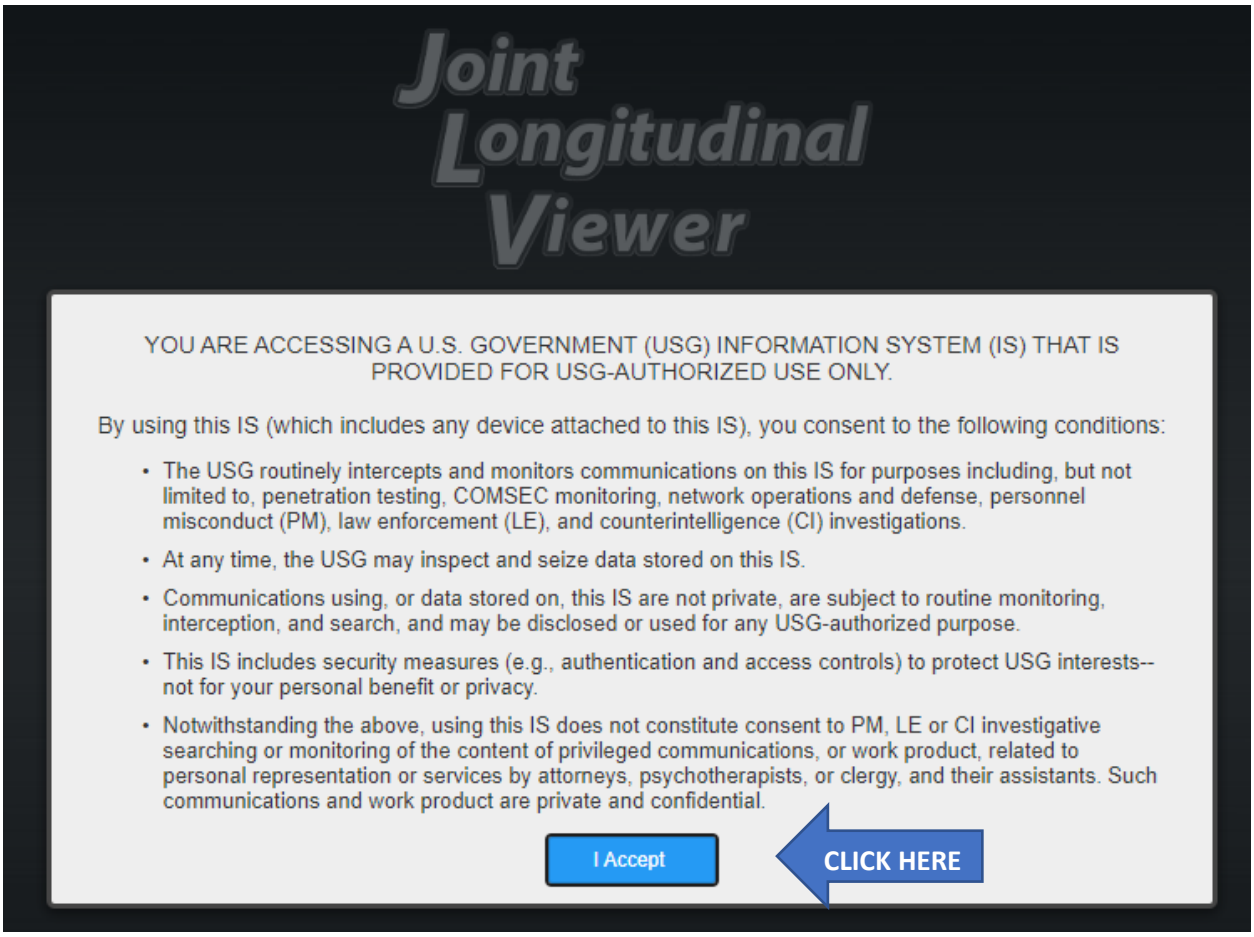
SIGNING INTO JLV

In order to sign in to JLV, you must first be signed into CPRS.

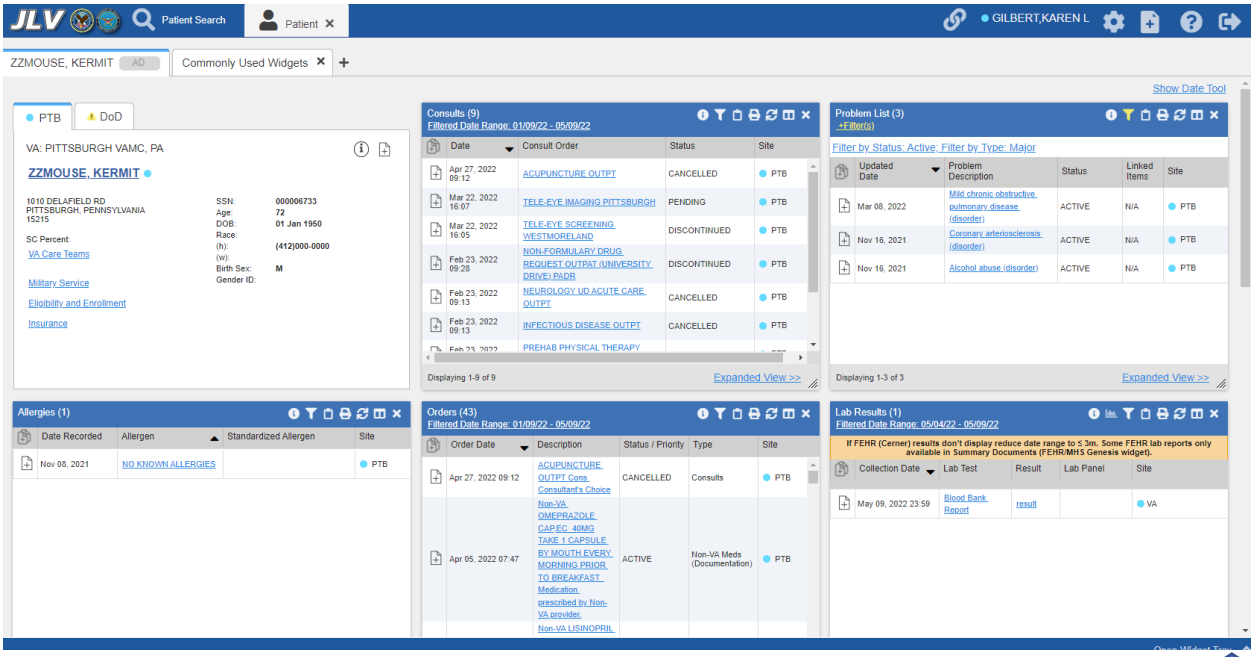




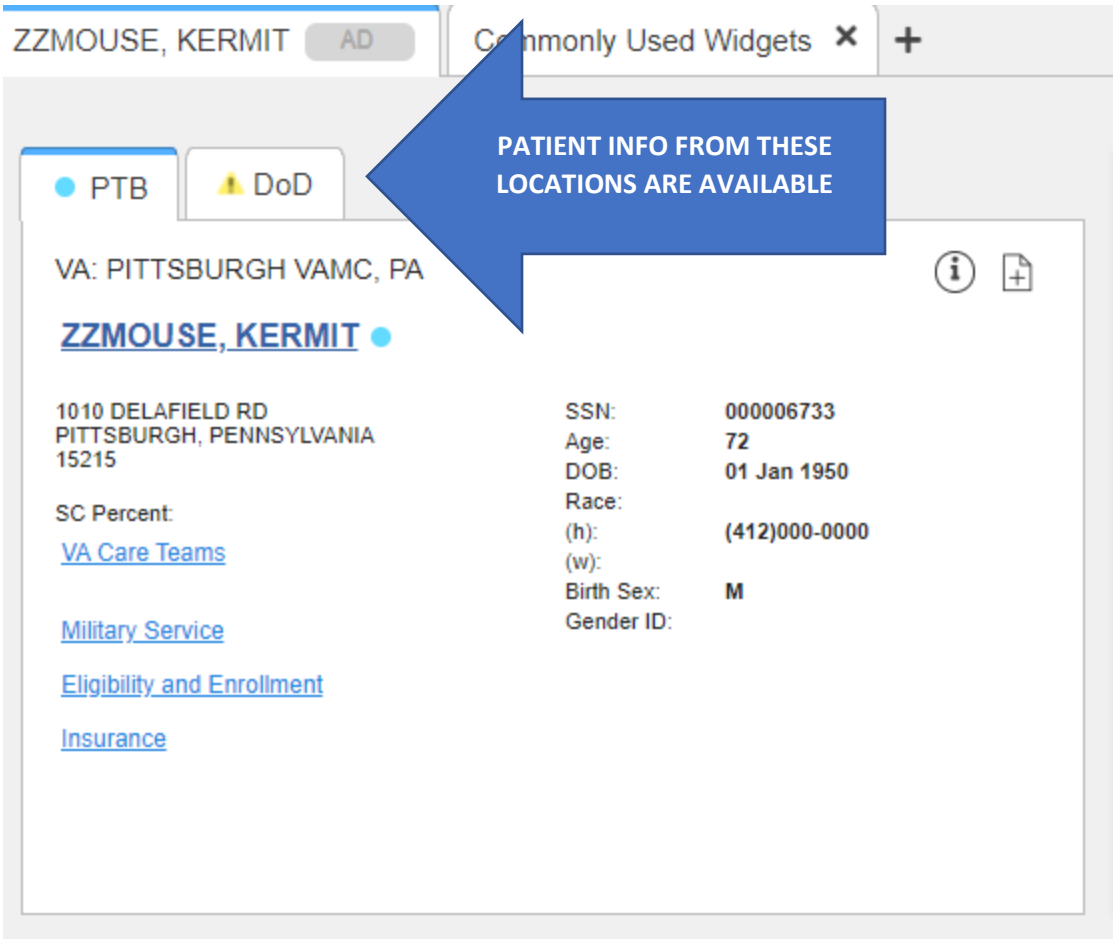

Select a certificate for authentication
Site pivlogon.iam.va.gov:443 needs your credentials:
[redacted]
Veterans Affairs User CA B1
[redacted]
7/14/2020
HIGHLIGHT YOUR CURRENT CERTIFICATE
Certificate information
OK
CLICK OK

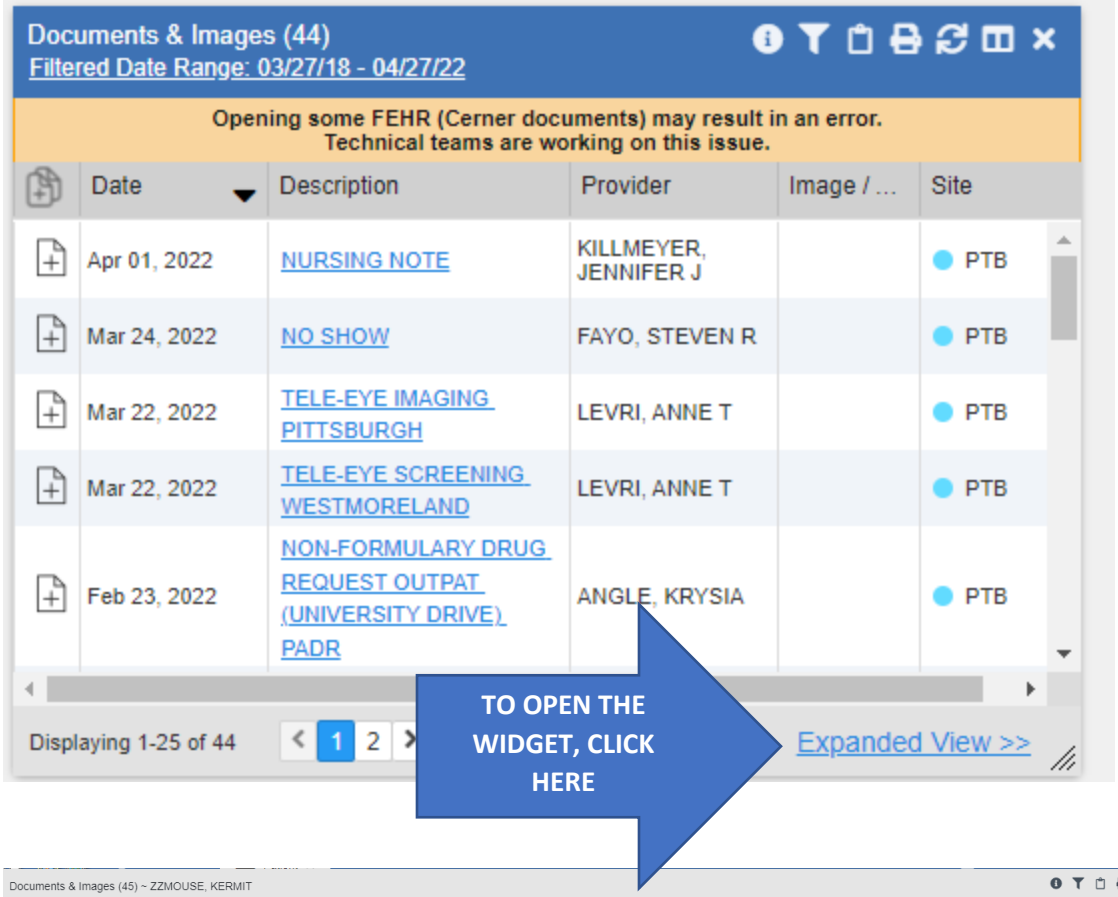

Joint
Longitudinal
Viewer
YOU ARE ACCESSING A U.S. GOVERNMENT (USG) INFORMATION SYSTEM (IS) THAT IS PROVIDED FOR USG-AUTHORIZED USE ONLY.
By using this IS (which includes any device attached to this IS), you consent to the following conditions:
• The USG routinely intercepts and monitors communications on this IS for purposes including, but not limited to, penetration testing, COMSEC monitoring, network operations and defense, personnel misconduct (PM), law enforcement (LE), and counterintelligence (CI) investigations.
• At any time, the USG may inspect and seize data stored on this IS.
• Communications using, or data stored on, this IS are not private, are subject to routine monitoring, interception, and search, and may be disclosed or used for any USG-authorized purpose.
• This IS includes security measures (e.g., authentication and access controls) to protect USG interests--not for your personal benefit or privacy.
• Notwithstanding the above, using this IS does not constitute consent to PM, LE or CI investigative searching or monitoring of the content of privileged communications, or work product, related to personal representation or services by attorneys, psychotherapists, or clergy, and their assistants. Such communications and work product are private and confidential.
I Accept
CLICK HERE

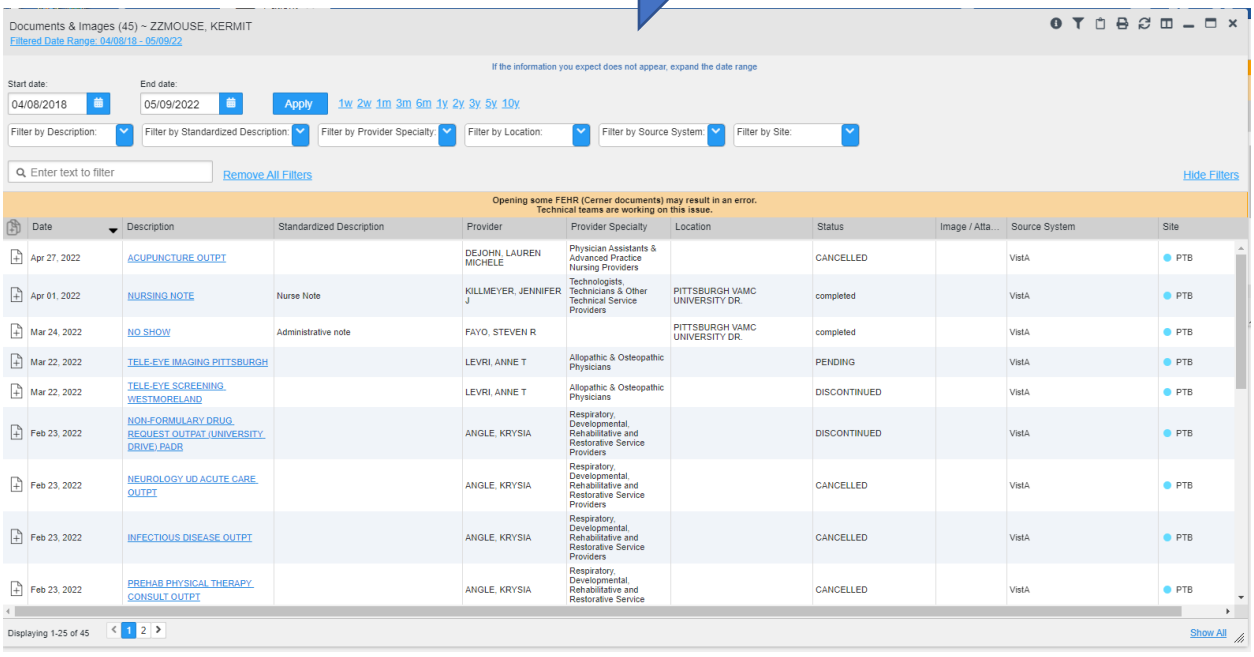
Multiple common "Widgets" will be immediately available.



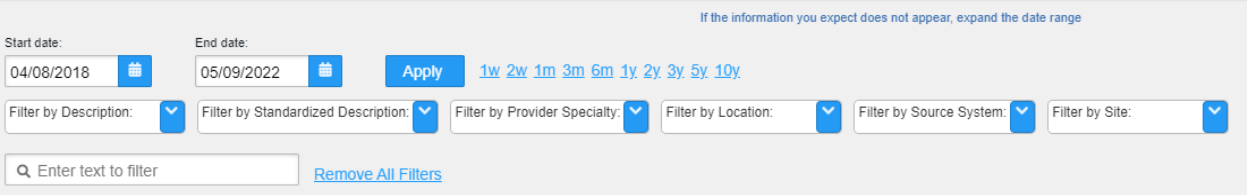
SCROLL TO SEE MORE


ZZMOUSE, KERMIT AD
Commonly Used Widgets
PTB
DoD
PATIENT INFO FROM THESE LOCATIONS ARE AVAILABLE
VA: PITTSBURGH VAMC, PA
ZZMOUSE, KERMIT
1010 DELAFIELD RD
PITTSBURGH, PENNSYLVANIA
15215
SC Percent:
VA Care Teams
Military Service
Eligibility and Enrollment
Insurance
SSN: 000006733
Age: 72
DOB: 01 Jan 1950
Race:
(h): (412)000-0000
(w):
Birth Sex: M
Gender ID:

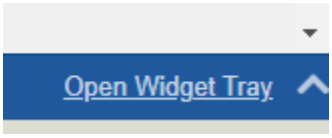

Documents & Images (44)
Filtered Date Range: 03/27/18 - 04/27/22
Opening some FEHR (Cerner documents) may result in an error.
Technical teams are working on this issue.
Date
Description
Provider
Image / ...
Site
Apr 01, 2022
NURSING NOTE
KILLMEYER, JENNIFER J
PTB
Mar 24, 2022
NO SHOW
FAYO, STEVEN R
PTB
Mar 22, 2022
TELE-EYE IMAGING PITTSBURGH
LEVRI, ANNE T
PTB
Mar 22, 2022
TELE-EYE SCREENING WESTMORELAND
LEVRI, ANNE T
PTB
Feb 23, 2022
NON-FORMULARY DRUG REQUEST OUTPAT (UNIVERSITY DRIVE) PADR
ANGLE, KRYSIA
PTB
Displaying 1-25 of 44
1
2
TO OPEN THE WIDGET, CLICK HERE
Expanded View >>

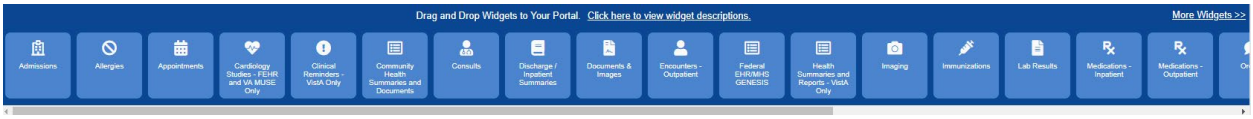

Documents & Images (45) ~ ZZMOUSE, KERMIT
Filtered Date Range: 04/08/18 - 05/09/22
If the information you expect does not appear, expand the date range
Start date:
04/08/2018
End date:
05/09/2022
Apply
1w 2w 1m 3m 6m 1y 2y 3y 5y 10y
Filter by Description:
Filter by Standardized Description:
Filter by Provider Specialty:
Filter by Location:
Filter by Source System:
Filter by Site:
Enter text to filter
Remove All Filters
Hide Filters
Opening some FEHR (Cerner documents) may result in an error.
Technical teams are working on this issue.
Date
Description
Standardized Description
Provider
Provider Specialty
Location
Status
Image / Atta...
Source System
Site
Apr 27, 2022
ACUPUNCTURE OUTPT
DEJOHN, LAUREN MICHELE
Physician Assistants & Advanced Practice Nursing Providers
CANCELLED
VistA
PTB
Apr 01, 2022
NURSING NOTE
Nurse Note
KILLMEYER, JENNIFER J
Technologists, Technicians & Other Technical Service Providers
PITTSBURGH VAMC UNIVERSITY DR.
completed
VistA
PTB
Mar 24, 2022
NO SHOW
Administrative note
FAYO, STEVEN R
PITTSBURGH VAMC UNIVERSITY DR.
completed
VistA
PTB
Mar 22, 2022
TELE-EYE IMAGING PITTSBURGH
LEVRI, ANNE T
Allopathic & Osteopathic Physicians
PENDING
VistA
PTB
Mar 22, 2022
TELE-EYE SCREENING WESTMORELAND
LEVRI, ANNE T
Allopathic & Osteopathic Physicians
DISCONTINUED
VistA
PTB
Feb 23, 2022
NON-FORMULARY DRUG REQUEST OUTPAT (UNIVERSITY DRIVE) PADR
ANGLE, KRYSIA
Respiratory, Developmental, Rehabilitative and Restorative Service Providers
DISCONTINUED
VistA
PTB
Feb 23, 2022
NEUROLOGY UD ACUTE CARE OUTPT
ANGLE, KRYSIA
Respiratory, Developmental, Rehabilitative and Restorative Service Providers
CANCELLED
VistA
PTB
Feb 23, 2022
INFECTIOUS DISEASE OUTPT
ANGLE, KRYSIA
Respiratory, Developmental, Rehabilitative and Restorative Service Providers
CANCELLED
VistA
PTB
Feb 23, 2022
PREHAB PHYSICAL THERAPY CONSULT OUTPT
ANGLE, KRYSIA
Respiratory, Developmental, Rehabilitative and Restorative Service
CANCELLED
VistA
PTB
Displaying 1-25 of 45
1
2
Show All

You can use filters to help you find something from a specific location, timeframe, provider, etc.

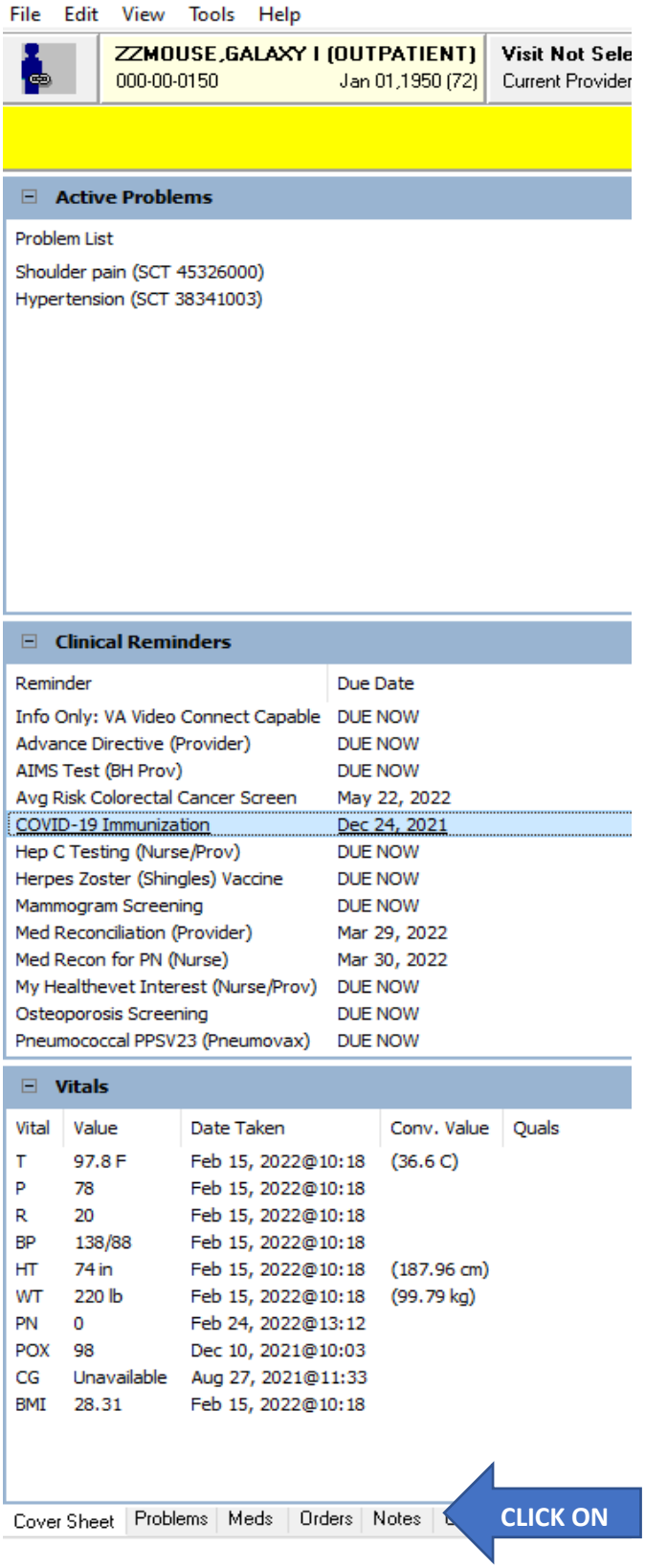


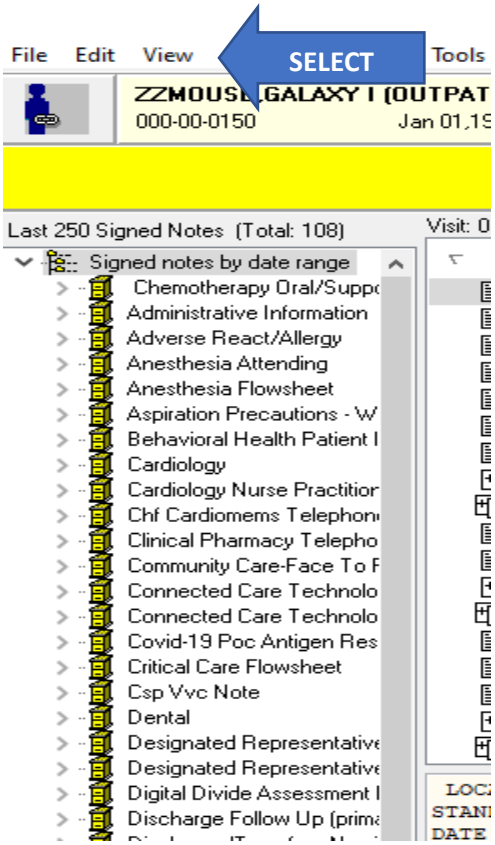
You can personalize the widgets you want to see by opening the widget tray and searching for what widgets you want on the screen.

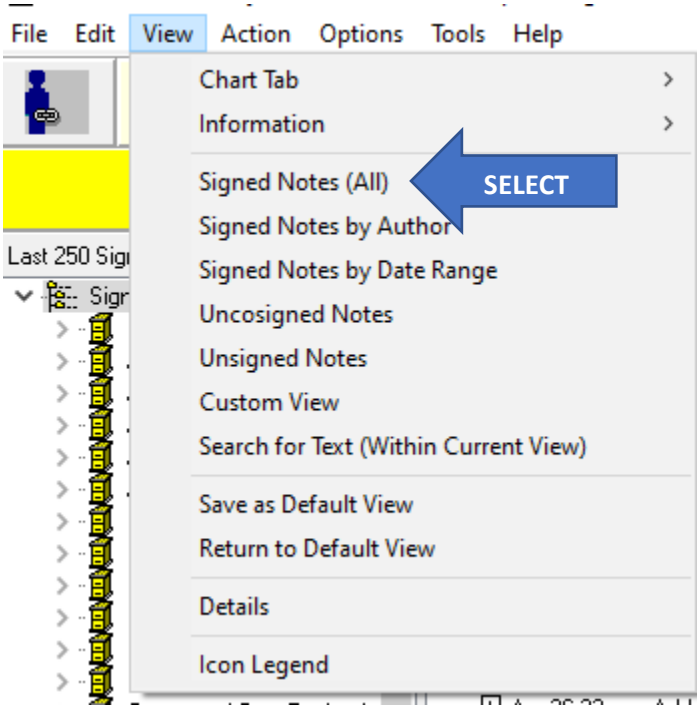




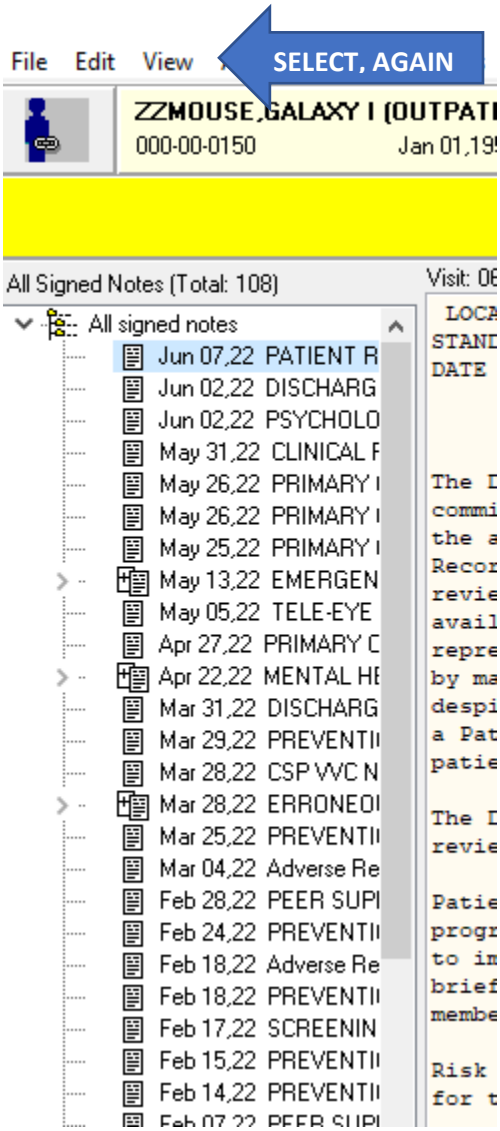
SEARCHING FOR "WORDS" IN CPRS

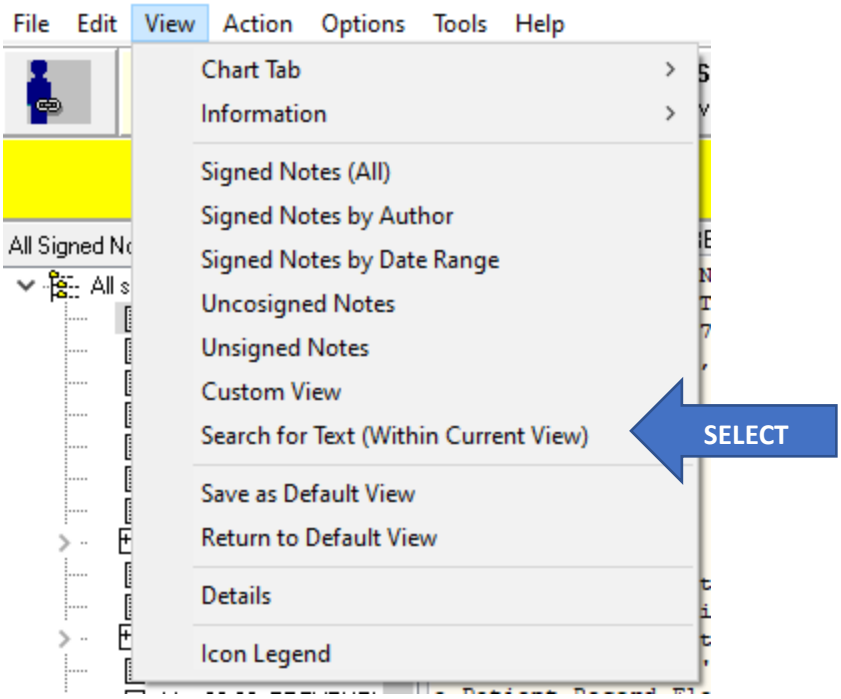


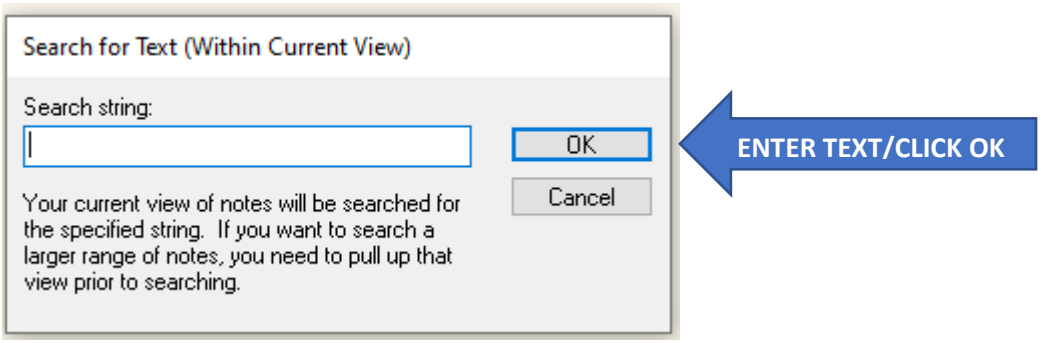

File
Edit
View
SELECT
Tools
000-00-0150
Jan 01,19
Last 250 Signed Notes (Total: 108)
Visit: 0
Signed notes by date range
Chemotherapy Oral/Suppo
Administrative Information
Adverse React/Allergy
Anesthesia Attending
Anesthesia Flowsheet
Aspiration Precautions - W
Behavioral Health Patient I
Cardiology
Cardiology Nurse Practitior
Chf Cardiomems Telephon
Clinical Pharmacy Telepho
Community Care-Face To F
Connected Care Technolo
Connected Care Technolo
Covid-19 Poc Antigen Res
Critical Care Flowsheet
Csp Vvc Note
Dental
Designated Representative
Designated Representative
Digital Divide Assessment I
Discharge Follow Up (prima


File
Edit
View
Action
Options
Tools
Help
Chart Tab
Information
Signed Notes (All)
SELECT
Signed Notes by Author
Signed Notes by Date Range
Uncosigned Notes
Unsigned Notes
Custom View
Search for Text (Within Current View)
Save as Default View
Return to Default View
Details
Icon Legend

This will open all notes in reverse chronological order.

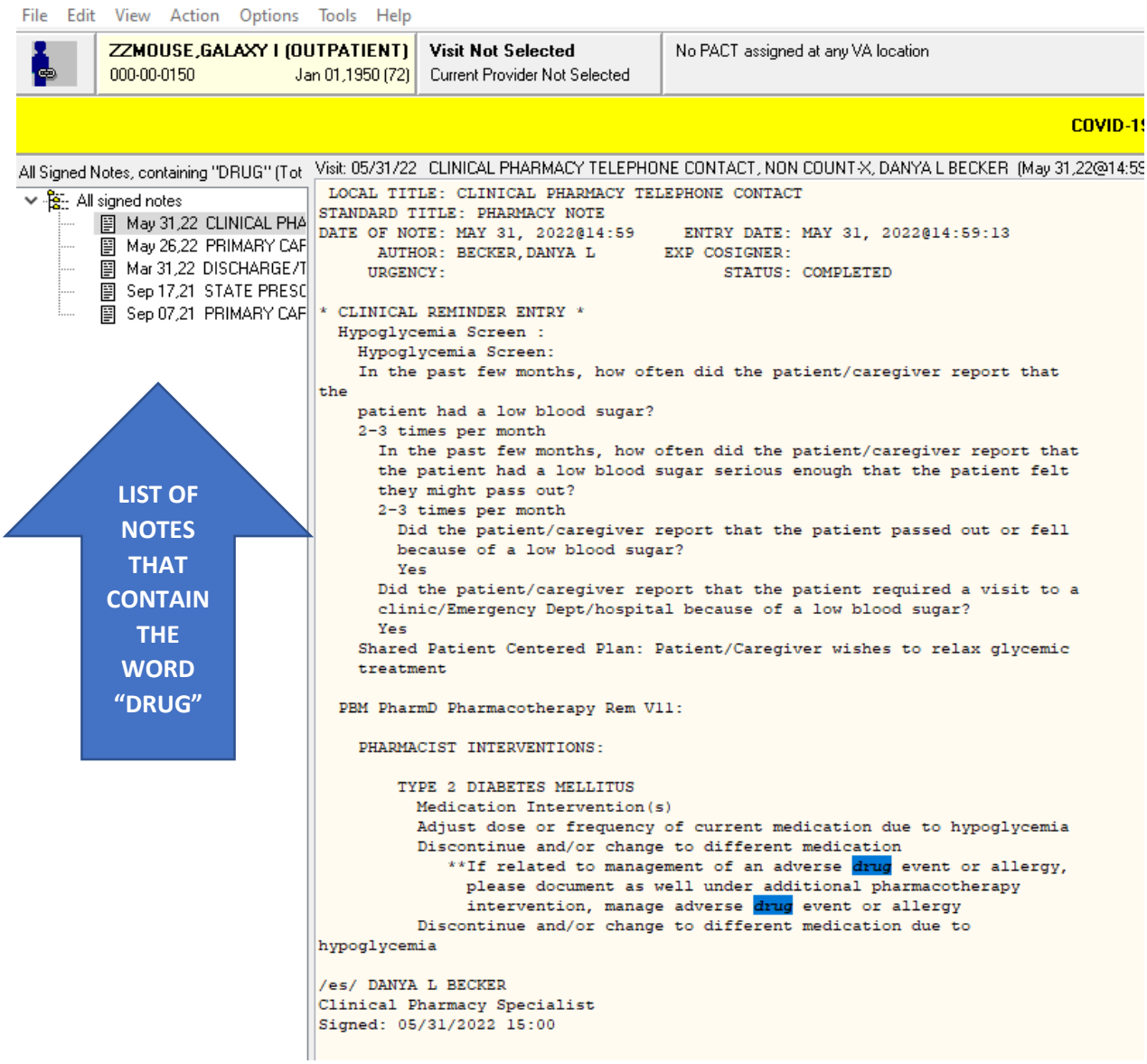






CPRS will search for the word/phrase that was entered. When all notes contain that word/phrase are isolated, a list of notes will be generated, and the word/phrase will be highlighted within each note.

The word searched was "drug".


File Edit View Action Options Tools Help
ZZMOUSE,GALAXY I (OUTPATIENT)
000-00-0150 Jan 01,1950 (72)
Visit Not Selected
Current Provider Not Selected
No PACT assigned at any VA location
COVID-19
All Signed Notes, containing "DRUG" (Tot
All signed notes
May 31,22 CLINICAL PHA
May 26,22 PRIMARY CAF
Mar 31,22 DISCHARGE/T
Sep 17,21 STATE PRESC
Sep 07,21 PRIMARY CAF
Visit: 05/31/22 CLINICAL PHARMACY TELEPHONE CONTACT, NON COUNT-X, DANYA L BECKER (May 31,22@14:59
LOCAL TITLE: CLINICAL PHARMACY TELEPHONE CONTACT
STANDARD TITLE: PHARMACY NOTE
DATE OF NOTE: MAY 31, 2022@14:59 ENTRY DATE: MAY 31, 2022@14:59:13
AUTHOR: BECKER,DANYA L EXP COSIGNER:
URGENCY: STATUS: COMPLETED
* CLINICAL REMINDER ENTRY *
Hypoglycemia Screen :
Hypoglycemia Screen:
In the past few months, how often did the patient/caregiver report that the
patient had a low blood sugar?
2-3 times per month
In the past few months, how often did the patient/caregiver report that the patient had a low blood sugar serious enough that the patient felt they might pass out?
2-3 times per month
Did the patient/caregiver report that the patient passed out or fell because of a low blood sugar?
Yes
Did the patient/caregiver report that the patient required a visit to a clinic/Emergency Dept/hospital because of a low blood sugar?
Yes
Shared Patient Centered Plan: Patient/Caregiver wishes to relax glycemic treatment
PBM PharmD Pharmacotherapy Rem V11:
PHARMACIST INTERVENTIONS:
TYPE 2 DIABETES MELLITUS
Medication Intervention(s)
Adjust dose or frequency of current medication due to hypoglycemia
Discontinue and/or change to different medication
**If related to management of an adverse drug event or allergy, please document as well under additional pharmacotherapy intervention, manage adverse drug event or allergy
Discontinue and/or change to different medication due to hypoglycemia
/es/ DANYA L BECKER
Clinical Pharmacy Specialist
Signed: 05/31/2022 15:00
LIST OF NOTES THAT CONTAIN THE WORD "DRUG"

SPECIMEN COLLECTION AND PROCESSING FOR CENTRAL LABS

Most studies require that specimens that are drawn for the study are sent to a central lab (LabCorp, ICON, MedPace, PPD). Study and visit specific lab kits are provided by the sponsor.

Specimens are to be collected, processed, and shipped according to the study protocol and lab manual.

Research Staff are NOT authorized to draw labs from a port or peripheral lines. Should such a draw be necessary, work with VASTL Nursing Staff.

Study sponsor supplied lab kits must be checked monthly to ensure that an appropriate number of kits are available and that they are in date.

If a patient is a "tough stick" and central labs are required, we can utilize the VASTL Lab.

It is the responsibility of the individual collecting the specimen to ensure it is delivered to the mailroom for pick-up. To ensure that your specimen/shipment is picked up by UPS and/or FedEx on the day of the draw, deliver your shipment to the mail room no later than 2:00PM.

Central Lab Reports

Central lab reports will be transmitted to the CRC/CRN via email or fax. Upon receipt, they should be shared with the PI and/or Co-I as soon as possible for review, signature and retention in the participant's study binder. Verify with the Sponsor/CRO whether signatures can be electronic or must be "wet".

Results that are "flagged" require immediate attention by the PI. Should additional steps need to be taken with the subject as a result of the labs, these should be documented in CPRS and co-signed by the PCP when appropriate. Note that if any lab abnormality is deemed clinically significant by the PI, the abnormality needs to be reported as an Adverse Event.

ECG COLLECTION

VA ECG Equipment in MUSE

ECGs that are collected on the equipment provided by the VA that is located in the MUSE are to be collected for research purposes only. The ECG is automatically sent to VA Cardiology for reading (Follow the instructions on ECG machine for sending report). The ECG will be read by a VA Cardiologist and in most incidences, should be signed by the PI. The report will be available in VISTA Imaging in CPRS.

Study Supplied ECG Equipment

ECGs that are collected on equipment supplied by the study sponsor may require assistance from IT and approval of file transfer programs by both the local and national ISSO. Each instance will be evaluated separately.

Please ensure you are following the study protocol specific guidelines for ECG Collection.

RESEARCH PHARMACIST AND INVESTIGATIONAL DRUGS

Personnel and Contact Information		
Research Pharmacist	**Research Pharmacy Technician**	
Kai Chen, PharmD		
Office Location	**Hours of operation**	**Phone and MS Teams**
John Cochran, Building 1, Room A91	Monday – Friday 6:30am-3:00PM	314-289-6372

By policy all investigational drugs should be:

1) delivered directly to the Research Pharmacy or CTU(C201)
2) stored and dispensed from the Research Pharmacy or CTU(C201); exceptions may be permitted-consult RESEARCH PHARMACIST

RESEARCH PHARMACIST responsibilities include but are not limited to the following:

- Storing, preparing, dispensing, and ordering of all the investigational drugs for the VA St. Louis.
- Follow the protocols, accurately document, and maintain all necessary records.
- Execute all the necessary steps to initiate, maintain, and close out studies.
- Actively maintain research pharmacy binders for all research studies that includes a study drug for compliance.
- Procurement and maintenance of the necessary equipment to run the research pharmacy.
- Collaborate with pharmacy informatics and the VA clinical application coordinators to enter new research drugs into the pharmacy drug package so they can be prescribed for research patients.
- Available to provide formal and informal drug information.
- Delivers presentations and in-services to patients, providers, and other health care staff.
- Passed all research study inspections and audits.
- Collaboration with the Clinical Trials Unit (CTU) to screen for potential research patients on studies.
- Work with PI's to pre-screen patients for potential studies to see if we have enough patients to meet the study requirements.
- Run medication reports for healthcare providers.
- Assist PI's with filling out the 10-9012 on new studies.
- Attending and provide research information at study site visits to help acquire new studies.
- Work with providers to obtain drug and research costs for obtaining grants.
- Utilize their scope in research to order and refill research medications for our patients.
- Responsible for developing and maintaining policies and procedures related to investigational drugs (SOPs and MCMs).

- Participation in the monthly AFIRM meetings to provide input and knowledge to better the research department.

Investigational drugs prepared for study participants:

In an inpatient setting, investigational drugs will be delivered to the study CRC/CRN/Principal investigator or directly to the patient care ward clinical staff/medication room.

In an outpatient setting:

1) In certain circumstances, investigational drugs may be shipped directly to the study participant as permitted by the sponsor
2) Delivered to the CRC/CRN/investigator and subsequently provided to the study participant

Contact RESEARCH PHARMACIST when:

Active Protocol Phase

- Notify RESEARCH PHARMACIST of upcoming study visits for enrolled participants verbally and in writing via email. Add study visit to shared calendar when research pharmacist is needed.
- PI or research pharmacist to enter order for enrolled research patients. Schedule sponsor site initiation visits and routine audits of investigational drugs and records
- Study team members will notify the research pharmacist of any updated study documents: IRB renewals, amendments, etc.

End of Study

- Notify RESEARCH PHARMACIST of study closure and provide letter from IRB
- Schedule sponsor closure visit for review of accountability records, remaining investigational drug inventory and provide instructions on final disposition of study medications
- For investigator- initiated protocols that will not have a sponsor closure visit: discuss final disposition of remaining inventory of investigational drugs

Informed Consent Form:

- Investigator or CRC/CRN will provide the Research Pharmacist a copy of an approved signed informed consent form prior and completed 10-9012 to the initial dispensing of investigational drug.

Dispensation and Delivery

- RESEARCH PHARMACIST will prepare, label and dispense the investigational drug ordered for the study participant as per study protocol requirements and all relevant policies and regulations.

- For investigational drugs intended for outpatient administration and dispensed from the Research Pharmacist and will be delivered directly to the study participant on site, to the study coordinator/investigator for provision to the study participant.
- In certain circumstances and as permitted by the sponsor, the investigational drug may be shipped directly to the study participant's address as listed in the VA system.
- For investigational drugs intended for inpatient administration RESEARCH Medication will be delivered to the study coordinator/investigator, the patient care area clinical staff or medication cart.

Investigational Drug Returns

- Previously dispensed unused investigational drugs may be returned to the study coordinator/investigator for compliance review as per study protocol/sponsor instructions.
- Returned unused investigational drug supplies may be provided to RESEARCH PHARMACIST for storage in the Pharmacy until a sponsor representative performs a review and/or provides instructions to RESEARCH PHARMACIST for disposition.

CPRS RESEARCH CLINICS

All research documentation must be charted in CPRS against a research clinic.

ENTERING RESEARCH NOTES INTO CPRS

Every patient visit requires the completion of a research note in CPRS.

If multiple initial "visits" are performed on the same day (e.g. Screening and Baseline/Screening and Enrollment, etc.), a Research Initial Consent Note, Research Study Alert and Research Note must all be completed. Thereafter, only a Research Note is necessary.

DISCLAIMER:

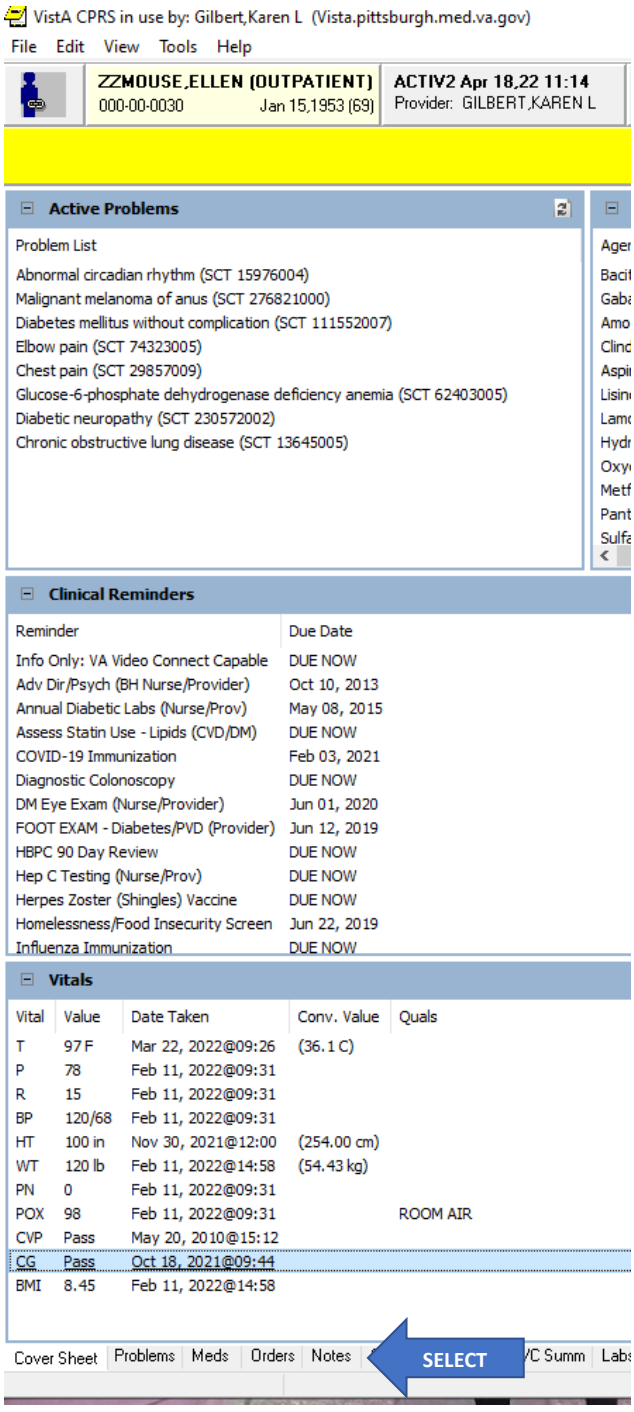
Every effort has been made to show how to enter items into CPRS correctly, however, things change ... If you see something different DON'T:

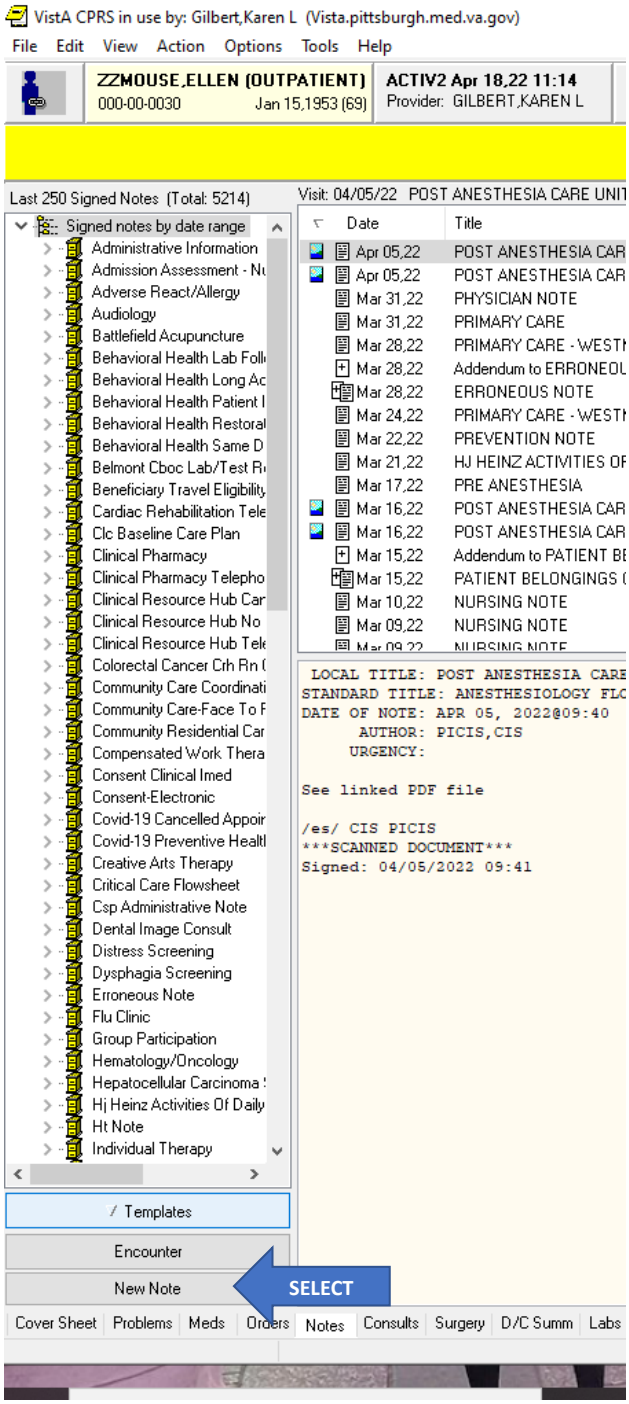
THINK YOU HAVE DONE SOMETHING WRONG

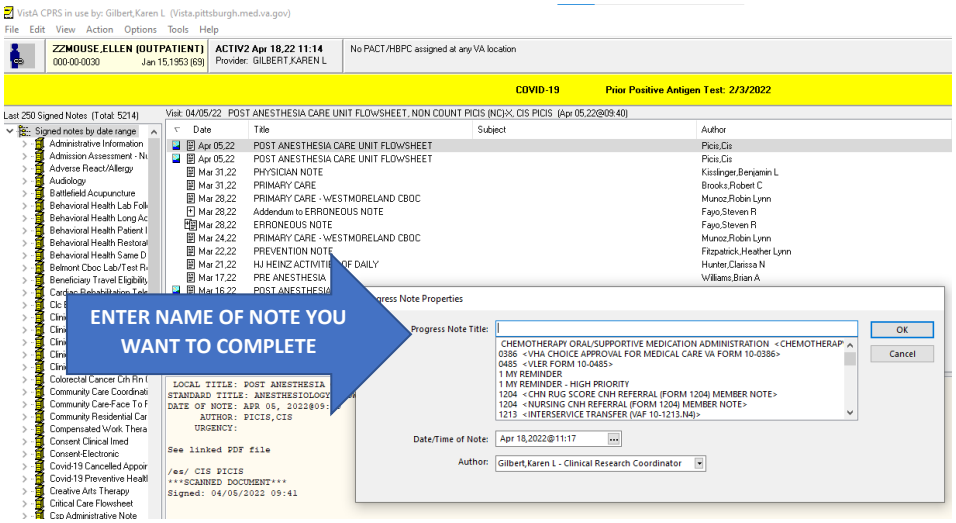
BE AFRAID TO ASK QUESTIONS

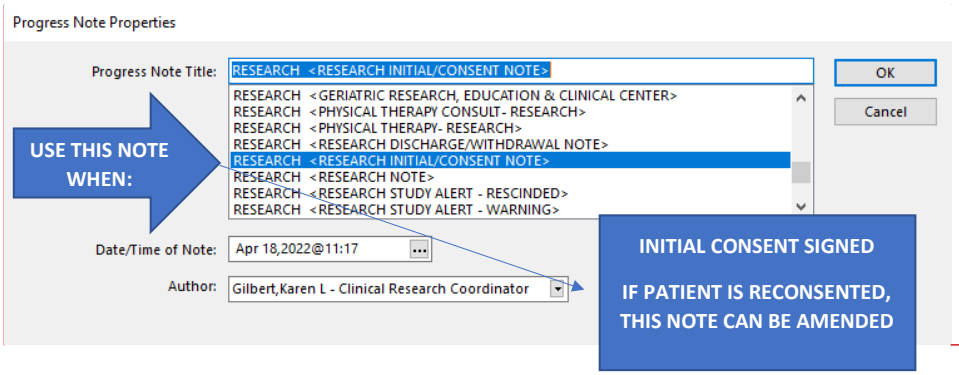
ASSUME EVERYONE ELSE IS AWARE OF THE DIFFERNCE. SHARE THE DIFFERENCE.

Example

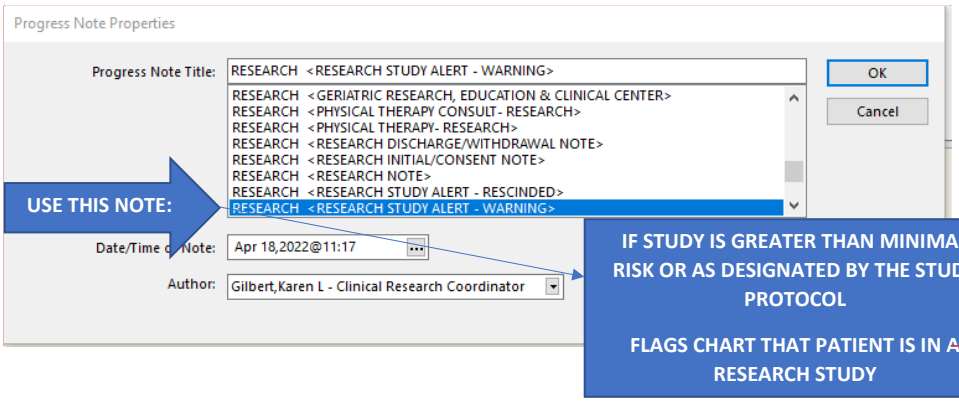

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Tools Help
ZZMOUSE,ELLEN (OUTPATIENT)
000-00-0030 Jan 15,1953 (69)
ACTIV2 Apr 18,22 11:14
Provider: GILBERT,KAREN L
Active Problems
Problem List
Abnormal circadian rhythm (SCT 15976004)
Malignant melanoma of anus (SCT 276821000)
Diabetes mellitus without complication (SCT 111552007)
Elbow pain (SCT 74323005)
Chest pain (SCT 29857009)
Glucose-6-phosphate dehydrogenase deficiency anemia (SCT 62403005)
Diabetic neuropathy (SCT 230572002)
Chronic obstructive lung disease (SCT 13645005)
Clinical Reminders
Reminder
Due Date
Info Only: VA Video Connect Capable DUE NOW
Adv Dir/Psych (BH Nurse/Provider) Oct 10, 2013
Annual Diabetic Labs (Nurse/Prov) May 08, 2015
Assess Statin Use - Lipids (CVD/DM) DUE NOW
COVID-19 Immunization Feb 03, 2021
Diagnostic Colonoscopy DUE NOW
DM Eye Exam (Nurse/Provider) Jun 01, 2020
FOOT EXAM - Diabetes/PVD (Provider) Jun 12, 2019
HBPC 90 Day Review DUE NOW
Hep C Testing (Nurse/Prov) DUE NOW
Herpes Zoster (Shingles) Vaccine DUE NOW
Homelessness/Food Insecurity Screen Jun 22, 2019
Influenza Immunization DUE NOW
Vitals
Vital Value Date Taken Conv. Value Quals
T 97 F Mar 22, 2022@09:26 (36.1 C)
P 78 Feb 11, 2022@09:31
R 15 Feb 11, 2022@09:31
BP 120/68 Feb 11, 2022@09:31
HT 100 in Nov 30, 2021@12:00 (254.00 cm)
WT 120 lb Feb 11, 2022@14:58 (54.43 kg)
PN 0 Feb 11, 2022@09:31
POX 98 Feb 11, 2022@09:31 ROOM AIR
CVP Pass May 20, 2010@15:12
CG Pass Oct 18, 2021@09:44
BMI 8.45 Feb 11, 2022@14:58
Cover Sheet
Problems
Meds
Orders
Notes
SELECT
Labs


VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,ELLEN (OUTPATIENT)
000-00-0030 Jan 15,1953 (69)
ACTIV2 Apr 18,22 11:14
Provider: GILBERT,KAREN L
Last 250 Signed Notes (Total: 5214)
Visit: 04/05/22 POST ANESTHESIA CARE UNIT
Signed notes by date range
Administrative Information
Admission Assessment - Nu
Adverse React/Allergy
Audiology
Battlefield Acupuncture
Behavioral Health Lab Foll
Behavioral Health Long Ac
Behavioral Health Patient I
Behavioral Health Restorat
Behavioral Health Same D
Belmont Cboc Lab/Test Ri
Beneficiary Travel Eligibility
Cardiac Rehabilitation Tele
Clc Baseline Care Plan
Clinical Pharmacy
Clinical Pharmacy Telepho
Clinical Resource Hub Car
Clinical Resource Hub No
Clinical Resource Hub Tel
Colorectal Cancer Crh Rn (
Community Care Coordinati
Community Care-Face To F
Community Residential Car
Compensated Work Thera
Consent Clinical Imed
Consent-Electronic
Covid-19 Cancelled Appoir
Covid-19 Preventive Healtl
Creative Arts Therapy
Critical Care Flowsheet
Csp Administrative Note
Dental Image Consult
Distress Screening
Dysphagia Screening
Erroneous Note
Flu Clinic
Group Participation
Hematology/Oncology
Hepatocellular Carcinoma
Hj Heinz Activities Of Daily
Ht Note
Individual Therapy
Date
Title
Apr 05,22 POST ANESTHESIA CAR
Apr 05,22 POST ANESTHESIA CAR
Mar 31,22 PHYSICIAN NOTE
Mar 31,22 PRIMARY CARE
Mar 28,22 PRIMARY CARE - WEST
Mar 28,22 Addendum to ERRONEOU
Mar 28,22 ERRONEOUS NOTE
Mar 24,22 PRIMARY CARE - WEST
Mar 22,22 PREVENTION NOTE
Mar 21,22 HJ HEINZ ACTIVITIES OF
Mar 17,22 PRE ANESTHESIA
Mar 16,22 POST ANESTHESIA CAR
Mar 16,22 POST ANESTHESIA CAR
Mar 15,22 Addendum to PATIENT BE
Mar 15,22 PATIENT BELONGINGS
Mar 10,22 NURSING NOTE
Mar 09,22 NURSING NOTE
LOCAL TITLE: POST ANESTHESIA CARE
STANDARD TITLE: ANESTHESIOLOGY FLO
DATE OF NOTE: APR 05, 2022@09:40
AUTHOR: PICIS,CIS
URGENCY:
See linked PDF file
/es/ CIS PICIS
SCANNED DOCUMENT
Signed: 04/05/2022 09:41
Templates
Encounter
New Note
SELECT
Cover Sheet Problems Meds Orders Notes Consults Surgery D/C Summ Labs

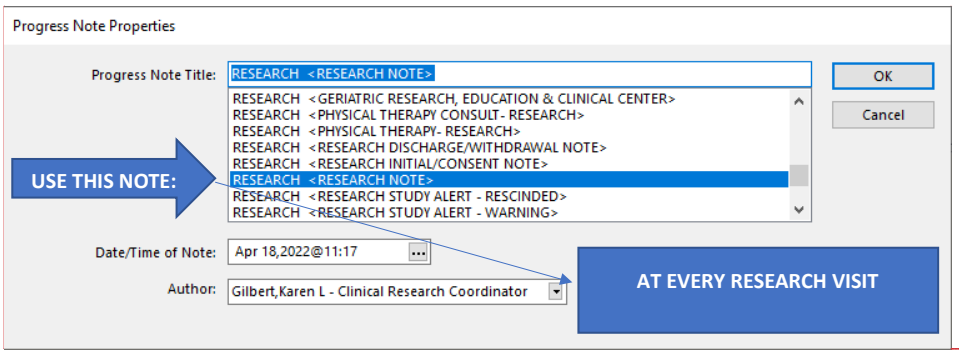




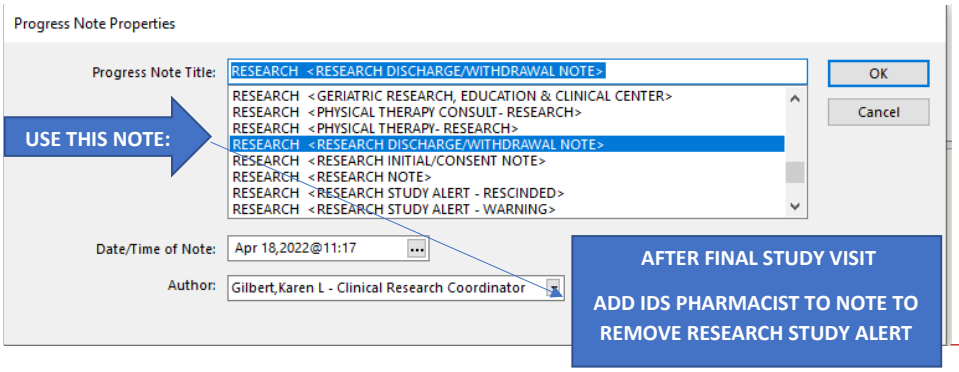
Commented [GAE(1]: Gary/Study Coordinators-Will need Screen Shot of our local Research Note options



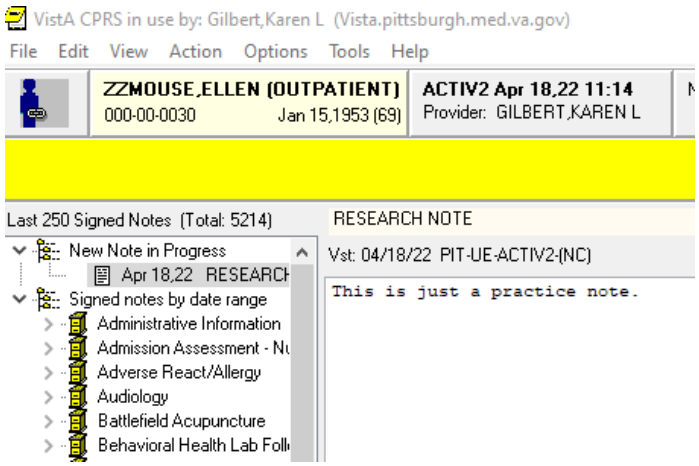
Commented [GAE(2]: Gary/Study Coordinators-Need to include local procedure "how to"/Screen Shot



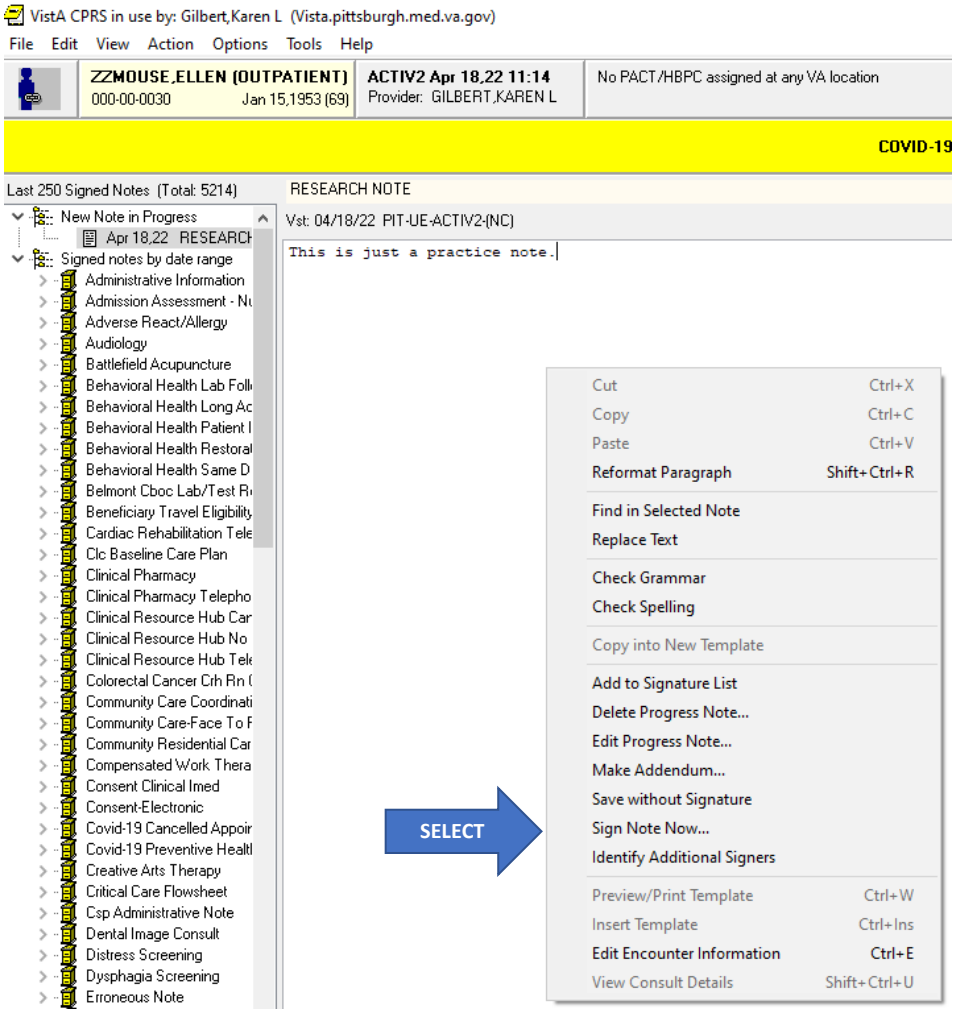
Commented [GAE(3]: Gary/Study Coordinators-Will need Screen Shot

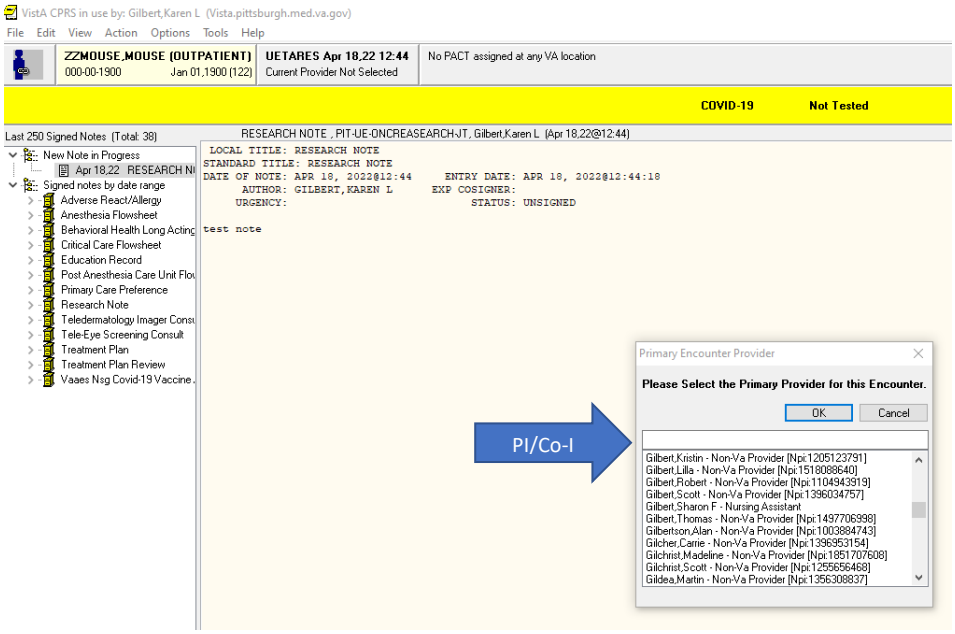


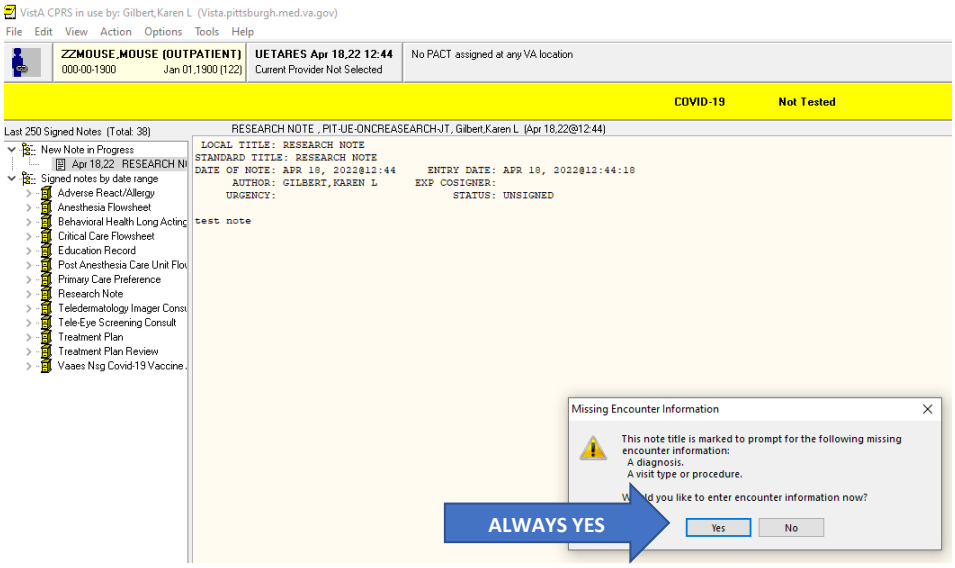
Commented [GAE(4]: Gary/Study Coordinators-Will need Screen Shot

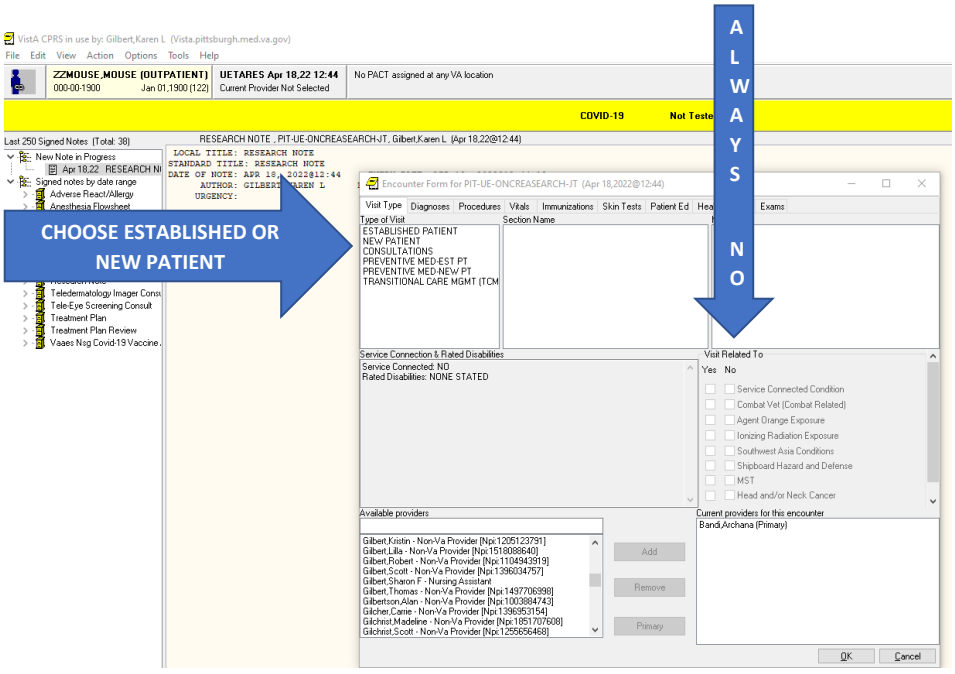


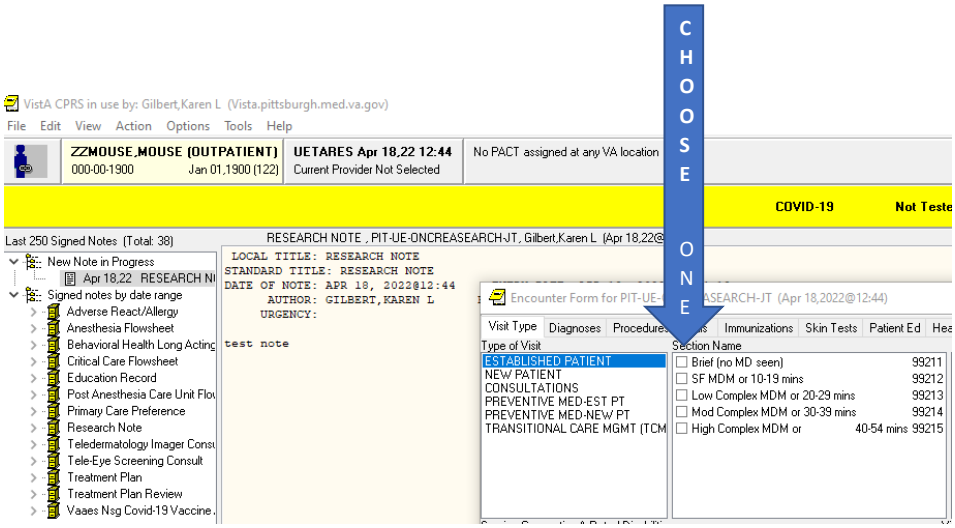
WHEN DONE WITH NOTE – RIGHT CLICK MOUSE TO SIGN



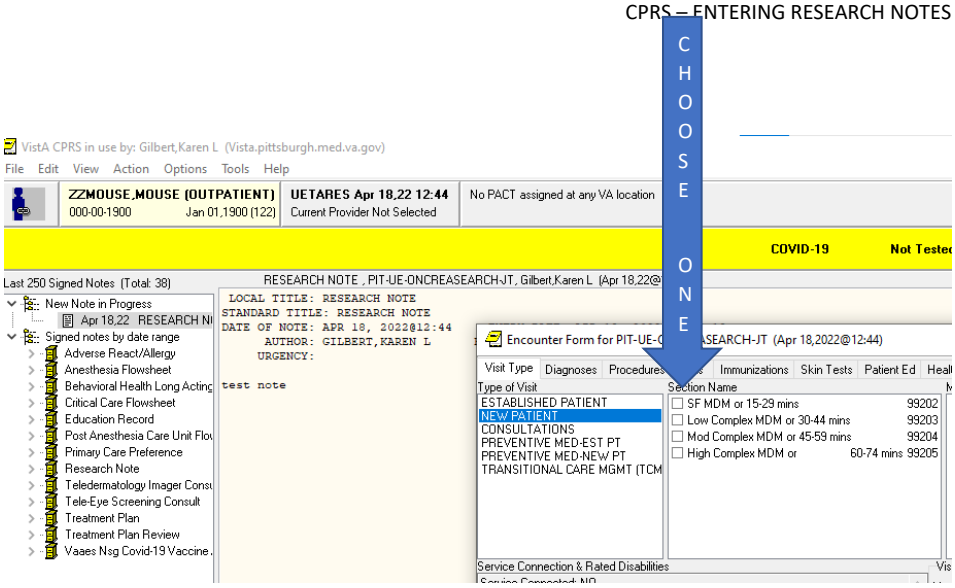

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA location
COVID-19 Not Tested
Last 250 Signed Notes (Total: 38)
New Note in Progress
Apr 18,22 RESEARCH N
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Cons
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Apr 18,22@12:44)
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44 ENTRY DATE: APR 18, 2022@12:44:18
AUTHOR: GILBERT,KAREN L EXP COSIGNER:
URGENCY: STATUS: UNSIGNED
test note
PI/Co-I
Primary Encounter Provider
Please Select the Primary Provider for this Encounter.
OK
Cancel
Gilbert,Kristin - Non-Va Provider [Npi:1205123791]
Gilbert,Lilla - Non-Va Provider [Npi:1518088640]
Gilbert,Robert - Non-Va Provider [Npi:1104943919]
Gilbert,Scott - Non-Va Provider [Npi:1396034757]
Gilbert,Sharon F - Nursing Assistant
Gilbert,Thomas - Non-Va Provider [Npi:1497706998]
Gilbertson,Alan - Non-Va Provider [Npi:1003884743]
Gilcher,Carrie - Non-Va Provider [Npi:1396953154]
Gilchrist,Madeline - Non-Va Provider [Npi:1851707608]
Gilchrist,Scott - Non-Va Provider [Npi:1255656468]
Gildea,Martin - Non-Va Provider [Npi:1356308837]

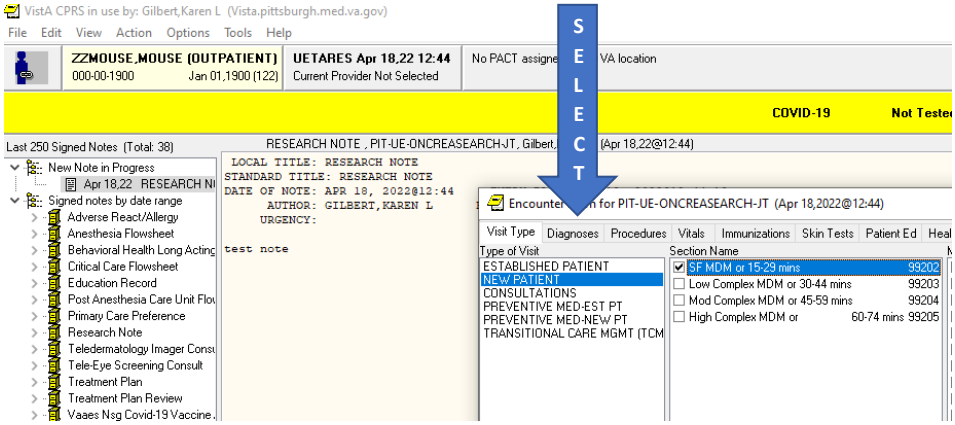

ALWAYS YES
Missing Encounter Information
This note title is marked to prompt for the following missing encounter information:
A diagnosis.
A visit type or procedure.
Yes
No

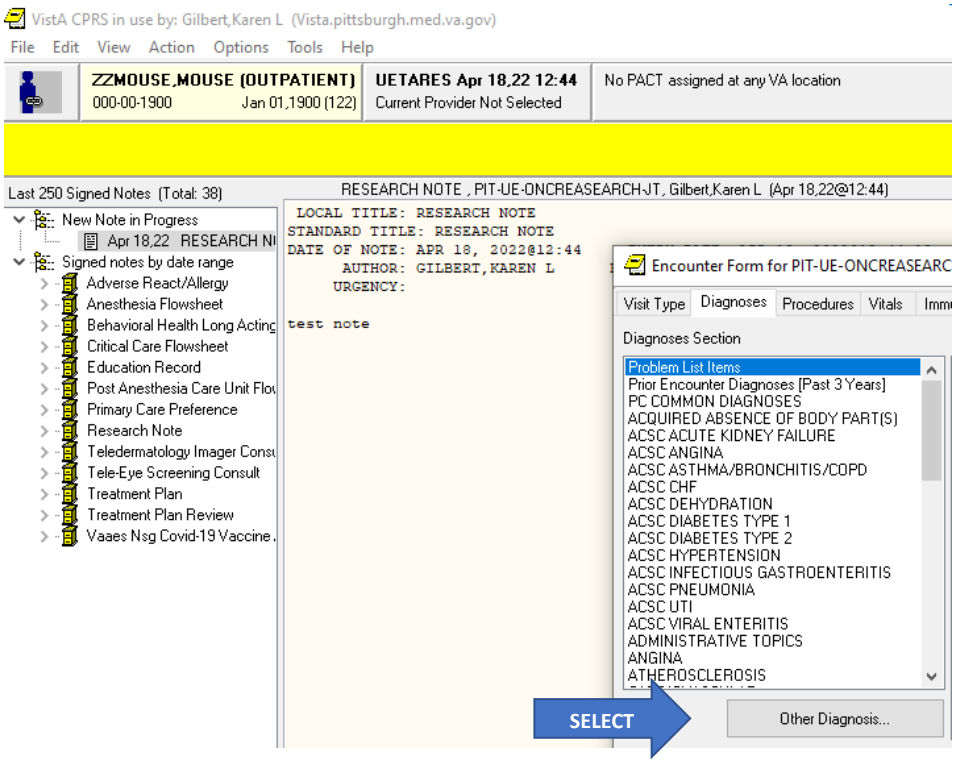

CHOOSE ESTABLISHED OR NEW PATIENT
ALWAYS NO

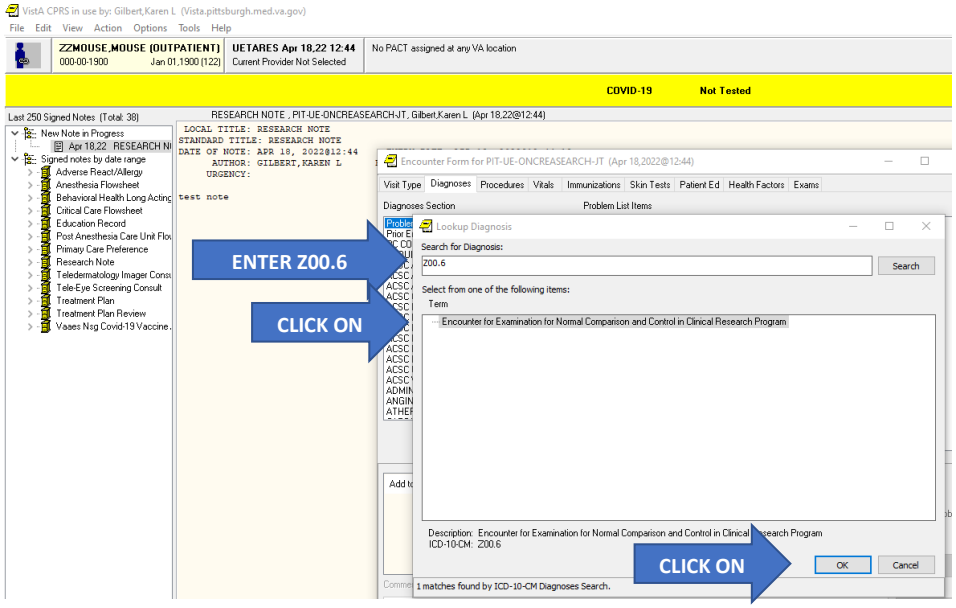

CHOOSE ONE
VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA location
COVID-19
Last 250 Signed Notes (Total: 38)
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Apr 18,22@
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
Encounter Form for PIT-UE-
ASEARCH-JT (Apr 18,2022@12:44)
Visit Type
Diagnoses
Procedures
Immunizations
Skin Tests
Patient Ed
Type of Visit
ESTABLISHED PATIENT
NEW PATIENT
CONSULTATIONS
PREVENTIVE MED-EST PT
PREVENTIVE MED-NEW PT
TRANSITIONAL CARE MGMT (TCM
Section Name
Brief (no MD seen) 99211
SF MDM or 10-19 mins 99212
Low Complex MDM or 20-29 mins 99213
Mod Complex MDM or 30-39 mins 99214
High Complex MDM or 40-54 mins 99215

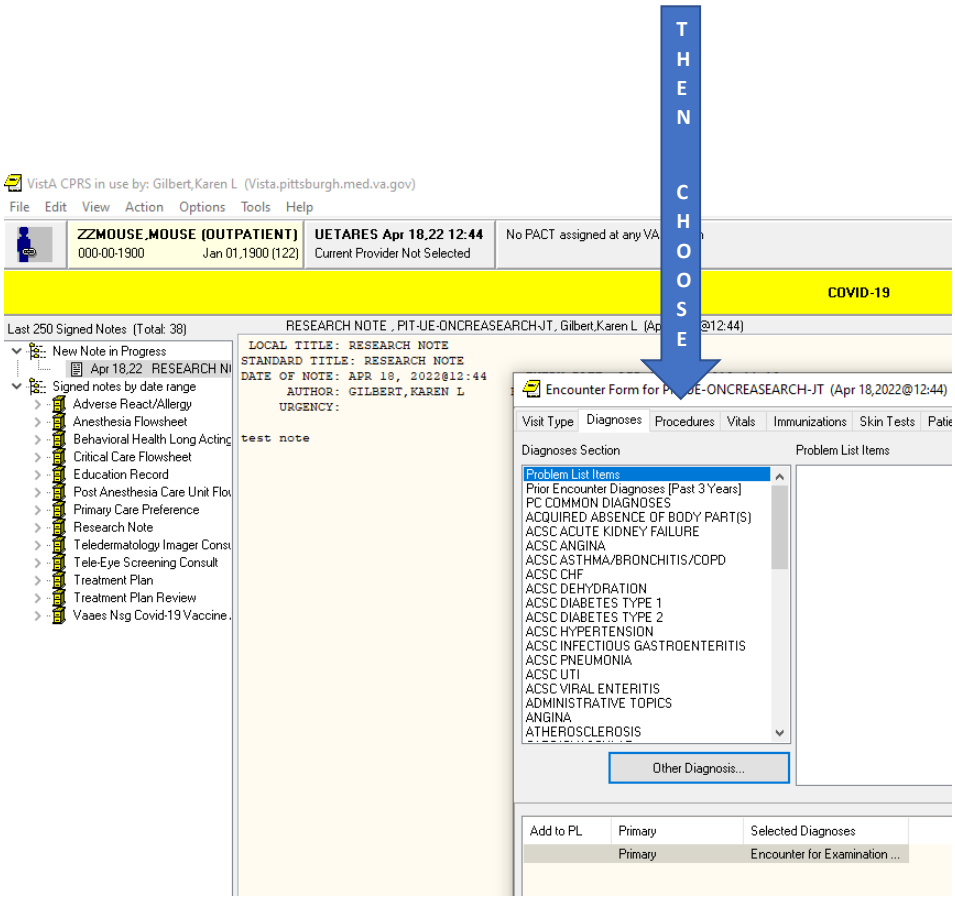
OR

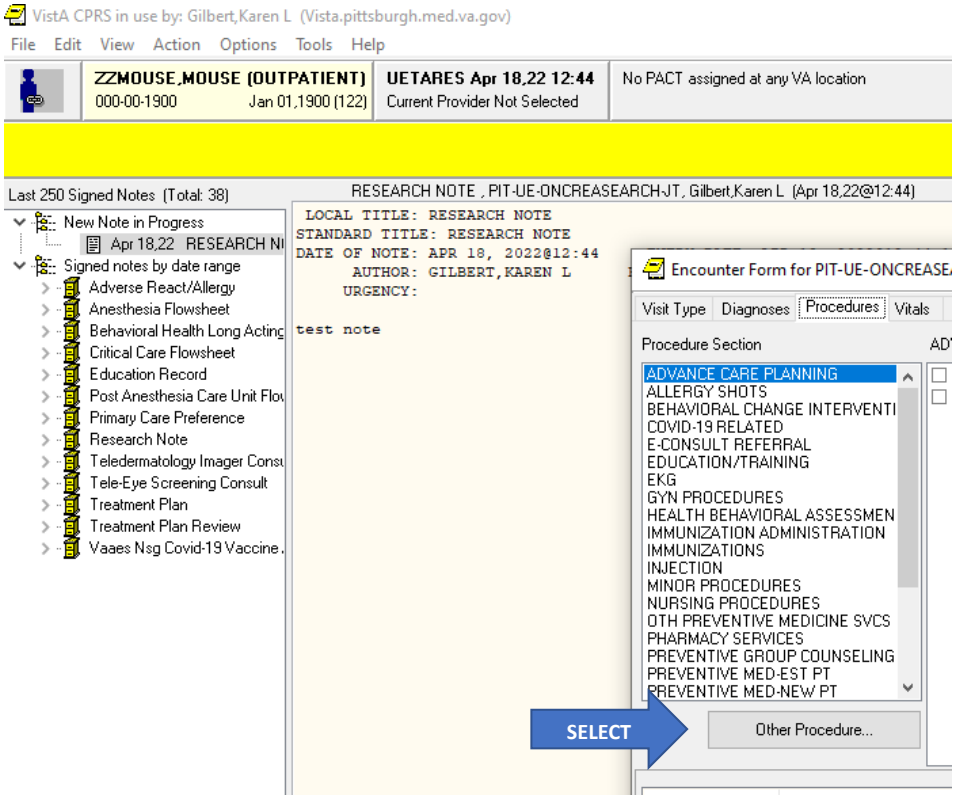

CHOOSE ONE
VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA location
COVID-19
Last 250 Signed Notes (Total: 38)
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Apr 18,22@
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
Encounter Form for PIT-UE-
SEARCH-JT (Apr 18,2022@12:44)
Visit Type
Diagnoses
Procedures
Immunizations
Skin Tests
Patient Ed
Type of Visit
ESTABLISHED PATIENT
NEW PATIENT
CONSULTATIONS
PREVENTIVE MED-EST PT
PREVENTIVE MED-NEW PT
TRANSITIONAL CARE MGMT (TCM
Section Name
SF MDM or 15-29 mins 99202
Low Complex MDM or 30-44 mins 99203
Mod Complex MDM or 45-59 mins 99204
High Complex MDM or 60-74 mins 99205
Service Connection & Rated Disabilities

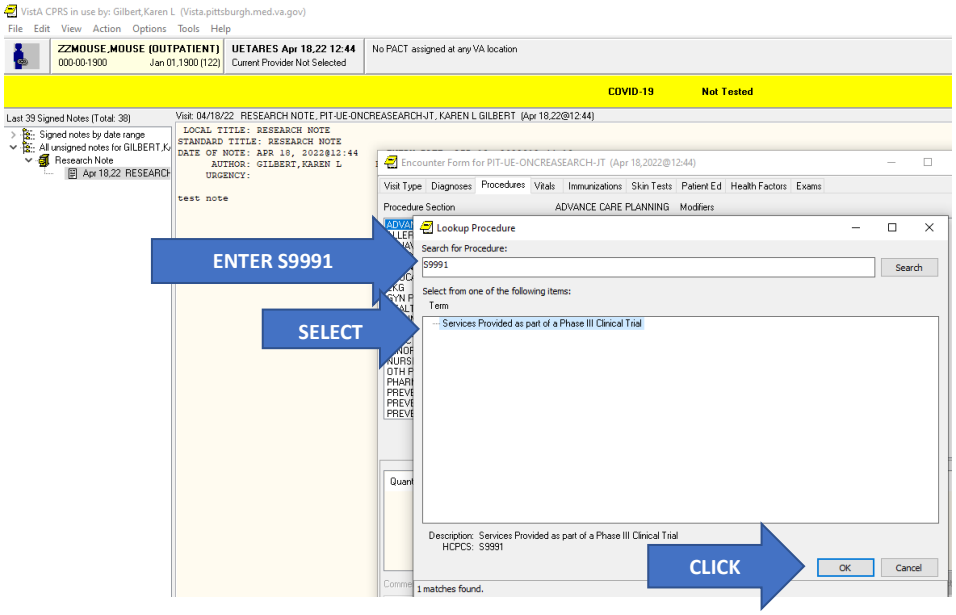

SELECT
VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
COVID-19
Last 250 Signed Notes (Total: 38)
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,
(Apr 18,22@12:44)
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
for PIT-UE-ONCREASEARCH-JT (Apr 18,2022@12:44)
Visit Type
Diagnoses
Procedures
Vitals
Immunizations
Skin Tests
Patient Ed
Type of Visit
ESTABLISHED PATIENT
NEW PATIENT
CONSULTATIONS
PREVENTIVE MED-EST PT
PREVENTIVE MED-NEW PT
TRANSITIONAL CARE MGMT (TCM
Section Name
SF MDM or 15-29 mins 99202
Low Complex MDM or 30-44 mins 99203
Mod Complex MDM or 45-59 mins 99204
High Complex MDM or 60-74 mins 99205

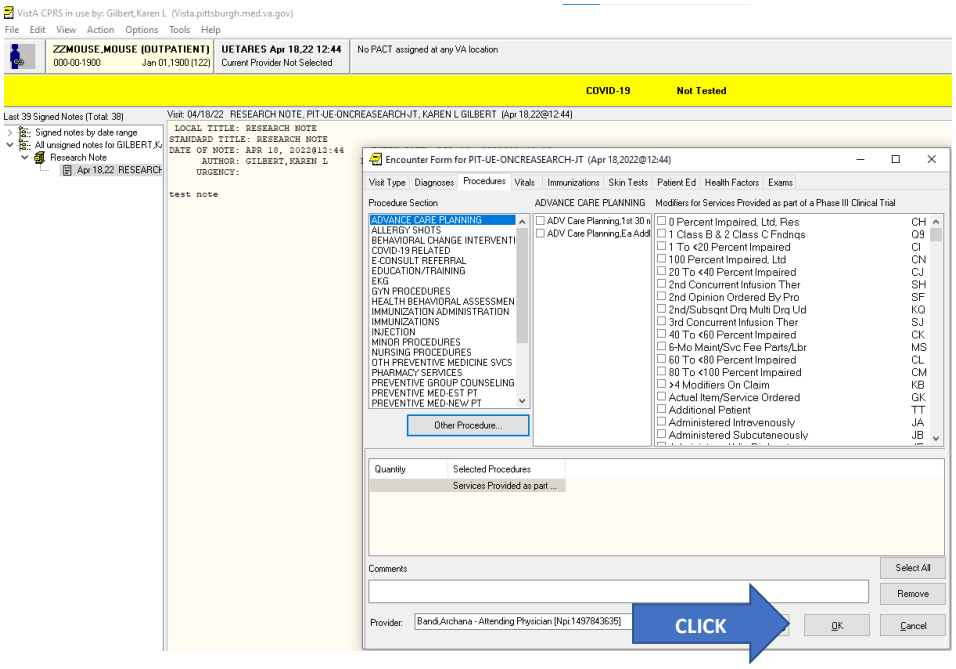

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA location
Last 250 Signed Notes (Total: 38)
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Apr 18,22@12:44)
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
Encounter Form for PIT-UE-ONCREASEARC
Visit Type
Diagnoses
Procedures
Vitals
Diagnoses Section
Problem List Items
Prior Encounter Diagnoses [Past 3 Years]
PC COMMON DIAGNOSES
ACQUIRED ABSENCE OF BODY PART(S)
ACSC ACUTE KIDNEY FAILURE
ACSC ANGINA
ACSC ASTHMA/BRONCHITIS/COPD
ACSC CHF
ACSC DEHYDRATION
ACSC DIABETES TYPE 1
ACSC DIABETES TYPE 2
ACSC HYPERTENSION
ACSC INFECTIOUS GASTROENTERITIS
ACSC PNEUMONIA
ACSC UTI
ACSC VIRAL ENTERITIS
ADMINISTRATIVE TOPICS
ANGINA
ATHEROSCLEROSIS
SELECT
Other Diagnosis...

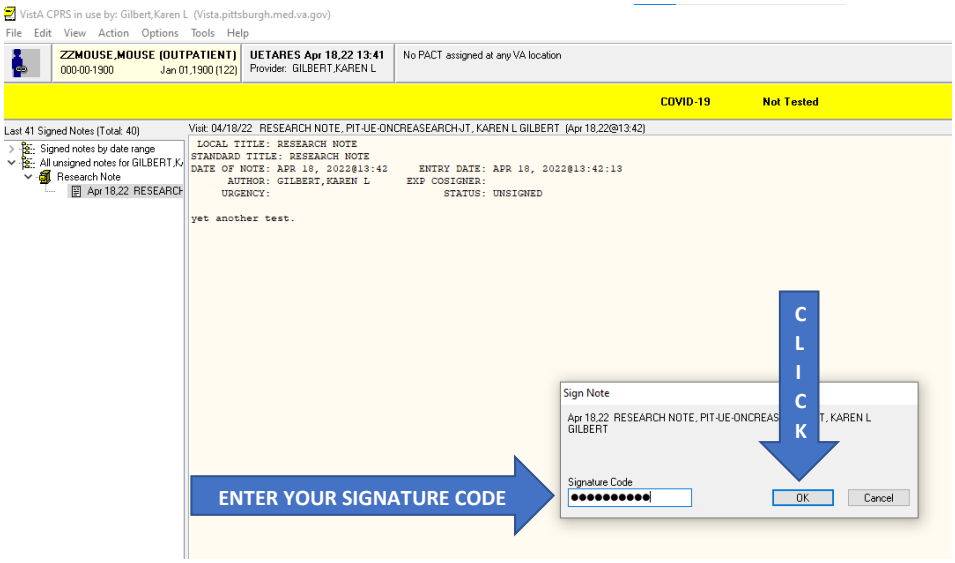

ENTER Z00.6
CLICK ON
CLICK ON


THEN CHOOSE
VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA
COVID-19
Last 250 Signed Notes (Total: 38)
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Ap @12:44)
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
Encounter Form for P E-ONCREASEARCH-JT (Apr 18,2022@12:44)
Visit Type Diagnoses Procedures Vitals Immunizations Skin Tests Patie
Diagnoses Section
Problem List Items
Problem List Items
Prior Encounter Diagnoses (Past 3 Years)
PC COMMON DIAGNOSES
ACQUIRED ABSENCE OF BODY PART(S)
ACSC ACUTE KIDNEY FAILURE
ACSC ANGINA
ACSC ASTHMA/BRONCHITIS/COPD
ACSC CHF
ACSC DEHYDRATION
ACSC DIABETES TYPE 1
ACSC DIABETES TYPE 2
ACSC HYPERTENSION
ACSC INFECTIOUS GASTROENTERITIS
ACSC PNEUMONIA
ACSC UTI
ACSC VIRAL ENTERITIS
ADMINISTRATIVE TOPICS
ANGINA
ATHEROSCLEROSIS
Other Diagnosis...
Add to PL
Primary
Selected Diagnoses
Primary
Encounter for Examination ...

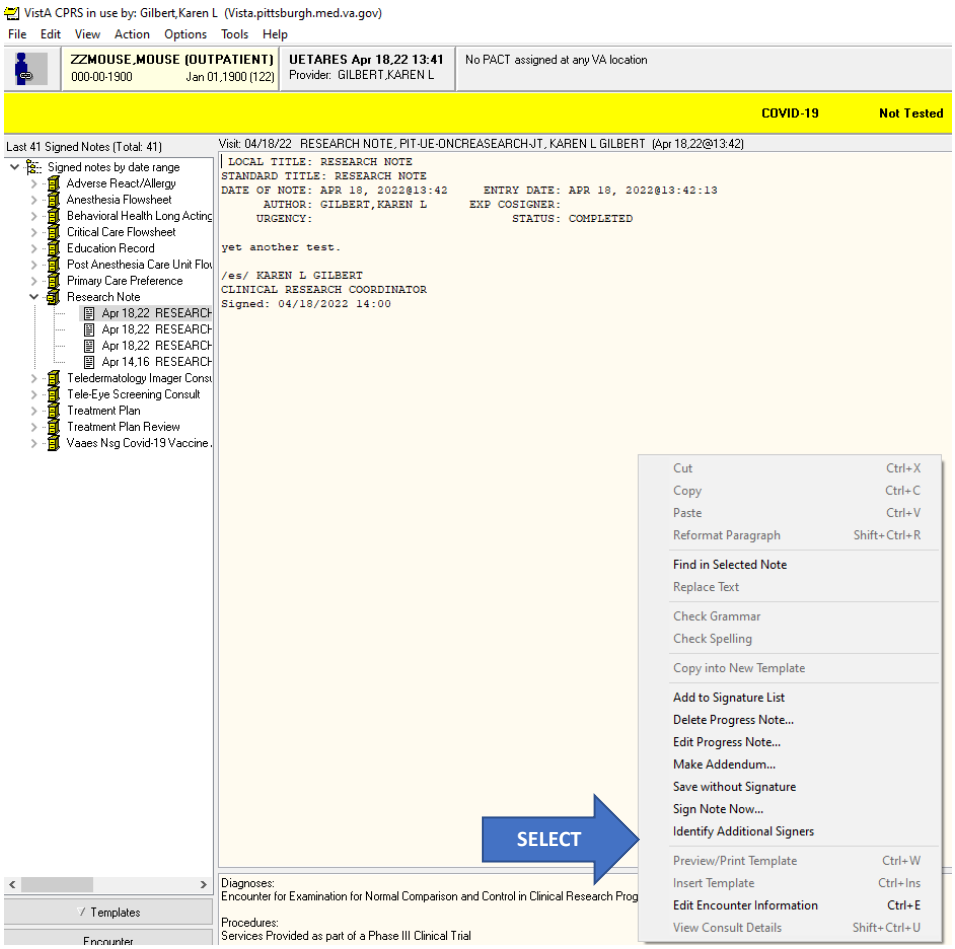

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 12:44
Current Provider Not Selected
No PACT assigned at any VA location
Last 250 Signed Notes (Total: 38)
New Note in Progress
Apr 18,22 RESEARCH NI
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flo
Primary Care Preference
Research Note
Teledermatology Imager Consu
Tele-Eye Screening Consult
Treatment Plan
Treatment Plan Review
Vaaes Nsg Covid-19 Vaccine
RESEARCH NOTE , PIT-UE-ONCREASEARCH-JT, Gilbert,Karen L (Apr 18,22@12:44)
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@12:44
AUTHOR: GILBERT,KAREN L
URGENCY:
test note
Encounter Form for PIT-UE-ONCREASE
Visit Type Diagnoses Procedures Vitals
Procedure Section
ADVANCE CARE PLANNING
ALLERGY SHOTS
BEHAVIORAL CHANGE INTERVENTI
COVID-19 RELATED
E-CONSULT REFERRAL
EDUCATION/TRAINING
EKG
GYN PROCEDURES
HEALTH BEHAVIORAL ASSESSMEN
IMMUNIZATION ADMINISTRATION
IMMUNIZATIONS
INJECTION
MINOR PROCEDURES
NURSING PROCEDURES
OTH PREVENTIVE MEDICINE SVCS
PHARMACY SERVICES
PREVENTIVE GROUP COUNSELING
PREVENTIVE MED-EST PT
PREVENTIVE MED-NEW PT
SELECT
Other Procedure...

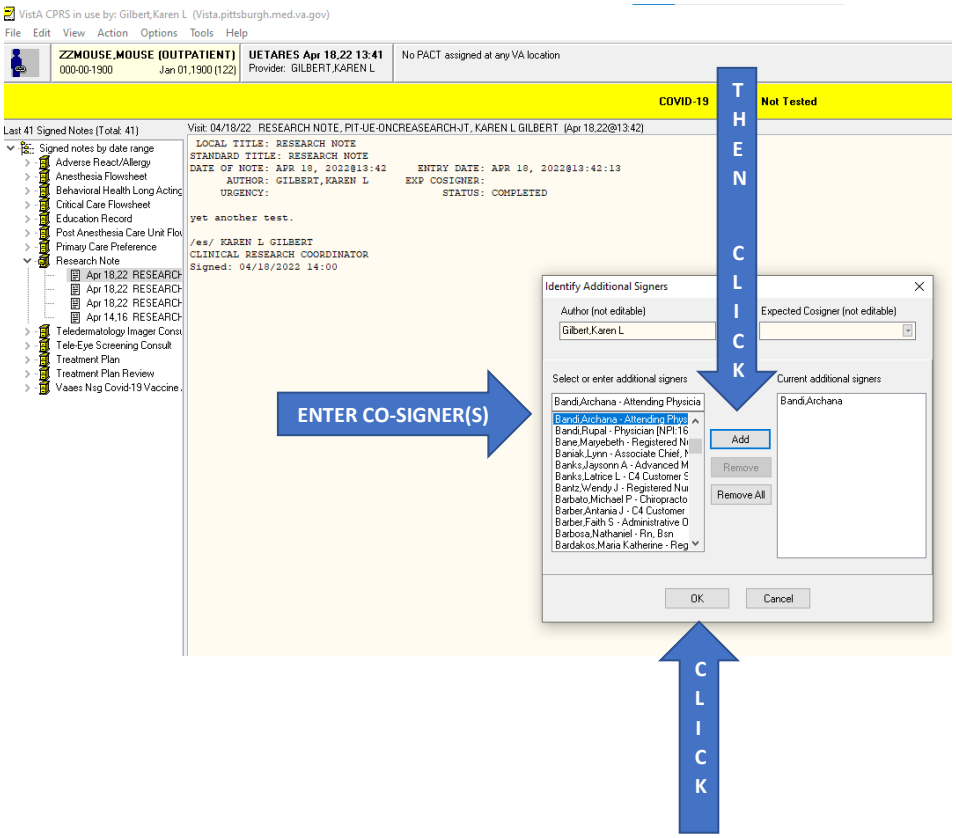

ENTER S9991
SELECT
CLICK


CLICK

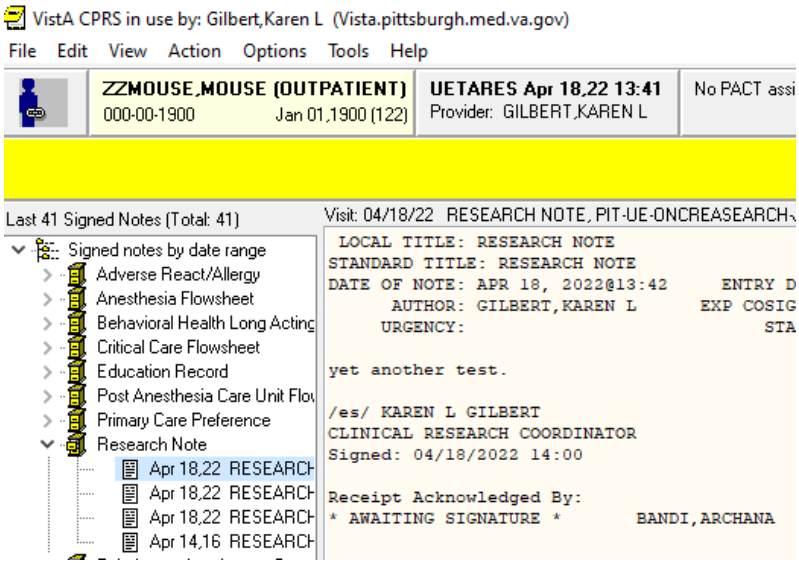

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 13:41
Provider: GILBERT,KAREN L
No PACT assigned at any VA location
COVID-19 Not Tested
Last 41 Signed Notes (Total: 40)
Signed notes by date range
All unsigned notes for GILBERT,K
Research Note
Apr 18,22 RESEARCH
Visit: 04/18/22 RESEARCH NOTE, PIT-UE-ONCREASEARCH-JT, KAREN L GILBERT (Apr 18,22@13:42)
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@13:42 ENTRY DATE: APR 18, 2022@13:42:13
AUTHOR: GILBERT,KAREN L EXP COSIGNER:
URGENCY: STATUS: UNSIGNED
yet another test.
CLICK
Sign Note
Apr 18,22 RESEARCH NOTE, PIT-UE-ONCREAS T, KAREN L GILBERT
Signature Code
OK
Cancel
ENTER YOUR SIGNATURE CODE

TO ADD ADDITIONAL SIGNER(S) – RIGHT CLICK MOUSE

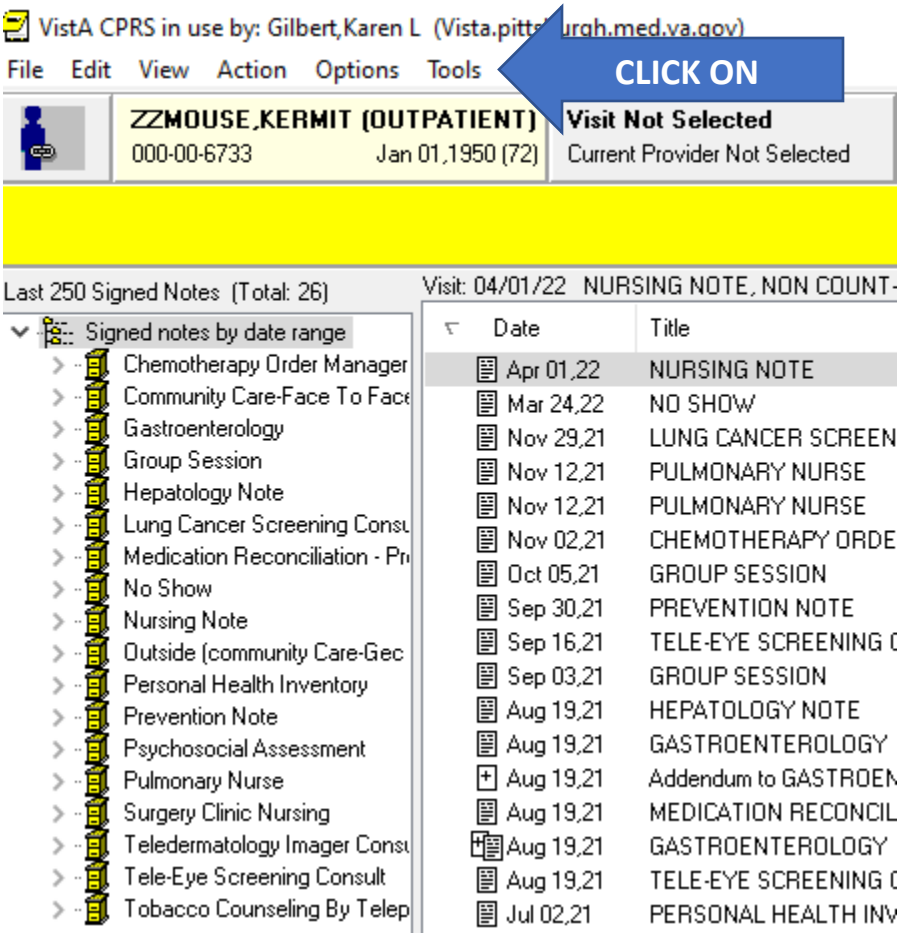


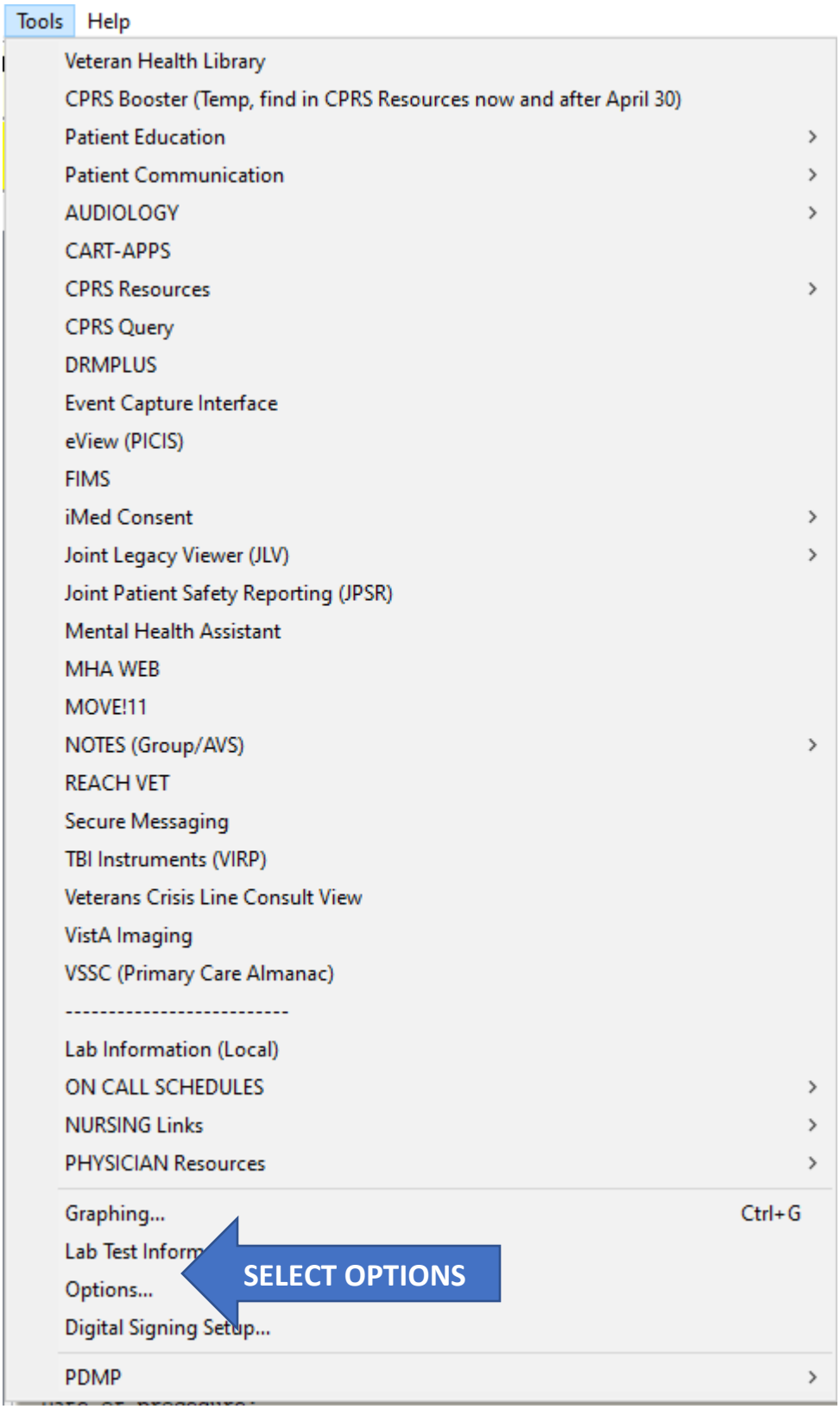


EVERY RESEARCH NOTE MUST BE CO-SIGNED BY THE PI. YOU MAY ADD ADDITIONAL CO-SIGNERS (PCP, SPECIALIST, ETC.) BEYOND THE PI SHOULD YOU FEEL THE INFORMATION IS IMPORTANT AND PROVIDER SHOULD BE MADE AWARE SOONER RATHER THAN LATER.

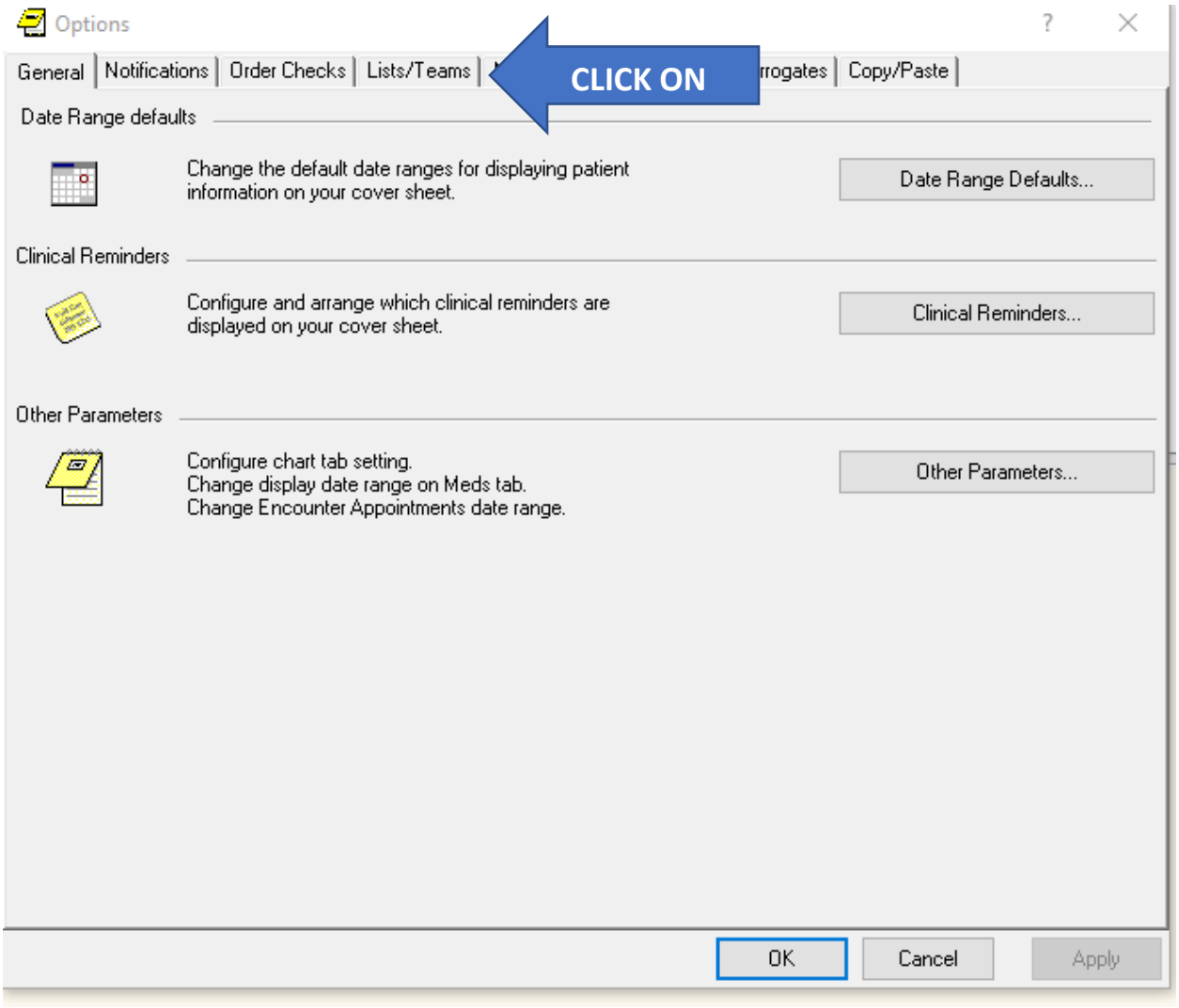

VistA CPRS in use by: Gilbert,Karen L (Vista.pittsburgh.med.va.gov)
File Edit View Action Options Tools Help
ZZMOUSE,MOUSE (OUTPATIENT)
000-00-1900 Jan 01,1900 (122)
UETARES Apr 18,22 13:41
Provider: GILBERT,KAREN L
No PACT assi
Last 41 Signed Notes (Total: 41)
Signed notes by date range
Adverse React/Allergy
Anesthesia Flowsheet
Behavioral Health Long Acting
Critical Care Flowsheet
Education Record
Post Anesthesia Care Unit Flow
Primary Care Preference
Research Note
Apr 18,22 RESEARCH
Apr 18,22 RESEARCH
Apr 18,22 RESEARCH
Apr 14,16 RESEARCH
Visit: 04/18/22 RESEARCH NOTE, PIT-UE-ONCREASEARCH
LOCAL TITLE: RESEARCH NOTE
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: APR 18, 2022@13:42 ENTRY D
AUTHOR: GILBERT,KAREN L EXP COSIG
URGENCY: STA
yet another test.
/es/ KAREN L GILBERT
CLINICAL RESEARCH COORDINATOR
Signed: 04/18/2022 14:00
Receipt Acknowledged By:
* AWAITING SIGNATURE * BANDI,ARCHANA

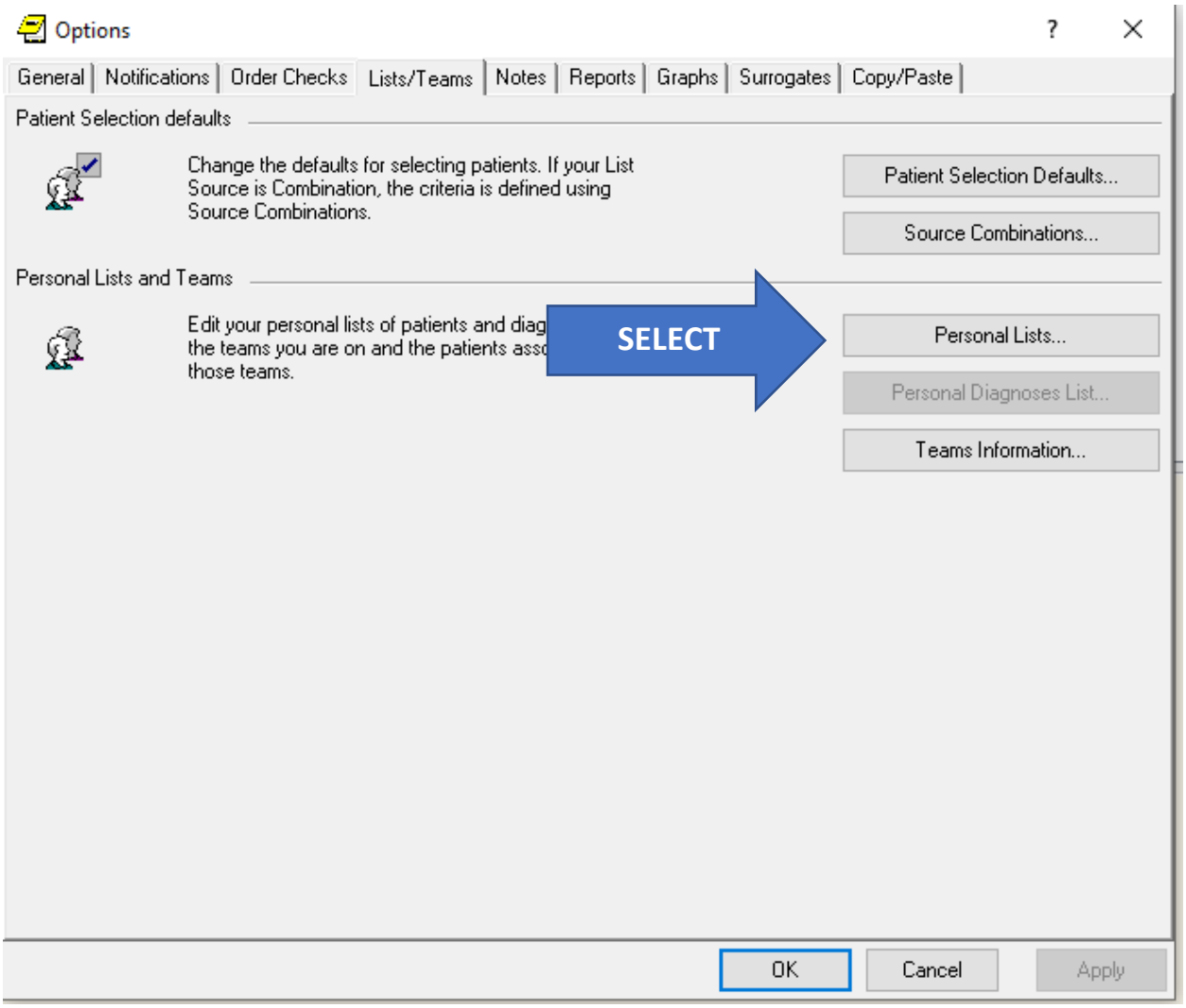
MAKING AND MANAGING YOUR OWN PERSONAL PATIENT LIST IN CPRS

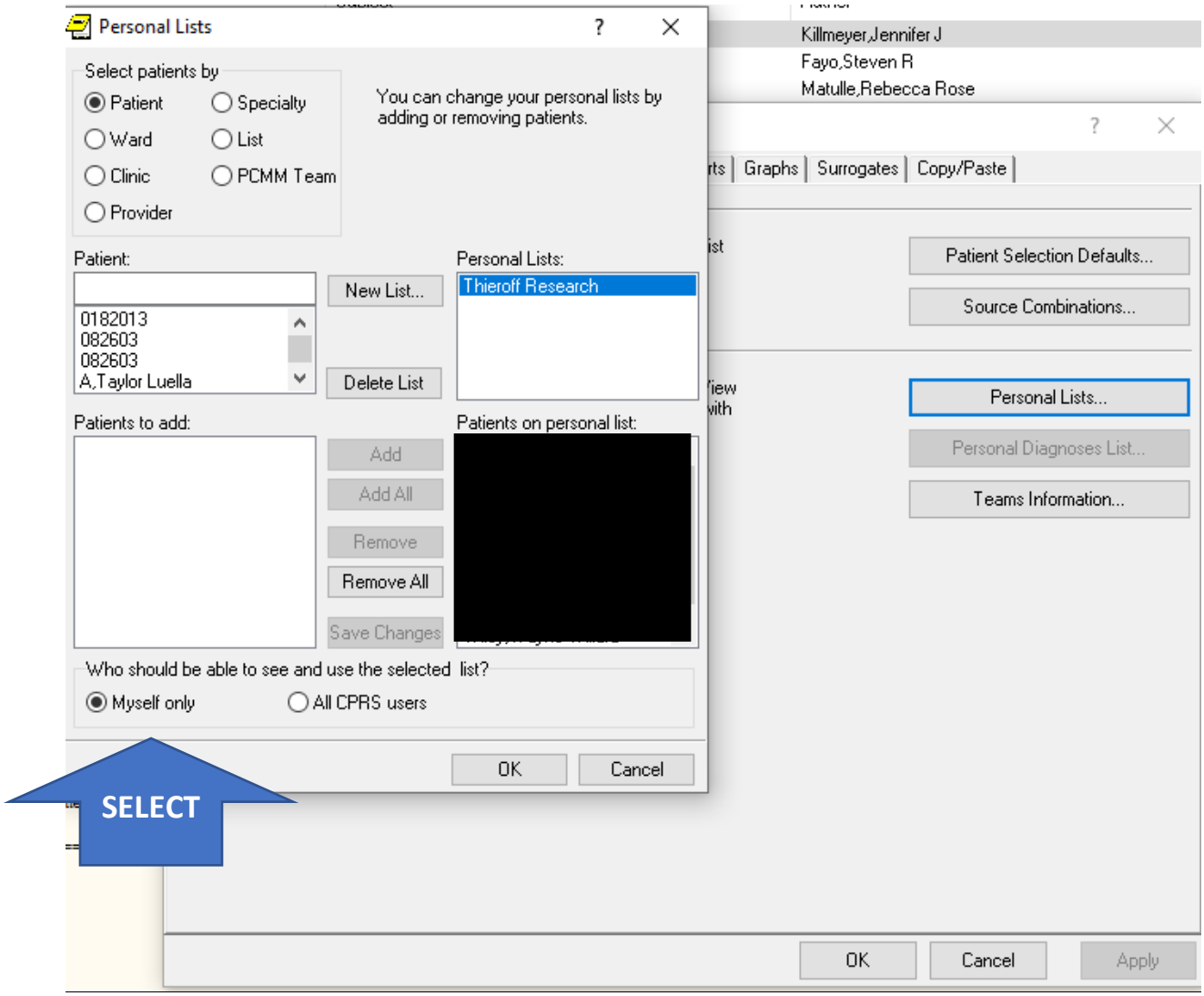


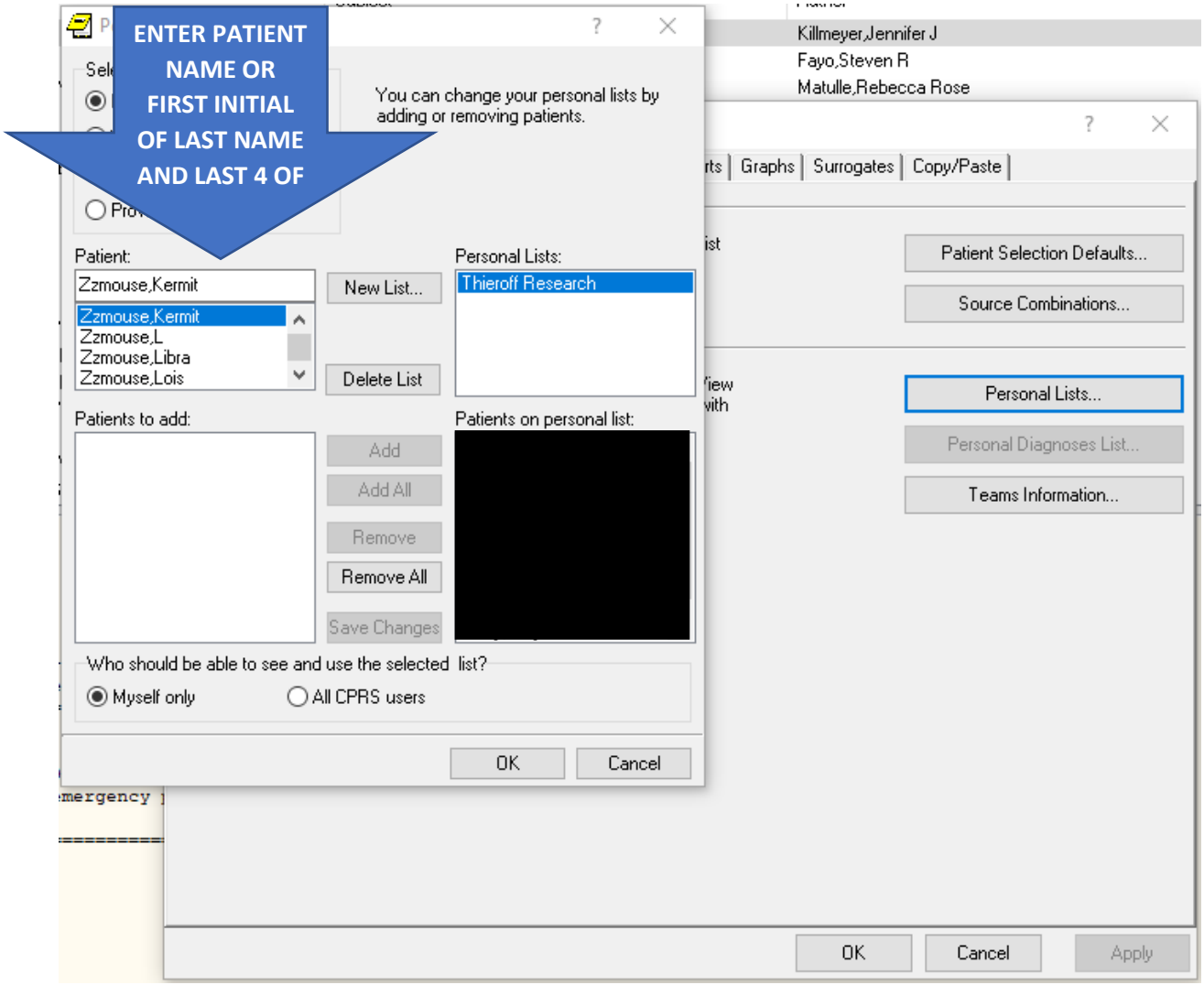

Tools
Help
Veteran Health Library
CPRS Booster (Temp, find in CPRS Resources now and after April 30)
Patient Education
Patient Communication
AUDIOLOGY
CART-APPS
CPRS Resources
CPRS Query
DRMPLUS
Event Capture Interface
eView (PICIS)
FIMS
iMed Consent
Joint Legacy Viewer (JLV)
Joint Patient Safety Reporting (JPSR)
Mental Health Assistant
MHA WEB
MOVE!11
NOTES (Group/AVS)
REACH VET
Secure Messaging
TBI Instruments (VIRP)
Veterans Crisis Line Consult View
VistA Imaging
VSSC (Primary Care Almanac)

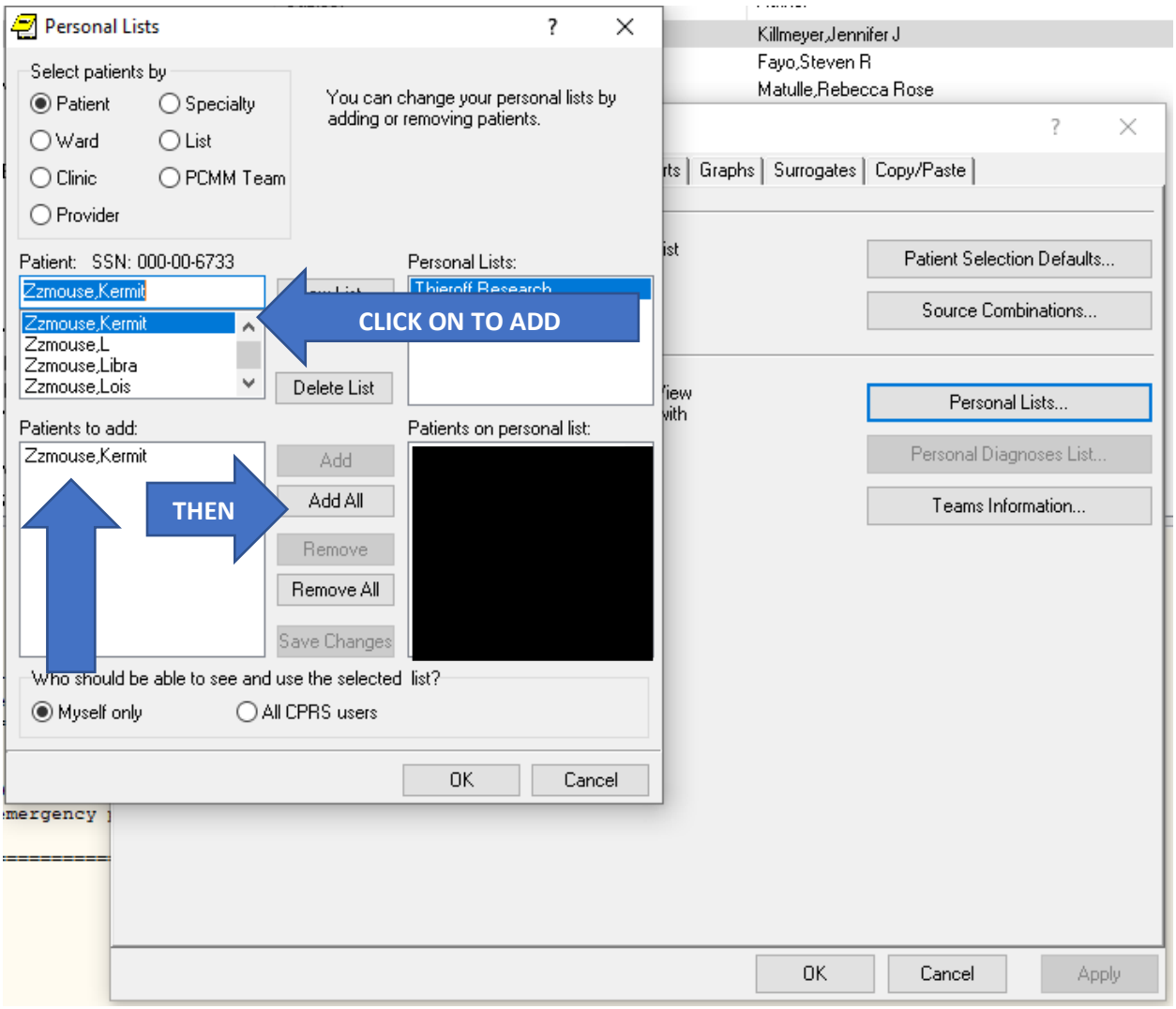
Lab Information (Local)
ON CALL SCHEDULES
NURSING Links
PHYSICIAN Resources
Graphing... Ctrl+G
Lab Test Inform
Options...
Digital Signing Setup...
PDMP
SELECT OPTIONS

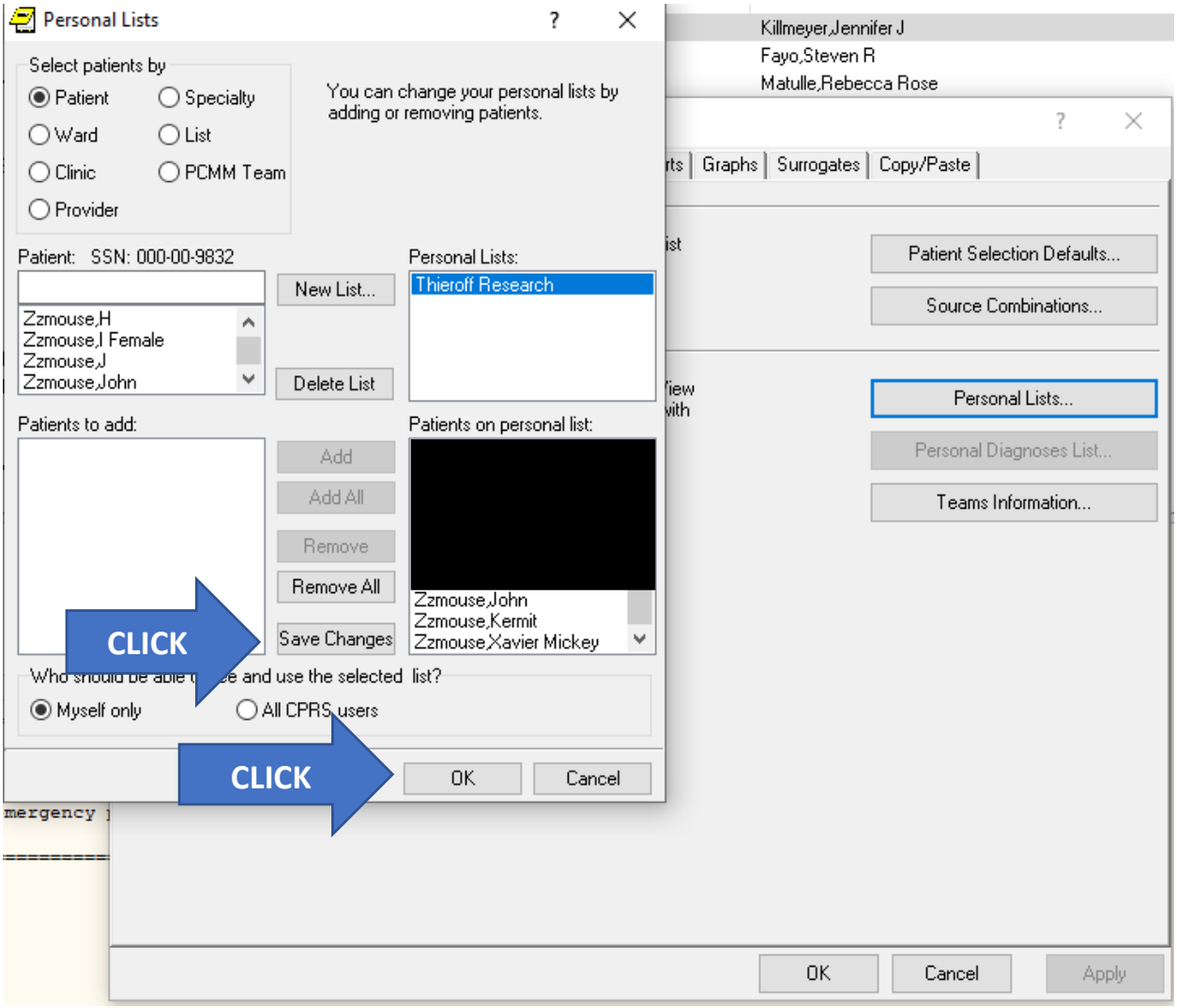

Options
General
Notifications
Order Checks
Lists/Teams
rrogates
Copy/Paste
CLICK ON
Date Range defaults
Change the default date ranges for displaying patient information on your cover sheet.
Date Range Defaults...
Clinical Reminders
Configure and arrange which clinical reminders are displayed on your cover sheet.
Clinical Reminders...
Other Parameters
Configure chart tab setting.
Change display date range on Meds tab.
Change Encounter Appointments date range.
Other Parameters...
OK
Cancel
Apply


Options
General
Notifications
Order Checks
Lists/Teams
Notes
Reports
Graphs
Surrogates
Copy/Paste
Patient Selection defaults
Change the defaults for selecting patients. If your List Source is Combination, the criteria is defined using Source Combinations.
Patient Selection Defaults...
Source Combinations...
Personal Lists and Teams
Edit your personal lists of patients and diag
the teams you are on and the patients ass
those teams.
SELECT
Personal Lists...
Personal Diagnoses List...
Teams Information...
OK
Cancel
Apply

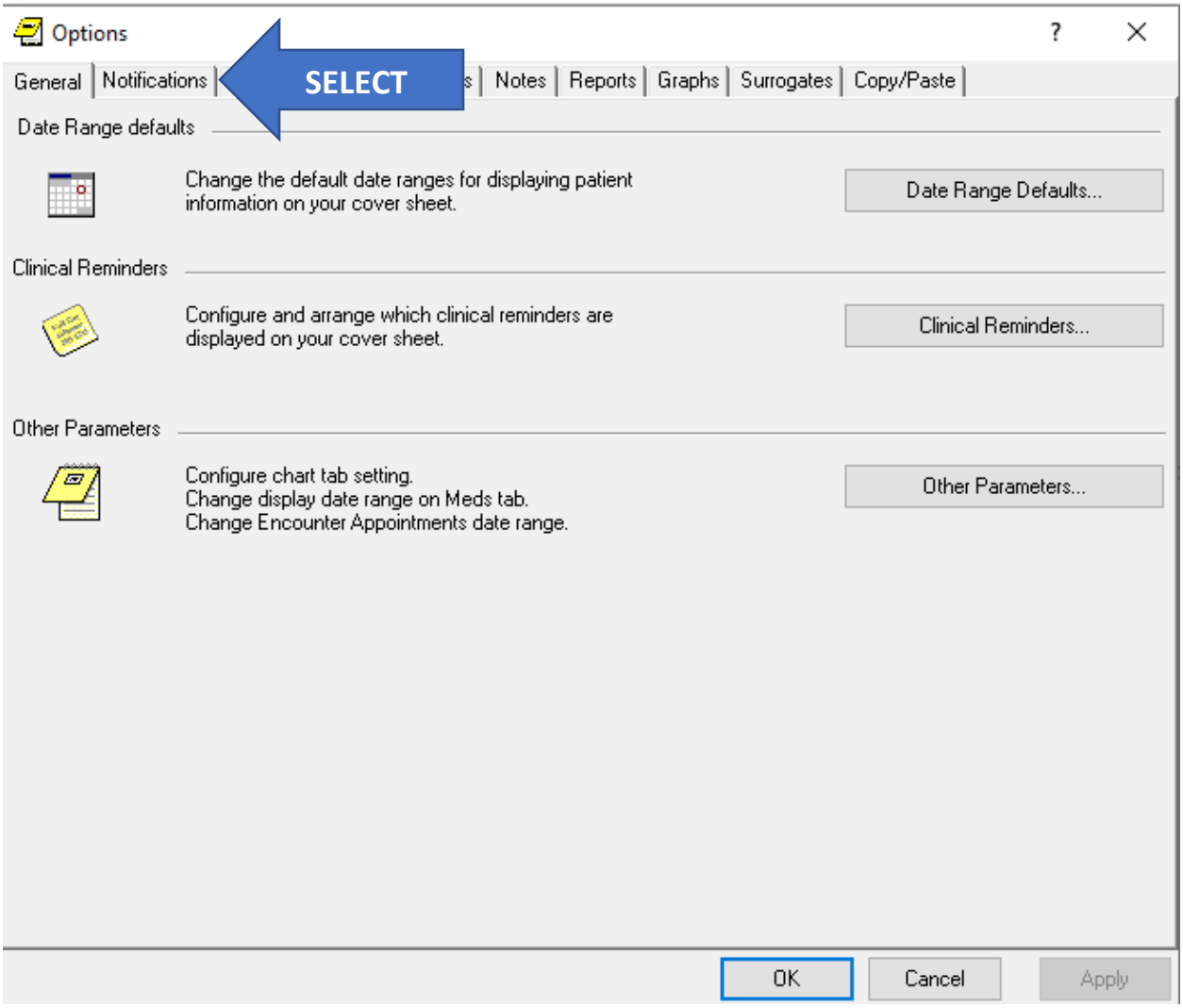

Personal Lists
Select patients by
Patient
Specialty
Ward
List
Clinic
PCMM Team
Provider
You can change your personal lists by adding or removing patients.
Patient:
0182013
082603
082603
A,Taylor Luella
New List...
Delete List
Personal Lists:
Thieroff Research
Patients to add:
Add
Add All
Remove
Remove All
Save Changes
Patients on personal list:
Who should be able to see and use the selected list?
Myself only
All CPRS users
OK
Cancel
SELECT
Killmeyer,Jennifer J
Fayo,Steven R
Matulle,Rebecca Rose
Graphs
Surrogates
Copy/Paste
Patient Selection Defaults...
Source Combinations...
Personal Lists...
Personal Diagnoses List...
Teams Information...
OK
Cancel
Apply

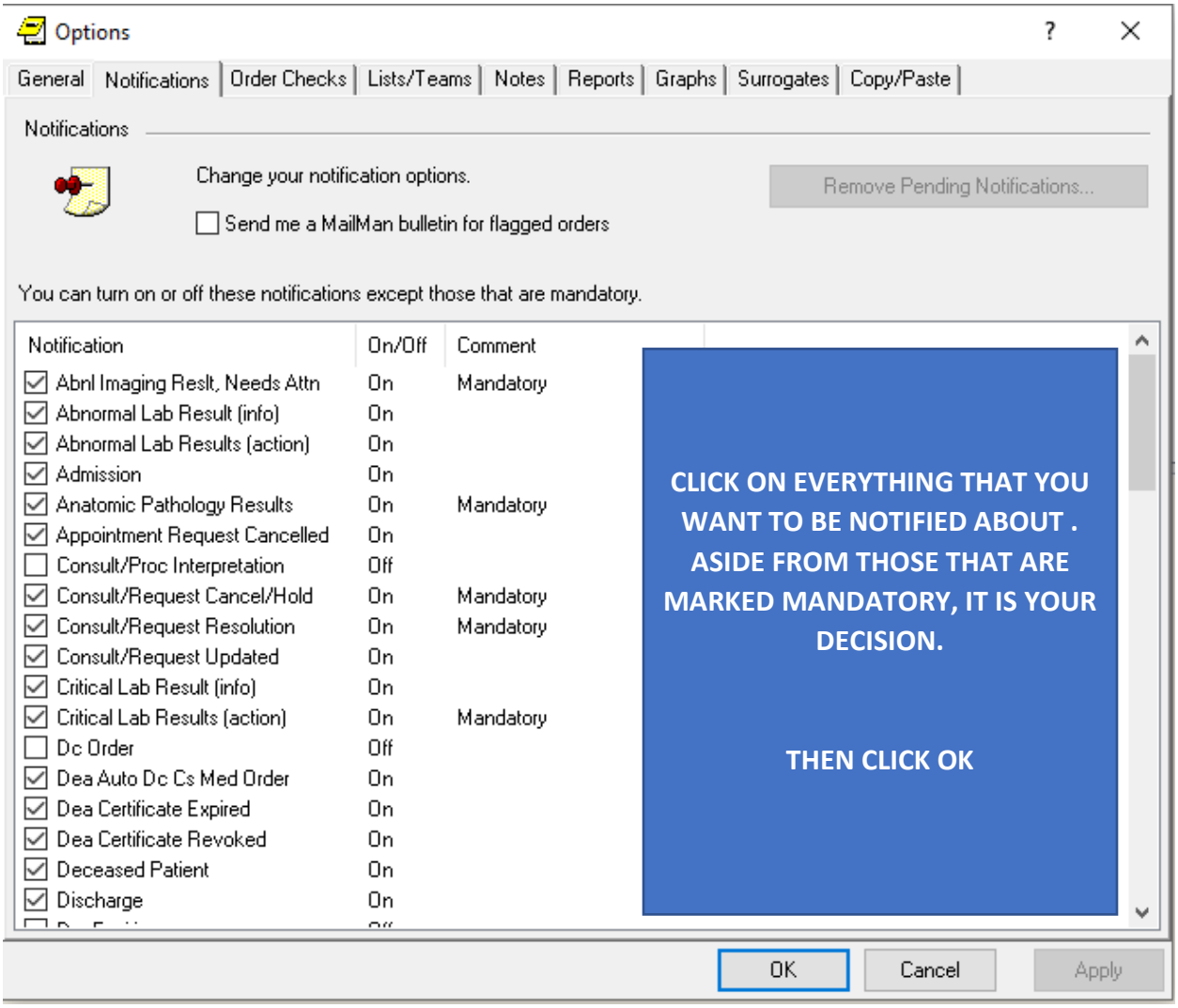

ENTER PATIENT NAME OR FIRST INITIAL OF LAST NAME AND LAST 4 OF
You can change your personal lists by adding or removing patients.
Patient:
Zzmouse,Kermit
Zzmouse,Kermit
Zzmouse,L
Zzmouse,Libra
Zzmouse,Lois
New List...
Delete List
Personal Lists:
Thieroff Research
Patients to add:
Add
Add All
Remove
Remove All
Save Changes
Patients on personal list:
Who should be able to see and use the selected list?
Myself only
All CPRS users
OK
Cancel
Killmeyer,Jennifer J
Fayo,Steven R
Matulle,Rebecca Rose
Graphs
Surrogates
Copy/Paste
Patient Selection Defaults...
Source Combinations...
Personal Lists...
Personal Diagnoses List...
Teams Information...
OK
Cancel
Apply


Personal Lists
Select patients by
Patient
Specialty
Ward
List
Clinic
PCMM Team
Provider
You can change your personal lists by adding or removing patients.
Patient: SSN: 000-00-6733
Zzmouse,Kermit
Zzmouse,Kermit
Zzmouse,L
Zzmouse,Libra
Zzmouse,Lois
CLICK ON TO ADD
Personal Lists:
Delete List
Patients to add:
Zzmouse,Kermit
THEN
Add
Add All
Remove
Remove All
Save Changes
Patients on personal list:
Who should be able to see and use the selected list?
Myself only
All CPRS users
OK
Cancel
Killmeyer,Jennifer J
Fayo,Steven R
Matulle,Rebecca Rose
Graphs
Surrogates
Copy/Paste
Patient Selection Defaults...
Source Combinations...
Personal Lists...
Personal Diagnoses List...
Teams Information...
OK
Cancel
Apply

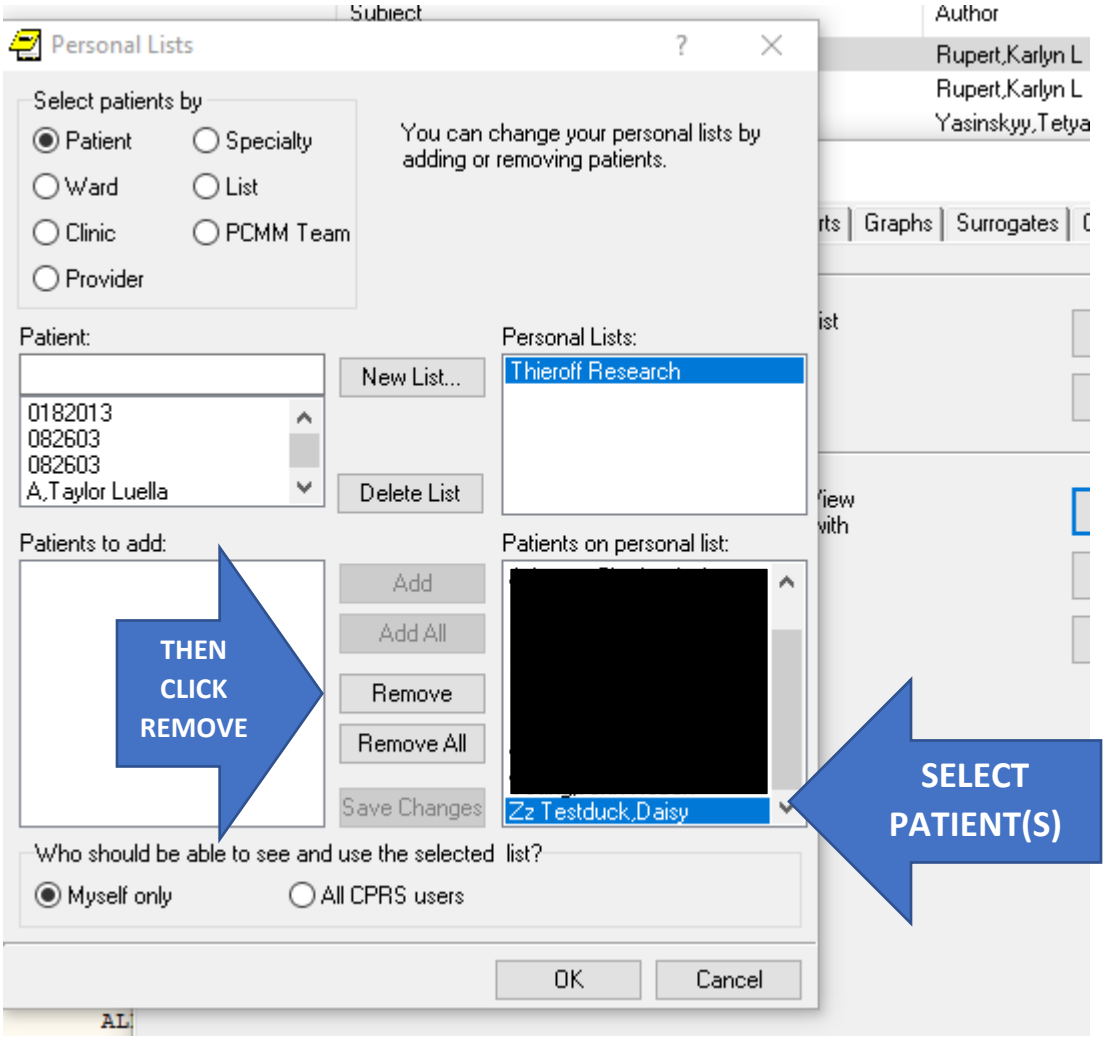

Personal Lists
Select patients by
Patient
Specialty
Ward
List
Clinic
PCMM Team
Provider
You can change your personal lists by adding or removing patients.
Patient: SSN: 000-00-9832
Zzmouse,H
Zzmouse,I Female
Zzmouse,J
Zzmouse,John
New List...
Delete List
Personal Lists:
Thieroff Research
Patients to add:
Add
Add All
Remove
Remove All
Save Changes
Patients on personal list:
Zzmouse,John
Zzmouse,Kermit
Zzmouse,Xavier Mickey
CLICK
Myself only
All CPRS users
CLICK
OK
Cancel
Killmeyer,Jennifer J
Fayo,Steven R
Matulle,Rebecca Rose
Graphs
Surrogates
Copy/Paste
Patient Selection Defaults...
Source Combinations...
Personal Lists...
Personal Diagnoses List...
Teams Information...
OK
Cancel
Apply

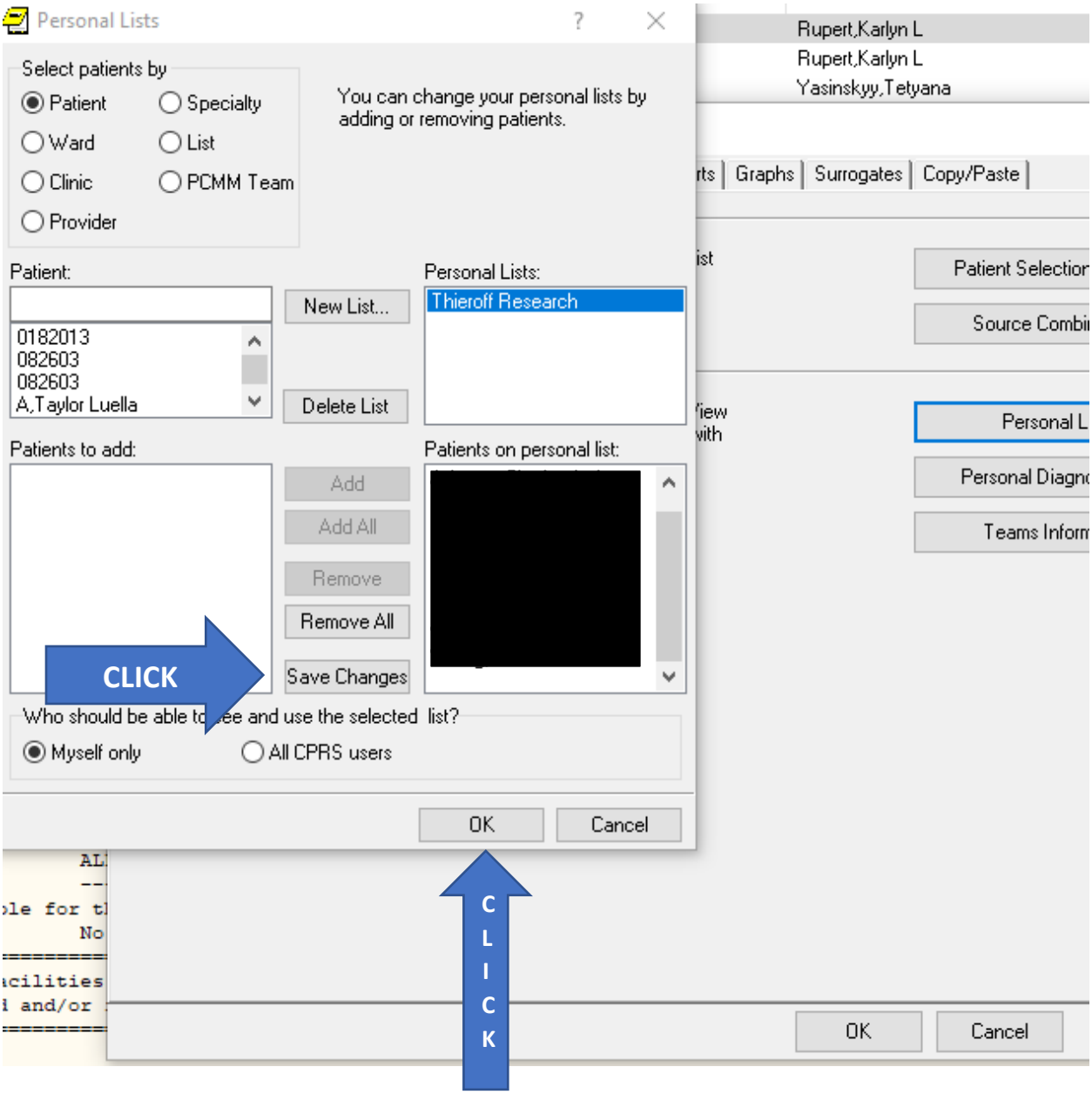
SETTING NOTIFICATIONS




Options
General
Notifications
Order Checks
Lists/Teams
Notes
Reports
Graphs
Surrogates
Copy/Paste
Notifications
Change your notification options.
Remove Pending Notifications...
Send me a MailMan bulletin for flagged orders
You can turn on or off these notifications except those that are mandatory.
Notification
On/Off
Comment
Abnl Imaging Reslt, Needs Attn On Mandatory
Abnormal Lab Result (info) On
Abnormal Lab Results (action) On
Admission On
Anatomic Pathology Results On Mandatory
Appointment Request Cancelled On
Consult/Proc Interpretation Off
Consult/Request Cancel/Hold On Mandatory
Consult/Request Resolution On Mandatory
Consult/Request Updated On
Critical Lab Result (info) On
Critical Lab Results (action) On Mandatory
Dc Order Off
Dea Auto Dc Cs Med Order On
Dea Certificate Expired On
Dea Certificate Revoked On
Deceased Patient On
Discharge On
CLICK ON EVERYTHING THAT YOU WANT TO BE NOTIFIED ABOUT . ASIDE FROM THOSE THAT ARE MARKED MANDATORY, IT IS YOUR DECISION.
THEN CLICK OK
OK
Cancel
Apply

REMOVING PATIENTS FROM YOUR PERSONAL LIST




Personal Lists
Select patients by
Patient
Specialty
Ward
List
Clinic
PCMM Team
Provider
You can change your personal lists by adding or removing patients.
Patient:
0182013
082603
082603
A,Taylor Luella
New List...
Delete List
Personal Lists:
Thieroff Research
Patients to add:
Patients on personal list:
Add
Add All
Remove
Remove All
Save Changes
CLICK
Who should be able to see and use the selected list?
Myself only
All CPRS users
OK
Cancel
CLICK
Rupert,Karlyn L
Rupert,Karlyn L
Yasinskyy,Tetyana
Graphs
Surrogates
Copy/Paste
Patient Selection
Source Combi
Personal L
Personal Diagnc
Teams Inform
OK
Cancel

MONITORING VISITS

The purposes of trial monitoring visits are to verify that:

- The rights and well-being of human subjects are protected.
- The reported trial data are accurate, complete, and verifiable from source documents.
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

There are three types of monitoring visits:

On-site Monitoring

- On-site monitoring involves in-person evaluation carried out by sponsor personnel or representatives at the investigation site.

Remote Monitoring

- Remote monitoring involves off-site evaluation performed by the monitor away from the site at which the clinical investigation is being conducted. This can take the form of phone or virtual visits.

Centralized Monitoring

- Centralized monitoring involves analytical evaluation carried out by sponsor personnel or representatives at a central location other than the site at which the clinical investigation is being conducted.

CRC/CRN's are responsible for the scheduling of interim monitoring visits (IMV). All departments which are affected by an IMV should be made aware of the visit in advance (PI, Research Pharmacist) via Calendar invite.

At the St. Louis VA, the CRC/CRN will complete our local Form X-Monitoring Report Form during the monitoring visit. At the conclusion of the visit, the CRC/CRN will submit the report to the research office for administrative review.

IMVs which occur over multiple days require that subject charts and regulatory binders be locked up at the close of each day in their original location.

In most instances, IMV and auditing reports are sent to the PI and CRC/CRN..

Any instance of non-compliance or inclusion/exclusion deviations must be immediately reported to the Clinical Trials Unit Manager.

Monitor Site Visit Resources: JC/JB Maps, Example Email to Monitor (located in the Appendix)

RESEARCH COMPLIANCE OFFICER AUDITS

Research Compliance Audits are performed by the Research Compliance Officer (RCO) following the guidelines established each year by VA's Office of Research Oversight (ORO). The RCO is an individual who reports directly to the facility Director and whose primary responsibilities are auditing documentation related to facility research projects and informing the facility Director and research review committees about compliance concerns.

All human research studies active at any time during the reporting period must receive an informed consent audit, whether or not any ICDs were required or signed during the reporting period. Human subjects' studies that no longer require continuing IRB review must be audited yearly as they are still under the oversight an IRB.

A complete audit must include a review of both the IRB study file and the Principal Investigator's records. Additional records to be reviewed may include, but not be limited to, case records, research personnel training records, and other research records.

Types of audits include:

- **For-cause**
  Initiated in response to specific allegations of, or information about, the occurrence of potentially serious noncompliance with the laws, regulations, and policies governing VA research.
- **Triennial Audit**
  Any human research protocol must have at least one RCO audit every three years. If the study is completed or closed to oversight less than 3 years after an RCO audit it does not require a final RCO audit at closure. However, any research followed by the IRB that is closed to oversight less than 3 years must have at least one RCO audit.
- **Informed Consent Documents (ICDs)**
  The RCO informed consent document audit requirement refers to the research ICDs as outlined in the Code of Federal Regulations (CFR) General Requirements for Informed Consent, Documentation of Informed Consent and VHA Directive 1200.05. Re-consents for research should also be audited and counted as a separate consent.

RCO Audit Templates and Guidelines located are located in the Appendix

STUDY CLOSEOUT AND RECORD STORAGE

Standard COV

A standard study closeout visit (COV) is conducted by the sponsor of the research study to ensure that all necessary aspects of the study closure have been addressed, to include organization and completion of documentation and reporting. A COV typically occurs once the sponsor's enrollment goal has been completed, or sufficient positive or negative data results have been collected. This process ensures that all the clinical trial activities are rightly reconciled, recorded, and reported at the end of the study trial. Usually, a study trial is considered closed once the electronic database (eDC) is locked.

Study Closure due to non-Enrollment

To ensure CTU resources are used appropriately, the CTU Manager & VREF Executive Director will review study accruals at six-month intervals and will consult with the Principal Investigator (PI) for those that have no subjects enrolled, to discuss barriers that may be affecting recruitment. If necessary, modifications will be made to the recruitment plan in order to increase enrollment.

If after one year, there are no study accruals, the CTU Manager & VREF Executive Director will consult with the PI to discuss closure of the study due to lack of enrollment. If there are extenuating circumstances for keeping the study open (e.g., the study is about a rarely seen condition), the PI will be required to submit in writing via email a justification to the CTU Manager & VREF Executive Director.

If the CTU Manager & VREF Executive Director determines that the extenuating circumstances do not justify leaving the study open, the CTU Manager & VREF Executive Director will notify the PI, the CRC/CRN that the study will close due to no enrollment.

Regardless of the reason for the COV, they should be scheduled and coordinated by the primary CRC/CRN, ensuring d IDS (if a drug study) are included in the process. All documents related to a study will be packed for long term storage following receipt of an IRB closure letter.

Record Storage

Once a study closure has been approved by all appropriate committees including RDC, all study records need to be archived properly and easily retrievable. Long term Storage is located at JB building 1. Records must be retained after completion of research project and destroyed after six (6) years. However, due to Federal & European General Data Protection regulations, records may require to be retained longer than the six (6) years if required by others. If an investigator leaves the VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The investigator is not the grantee, nor does the investigator own the data.

Boxes should be labeled with a brief description of the box's contents (i.e. Study Title – PI last name). A VA7468 form should be completed for each box of records.

Once all boxes are ready and the VA7468 form is completed, an email should be sent to the Research Office asking them to schedule a pickup. In the body of the email, include the number of boxes as well as their exact location (Room #/Cubicle #/Shelf #/etc.). The Records Manager (RM) will confirm receipt of your email and will schedule the pickup. They will email when the pickup is scheduled. A study team member should be available during the scheduled pickup time. The Records Liaison Officer (RLO) will be included in the email.

If you have any questions regarding long term storage and process, please contact the St. Louis VA Research Office.

REMOTE ACCESS/VA TELEWORK/CAG

The request and need for remote access should be determined by the VREF Executive Director/STL VA Research AO/CTU Manager in collaboration with the PI based off the needs of the study protocol and subject visit requirements. For example, if a collaborative research study has subject visits located at both the St. Louis VA Health Care System and the affiliate-Washington University, the CRC/CRN may need to obtain remote access to gain access to the VA's network & software in order to complete study related tasks o the VA Network.

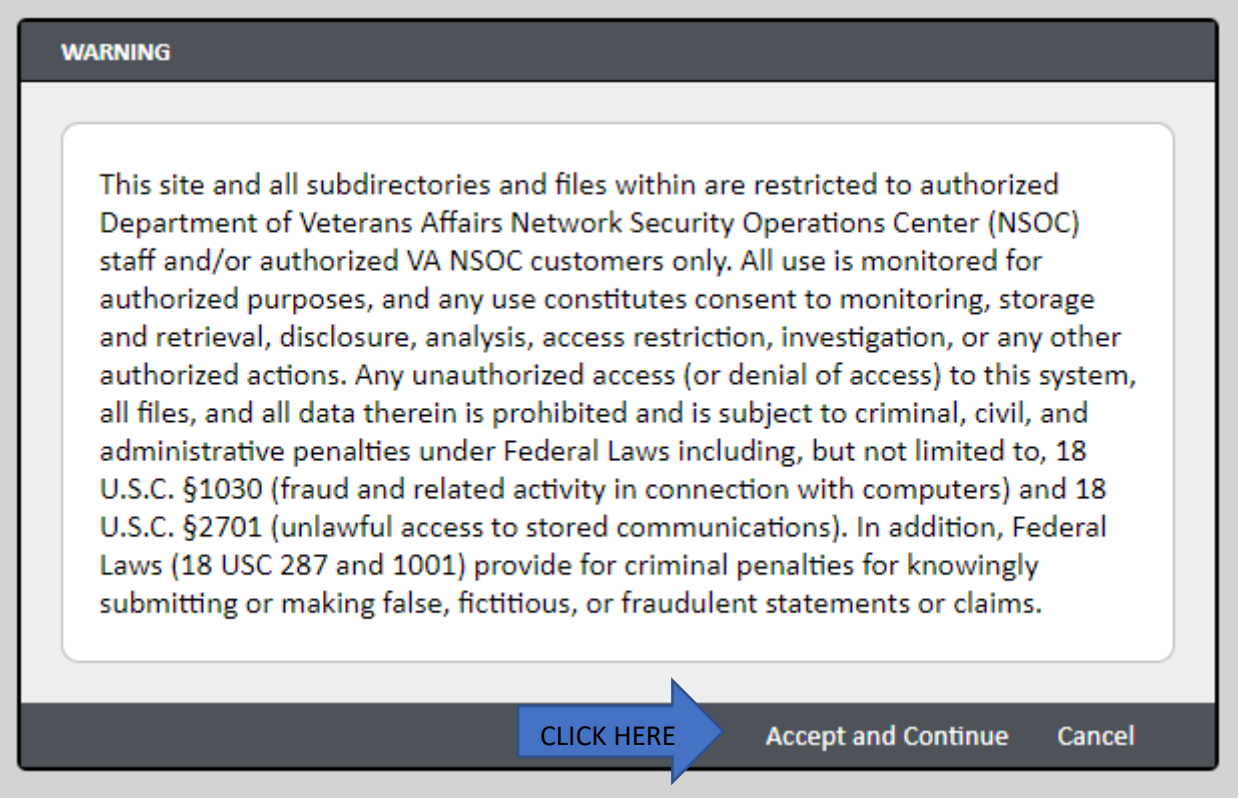
Request access https://vaww.ramp.vansoc.va.gov/

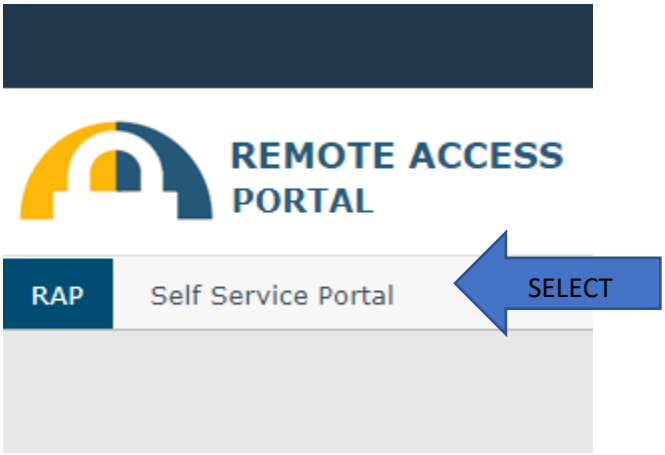
- **VA Remote Access**
  The VA Knowledge Service (KS) and Rules of Behavior (both only accessible from within the VA's internal network) identify the compliance requirements for VA remote access users. VA primarily supports remote access with three different access methods:

  1. Citrix Access Gateway (CAG)
  2. Azure Virtual Desktop (AVD)
  3. Cisco AnyConnect VPN (RESCUE)

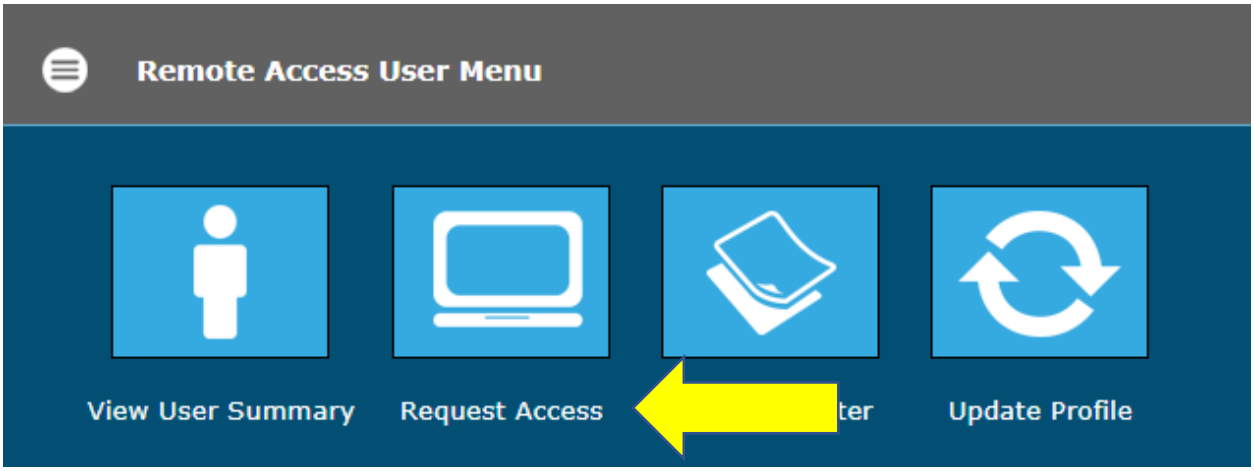
CAG and AVD are designed for users who **do not** have VA Government Furnished Equipment (GFE) – they are good options to allow users access to general applications such as email and chat. They are also good backup methods for users with GFE in the event of an issue with VPN or GFE. The Cisco VPN Client (RESCUE) is only for use on VA GFE. Users need to request remote access and have their remote access accounts enabled for use with CAG, AVD, and/or RESCUE.

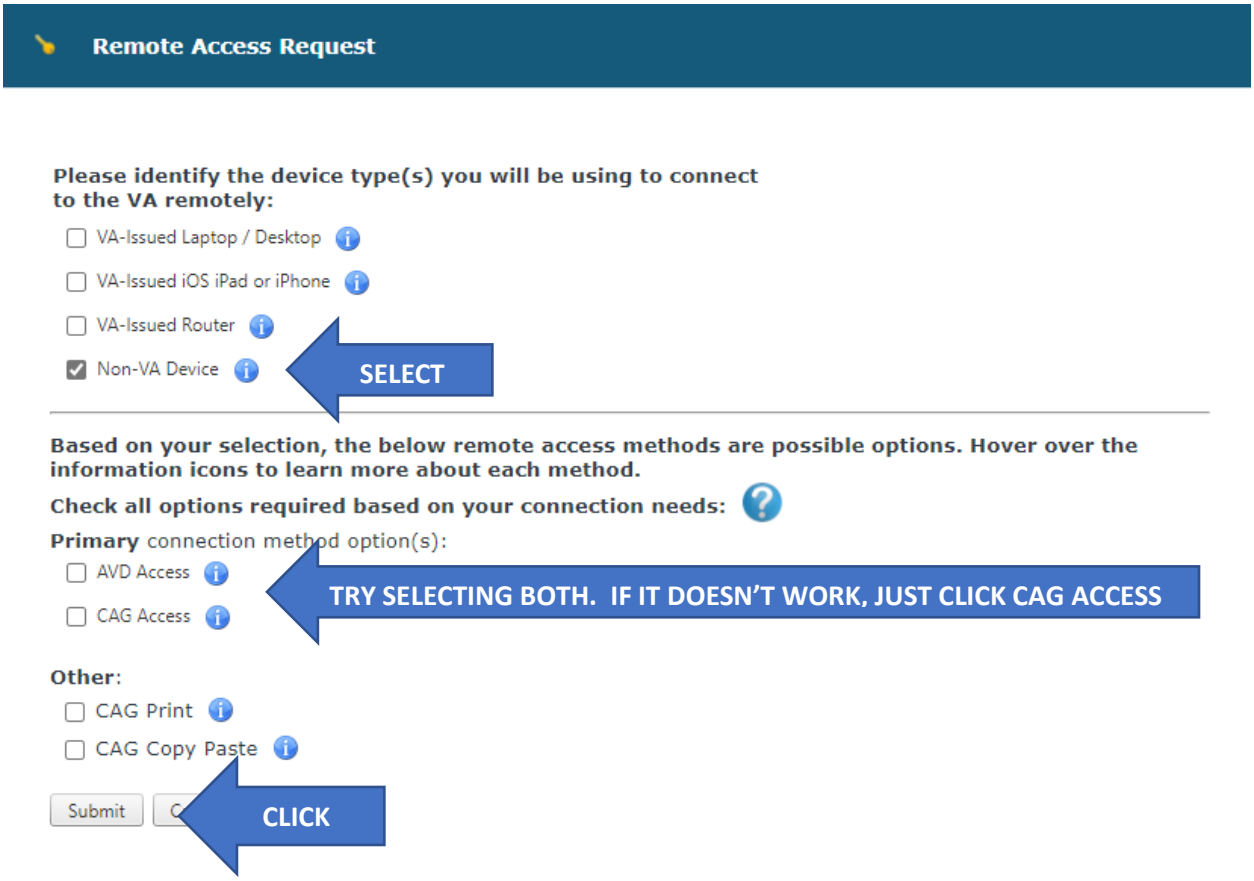
Remote access may be requested by visiting the Remote Access Portal (only available while on VA's internal network) and clicking on *Self Service Portal*. Users who do not have access to the VA network should request their supervisor or Contracting Officer Representative (COR) initiate a request on their behalf.


WARNING
This site and all subdirectories and files within are restricted to authorized Department of Veterans Affairs Network Security Operations Center (NSOC) staff and/or authorized VA NSOC customers only. All use is monitored for authorized purposes, and any use constitutes consent to monitoring, storage and retrieval, disclosure, analysis, access restriction, investigation, or any other authorized actions. Any unauthorized access (or denial of access) to this system, all files, and all data therein is prohibited and is subject to criminal, civil, and administrative penalties under Federal Laws including, but not limited to, 18 U.S.C. §1030 (fraud and related activity in connection with computers) and 18 U.S.C. §2701 (unlawful access to stored communications). In addition, Federal Laws (18 USC 287 and 1001) provide for criminal penalties for knowingly submitting or making false, fictitious, or fraudulent statements or claims.
CLICK HERE
Accept and Continue
Cancel


REMOTE ACCESS PORTAL
RAP
Self Service Portal
SELECT

When requesting access, if Samantha is not listed in the drop-down list to approve remote access, you can select Kathleen Parks (All Other).





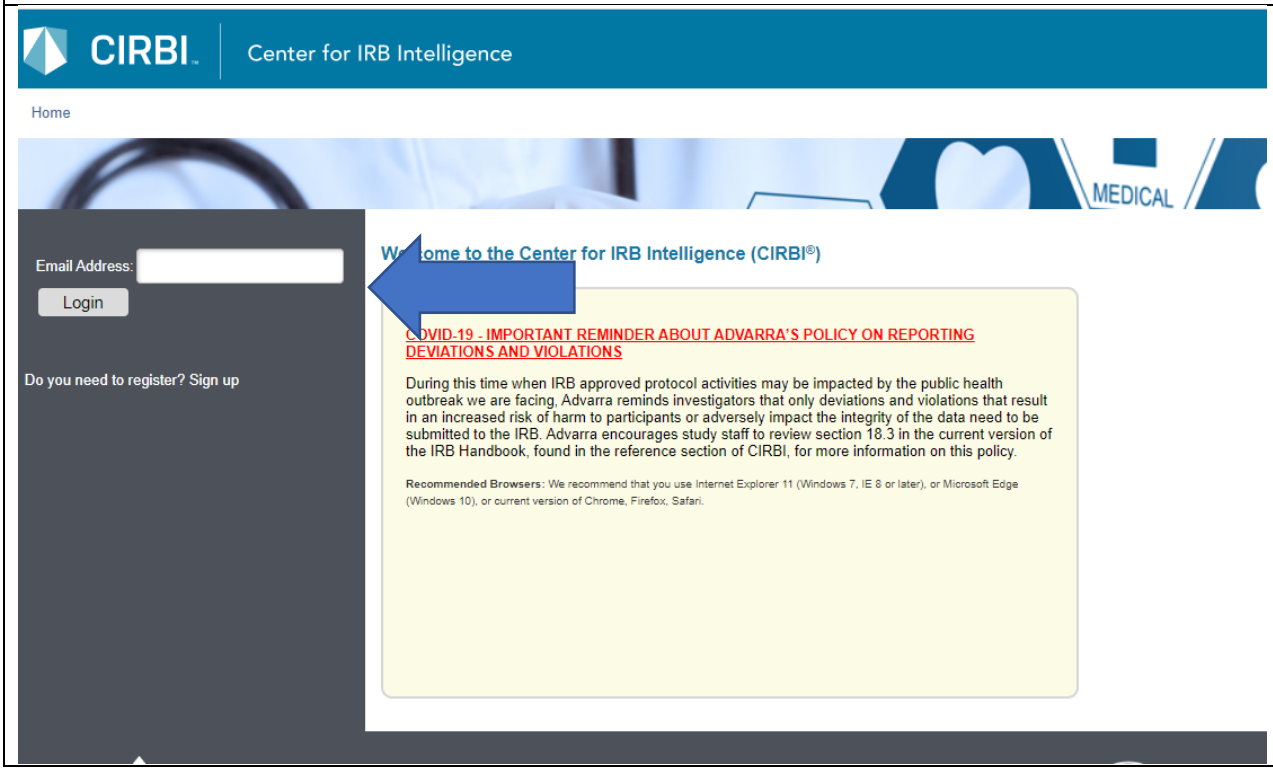
IRBNet & Commercial IRB (Advarra) Log In Examples

The VA Innovation and Research Review System (VAIRRS) is the VA's enterprise instance of IRBNet. VAIRRS (IRBNet) is used by all VA medical centers with research programs and provides an enterprise platform to support the management of research oversight committees.

Training resources and webinars for VAIRRS (IRBNet) can be found on the ORD Website (Office of Research & Development (va.gov), under ORD Programs→ Office of Research Protections, Policy, & Education (ORPP&E)→ VA Innovation and Research Review System (VAIRRS).

Instructions for how to register in IRBNet are located in the Appendix.

Sign into ADVARRA here: https://www.cirbi.net



CIRBI | Center for IRB Intelligence

Sign Up

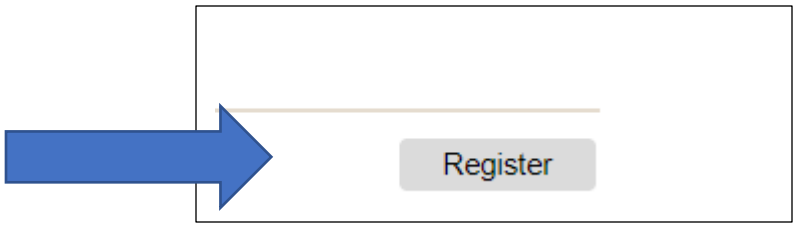
Registration for CIRBI

Registration is required in order to create, submit and track the progress of Research Protocols and Study Sites/Locations.

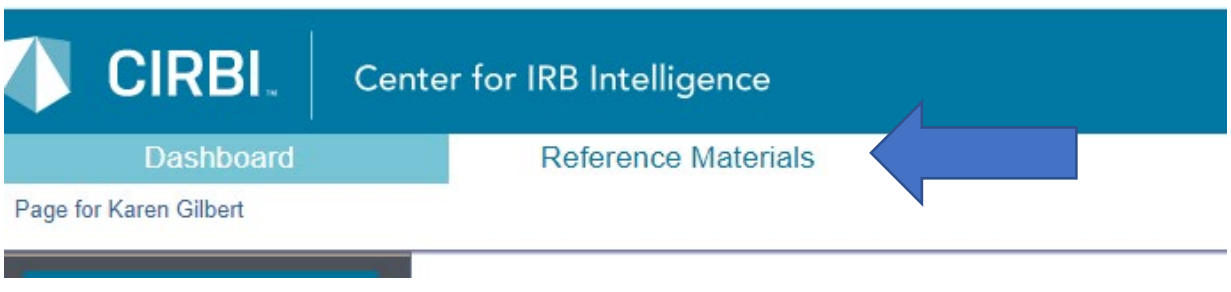
Fill in the following information and click the 'Register' button. Advarra IRB will review your request, configure a new account and then contact you via email with a Username and Password for site login.

Note: The email address that you provide will be used to create your Username which, along with your password, is *case-sensitive*. Also, you need to register only **once**.

* First Name:
Middle Name:
* Last Name:
Credentials/Degree(s):
enter for PI registration
* E-mail Address:
* Organization/Company Name (Please do not use acronyms):
* Role/Type:
* Address 1:
Address 2:
* City:
State/Province:
* Zip/Postal Code:
* Country:
* Phone Number:



For ADVARRA policies and SOPs:



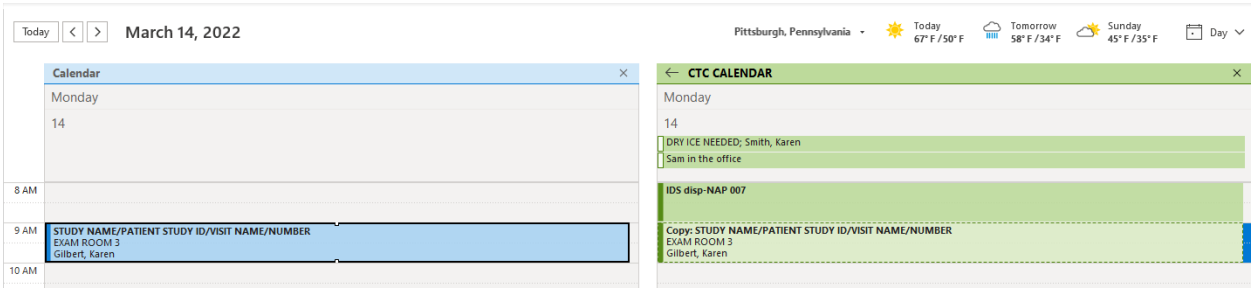
EXAMPLE

SCHEDULING EXAM ROOM AND/OR INTERVIEW ROOMS

All staff are required to secure appropriate space to conduct study participant/monitoring visits in advance of the visit. Prior to scheduling any visits, ensure that space is available in the CTU by viewing the shared CTU Calendar. Access to this calendar will be granted by the CTU Manager.

VASTL Shared Outlook CTU Calendar

Visits that require the PI, IDS, Regulatory and/or the CRA should indicate this by including them in a calendar Invite.



PAYMENT TO RESEARCH SUBJECTS

Paying research subjects in exchange for their participation is a common practice in research. However, payments are not to be so large as to induce prospective subjects to consent to participate in the research.

When the PI, Research Staff, or Prep Team submit the study to the IRB for initial approval, information regarding the rationale for payment, what dollar amount has been decided upon and how and when payment will be made. This information is included in the IRB application and as well as in the Informed Consent.

Participant compensation amount(s) can be determined in several different ways. For example, the study sponsor in collaboration with the VREF Executive Director during the contract negotiation phase will determine the payment amount for each study visit completed or compensation amount could even be determined at the time of initial granting writing when building the preliminary budget for the project.

For all VA funded studies, there are currently 2 approved methods for participant compensation: VA study vouchers or payments made via EFT.

- **Study Vouchers**
  - Study vouchers with preset value amounts ($25, $50, $100, etc) will be provided to the PI and study team by the VA Research Budget Analyst. The study participant will fill out the study voucher at the completion of the study visit and the study coordinator will make a copy to keep in the participant's regulatory binder. This form will require the participant to provide their name, address, & SSN. A member of the research team will escort the study participant to the VA agent cashier's office where they will be able to exchange the study voucher for cash payment at the end of the study visit.

- **EFT in the form of Direct Deposit**
  - At the time of the study visit, study participants will be asked to fill out VA Form 10091 and provide the following information: Legal name, 9-digit SSN, current address, US Banking name, routing number, & account number, account type. The completed VA From 10091 will be sent by a study team member to the St. Louis VA Department of Research & Education via encrypted email for processing and vendorization. The St. Louis VA Research and Education budget analyst will then submit a study voucher to the St. Louis VA Financial Services Department, who will process for payment via direct deposit. Participant will receive compensation within 6-8 weeks.

For all VREF funded studies, there are currently 2 approved methods for participant compensation: Physical Checks or Greenphire ClinCard. The VREF is in the process of transitioning studies from check to Greenphire Clincards as needed.

- **Physical Checks from the Foundation**
  - Once the study has officially opened, the study coordinator should contact (email is preferred method) the VREF Executive Director to request physical checks. The request should include the number of checks needed, the study name, PI and check amount.

The VREF Executive Director will approve the request and deliver the checks to the study coordinator for disbursement to the study participants. The study coordinator should fill in the date and participant's name on the check when issued. The study coordinator is responsible for keeping the checks in a secure location. The study coordinator should contact the VREF Executive Director for more checks as needed.

- **Greenphire ClinCard**
  - Payments are made through a prepaid debit card by the current VREFOur current vendor Greenphire, via PrepaidClinCard.
  - VREF's Executive Director will add new users and give access to users in the Greenphire Clincard System.

Upon study enrollment, the participant will also be asked to complete an IRS W9 Form (Request for Taxpayer Identification Number and Certification) which serves two purposes. It is used by the Foundation Business Office to collect identifying information to help file information returns with the IRS. It requests the name, address, and taxpayer identification information of a taxpayer (in the form of a Social Security Number or Employer Identification Number). The form is never actually sent to the IRS but is maintained for verification purposes. If the participant is paid $600.00 or more in a calendar year, the information on the Form W-9 and the payments made are reported on a Form 1099.

You will have a supply of ClinCards to distribute to your patients. They are in no specific order. Prior to giving a card to a patient, take the instruction sheet out of the envelope, flip the card over to show the card numbers, make a copy of the instruction sheet and card. You will need this information to register and assign the card to the patient. As some studies may extend beyond the expiration date of the card, it is important to keep your eye on those dates. A new card can be assigned to the participant when needed.

Example of Greenphire ClinCard Registration Process outlined on the next pages.

Study/Program Name: VETERANS HEALTH FOUNDATION CLINCARD

Valued Cardholder

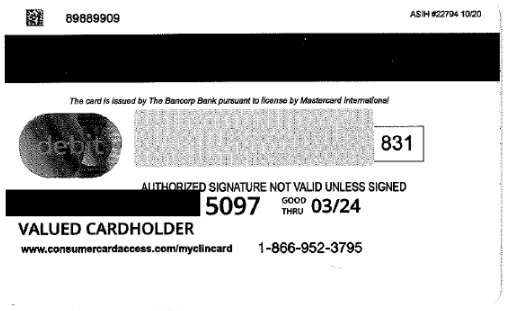
Token #[redacted]

Expiration Date: 03/24

By Phone:
1-866-952-3795

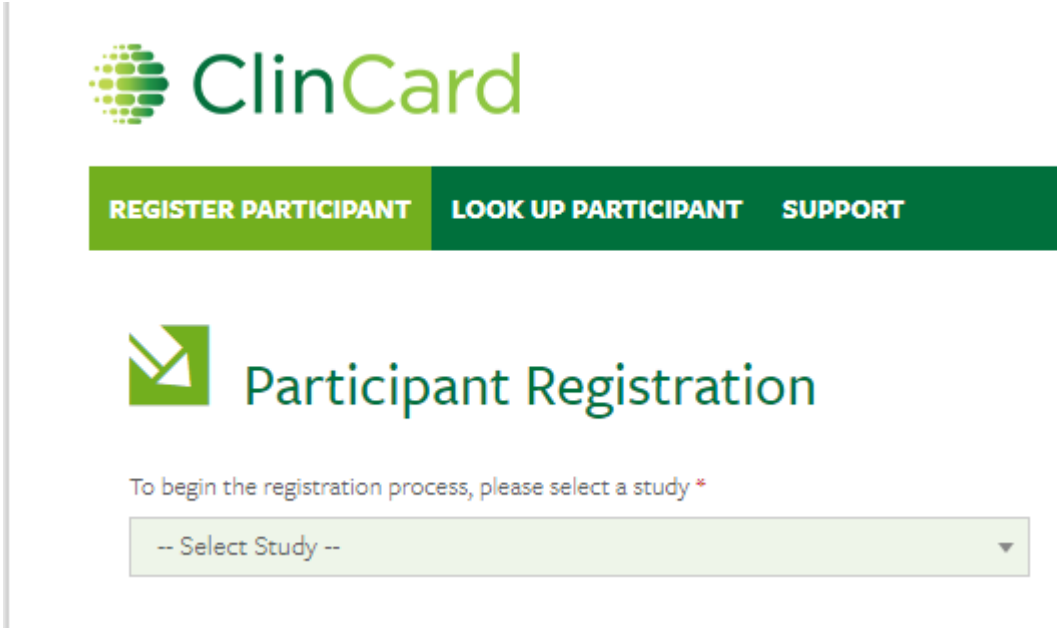
Get started with your ClinCard with these easy steps:

1. Your ClinCard Prepaid Mastercard® is active once registered to you. It can immediately be used once funds are loaded onto the card.
2. Your ClinCard comes with a pre-set PIN. In order to use your ClinCard for certain transactions, please call **1-866-952-3795** to retrieve your PIN.
3. Your card can be used:
   - To withdraw cash at ATM locations
   - At any merchant that accepts Mastercard
   - For online purchases
   - To get cash at banks: Go to any Mastercard member bank and ask for an over-the-counter (bank teller) cash withdrawal for up to the total balance on your card
4. Please do not discard the prepaid Mastercard as this is a reloadable card and additional funds may be credited. The card is only reloadable by the program sponsor and as the cardholder, you do not have the ability to add additional funds to this card. Card funds do not expire.

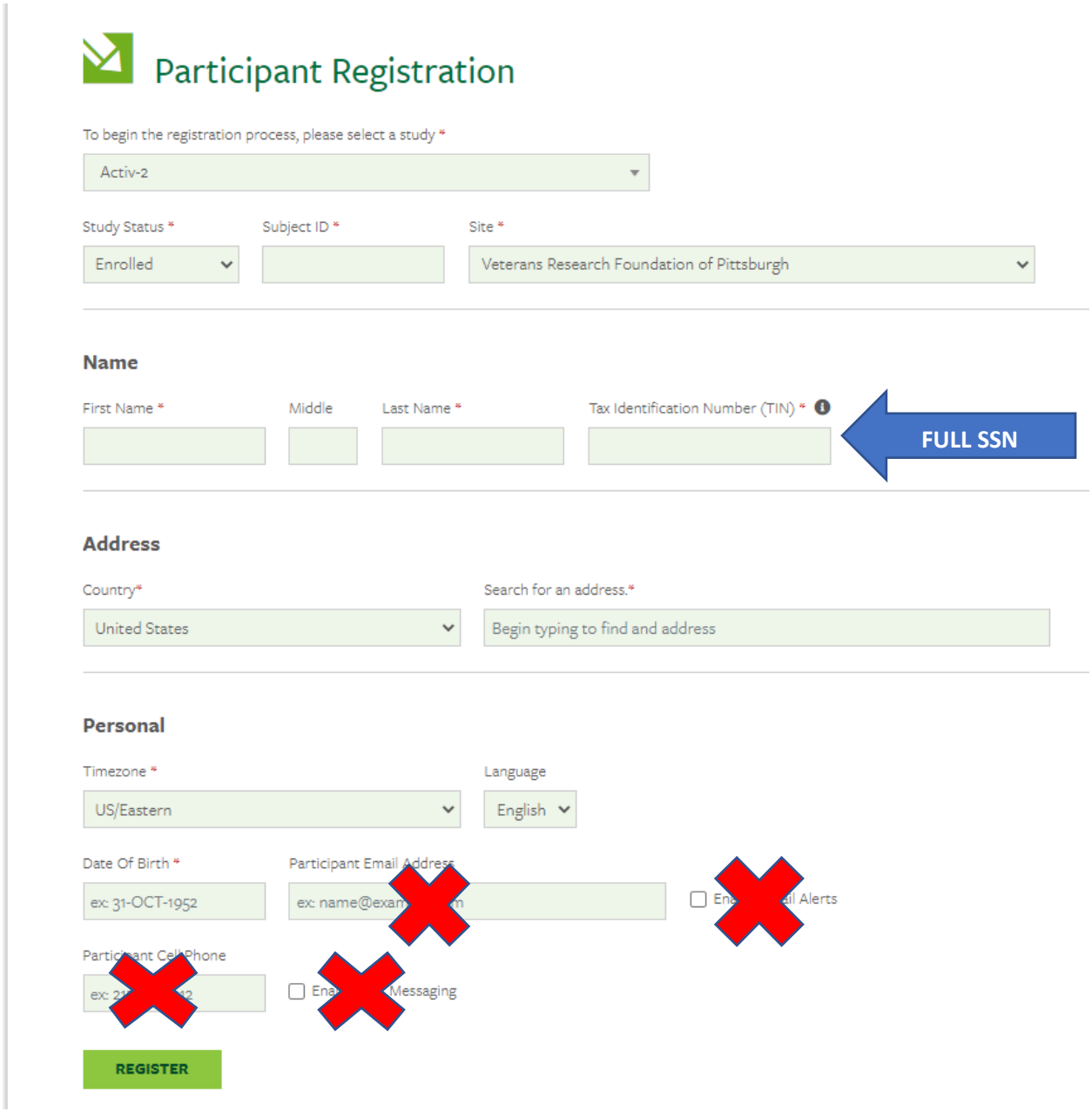


REGISTERING A PARTICIPANT IN CLINCARD

Sign in to ClinCard https://clincard.com/login/ Select Register Participant. Then Select Study from dropdown.



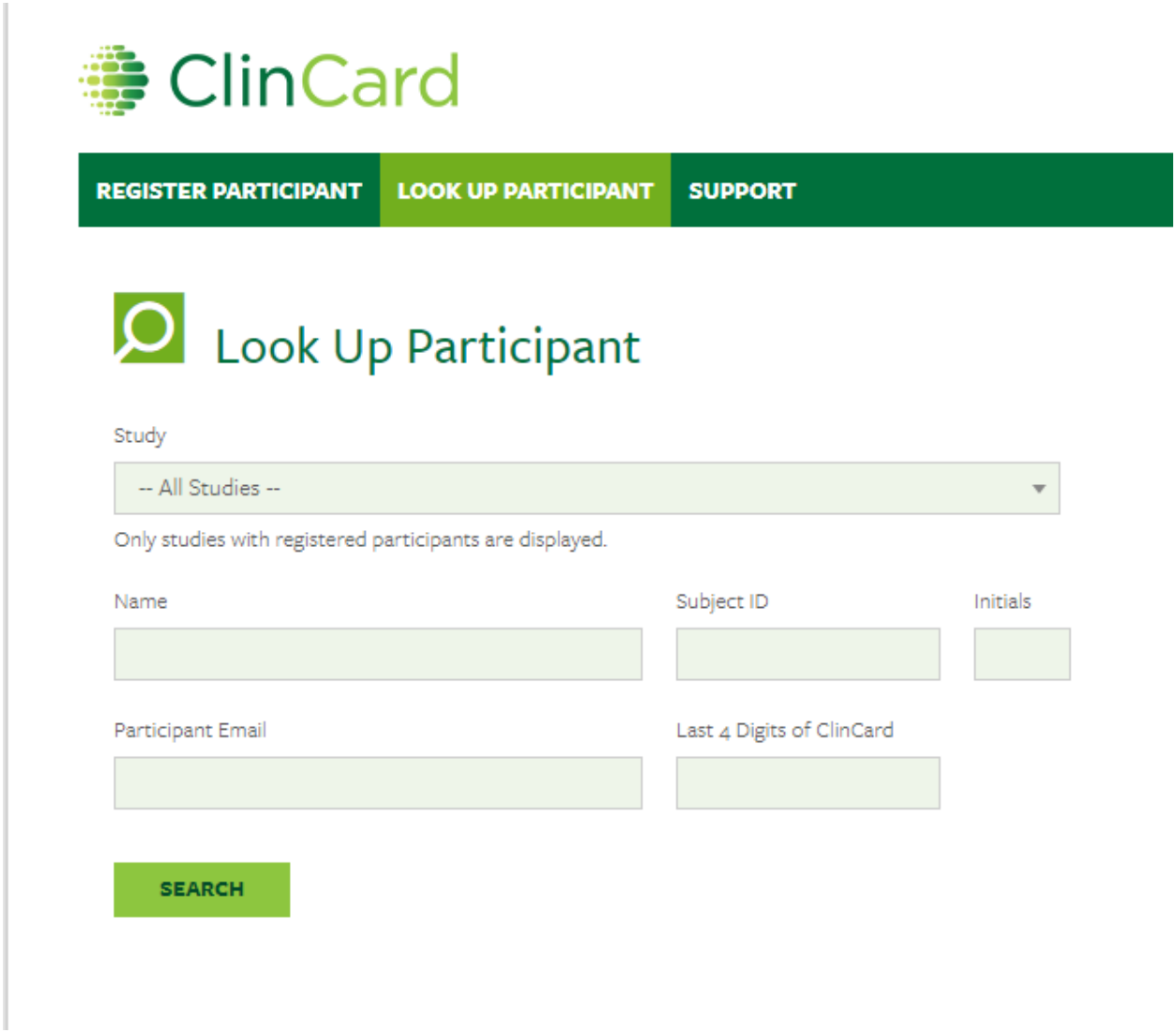
Complete all information BUT Participant Email Address and Participant Cell Phone. Click REGISTER

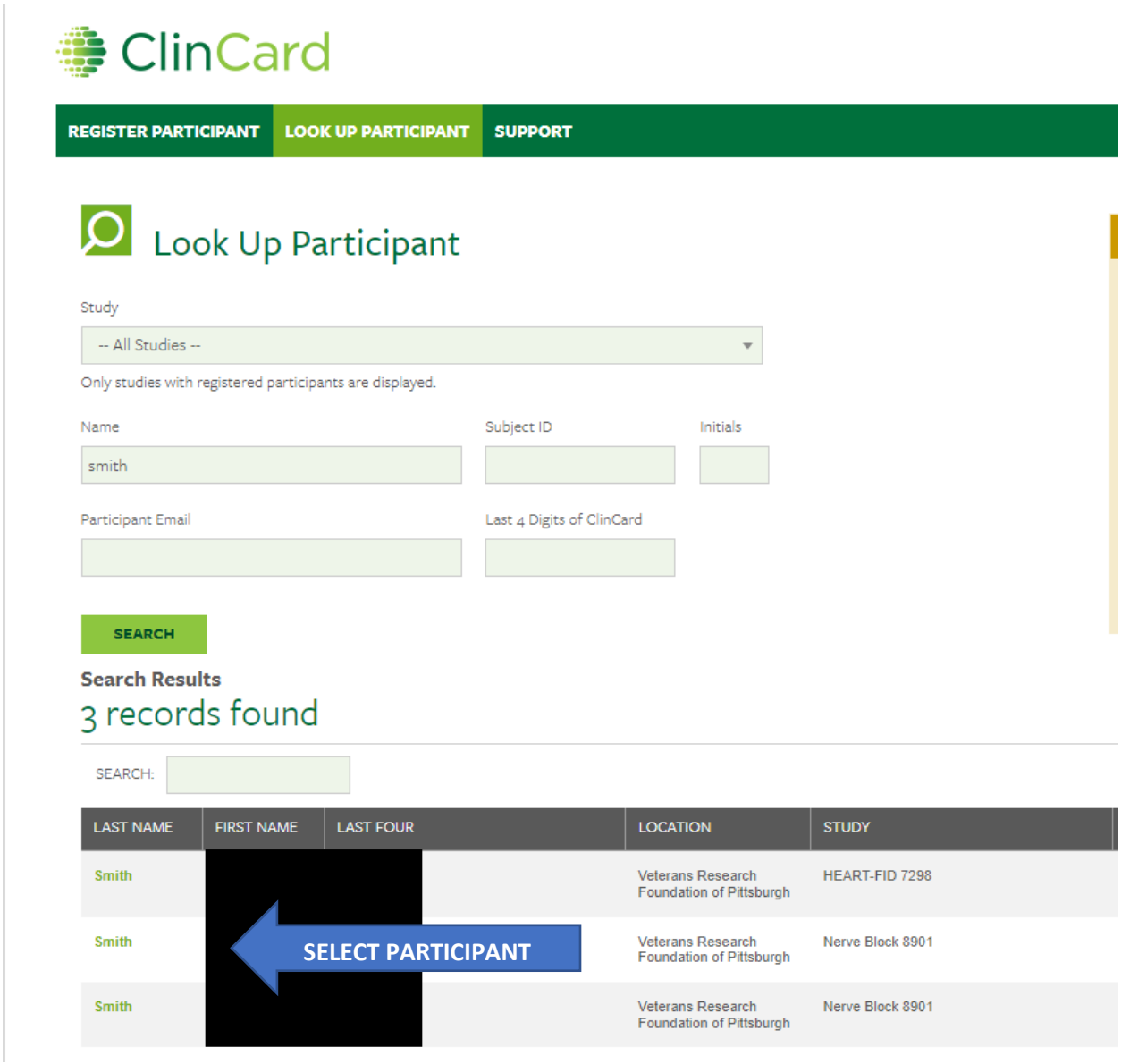


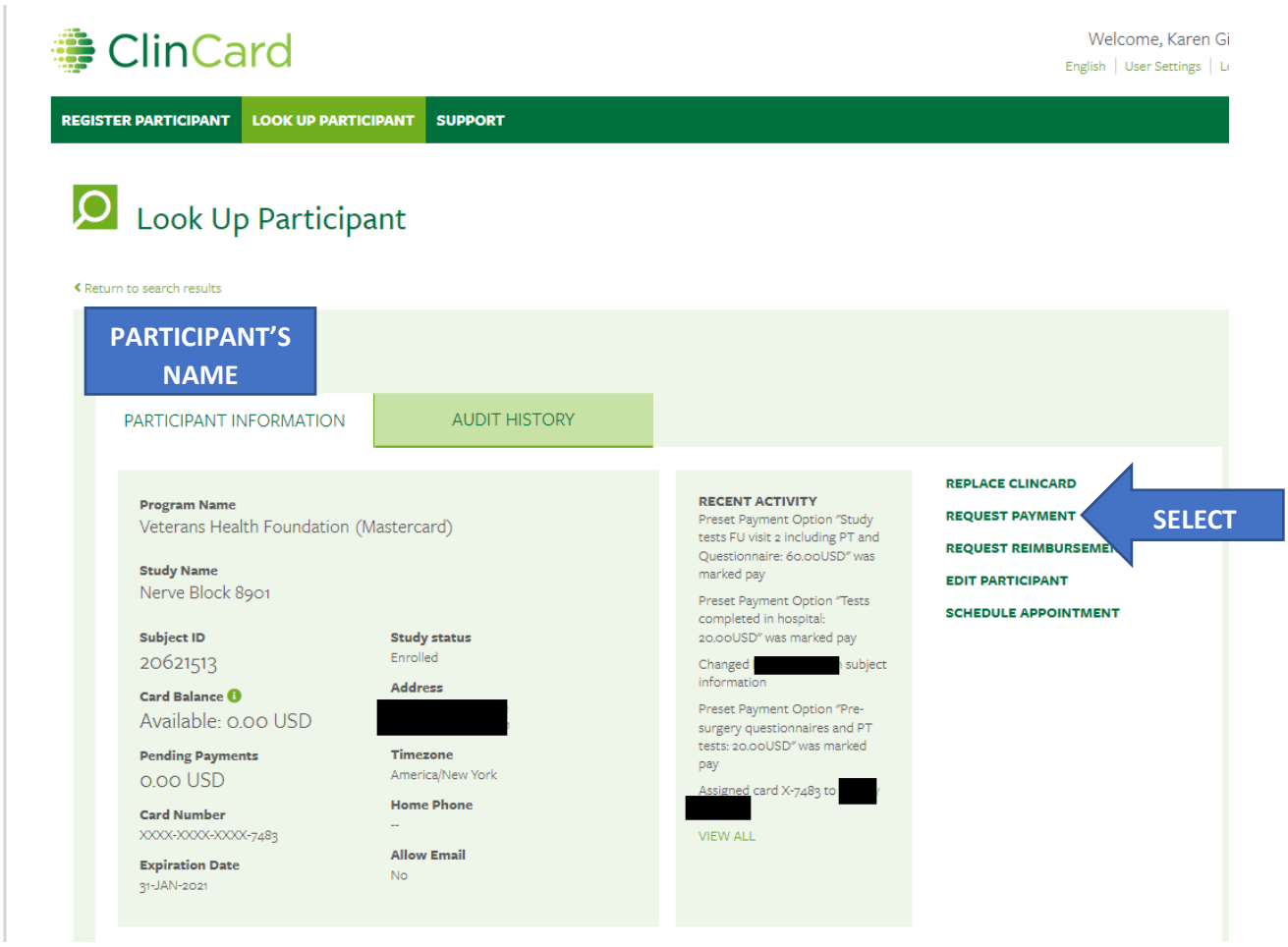
PAYING A PARTICIPANT IN CLINCARD

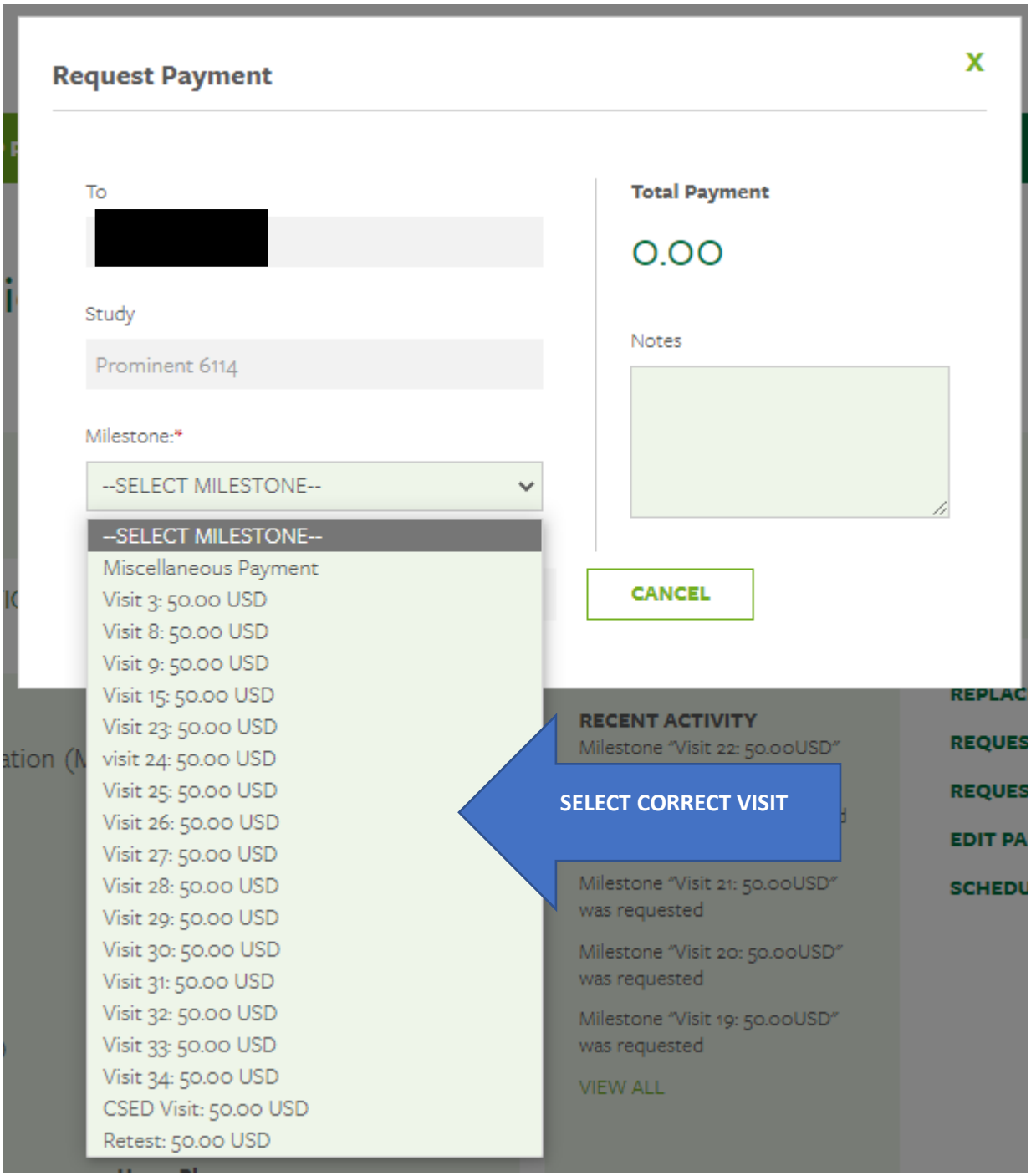
Sign in to ClinCard https://clincard.com/login/ Select Look Up Participant.

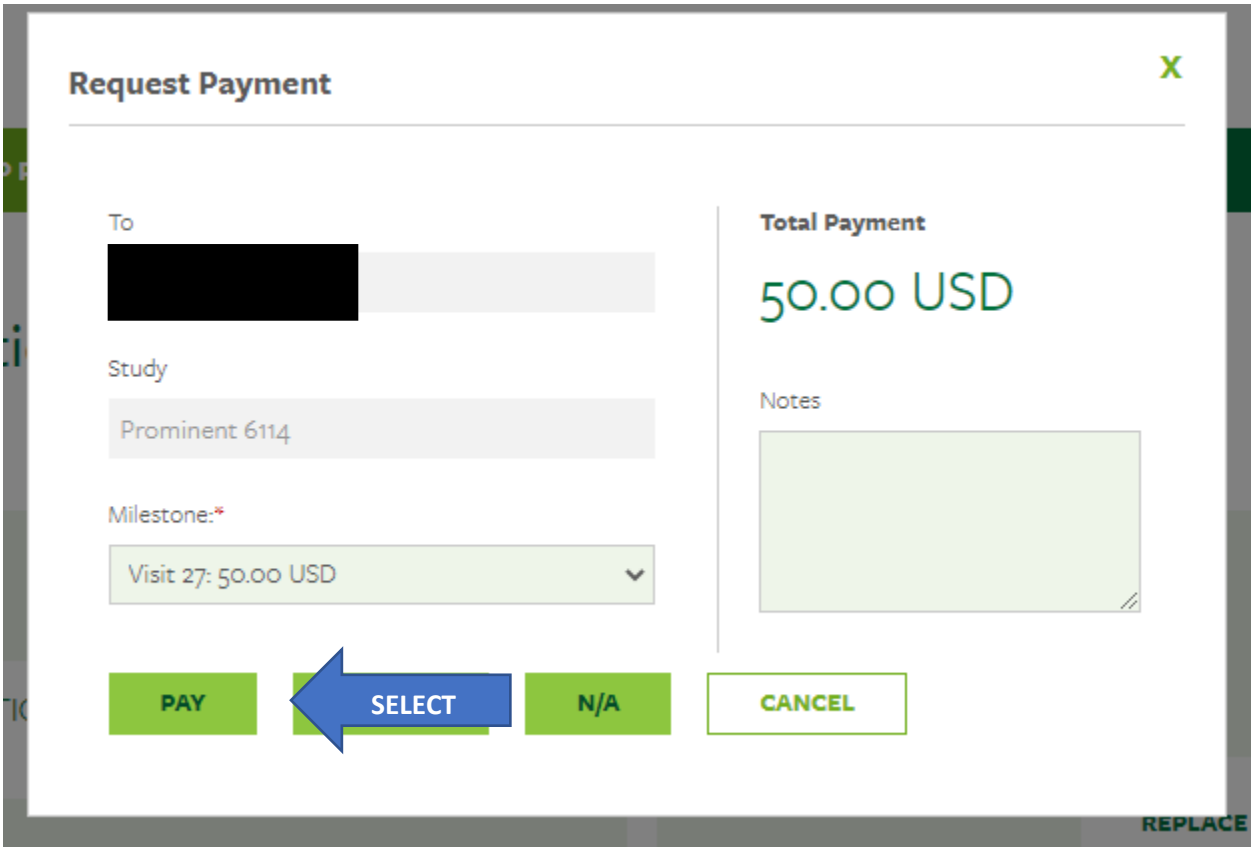
You can search by Study using the dropdown menu, Participant's last name, Subject ID or last 4 digits of the ClinCard. Easiest…Participant's last name.




ClinCard
REGISTER PARTICIPANT
LOOK UP PARTICIPANT
SUPPORT
Look Up Participant
Study
-- All Studies --
Only studies with registered participants are displayed.
Name
smith
Subject ID
Initials
Participant Email
Last 4 Digits of ClinCard
SEARCH
Search Results
3 records found
SEARCH:
LAST NAME
FIRST NAME
LAST FOUR
LOCATION
STUDY
Smith
Veterans Research Foundation of Pittsburgh
HEART-FID 7298
Smith
SELECT PARTICIPANT
Veterans Research Foundation of Pittsburgh
Nerve Block 8901
Smith
Veterans Research Foundation of Pittsburgh
Nerve Block 8901


ClinCard
Welcome, Karen Gi
English | User Settings | L
REGISTER PARTICIPANT
LOOK UP PARTICIPANT
SUPPORT
Look Up Participant
Return to search results
PARTICIPANT'S NAME
PARTICIPANT INFORMATION
AUDIT HISTORY
Program Name
Veterans Health Foundation (Mastercard)
Study Name
Nerve Block 8901
Subject ID
20621513
Card Balance
Available: 0.00 USD
Pending Payments
0.00 USD
Card Number
XXXX-XXXX-XXXX-7483
Expiration Date
31-JAN-2021
Study status
Enrolled
Address
[redacted]
Timezone
America/New York
Home Phone
--
Allow Email
No
RECENT ACTIVITY
Preset Payment Option "Study tests FU visit 2 including PT and Questionnaire: 60.00USD" was marked pay
Preset Payment Option "Tests completed in hospital: 20.00USD" was marked pay
Changed [redacted] subject information
Preset Payment Option "Pre-surgery questionnaires and PT tests: 20.00USD" was marked pay
Assigned card X-7483 to [redacted]
VIEW ALL
REPLACE CLINCARD
REQUEST PAYMENT
REQUEST REIMBURSEME
EDIT PARTICIPANT
SCHEDULE APPOINTMENT
SELECT


Request Payment
X
To
[redacted]
Study
Prominent 6114
Milestone:*
--SELECT MILESTONE--
Total Payment
0.00
Notes
CANCEL
--SELECT MILESTONE--
Miscellaneous Payment
Visit 3: 50.00 USD
Visit 8: 50.00 USD
Visit 9: 50.00 USD
Visit 15: 50.00 USD
Visit 23: 50.00 USD
visit 24: 50.00 USD
Visit 25: 50.00 USD
Visit 26: 50.00 USD
Visit 27: 50.00 USD
Visit 28: 50.00 USD
Visit 29: 50.00 USD
Visit 30: 50.00 USD
Visit 31: 50.00 USD
Visit 32: 50.00 USD
Visit 33: 50.00 USD
Visit 34: 50.00 USD
CSED Visit: 50.00 USD
Retest: 50.00 USD
SELECT CORRECT VISIT
RECENT ACTIVITY
Milestone "Visit 22: 50.00USD"
Milestone "Visit 21: 50.00USD" was requested
Milestone "Visit 20: 50.00USD" was requested
Milestone "Visit 19: 50.00USD" was requested
VIEW ALL


Request Payment
X
To
[redacted]
Study
Prominent 6114
Milestone:*
Visit 27: 50.00 USD
Total Payment
50.00 USD
Notes
PAY
SELECT
N/A
CANCEL
REPLACE

GLOSSARY OF TERMS

AAHRP (Association for the Accreditation of Human Research Protection Programs): Independent, non-profit accrediting body. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

ACOS/R&D: Associate Chief of Staff/Research & Development

ACRP (Association of Clinical Research Professionals): Non-profit educational membership organization for persons involved in clinical research activities.

Administrative Hold: A voluntary interruption of research enrollments and ongoing research activities by an appropriate facility official, research investigator, or sponsor that is not related to concerns regarding the safety, rights, or welfare of human subjects, research investigators, research staff, or others.

ADR (Adverse Drug Reaction): An unintended effect of a medication that is harmful or unpleasant.

AE (Adverse Event): An adverse event in human subjects research is any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research, the research intervention, or the assessment.

AESI (Adverse Event of Special Interest): A medical concern specific to the study

ALCOAC+:

Attributable – It should be clear who has documented the data.

Legible – Readable and signatures identifiable

Contemporaneous – Data is recorded when the work was performed

Original – The first record made by the appropriate person. The investigator should have the original source document.

Accurate – Consistent and real representation of facts.

Complete – Ensures everything is included and nothing is missing

Consistent – Data in sequential manner with a sign and date

Enduring – Using media that mains and protects records

Available – Available for review at any time

Assurance: An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule.

Audit: Site visits conducted by the sponsor/CRO as part of the sponsor's/CRO's overall quality assurance system

BCMA (Bar Code Medication Administration): Bar code system that is used by the VA on all inpatient units to verify each medication given by a Nurse.

CBOC (Community-Based Outpatient Clinics): VA-operated clinic or a VA-funded or reimbursed health care facility or site that is geographically distinct or separate from the parent medical facility.

CCRC (Certified Clinical Research Coordinator): ACRP certification

CCRP (Certified Clinical Research Professional): SoCRA certification

CDA (Confidential Disclosure Agreement): May be used where VA and/or a third party wish to share confidential information in anticipation of a future relationship. A CDA may be used to allow for the sharing of information needed to determine whether a CRADA is feasible.

Central Office/ Veterans Affairs Central Office (VACO): Directs the activities of the VA regional offices and the VA medical centers. The Central Office dictates standard rules and procedures the regional offices and medical centers must follow when handling claims.

Certificate of Confidentiality: A certificate of confidentiality is a document issued by a component of HHS to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Certified Copy: A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure as the original.

CFR (Code of Federal Regulations): Codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.

~~**CHERP (Center for Health Equity Research and Promotion):** A VA HSR&D Center of Innovation (COIN). It is a dual-site, cross-VISN center, with investigators in St. Louisand Philadelphia whose goal is to advance the quality and equity of health and health care for vulnerable Veteran populations~~

CIRB (Central IRB): An IRB that is available for clinical sites that are not already affiliated with an IRB that investigators and sponsors can engage to conduct reviews on behalf of all study sites involved in a multicenter trial

CITI (Collaborative IRB Training Initiative) Training: An educational program for the protection of human subjects in research

CLIA (Clinical Laboratory Improvement Amendments): Program to ensure quality laboratory testing.

Clinical Investigation: The Food and Drug Administration (FDA) considers the term clinical investigation to mean any experiment that involves a test article and one or more human subjects, and that either:

(1) Meets the requirements for prior submission to the FDA under Sections 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, **or**

(2) Does not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

CRA (Clinical Research Associate): [aka clinical monitor or trial monitor] The main function of a clinical research associate is to monitor clinical trials.

CRADA (Cooperative R&D Agreement): An agreement established between Department of Veterans Affairs (VA) and one or more non-Federal and/or Federal parties under which VA may accept, retain and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other partner.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

CS (Clinically Significant): Practical importance of a treatment effect—whether it has a real genuine, palpable, noticeable effect on daily life.

COV (Close Out Visit): This visit is conducted by the CRO/sponsor. This is the last visit of the study prior to IRB closure. Essential documents are collected, site supplies and drug are either returned or destroyed and all subject records are verified.

Collaborative Research: Collaborative research is human subjects research activities involving investigators from VA and at least one non-VA institution. Collaborative research includes VA and non-VA institutions.

CoI/FCOI (Conflict of Interest/Financial Conflict of Interest): A conflict of interest exists when financial interests or other obligations interfere, or appear to interfere, with an individual's or group's professional judgment in conducting, reviewing, or reporting research. This may include both financial and non-financial conflicts of interest.

(VA) Cooperative Studies Program (CSP): Part of the Department of Veterans Affairs (VA) Office of Research & Development (ORD). The CSP mission is to advance the health of Veterans through cooperative research studies that produce innovative and effective solutions to Veteran and national health care problems.

Coordinating Facility/Center: Location where an investigator is responsible for the overall supervision of more than one participating facility.

Co-I (Co-Investigator): An individual under the direction of the Principal Investigator who is involved in some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts.

Co-PI (Co-Principal Investigator): A Co-Principal Investigator may be designated when two or more Principal Investigators share equally in the accountability for a study.

Commercial IRB: An independent pay-for-services IRB external to a university or research institution that provides services for academic and non-academic researchers. (Advarra, Sterling, WCG)

CPRS (Computerized Patient Record System): Patient charting system that enables you to enter, review, and continuously update all the information connected with any patient.

CRADA (Cooperative Research and Development Agreement): Agreement established between VA and one or more non-Federal parties under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other party, as well as provide personnel, services, facilities, intellectual property, equipment or other resources, excluding funding, toward the conduct of specified research and development that is consistent with VA's mission.

CRC: Clinical Research Coordinator

CRF/eCRF (Case Report Form/electronic Case Report Form): Paper or electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient.

COA (Clinical Outcome Assessment): A measurement that describes or reflects how a patient feels, functions, or survives. Examples:

> **PROs (Patient-Reported Outcome)** - A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response. Symptoms or other unobservable concepts known only to the patient can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others.
>
> **ObsROs (Observer-Reported Outcome)** - A measurement based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a health professional. Generally, ObsROs are reported by a parent, caregiver, or someone who observes the patient in daily life and are particularly useful for patients who cannot report for themselves (e.g., infants or individuals who are cognitively impaired). An ObsRO measure does not include medical judgment or interpretation.
>
> **ClinRO (Clinician-Reported Outcome) -** A measurement based on a report that comes from a trained health-care professional after observation of a patient's health condition. Most ClinRO measures involve a clinical judgment or interpretation of the observable signs, behaviors, or other manifestations related to a disease or condition. ClinRO measures cannot directly assess symptoms that are known only to the patient.
>
> Reports of particular clinical findings (e.g., presence of a skin lesion or swollen lymph nodes) or clinical events (stroke, heart attack, death, hospitalization for a particular cause), which can be based on clinical observations together with biomarker data, such as electrocardiogram (ECG) and creatine phosphokinase (CPK) results supporting a myocardial infarction

PerfO (Performance Outcome) - A measurement based on standardized task(s) actively undertaken by a patient according to a set of instructions. A PerfO assessment may be administered by an appropriately trained individual or completed by the patient independently. PerfO assessments include gait speed (e.g., timed 25 foot walk test using a stopwatch or using sensors on ankles) and measures of memory (e.g., word recall test)

CRO (Clinical/Contract Research Organization): Company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance.

CTA (Clinical Trial Agreement): A legally binding contract between a sponsor, site, and researcher, that outline each party's responsibilities and obligations for the clinical trial.

CTMS (Clinical Trials Management System): A software system to manage clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.

Decentralized/Virtual Trials: A non-traditional clinical trial model that utilizes technology and processes to create options for participation beyond an exclusive physical presence at research sites.

De-identified Information: Health information that is presumed not to identify an individual, and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual, because the 18 patient identifiers described in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule have been removed or a qualified biostatistician has determined that the health information has been de-identified.

Del Log (Delegation of Authority/Responsibilities/Tasks): A comprehensive list of study staff members and the duties that have been delegated to them by the PI.

DoD: Department of Defense

DMC/DSMB/IDMC (Data Monitoring Committees/Data and Safety Monitoring Board/Independent Drug Monitoring Committee): An independent group of experts that serve in an individual capacity and provide their expertise and recommendations that reviews on a regular basis accumulating data from one or more ongoing clinical trials. Advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

DUA (Data Use Agreement): A contractual document used for the transfer of data that has been developed by nonprofit, government, or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use.

EAP (Early Access Program)/Compassionate Use: Potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

eCOA (Electronic Clinical Outcome Assessments): digital version of a COA (Clinical Outcome Assessment), which measures and records how a patient is feeling or functioning. It is used as part of a clinical trial to measure the efficacy of a health intervention.

EDC (Electronic Data Capture): Software that stores patient data collected in clinical trials.

EHR (Electronic Health Record): Contain information from all the clinicians involved in the patient's care and is designed to share information with other health care providers.

EMR (Electronic Medical Record): A digital version of the paper charts in the clinician's office which contains the medical and treatment history of the patients in one practice.

ePHI (Electronic Protected Health Information): Electronic health data created, received, stored, or transmitted by HIPAA-covered entities and their business associates in relation to the provision of healthcare, healthcare operations and payment for healthcare services.

ePRO (Electronic Patient Reported Outcomes): Clinical trials software which enables patients to digitally report their trial experience via their smartphone, tablet or computer.

ERDSP (Enterprise Research Data Security Plan): A mechanism to account for the security of research protocol data during each stage of the data management life cycle and is a reliable way to ensure the consistent evaluation of a research protocol's data usage, storage, sharing, and transmission requirements. The ERDSP is a collaborative effort between VHA Data Owners to balance security needs and security control requirements against the Mission of VHA Research, Operational Use of the Data within the Environment, Identified Risks and Available Resources

Essential Documents: documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced.

EUA (Emergency Use Authorization): Unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN (Chemical, Biological, Radiological, Nuclear) threat agents when there are no adequate, approved, and available alternatives.

Engaged in Research: An institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

Exempt: Research on human subjects that poses minimal risk, e.g., anonymous surveys, observation in a public place, or analysis of secondary data.

Expected AEs: AEs that have been identified as likely to occur according to the information contained in the IB or other labeling document (package insert).

Experimental Subject: As defined by the DOD, a human subject involved in research under a DOD Addendum that involves an intervention or interaction with the subject for the primary purpose of obtaining data regarding the effect of either.

FDA Form 482 – Notice of Inspection: Official notice of FDA for inspection which shows that the inspector has authorization to inspect the facility and indicates what the inspector may inspect.

FDA Form 483 – Inspectional Observations: Issued at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

FDA Form 1572 – Statement of Investigator: An agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

FWA (Federalwide Assurance): An assurance approved for Federalwide use by the Office of Human Research Protections (OHRP)

FWA Department of Defense (DOD) Addendum: Addendum to FWA that must be filed by when a study is sponsored by the Department of Defense and the DOD requires it. Such an addendum describes specific DOD responsibilities for the study. As of this version of the SOP, The U.S. Air Force and Army no longer require an addendum to the FWA for institutions already having an FWA.

GCP (Good Clinical Practice) Training: Intends to assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials.

GRECC (Geriatric Research Education and Clinical Center): VA geriatric centers of excellence focused on aging.

GTMR (Greater Than Minimal Risk): The probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater.

~~**HERL (Human Engineering Research Laboratories):** A collaboration between the Washington University of St. Louis/St. Louis University and the VA St. Louis Healthcare System is dedicated to wheelchair and mobility research, specifically by improving the mobility and function of people with disabilities through advanced engineering in clinical research and medical rehabilitation as well as studying athletics in rehabilitation, assistive living spaces, the efficiency of wheelchair transfers, clinician training, and force and vibration on wheelchair users.~~

HIPAA: Health Insurance Portability and Accountability Act

Home Telehealth (HT): Is a program into which Veterans are enrolled that applies care and case management principles to coordinate care using health informatics, disease management and technologies such as in-home and mobile monitoring, messaging and/or video technologies.

HSR&D (Health Services Research & Development): Identifies and evaluates innovative strategies that lead to accessible, high quality, cost-effective care for Veterans and the nation.

HRPP (Human Research Protection Program): System to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the VA facility Director, Associate Chief of Staff for Research and Development (ACOS/R&D), the Business

Manager, the Administrative Officer (AO) for R&D, the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), research compliance officer (RCO), information system security officers (ISSOs), privacy officers (POs), and research investigational drug service staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

Human Subject: A human subject is a living individual about whom an investigator (whether professional or student) conducts research, and:

1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens

2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

3) Individuals who receive test articles or who serve as controls in clinical investigations. directive.

Human Subject Research: Research involving human subjects or one or more identifiable human biological specimens.

HUD (Humanitarian Use Device): A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

IB (Investigator's Brochure) or IDB (Investigational Drug Brochure): A compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the clinical trial.

IBC (Institutional Biosafety Committee): Committee responsible for reviewing all research that involves biological/chemical hazards, radiation/use of radioactive materials, controlled substances, rDNA and/or physical hazards.

ICF (Informed Consent Form): Provides a potential study/research participant with adequate information to allow for an informed decision about participation in the clinical investigation and facilitates the potential participant's understanding of the information.

ICH (International Conference on Harmonization): An initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.

IDE (Investigational Device Exemption): allows an investigational device to be used in order to collect safety and effectiveness data required to support a premarket approval application or a premarket notification submission to the FDA

Identifiable Private Information: Identifiable private information is information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Biospecimen: An identifiable biospecimen in one in which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.

IDMC (Independent Drug Monitoring Committee): periodically review and evaluate interim data with an emphasis on the safety and effectiveness in clinical trials.

IDS: Investigational Drug Service (Pharmacy)

IFC (Interfacilty Consult): Allow consults and requests to be transmitted between Veterans Health Administration (VHA) facilities.

IMV/RMV (Interim/Routine Monitoring Visit): Any visit that occurs by the CRO/sponsor after the site is initiated and up until the site is closed out. The monitors visit sites periodically to ensure that they are compliant with all of the regulations, subject safety is being adequately followed, data is being captured in a timely and reliable manner and the IP is being handled in an appropriate manner.

IND (Investigational New Drug [Program]): Means by which a pharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines before a marketing application for the drug has been approved.

Individually-identifiable information (III): Any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is retrieved by the individual's name or other unique identifier. Individually-identifiable health information is covered regardless of whether or not the information is retrieved by name.

Inspection: Official site visit conducted by a regulatory authority

Intervention: Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Investigator: An investigator is any individual who conducts research including, but not limited to, the Principal Investigator (PI), ~~sub-investigator or~~ co-investigator, and Site Investigator or Local Site Investigator (LSI). All VA investigators on a VA research study or program must hold a VA appointment.

IIT/S (Investigator Initiated Trial/Study): A clinical trial in which the investigator conceives the research, develops the protocol and serves as sponsor investigator. The sponsor investigator initiates and conducts a clinical trial – alone or with a team.

Interaction: Interaction includes communication or interpersonal contact between investigator and subject.

IP (Investigational Product): Drug/Placebo used in a research study

IPA (Intergovernmental Personnel Act): Temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations.

IRB (Institutional Review Board): A board, committee, or other group formally designated by an institution to review, approve, require modification, disapprove, and conduct continuing oversight of human subject.

> **Central IRB:** For multicenter studies, the central IRB is the IRB that conducts reviews on behalf of all study sites that agree to participate in the centralized review process.
>
> **Commercial IRB:** Independent pay-for-service IRBs that provide regulatory and ethical review services for academic and non-academic institutions to conduct reviews of research involving human subjects.
>
> **Local IRB:** A function of an academic institution that conducts research and reviews only their trials and oversees research at just its location.

IRBNet (VAIRRS): Electronic research compliance management platform

IRT (Interactive Response Technology): A central piece of trial management that enables patient randomization, real-time drug allocation, and dynamic drug supply forecasting.

ISSO (Information Systems Security Officer): Part of a team that is responsible for:

1) Ensuring the HIPAA Security Rule is properly implemented
2) Conducting continuous monitoring as set forth by VA policy to ensure continued compliance with HIPAA Security Rule standards and specifications
3) Ensuring all complaints, incidents, or suspected breaches of e-PHI are investigated and resolved promptly in accordance with the Department's incident response policy
4) Conducting security-related reviews for contracts, research project proposals, and affiliate agreements involving e-PHI in accordance with Department and VHA policy

ITT (Intent(ion)-to-treat): A method for analyzing results in a prospective randomized study where all participants who are randomized are included in the statistical analysis and analyzed according to the group they were originally assigned, regardless of what treatment (if any) they received.

IWRS/IVRS (Interactive Web Response Systems/Interactive Voice Response Systems): Technologies that research sites use to enroll patients into clinical trials, randomize patients, and manage study drug supplies. The two technologies fall under the umbrella term Interactive Response Technology (IRT).

JLV (Joint Legacy Viewer): Source of health information from DoD, the Department of Veterans Affairs and private healthcare exchanges.

LAR (Legally Authorized Representative): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

LOS (Letter of Support): Required for all VA research studies that involve research only procedures. All impacted service line chairs must review and sign off on all research only procedures that affect the staff or space within their service line.

LSI (Local Site Investigator): Individual at a site participating in a multi-site project who oversees the scientific, technical, and day-to-day management of the research at the local site.

Medical Power of Attorney: Allows a person ("principal") to select an agent to make health care decisions on their behalf. This agent's powers go into effect only after the principal is considered not able to make their own decisions (incapacitated). A medical power of attorney is always a durable power of attorney.

Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

~~**MIRECC (Mental Illness Research Education Clinical Center):** *Mission* - To generate new knowledge about the causes and treatments of mental disorders, apply new findings to model clinical programs, and widely disseminate new findings through education to improve the quality of veterans' lives and their daily functioning in their recovering from mental illness.~~

Monitoring Visit: Routine site visits by the sponsor/CRO (e.g., site monitor/CRA) to oversee the site progress and quality of data

MOP (Manual of Procedures): Reference document that guides the study's conduct and operations

MoU (Memoranda of Understanding): A document that records the common intent and agreement between two or more parties. It defines the working relationships and guidelines between collaborating groups or parties. MoUs can help clarify roles and responsibilities, intent, and goals.

Multi-site Research: Multi-site research involves more than one research site. It may include VA and non-VA institutions and may include both collaborative research and research conducted under a CRADA with a pharmaceutical company or other non-Federal entity.

NAVREF (National Association of Veterans' Research and Education Foundations): Nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs (VA) medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), are authorized by Congress to provide flexible funding mechanisms for the conduct of research and education at VA facilities nationwide.

Non-Compliance: Failure to follow the federal regulations, VA requirements (including VA directives and handbooks), Institutional Review Board (IRB) requirements or determinations, and/or institutional policies and procedures related to the protection of human research participants. Non-compliance can be deemed serious or not serious. It can also be deemed continuing or not continuing.

NPC (Nonprofit Research and Education Corporations): VA-affiliated nonprofit research and education corporations that provides flexible funding mechanisms for the conduct of research and education at one or more VA facilities.

NCS (Not Clinically Significant): Practical importance of a treatment effect—whether it has a real genuine, palpable, noticeable effect on daily life**.**

OHRP (Office for Human Research Protections): Provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

Outside Hospital (OSH) – Non-VA facility

ORO (Office of Research Oversight): Promotes the responsible conduct of Department of Veterans Affairs (VA) research for the protection of Veterans and others who volunteer in VA research. ORO monitors, reviews, and investigates matters of research compliance that involve VA research. Specifically, ORO provides oversight of compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. ORO also provides training to facility Research Compliance Officers (RCO) and oversight of RCO auditing programs.

PD (Pharmacodynamics): Branch of pharmacology concerned with the effects of drugs and the mechanism of their action

Personal Representative: A personal representative is a person who, under applicable law, has authority to act on behalf of another individual. This may include power of attorney, legal guardianship of an individual, the executor of an estate of a deceased individual, or someone under Federal, state, local, or tribal law with such authority.

PHI (Protected Health Information): All individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. 'Protected' means the information is protected under the HIPAA Privacy Rule.

PII (Personally Identifiable Information): Any information about an individual that can be used to distinguish or trace an individual's identity, alone, or when combined with other information which is linked or linkable to a specific individual

PK (Pharmacokinetics): Branch of pharmacology concerned with the movement of drugs within the body

Pregnancy: Pregnancy encompasses the period from implantation until delivery.

PI (Principal Investigator): Qualified person who directs a research study or program. The PI oversees scientific, technical, and day-to-day management of the research. If a study is conducted by a team of individuals, the PI is the responsible leader of that team.

PO (Privacy Officer): Promotes employee awareness of VA's responsibility to protect the personally identifiable information (PII) of Veterans, their families, beneficiaries, and fellow employees.

POCT (Point-of-Care Testing): medical diagnostic testing that analyzes study specimens outside the clinical lab

Private Information: Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Program Office: Program Office is any office within the VHA Office of the Under Secretary for Health. A Program Office includes all its component offices and subdivisions, regardless of physical location.

Protocol Deviation: Any change, divergence, or departure from the study design or procedures of an IRB approved research protocol that has not been approved by the IRB.

Protocol Exception: A one-time event requested by an investigator when he or she knows in advance that the protocol will be deviated from, but the implementation of the deviation will not change the approved protocol. Examples include (a) enrollment of a subject who fails to meet current IRB approved inclusion or exclusion criteria or (b) deviations from scheduled visits or procedures.

PSP (Protocol Signature Page): The page in a research protocol that the local PI must sign that states he/she has received and read the protocol.

RSC (Radiation Safety Committee): The local VA committee that is responsible for reviewing and approving any research done at the VA that involves research only radiation or the use of radioactive materials.

RCO (Research Compliance Officer): Performs routine audits to evaluate the VA's research program. The RCO evaluates compliance with all applicable laws, regulations, and policies related to the conduct of research. The RCO conducts two kinds of audits:

1) Consent audits: The RCO reviews all signed consents
2) Triennial audits: The RCO conducts comprehensive review of studies approaching three years of being active, as well as research that closes without a previous audit. Audits may be conducted prior to the 3-year mark for new investigators and/or higher risk studies.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

1) Fabrication is making up data or results and recording or reporting them
2) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
3) Plagiarism is the appropriation of another person's ideas, processes, or results, or words without giving appropriate credit and can occur in proposing, performing, or reviewing research, or in reporting research results.

Research Records: Research records include, but are not limited to, IRB and R&D Committee records, records of all observations, subject recruitment activities, other data relevant to the investigation, progress notes, research study forms, surveys, questionnaires, and other documentation regarding the study

R&D (Research and Development Committee): Committee responsible, through the Associate Chief of Staff (ACOS) to the VA facility Medical Director, for oversight of the facility's research program and for maintenance of high standards throughout that program Research Protocol.

SAE (Serious Adverse Event): An adverse event that is serious and should be reported when the patient outcome is:

1) Death
2) Life-threatening
3) Hospitalization (initial or prolonged)
4) Disability or Permanent Damage
5) Congenital Anomaly/Birth Defect
6) Other Serious (Important Medical Events)
7) Required Intervention to Prevent Permanent Impairment or Damage (Devices)

~~**RIPP (Research Information Protection Program):** the mechanisms and procedures utilized to ensure that any research information collected, transferred, transmitted, and/or stored in conjunction with VAPHS research is done so in a manner that is compliant with VA Information Security and Privacy requirements~~

SC (Service Connected): Veterans who are disabled by an injury or illness that was incurred or aggravated during active military service.

Service Line: An approach to health care delivery that is organized around broad categories of care (e.g.: Primary Care, Lab, Pharmacy)

SIV/PSV (Site Initiation Visit/Pre-Study Visit): This visit is conducted by the CRO or sponsor and occurs prior to any research activities being conducted at the site. This visit typically happens after IRB approval and is a training visit for the study team on the research protocol.

SOA/SOE/Study Calendar (Schedule of Events/Schedule of Assessments): Outline of the activities that are to be performed for the research study. This includes a plan for administration of study treatment and a list of assessments and procedures that are to be performed for the duration of the study.

SOC (Standard of Care): A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.

SoCRA (Society of Clinical Research Associates): Non-profit educational membership organization for persons involved in clinical research activities.

SOP (Standard Operating Procedures): Detailed written instructions that describes standard practices and processes that contribute to uniformity and avert procedural deviations

Source Documents: Document in which data collected for a clinical trial is first recorded. Examples of source documents:

1) Hospital records
2) Clinical and office charts
3) Laboratory notes/results
4) Memorandum

5) Subjects' diaries or evaluation checklists
6) Pharmacy dispensing records
7) Recorded data from automated instruments
8) Copies or transcriptions certified after verification as being accurate copies

Sponsor: A sponsor is the company, institution, individual donor, or organization responsible for the initiation, management, or financing of a research study. Sponsors may enter into agreements with intermediaries that act as agents, such as contract research organizations (CRO) or coordinating centers.

Sponsor-Investigator: An individual who both initiates and actually conducts, alone or with others, a clinical investigation; i.e., under whose immediate direction the investigational drug or device is administered, dispensed, or used.

SSV (Site Selection Visit): This visit is conducted by the CRO, sponsor or another third-party vendor. This visit is conducted to help both parties (sponsor and the site) decide if this research trial is feasible for that site. The sponsor/CRO will discuss the study with the study team as well as assess their ability to appropriately conduct the study at that site. They will tour the facility and ask the study team questions to determine if the site should be chosen as a site.

~~**StatCore (Research Statistical and Bioinformatics Core):** Provides statistical and data support to VA clinical and administrative staff and to research investigators with projects that are extramurally funded (VA, DoD, NIH, VISN, private foundations, rural health funds).~~

SUSAR: **S**erious **U**nexpected **S**uspected **A**dverse **R**eaction

Suspension: Refers to a temporary interruption in selected research activities (e.g., the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities due to concerns) due to concerns about the safety, rights or welfare of human subjects, research personnel or others, regardless of whether the action to suspend was taken by an investigator, facility official, research review committee (e.g., IRB), or external entity

Systemic Deficiency: A fundamental, underlying problem that jeopardizes the effectiveness of the facility's research protection systems.

Termination: Refers to a permanent halt in all research activities due to concerns regarding the safety, rights, or welfare of human subjects, research personnel or others regardless of whether the action was taken by an investigator, facility official, research review committee (e.g., IRB), or external entity.

Unanticipated or Unexpected: The terms unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

UPIRTSO (Unanticipated Problem Involving Risk to Subjects or Others): An incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. An unexpected SAE that is related or possibly related to participation in human subjects research

VA Directives: Mandatory department-wide policies

VA Handbooks: Describe mandatory department-wide procedures or operational requirements implementing policies contained in directives**.**

VAIRRS (VA Innovation and Research Review System): Research committee software management platform for all VA medical centers with research programs [IRBNet]

~~**VAPHS**~~**VASTL**: Veterans Administration St. Louis Healthcare System

VA Research: VA research is research that is conducted by investigators (serving on VA compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have R&D Committee approval before it is considered VA research and before it can be initiated. All research activities approved by the R&D Committee are considered VA research.

VISN (**Veterans Integrated Service Networks):** Veterans' health care is separated geographically into 19 regions with systems within each network headed by medical centers, and hierarchically within each system by division level of care or type.

WOC (Without Compensation): VA appointment used by VA to employ individuals to do VA work (e.g., a task, service, research) without compensation. A WOC is a federal employee for all purposes except for salary and benefits.

MISCELLANEOUS INFO AND HOPEFULLY HELPFUL HINTS

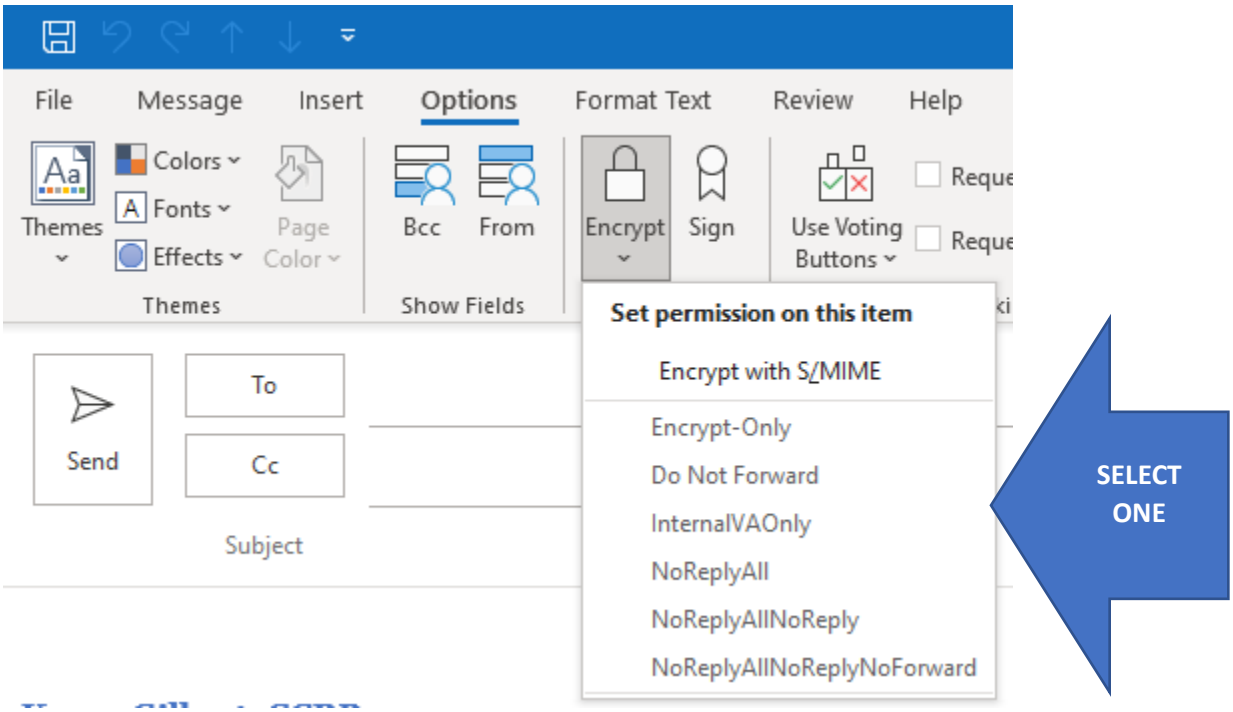
Any CTU staff member who is notified of the arrival of a subject who is scheduled for a visit should escort the subject into the scheduled exam room.

Any procedures conducted should be documented by the team member who completes the procedure on the appropriate source document worksheets

Every patient that signs consent is ENROLLED. However, not every patient that is enrolled will be a study participant.

When sending an email to anyone that contains ***ANY*** patient information…

ENCRYPT! ENCRYPT! ENCRYPT!



When sending *ANY* patient information to a sponsor…

De-identify!

TYPES OF IDENTIFIERS		
Names or initials	Medical Record Numbers	URLs
Biometric Identifiers (finger/voice prints)	SSNs (straight or scrambled)	All geographic subdivisions small than a state
All elements of dates except the year and ALL ages over 89	Health plan beneficiary numbers	Vehicle identifiers and license plate numbers
Telephone Numbers	Account Numbers	Full-face photos/Any comparable images
Fax Numbers	Certificate or license numbers	Device identifiers/Serial numbers
Email addresses	IP addresses	Any other unique identifying number/characteristic/code

THE FOLLOWING WORDS ARE INTERCHANGEABLE…

Study = Protocol

Patient = Subject = Participant

HOW TO CALCULATE MEDICATION COMPLIANCE:

Study drug supply

60 Days = 120 Tabs

Number of days from initial/new supply until next scheduled study visit

July 1 – August 30 = 60 Days

Dosing instructions

Take 2 Tabs Daily

Multiply times the number of doses to be taken during this period

2 Tabs Daily X 60 Days = 120 Tabs

Number of Tabs Taken

114 Tabs Taken

Number of Tabs Taken divided by the Number of Tabs Taken

114 ÷ 120 = 0.95% Compliant

Anthropometric Conversions

Height Conversion

Height (inches) x 2.54= Height (cm)

Weight Conversion

Weight (pounds) x 2.2=Weight (kg)

Smoking

How to calculate the pack years?

To calculate the pack year (PY), multiply the number of packs of cigarettes smoked per day (Packs) by the number of years (Years) the person has smoked.

- PY = Packs * Years

or

- PY = (Cigarettes per day/Pack size) * Years, if your pack size is different than standard 20 cigarettes.

If you want to know how many packs (PL) or cigarettes (CL) you already smoked in your life, use the formula:

- PL = Cigarettes per day * 365.24 * Years
- CL = (Cigarettes per day/Pack_size) * 365.24 * Years

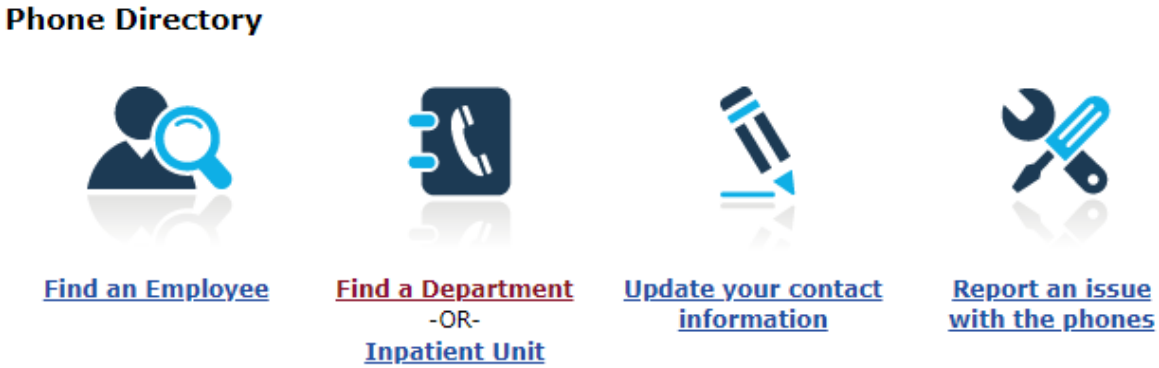
Example of pack year calculation:

One pack year is equivalent to smoking 20 cigarettes a day for one year (1 pack * 1 year). If you are smoking ten cigarettes daily for two years (0.5 pack * 2 years), or two cigarettes per day in your ten years smoking history (0.1 pack * 10 years), it still gives us one smoking pack year.

However, it is still debatable if pack years are good enough for assessing the risk of lung cancer. Some researchers claim that more prolonged exposure to smoke (e.g., 40 years, a half pack per day) poses a higher risk than shorter periods (10 years with two packs per day) even though the number of pack years is the same in both cases.

EXAMPLE

INFORMATION THAT CAN BE FOUND ON THE VA WEBSITE



NEED TO REPORT A COMPUTER PROBLEM? USE THIS ICON ON YOUR DESKTOP.

General Information Regarding VA Research

WHAT IS A WOC?

Employees of VREF are Without Compensation (WOCs). WOCs are used by the VA to employ individuals to do VA work (e.g., a task, service, research) without compensation from the VA. A WOC is a federal employee for all purposes except for salary, benefits, scheduling and are subject to the Government ethics laws and rules. VA Research Training Coordinator will provide a comprehensive list of the documents required for the WOC to complete.

ADDITIONAL RESOURCES:

Although not VA specific, the following are free resources that offer insight into the general research practices.

The Only Crash Course To Clinical Research You'll Ever Need (full 5 hour OFFICIAL video) - YouTube

ACRP Course Catalog - Training for Clinical Research Professionals (acrpnet.org)

Introduction to Clinical Trials - ACRP (acrpnet.org)

https://www.ecshsr.pitt.edu/video-presentations-library

Bottom line – There's no such thing as a stupid question if YOU don't know the answer.