

Department of Veterans Affairs (VA)
Veterans Health Administration (VHA)
Malcom Randall VA Medical Center (MRVAMC)



Research Coordinator Guidebook

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Purpose

The Malcom Randall VAMC *Research Coordinator Guidebook* serves as a source of information, tools, and tips for new coordinators and as an additional resource for seasoned coordinators as follows:

- This guidebook contains important information ranging from generalized information about the Malcom Randall VAMC (MRVAMC) to coordinator-specific duties and uses of VA facilities and software. The *Guidebook* is designed to be comprehensive and to serve as the framework for Research Coordinators, thus it is **not** PI/study specific.
- There will be frequent links to the VA Research Resources webpage ([Research Webpage](#)) hosted by NFFRE, where forms and other resources, such as documents, maps, and presentations, are linked for easy access. Note there is a special section for the *Research Coordinator Guidebook* and the documents and links it refers to.
- The *Guidebook* is meant to be a fluid document and thus the guidelines and information are subject to change as Research Coordinators provide feedback and as Research Service, Office of Research and Development, and VHA information or policies change.
- This guide does not replace or supersede VA Policies.
- Questions, concerns, and suggestions regarding this guidebook should be directed to Juliana.Venetucci@va.gov

Malcom Randall VAMC

The MRVAMC is the hub of the North Florida/South Georgia Veterans Health System (NF/SG VHS) and where Research Service is responsible for conducting VA research within the region. As a Research Coordinator within the Research Service department your main duty station will be in Gainesville, FL at the MRVAMC. The following information will detail the layout of the facility, including clinics and parking, as well as contact information for commonly utilized services.

Parking Map

Parking is free and a map of the MRVAMC parking areas is available [on this web page](#). Patients can park in any open lot or in the garages or can use valet parking.

Employees must have a parking sticker for their cars. To obtain the sticker, register your vehicle by taking your PIV badge, vehicle registration, and insurance card to the Police Service office in the basement, Room EB01A-1. Place the sticker on the bottom left corner of the back window of your vehicle.

Facility Map

Information about each floor of the MRVAMC is available in the [Wayfinding Booklet](#) on the MRVAMC website.

NOTE: The Primary Care, Mental Health, and Women's Health Clinics have moved from the main hospital to the [Gainesville VA Clinic](#) at 5469 SW 34th St, Gainesville, FL 32608. This clinic offers CT scans, MRIs, specimen collection, prosthetics and orthotics, and physical and occupational therapy.

Services

Most services, like IT, Interior Design, and Engineering, will require a work order to be placed before services can be provided. A comprehensive list of services and their extensions can be found on the [Research Webpage](#). If you would like to request an update to the list, or you know an extension is incorrect, please use this [link](#) to submit an update request. A [directory of NF/SG VHA service contacts and related information on SharePoint](#) can be accessed from any VA network computer.

These numbers are important to have on hand for urgent and/or work-stoppage matters:

- Chemical Spills: x104043
- Chemical Waste: x103631 Engineering: x106025 (repairs, plumbing, etc.)
- Fire Emergency: x106911
- Housekeeping Supervisor: x102301
- Information Technology Service Desk: x106093 (computer, printer, computerized patient record system [CPRS], network issues, etc.) Patient Transport: x106674
- Pest Control: x107149 (or call housekeeping supervisor)
- Police Emergency: x104091/x106911
- Warehouse: x106673 (shipping, receiving, return of equipment)
- Xerox Contractor: 855-915-0383 (ink/toner refills)-please have serial number handy when calling

Housekeeping

- **Environmental Management Service (EMS)**. These employees provide housekeeping at the MRVAMC including emptying trashcans, sweeping and mopping floors, and cleaning bathrooms. If you would like your trash emptied at the end of the day, leave the bin outside your office door.
- **EMS is not responsible for cleaning offices**. It is up to Research Service employees to keep common areas, such as break rooms and conference rooms, clean. If you use a shared refrigerator in break rooms, please keep all food in sealed containers and do not leave any food over the weekends. If you use the microwave, please clean it after use.
- **Relocation**. Moving offices? Cleaning out lab space? EMS can provide you a large red bin for trash. Call 102301 and request a large red garbage bin. Once full, call again and request it be picked up. EMS will also provide paper towel, toilet paper and garbage bags as needed.

Employee Health

- 352-548-6000 x105158
- 2nd floor in Room D230
- Resource for seasonal vaccines, accidental needle sticks, and mental health services.
- More information available on the VA SharePoint under the Employees tab, or at <https://vaww.northflorida.va.gov/NORTHFLORIDA/employees/index.asp>.

Employee Wellness Center

The MRVAMC has an employee gym that is located in the basement, room A30 directly across from the locker rooms. The gym is a non-supervised fitness center available to all VAMC employees and is open 24/7. To access the gym, you must submit a new NFSG Individual Fitness Certification form, linked on

the [Research Webpage](#). Please be courteous after working out on equipment and clean it after each use.

For other offerings, check out the [Employee Whole Health](#) SharePoint.

Warehouse

The warehouse is located in the basement between elevator B and the information desk. The warehouse is the home of supply chain management, the mailroom, and reproduction. All deliveries and shipments will go through the warehouse. FedEx, UPS, and USPS all deliver directly to the warehouse and are distributed to service areas by the mail clerks and package delivery.

To access the warehouse, press the doorbell to the right of the double doors. All visitors must sign in at the reception desk when entering and sign out when leaving.

Mailing Letters

- **Return address:** All outgoing mail must have the mail code RESEARCH 151 or 151A (BRRC) or NFFRE EB68 in the return address to ensure that the correct service is billed and that returned mail gets placed in the proper mailbox.
- **Outgoing letters:** These can be dropped in the two mail bins next to the front desk in the warehouse.
- **Letters for official VA business:** These do not require a stamp; the mail room will provide the postage.
- **Personal Mail:** These can be sent through the mailroom but will need postage provided by the mailer.

UPS/FedEx Shipments

- **Pick up location:** FedEx Air and UPS Ground and Air all have pick up at the warehouse.
- **Days and time:** Picks up occur Monday-Friday usually around 4pm, so it is advisable to drop off any packages by 3:30pm for guaranteed same day shipping.
- **Waybills and forms:** For UPS/FedEx, Air Waybills should be attached to the package. Additionally, VA Form 222 is required. This form will be returned to you via mail clerk delivery for confirmation of shipment. Best practice, however, is to scan this form into your study folder for your records, especially if returning study equipment or shipping participant samples.
 - If you are not provided a UPS/FedEx label from the study/sponsor, fill out a Form 222 with all the requested information and bring the package to the warehouse. The Warehouse staff will assist you with creating a UPS/FedEx label.

Reproduction

- **Services:** Printing documents such as copies, brochures, business cards, and posters.
- **Request Form:** A reproduction request form must be submitted at least 2 weeks in advance and all fields in the form must be answered to prevent delays and to ensure materials are printed properly.
 - **Submit in person:** The reproduction center is located near the basement entrance to the medical center, Room FB27-1.
 - **Submit online:** A Reproduction Request can be placed online in Sharepoint here: https://leaf.va.gov/VISN8/573/nf_sg_reproduction_request/

Medical Media

- Services
 - Digital and print images including graphic designs, logos, flyers, brochures, and posters
 - Professional portraits for individuals and groups
 - Filming for educational and training purposes
 - Requests for the GNV Auditorium event space rentals including equipment requests for training laptops, projectors, and easels
- Request Form
 - Submit a Medical Media Request online: <https://leaf.va.gov/VISN8/573/medicalmedia/>
 - Order pick up: Go to the Medical Media office, E432-1, on the 4th floor. Take elevator B to the 4th floor and follow the signage for Medical Media.
- Phone: 352-548-7125

Conference Rooms

When feasible, the use of virtual meetings, such as Microsoft Teams, is strongly encouraged. There are three conference rooms available for meetings, presentations, and special events by reservation: E544, D204, and Res Admin Bldg 14, Room 105. These rooms are equipped with a computer, projector, and intranet access.

Reserving a conference room

- **Request.** Submit a request at this VA SharePoint link:
<https://dvagov.sharepoint.com/sites/vhanflapp/cal/SitePages/Home.aspx>
NOTE: Wait for a confirmation email from the scheduler before planning your event.
- **Room use.** The employee(s) making the room request is responsible for preparations and clean up as follows:
 - **After the event:** Restore the room to pre-event condition by assuring all room furniture is returned to proper locations and by cleaning tables and disposing of all trashes.
 - **Cancellation:** Cancel the reservation if/when you no longer need the room.

Veterans Canteen Services (VCS)

VCS Retail Store

The Veterans Canteen Service store is open 7am to 8pm M-F and 9am to 3pm Saturday and Sunday. It is located on the basement floor by Elevator A. The retail store has clothing options for both men and women, professional and casual. The store also has electronics, perfumes, home décor, and more. The store also serves convenience items such as assorted chips, chocolates, and drinks.

Canteen

The Canteen, or cafeteria, is open Monday-Friday for breakfast 7am-10am and Monday-Friday for lunch from 11am-2pm. It is located on the basement floor by Elevator A. The canteen offers a breakfast buffet line as well as a breakfast grill station for custom omelets and sandwiches. For lunch, daily specials are available on the hot lunch line. The grill is available for burgers, chicken sandwiches, fish sandwiches, and assorted sides. There is also a salad station and a sushi station. Pre-made salads, sandwiches, sushi, and bento boxes are available for quick grab and go meals.

Patriot Brew Coffee Shop

There are 2 coffee shops located at the MRVAMC.

- **The Patriot Brew.**
 - Located in the basement by Elevator A and open M-F 630am-2pm.
 - This shop serves Starbucks coffee and offers specialty coffees and blended beverages along with breakfast sandwiches, pastries, and muffins. The coffee shop also serves small salads, lunch sandwiches, and assorted waters and sodas.
- **Main entrance coffee shop.** Located on the first floor at the main entrance and open M-F 7am-2pm.

PIV Badges

- A Personal Identify Verification (PIV) badge is required for all VA employees, Without Compensation employees (WOCs), and volunteers and must be renewed every 3-5 years. The PIV badge is required to be worn at all times while on VA property.
- PIV badges are issued on completion of all hiring activities. An HR representative and/or designated supervisor serves as a “PIV sponsor.” To pick up a PIV badge, 2 forms of identification are required **specifically** as listed in this [matrix](#).
- Based on your position and credentialing, the PIV badge is how you access your assigned designated offices and is required to log on to a VA computer.
- If you have any questions regarding who your sponsor is, your contact depends on your VA service:
 - Research Service employees – contact Michael Merritt,
 - BRRC employees – contact Margaret McCallum.
 - WOC employees – contact Helen Vaillancourt
- **Required PIV protocols**
 - Can only be used by the assigned employee and are to be taken with you when you leave your duty station.
 - Never leave your PIV badge in your computer. Lock your computer and take your badge with you when you leave your office, even if just leaving for a short time such as going to the bathroom.
 - If you are having issues with your PIV badge, see the [FAQ Document](#) on the [Research Webpage](#) and/or call the PIV office or schedule an appointment.
 - **Report a lost or stolen PIV card as soon as possible to your supervisor and Information System Security Officer.**

Departing Employees

- **Research Investigator Departure Checklist.** Whether retiring or transferring to another VA station or a different institution entirely, investigators are required to fill out the Research Investigator Departure checklist. This checklist assures that all research is either completed or transferred to another credentialed PI prior to the departure of the investigator. The checklist will also ensure all equipment is accounted for and laboratory space is cleaned and there are no outstanding activities to be completed prior to departure.
- **VA Form 10-0708.** This form is used to attest that the departing employee is not removing Federal records from VA custody and that all records in the control of the employee have been transferred and made available to their supervisor or other specific individual designated to assume custody of said records. Please email the signed form to your supervisor and the records officer for completion.
- **PIV Turn In.** PIV badges must be turned in to Helen Vaillancourt in Research Service in Building 14.

Employee Payment Services

GovTA

GovTA will replace VATAS as the Time and Attendance tracker for the VA. GovTA will be used to request leave, calculate leave balances, and confirm time and attendance is accurately reflected on your timecard. Training and additional information can be found at the [GovTA website](#).

MyPay/DFAS

The [myPay DFAS portal](#) is where VA employees can view Leave and Earnings Statements every 2 weeks. You can also see yearly tax documents, Employee Health Benefit information, and Thrift Savings Plan information. On this website you can update your direct deposit information, TSP contributions, and healthcare plans.

- There is a FAQ section of the DFAS Portal myPay website that provides information about myPay accounts.
- **To keep your myPay account active, you must access it at least every 90 days.**

Employee Travel

Work travel may be required at some point in your VA tenure. Studies may hold conferences and investigator meetings and invite site staff to attend for educational and collaborative experiences. Instructions for submitting required documents for travel are located on the NF/SGVHS [Employee Travel SharePoint site](#) and an Employee Travel SOP is available on the [Research Webpage](#).

Research Service

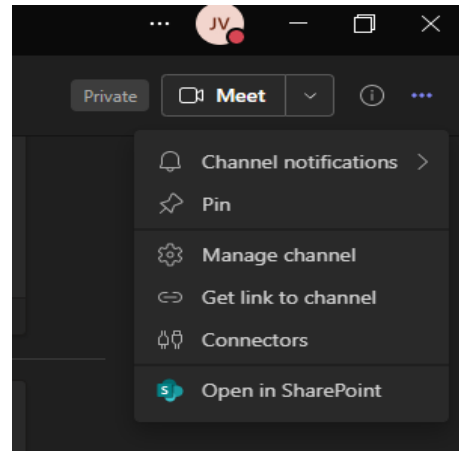
Administrative Contacts

The administrative team and their contact information is provided on the [Research Webpage](#). The Research Service administration offices are located in Building 14 at the MRVAMC. The BRRRC administrative team is located on the 5th floor, Room E579. Contact information for BRRRC administrators is also provided on the [Research Webpage](#). Microsoft Teams Group for Research Coordinators

Research Administrators and the Lead Coordinator have created a Microsoft Teams Group to facilitate sharing of resources, knowledge, and advice by Research Coordinators and Assistants. Although also communicated via email, important updates and guidance documents are available through the channel. The Research Coordinator Teams Group can be used to pose questions, collaborate with colleagues, seek advice, and stay up to date on Research Service initiatives.

On completion of on-boarding and training with Research Service, coordinators can be added to the Microsoft Teams Group: *NF/SG VA Research Coordinators*. Once computer access has been established and Microsoft Teams is up and running, please send a message to the Lead Research Coordinator, requesting to be added to the group. Once added to the group, please turn on notifications for the group, so you get alerts when updates are posted.

- Once within the Teams Channel, in the top right corner, click the three dots to the right of the meet button. Then select the option Channel Notifications. You can then update your preferences to “All Activity.” This will ensure you receive updates in real time via Teams.



Laboratory Management

It is the responsibility of the Principal Investigator (PI) to maintain an organized, safe, and sanitary lab and/or office environment. Management of PI spaces includes keeping up with equipment assigned to the PI by using the ***Equipment Inventory List (EIL)*** (available at [Research Webpage](#)), updating laboratory contacts as staff is hired/separated, and maintaining a clean and sanitary research space. PIs will have an assigned Point of Contact (POC) for their lab spaces who will be responsible for the upkeep of inventory lists and lab cleanliness and who will be the first line of response for lab inquiries. It is important to note who the POC is for your team and to keep the POC updated with any changes to your lab/office space.

Lab Cleanliness

Laboratory inspections will occur at least twice yearly to ensure labs comply with the Laboratory Housekeeping Guidelines. The SOP for General Cleanliness can be found on the [Research Webpage](#).

Equipment Management

Every piece of VA equipment is assigned to an EIL. The purpose of the EIL is to keep track of equipment inventory and provide a responsible party for research equipment. Equipment is usually assigned to the Principal Investigator's EIL, who takes responsibility for keeping track of the equipment. Equipment is provided a tracking number (EE#) for inventory purposes. There will be a barcode sticker placed on each piece of equipment with the EE# and brief descriptive name for the equipment. This barcode is periodically scanned along with the room/area the equipment is stored in to keep a running log of VA equipment and where it is being stored. Equipment is inventoried at least once per year by the Supply Chain Management Team.

Moving Equipment

To move a piece of equipment to a different area, coordinate with the Administrative Officer of your service and the Supply Chain Management Team. Interior Design can help with the movement of heavy pieces of equipment. Ensure the equipment is re-scanned to the room it was moved to for tracking purposes and updates to the EIL in real time.

Equipment Turn-in

If you are no longer in need of a piece of equipment, the equipment is beyond repair, or should be returned to a sponsor, please coordinate with the warehouse to have the equipment picked up, turned in, and removed from your EIL. Send an email to Supply Chain Management Lead Supply Technician, currently Dwayne Surray (Dwayne.Surray@va.gov) and attach VA Form VA2237. Form VA2237 is required for all equipment turn-in requests and requires information such as requested pick up date, item number, description and quantity of the item, and the signature of the initiator of the request.

Individual Team Equipment Tracking

Although equipment is tagged and tracked centrally, it is best practice to keep a running list of equipment belonging to your team/investigator and room placement of the equipment. For continuity purposes, an example of how this spreadsheet should look is available on the [Research Webpage](#). The format of the spreadsheet should allow for the creation of a fluid document that is easily followed and updated as equipment is received/turned in or relocated.

Research Project Management

IRBnet/VAIRRS

The VA Innovation and Research Review System is used by all VAs with research programs and is a platform to support the management of research oversight committees. IRBnet is where research trainings and credentials will be uploaded, projects will be created, and revisions/renewals/closures will be submitted to IRBs, HRPP, and the Safety Committee. Tutorials for researchers are linked on the [Research Webpage](#). These trainings are very comprehensive and video tutorials are also provided.

VAIRRS University is an educational initiative that was designed to optimize training for VA Research employees. Webinars, past newsletters, and a curated list of resources for role specific duties can be found on the [VAIRRS SharePoint](#).

Research Submissions

All submissions for VA research projects, from new study submissions to closures, will be completed through [IRBnet](#). Through IRBnet, you are able to submit packages to VA CIRB, WCG IRB, HRPP, SRS, the NF/SG COI team.

All VA research is required to obtain both IRB and R&D approval prior to starting ANY research activities.

All study closures are required to be submitted to the IRB as well as locally to HRPP and SRS. A checklist with close-out procedures is available for reference.

For additional information regarding the VA's regulatory policies, including information about the Office of Research, Protections, Policy and Education (ORPP&E) as well as Information Technology and Security, please see the [Research Webpage](#).

Recruiting Subjects

Once a research study has been approved by both the IRB of record and the local R&D Committee, you may start recruiting subjects to participate. Approved recruitment methods will vary by study and all

handouts, posters, web advertisements, etc. will need to be IRB approved before they are posted throughout the facility.

Prior to IRB approval, feasibility assessments can be completed to estimate the eligible patient population for an upcoming study. Two ways to complete a feasibility assessment are as follows:

Preparatory to Research

VA Researchers, under a covered entity, are allowed to prepare for recruitment of research subjects using medical records. However, the use of medical records will only be to determine if there is a sufficient number of subjects to conduct the research. Preparation can include patient database searches for specific ICD codes, age, zip codes, etc. Researchers are allowed to use these measures to identify, but not contact, potential study participants. More information is available on the [Research Webpage](#) under “Recruiting Research Subjects.”

VINCI Services

VINCI allows researchers to access data within the DART system for recruiting purposes. Researchers can obtain contact information for subjects who meet study specific inclusion/exclusion criteria and can request that updated patient lists are sent at specified time intervals throughout the duration of the study.

Prior to VINCI services providing lists, an approved DART request is required. Detailed instructions on how to Submit a DART request and what to do after obtaining approval are provided on the [Research Webpage](#).

Investigational Drug Study Procedures

Current Pharmacy Contacts:

- Lisa Zumberg, PharmD – Lisa.Zumberg@va.gov 352-548-6000 x104495
- Alan Mumford, PharmD – Alan.mumford@va.gov 352-548-6000 x103051
- Kelly Parks, CPhT – Kelly.Parks@va.gov 352-548-6000 x104369

All study protocols including the use of investigational drugs are to be sent to the Research Pharmacist of record for review. The research pharmacy will be responsible for the receipt and storage of all investigational project and keep an accountability/inventory log. All investigational product orders will be managed through the Research Pharmacy. It is important to contact the Research Pharmacy team to set up how the IP should be ordered. Additional information about the Research Pharmacy and investigational drug procedures can be found on the [Research Webpage](#).

Records Management

All study records generated during the course of VA research must be retained for at least 6 years, and longer if required by other Federal Regulations (FDA) or the sponsor. Research records are the property of Malcom Randall VAMC and under the control and responsibility of the Principal Investigator.

Paper Records

All paper study records are required to be double locked and stored in a space with limited access to authorized personnel only. At study close out, work with your PI, Records Liaison, and ACOS to complete close out procedures and come up with a record storage/destruction timeline.

Electronic Records

All electronic records need to be organized on the Share Drive or other VA approved electronic information system identified by the service. VA Research Service will use the **R: Drive**.

MetaKnowledge Repository (MKR)

To maintain a compliant file plan and inventory, Research Service will utilize the. The use of the MKR:

- Helps to create, maintain and produce consolidated electronic plans and inventories.
- Provides a central location for file information.
- Provides a location (physical or virtual) of the actual record but does not store the record itself.

For a detailed presentation on how to register and use the MKR, FAQs, and trainings please see the [Research Webpage](#).

Telework and Remote Access

VA Remote Access and Telework privileges are awarded on a case-by-case basis and must be approved by your supervisor. Details regarding Telework requests and Remote Access approvals can be found on the [Research Webpage](#).

If you are working from home on a VA furnished laptop or just going to be working off-site for the day, you can have your office phone ring to your laptop. Put in an IT request for software, CISCO Jabber, which will allow calls from your VA extension to ring on your VA laptop.

Dry Ice

If obtaining dry ice is a requirement for your study protocol, you will be required to obtain a purchase order from the company you will obtain dry ice from and submit the PO to Susan Wheeler, budget analyst for research service. You will need to coordinate the delivery or pick-up of dry ice on your own.

If the study you are obtaining dry ice for is a NFFRE study, you will need to place an order with the Fisher store at the University of Florida. They receive dry ice shipments on Mondays and Wednesdays. If you need more than 10 pounds of dry ice, you must call and order it ahead of time. Call 352-338-0346 and request the amount of dry ice you need. Please contact Juliana Venetucci, Juliana.Venetucci@va.gov once you have ordered your ice and she will set up a time to deliver you the P card for purchase.

Advertisement of Studies on VA Research Website

NFFRE and Research Service have created a new webpage to help with recruitment of research participants. The webpage can be used as a landing page for QR codes placed on recruitment flyers and social media posts. Only VA research that has been approved by the R&D Committee will be eligible for advertising on this page. For instructions on how to place a recruitment advertisement for your study, please navigate to the [Research Webpage](#) and look for “Request Form for Web Advertisement.”

Follow the instructions to fill out the advertisement with your study-specific information and submit to your IRB of record for approval.

Once your request for advertisement has been approved, you will see your VA research project here: <https://www.nffre-research.org/how-to-help/studies-seeking-participants>

FINDpro

VA ORD has developed a focused inquiry database that returns relevant and rank-ordered search results regarding VA research policy, guidance, and FAQs called [FINDpro](#). FINDpro provides a portal to ask ORD questions and for researchers to provide feedback that will be read and discussed by the FIND Pro team and escalated to leadership as needed.

Documents on this website include:

- All VHA and VA directives and handbooks
- ORD Program Guides
- ORD Guidance and FAQs

Note: You will only be able to access the FINDpro tool from a VA network.

ECFax

The NF/SG VHS has transitioned to the ECFax system which allows users to send and receive faxes. With this transition, your fax number may have changed, and the new number can be found on the [ECFax web portal](#).

For ECFax support, FAQs and trainings/office hours, please visit the [ECFax SharePoint](#) page.

Sending a Fax

Quick Tips:

- You must log on to your ECFax every 30 days to keep your account active (I suggest setting a calendar reminder once a month)
- You must enter a fax number in the following format 1+areacode+fax number (ex: 13525486000), no dial out number is needed.
- The only special character you may use in the contact name is a **hyphen (-)** or the system will not send the fax.
- A HIPAA notice is included as the cover sheet on every fax, unless you tick the “no cover page” box

Receiving a Fax

COMING SOON- Please continue to use current Xerox machines to receive faxes at this time.

North Florida Foundation for Research and Education

The North Florida Foundation for Research and Education (NFFRE) is a VA-affiliated non-profit organization established by Congress to maximize funding opportunities for VA research. NFFRE research is conducted with grant funding from sources such as NIH and other government agencies or private foundations or with industry funding to test their products.

Clinical Trial Center (CTC)

NFFRE houses a [Clinical Trial Center \(CTC\)](#) that is available for research funded by either industry or grants. The CTC has three dedicated patient rooms, lab processing area, private monitoring rooms, refrigerators for storage (ambient, -20, -80) and a quiet, private space for consenting research participants. The CTC is staffed with skilled coordinators, a dedicated regulatory team, and investigators who are board-certified in a wide range of specialties.

CTC rooms are available for use by Research Service staff, however, prior reservation is required. To reserve CTC space, please reach out to Juliana Venetucci at Juliana.Venetucci@va.gov.

Industry-Funded Research

Research sponsored by corporations such as AstraZeneca or Novartis must be conducted under the NFFRE umbrella. Detailed information on this type of research, which can range from data collection and management to Phase IV and investigational device trials, can be found on [the NFFRE Industry-Funded Research web page](#).

Local and Commercial IRBs

To conduct industry-sponsored trials, review by a commercial IRB or the University of Florida IRB is required. The appropriate IRB to use depends on factors such as funding source, other facilities involved, and sponsorship. Most studies that include project sites at other VA facilities are reviewed by VA Central IRB (VA CIRB). The NF/SG VHS Research Service uses VA CIRB, UF IRB, National Cancer Institute IRB, Advarra, INC, or the WCG IRB.

NFFRE Contact

For questions regarding NFFRE practices, policies, or research: VHANFLNFFREAdmin@va.gov.

For questions about NFFRE communications, website, or to provide information for dissemination: VHANFLNFFRENews@va.gov.

Teresa “Angie” Smith, Executive Director – Areas of assistance:

- Questions about official agreements and consortiums
- Industry sponsors
- Grant funding – Post-award information/questions
- Clinical Trial Center

Autumn Smith, Operations Manager – Areas of assistance:

- Requests for supplies and equipment
- Requests for reimbursement
- Clinical Trial Center – CRADA and budget

Lynn Dirk – Areas of assistance:

- Grant funding
 - o Pre-award information/questions
 - o Submissions

- Web and dissemination

Research Service Informed Consent Process

Obtaining informed consent from research subjects is required by law and an important way to provide protections for human subjects in research studies. Participants must be informed about the risks and benefits of the study and voluntary consent must be obtained. The federal government has developed uniform standards on obtaining informed consent for federally funded research; Specifically, the VA follows the Common Rule.

Research Compliance Officers (RCOs) Katie Yeckring and Marlene Thomas have provided a detailed presentation explaining the responsibilities of the staff member obtaining informed consent from research participants. Katie and Marlene are located onsite at the MRVAMC and require Investigators and delegated study staff to complete a consent training before the release of the R&D approval letter to start research activities. This training serves as a refresher to the PI and study staff on the importance of correct consenting procedures.

- Katie Yeckring: Katie.Yeckring@va.gov 352-548-6000 x105542
- Marlene Thomas: Marlene.Thomas@va.gov 352-548-6000 x102029

It is important to note that the VA HIPAA Authorization is usually a separate document from the informed consent. The VA approved HIPAA cannot be altered, and language may not be changed. The form receives extensive reviews to ensure compliance with Federal and State regulations governing the privacy of medical information.

Using DocuSign for electronic Consent


If your study would benefit from electronic consent, a request can be submitted through SharePoint DocuSign Requests. [This](#) can be done prior to or after IRB approval to ensure this method will be approved on a study-by-study basis. For more information, from your VA computer, go to [this VA Sharepoint site](#) and review “Requesting Use of DocuSign for VA-approved Research.”

There is also a DocuSign Request Informational PDF uploaded to the [Research Webpage](#) for reference. Once your study has approval to use DocuSign and envelopes are provided, please use the DocuSign Instructions PDF uploaded to the [Research Webpage for a step by step guide from set up to implementation.](#)

Documenting Informed Consent and Uploading to Medical Records

Once consent has been obtained from the research participant, all signatures have been captured on the informed consent form (ICF) and the HIPAA Authorization, and the participant has been enrolled in the study, a Research W(T) note must be placed in the participant’s medical record. This note will create a flag in the record that will alert providers to study participation. Please refer to the section titled [CPRS](#) to review how to create a Research W(T) note in a participant’s medical record.

Print a copy of the W(t) note from the patient record and attach it to a copy of the ICF. Bring the copy of the ICF with the W(t) note attached to Room E584 and fill out all the information requested on the clipboard on top of the safe. Place the copy of the ICF/W(t) note in an envelope marked either “scan” or

“no scan” depending on whether it is an initial consent or a re-consent, so that the Research Compliance Officer knows to bring it to the  Medical Records office for upload to the subject’s medical record. The Medical Records office is responsible for uploading ICF/HIPAA documents to the participant’s medical record. A copy of the ICF/HIPAA will be uploaded to the medical record and attached to the W(T) Note for reference. ICF Audits

The RCOs are responsible for reviewing 100% of all signed consents, this includes screen failures and reconsents. For easy auditing and upload to the patient medical record, ICFs and HIPAAs will be placed in the safe in room E584. It is the responsibility of the PI/Coordinator to keep track of all signed ICF/HIPAA documents.

At the end of the audit period, the RCO will reach out to study staff to confirm the number of ICF/HIPAA forms that have been signed for the study. If the number of documents reviewed by the RCOs does not match the number of total documents signed, you must work with the RCOs to determine which documents still need to be audited.

Training

There are a variety of training courses required by the VA. Most required trainings are offered through the Talent Management System (TMS) and the Collaborative Institutional Training Initiative (CITI).

Talent Management System (TMS)

TMS delivers and tracks all mandatory online VA training. You will be assigned a variety of courses depending upon your role in Research Service. TMS will display course names and due dates for each course. Some courses are only required to be taken and passed one time; others require yearly renewal.

- Single Sign-on access is available for TMS when using government furnished equipment at the [VA Identity and Access Management System \(IAM\)](#)
- TMS accounts are set up for new employees by Education Service during New Employee Orientation.
- WOCs will need to register for TMS to begin trainings.

Once complete, please upload VA Privacy and HIPAA training to IRBnet; instructions available on the [Research Webpage](#).

Collaborative Institutional Training Initiative (CITI)

ORD has specific training requirements for research involving humans and animals. A training curriculum has been developed and added to CITI to satisfy these requirements.

CITI refresher training is required every three years. CITI will provide reminder emails when refresher training courses are due.

Instructions for CITI Training

If you have already created a CITI account, you may add VA affiliation to your existing account. To affiliate with the NF/SG VHS click the “Add Affiliation” button. Type VA Gainesville, FL-573 into the

search box and press enter. Agree to the terms of service and affirm that you are an affiliate of VA Gainesville, FL-573.

New to CITI

1. In the box that says “Create an Account” click on “Register”
2. Select the organization affiliation “VA Gainesville, FL- 573”
3. Enter your personal information to finish creating your account
4. Follow instructions and links to enter all other requested information, including what type of research (human/animal) you will be working with.

Based on the answers to the questions in the registration process, CITI will create a menu of courses that apply to you. If courses you do not need are showing up, click the “Add a Course or Update Learner Groups” from My Learner Tools Menu. You can select “Update Groups” and answer the questions again.

To take a course, click on the title of the course. This will populate a list of modules to complete. When you have finished a course, save the “completion report” for your records. The minimum score to “pass” a course is 80%. Quizzes can be taken more than once to improve score by returning to the content section of the course. Your best score will be recorded on the completion report.

Most importantly, you will need to link your CITI account to IRBnet to ensure all training certificates are uploaded and updated in real time. Instructions for linking your CITI account to IRBnet are available on the [Research Webpage](#).

Professional Development and Continuing Education

The ACOS for Education has a [SharePoint](#) page filled with many helpful links such as employee professional development opportunities, TMS training help, scholarships, and new education opportunities. On the SharePoint, you can access the Employee Education Opportunities Calendar, where a schedule of meetings can be found, and courses can be signed up for/attended.

Research Professional Network

The Research Professional Network (RPN) holds a series of peer-led, collaborative workshops focused on topics relevant to research professional staff. To become a part of the network, please go to the [RPN Website](#), where you can view workshop schedules, previous workshop recordings/slide, and join the local institution’s RPN (UF),

HubTalk

HubTalk, presented by the UF College of Medicine Clinical Research Hub is a monthly forum to engage the research community in ongoing dialogue in order to evaluate current clinical trial processes, identify opportunities for improvement, and look for opportunities to further advance the research enterprise. The hope of the series is to foster engaging conversations to identify barriers that might exist and develop solutions to improve processes and provide educational updates. In addition, it is an opportunity for stakeholders to share resources and innovations.

Please find more information regarding the Clinical Research Hub and HubTalk [here](#).

UF IRB Education and Training

IRB Educational Courses- group presentations that can be arranged through the IRB educator. Include topics such as Informed Consent, Project Revisions and Continuing Reviews, Adverse Event Reporting, and more.

IRB Brown Bags provide regular educational events and address current human subjects' protection topics. These events are recorded and can be found here. If you would like to join the IRB Listserv to receive IRB announcements to your email, please send an email to listserv@lists.ufl.edu with only the following text in the body of the email: subscribe IRBMAIL-L

IRB Newsletter- The InvestiGATOR is a weekly newsletter published via email that highlights new information, recurring issues, and other significant topics. If you would like to be added to the newsletter mailing list, [click here](#).

Previous editions of the InvestiGATOR can be found [here](#).

Basic Life Support

BLS certification is only required by the VA for employees who are clinically credentialed. However, all researchers who work with human subjects are strongly recommended to have the BLS HeartCode certification, which must be renewed every 2 years. For questions/assistance, please contact VHANFLBLSHELP@va.gov.

On the Education SharePoint, there is a link to BLS Training. In-house training is provided to VA employees and can be requested by your supervisor via the BLS primary contacts or NF/SGVHS TMS Help Desk. There are 2 options for BLS training:

- Complete didactic training online and perform a skills test on a Voice Activated Mannequin (VAM), this certification is good for 2 years.
- Participate in quarterly didactic and skills checks as part of Resuscitation Quality Improvement (RQI), this certification does not expire.

Microsoft Teams

Microsoft Teams is the official electronic communication platform for the VA. Teams allows for quick and easy communication between anyone within the VA network. Teams is utilized for meetings, creating a collaborative space, and expanding communication methods between VA services. A detailed guide and training videos are available [here](#) on the Education SharePoint.

Safety Best Practices

The safety of Research Service employees, study participants, and visitors is our highest priority. It is the responsibility of all staff to be aware of their surroundings. Employees should secure personal belongings in a locked cabinet or office. PIV badges are to be worn at all times for proper identification.

Any suspicious activity should be reported to a supervisor and a call should be made to VA police x106911.

Patient Complaints

As a VA employee, you are responsible for practicing VA ICARE principles: Integrity, Commitment, Advocacy, Respect, and Excellence. If you are made aware of a patient complaint through the Patient Advocate office or directly from a research participant, you are responsible for handling the complaint to the conclusion. A complaint may be expressed verbally, electronically, or in writing to any employee as well as to officials outside the facility.

If you are notified of a Veteran complaint by patient advocate, you are required to notify the appropriate local offices, notify the study manager (if applicable) and address the complaint as deemed necessary. You will be required to provide the Patient Advocate office of resolution or outcome of the contact with the complainant.

If you directly receive a patient complaint, it is your responsibility to offer the veteran official documentation procedures, and escort them to the patient advocate office.

Adding a Printer/Scanner

Navigate to VA Shortcuts on your desktop. Open the folder NFL Shortcuts. Choose PRINT SERVER. Enter the name of the printer you want to add in the search bar. Once found, double click on the printer you want to add. After the software is successfully added, you will receive confirmation in the form of a pop up. The pop up will be a blank task list for the specific printer you have added. You may close the task list and now use the printer/scanner.

Sending a Fax

To send a fax, hit the Cleo app on the xerox. Enter the phone number you will be faxing your document to in the blank space. You must enter 91 then the area code to successfully fax your document. When you have entered the recipient information, you can press the orange FAX button on the bottom right of the screen. The xerox will print out a report which will tell you if the fax was successfully sent.

Scanning a Document

To scan a document, insert your PIV badge into the xerox and when prompted enter your 6-digit passcode. Once you are signed in, choose the Print and Scan app on the xerox. When the app opens, click the top right button that looks like the opening of a printer top. Click "start workflow" in the middle of the screen. This will bring you to the page where you can name your document. Once you have named the document, click the scan button. Once the scan is complete, you can find your document in your scan folder. Navigate to the SCAN folder on your VA Desktop. You should see your scanned document in this folder.

Paying Participants

Some research studies provide stipends to subjects for expenses such as time, travel, and hotel expenses. The study will specify in the start-up period whether or not subjects will be paid for visits and how much each visit voucher will be. For industry-sponsored NFFRE trials, the use of a ClinCard may be used for participant payment. For more information on paying participants for industry-sponsored trials, [see](#) . For VA-funded research, the most common methods are the Electronic Vendor File Request or Setting up a Funding Account with Research Service Budget Office. Information about both options follows.

Electronic Vendor File Request

The purpose of the Vendor File Request is to create a financial account for Veterans. Research subjects are required to sign up as vendors to be paid by direct deposit for their participation or reimbursed for hotel stays/travel. The sign-up process has transitioned to an electronic platform and requires the use of ID.me to validate Veteran information. *If the Veteran already has a vendor account set up (as when travel reimbursement has been received before), you will not have to set up a new Vendor File Request, and you can go straight to Submitting a Voucher.*

Navigate to <https://www.cep.fsc.va.gov>. On the left-hand side, have the participant click the Login button for Vendor Account Setup and Updates. Veterans are required to sign into the Vendor system with a secure VA partner the ID.me option should be selected. A Veteran who already has an ID.me account can sign ; if not, assist the Veteran in creating an ID.me account, as this is the only way to enter the Vendor Account setup. Please see information regarding ID.me [here](#).

Once logged in and the Customer Engagement Portal is accessible, a vendor file can be created for your participant as follows:

The Veteran will need to have the following information:

- Current banking information where the payment needs to go; if this is an update to a previous enrollment, the old bank account information will also be needed.
 - Name on account
 - Account number
 - Routing number
- SSN, address, and additional authorized user information

Setting up a Funding Account with Research Service Budget Office

Prior to submitting a voucher request to finance, you must ensure you have set up a Research Finance Account. To have a Research Finance Account, send an email to the Research Service Budget Analyst and CC the Research Service AO with the following information:

Subject line: Creation of Research Finance Account/PI NAME/NAME OF STUDY

In the body of the email, include PI name, name of the grant, coordinator contact information.

The Budget Analyst will request any additional information needed and the account to be created and provide you with the information you need to provide to Finance when you fill out the voucher for patient payment.

Submitting a Voucher to Finance

Research subjects who have a completed Vendor File will be compensated for research participation if offered by the study. Please see the above section for setting up a finance account with Research Service to ensure funds are available to pay research subjects. When a research subject attends a visit, and they are to be paid for that visit, you will create a Patient Participation Payment Voucher. The subject will need to provide their signature on the voucher in order for it to be processed by Finance.

All the information to fill out the voucher should be provided by the Veteran, research budget office, and finance. Ensure you are able to answer all questions on the form prior to the patient visit to avoid delay of payment.

Once completed, please send the voucher form in an **encrypted** email to the Finance office. In the email, confirm that the patient has a completed vendor file. **A blank voucher form is available at [Research Webpage](#).**

Scheduling a Hotel Room

Studies will sometimes require participants to attend visits multiple days in a row. When this occurs, the study may provide funding for subject lodging. Please contact the Research Service Budget Analyst, as soon as possible when you know a study will offer this. It is important to give the budget office and hotel advanced notice to ensure room availability and payment processing.

VISTA - R3

In this section, common uses of the VISTA-R3 application are discussed in detail. The VISTA-R3 application can be found in the VA Shortcuts folder on your VA desktop indicated by the gold star.

How to Place a Work Order

Most services require a work order to be placed prior to assisting with installations, repairs, etc. In emergency situations (burst pipe, gas smell, emerging ceiling stains, localized power outage, etc.) place a call to the appropriate service, and complete the work order after the call, as directed.

For instructions on how to place a work order, please see the [Research Webpage](#).

Signing for Equipment

Employees with Government Furnished Equipment (GFE) are required to sign for the equipment yearly or turn in the equipment. OIT recommends that the equipment be signed for every 90 days to keep the employee's vista account active and avoid going over the 365 day mark. Equipment that is overdue for signature is subject to disablement and recovery by OIT.

For instructions on how to sign for equipment in VISTA-R3, please see the [Research Webpage](#).

Computerized Patient Record System (CPRS)

CPRS is the record keeping system used by the North Florida/South Georgia Veterans Health System, as well as neighboring VA systems. As a Research Coordinator/Research Assistant you will use CPRS to screen research potentials, create research flags, order labs/medications, and enter visit notes into patient charts. The information provided in this section is a comprehensive, research specific guide. Also to be provided is a link to the clinical informatics sharepoint which houses broad CPRS training guides and topics.

[Clinical Informatics - Training - All Documents \(sharepoint.com\)](#)

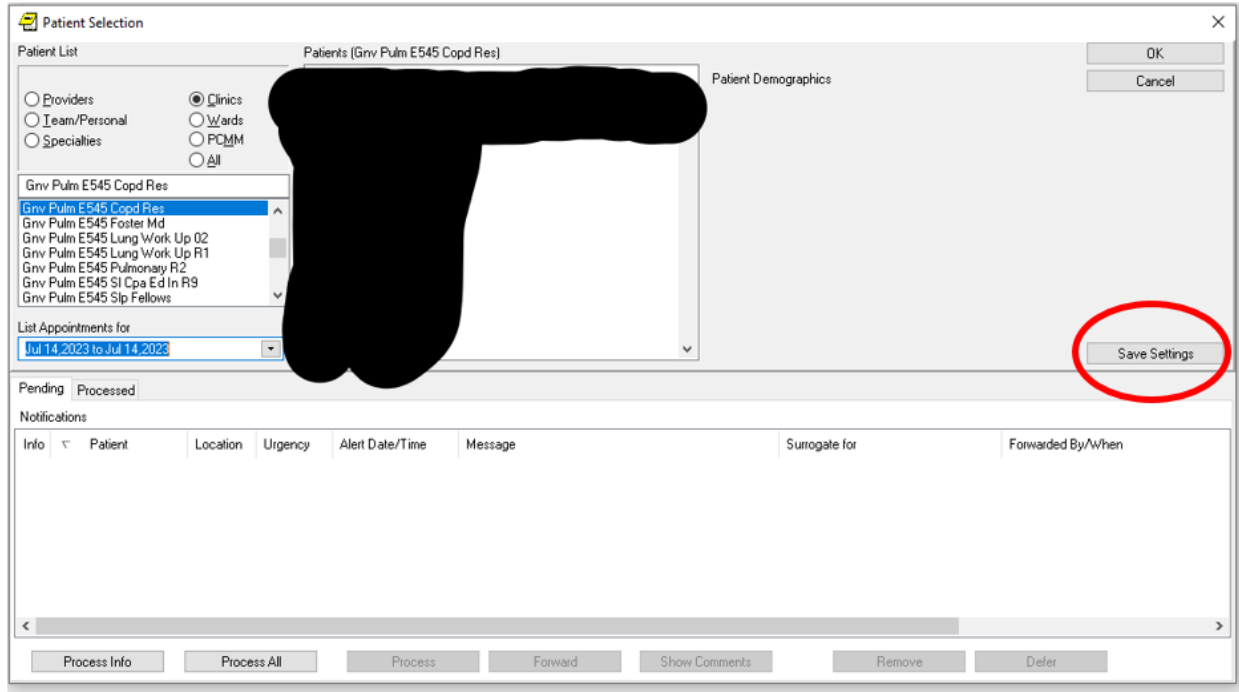
Screening Medical Records for VA Approved Studies

Using CPRS to pre-screen potential study participants can be done only if it is an approved recruitment method for the specific study you are working on. For each study, you should create a Pre-Screening Log, which will house de-identified demographic information regarding Veterans screened in CPRS. A deidentified pre-screening log should have the following information: Age, Sex, Eligibility Determination, Number of Inclusion/Exclusion Criteria not met/met. The Pre-Screening Log can be kept on a password protected Excel spreadsheet, example below.

Age	Sex	Eligible? (Y/N)	Criteria not met

Screening Using VA Clinic Lists

Under the Clinics tab is the Patient Selection window. Clinics produces a clinics list that can be pulled for specific date ranges and settings, which can be saved to pull lists on certain days of the week. If searching locally, most likely the clinic name will begin with GNV. In the example below, you can see that the list pulled is for the GNV PULM E545 COPD RES for the date 07/14/2023 (List Appointments For field). The list of names (blacked out for privacy) will show under Patients (in the middle of the window). Note the Save Settings button (circled in RED); this allows you to come back to this exact page each time you choose Select New Patient so you do not have to start the search all over again.



Basic Screening Methods

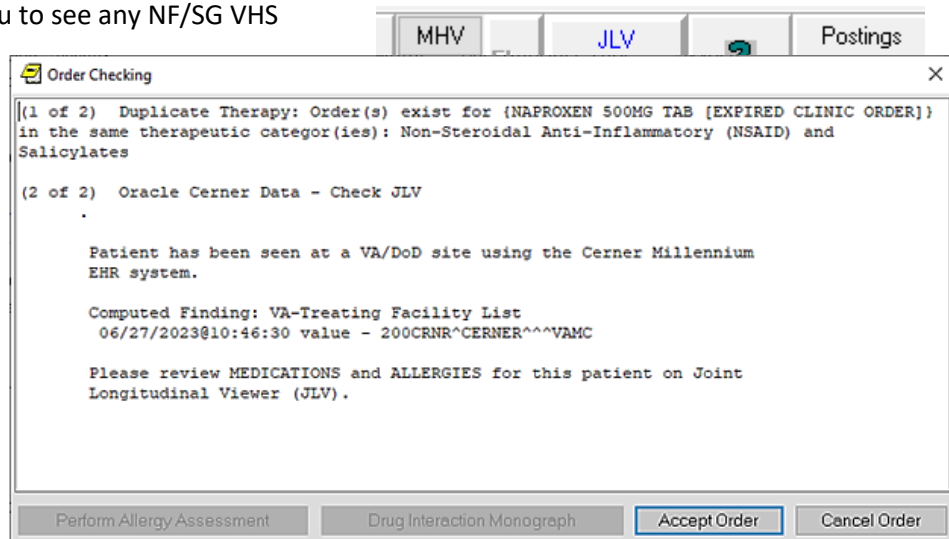
Once you have selected a patient from the clinic, you can screen their medical records using the Inclusion/Exclusion criteria provided by the study.



Most necessary information to determine eligibility can be obtained from the tabs listed above. Lab values, physician visits notes, current and previous medications, vital sign history and concurrent medical conditions can all be found within these tabs. Training pertaining to specifics found in each tab and where to find additional information can be found using the Clinical Informatics SharePoint link provided above.

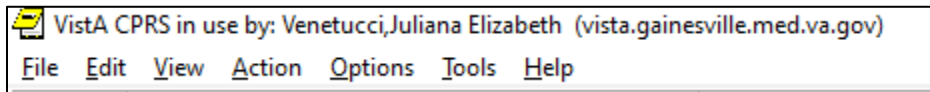
Your CPRS access allows you to see any NF/SG VHS catchment area notes; many Veterans, however, have received care at outside VA facilities. These records can be accessed through JLV, the link to which is in the top right corner of CPRS.

Other facilities might also utilize Cerner Millennium EHR systems which will create an order check,



such as the one pictured at right. When this alert is generated in the orders tab, please also use JLV, as indicated in the alert, to review current medications that may not show up in the CPRS record.

An additional resource within CPRS that can be used to view images such as CT scans, PFT results, MRIs, EKGs, and any private physician medical records is IMaging. Access to IMaging is an additional approval than CPRS, so it is important to check access to this feature. You can locate the IMaging portal by choosing the “tools” tab in the top left corner of CPRS. When you open the IMaging portal, you will be prompted to sign in using your PIV badge.

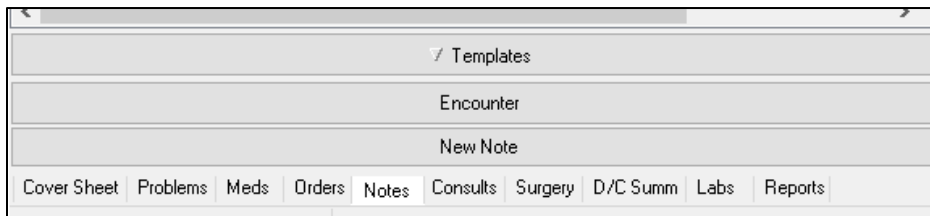


Placing a Note into the Electronic Medical Record

It is important to document research encounters in the participant’s medical record and to record what is and what is not done during a study visit. Documentation should always clearly demonstrate who was present at the visit. All visit encounters should be co-signed by the investigator and any other coordinator present at the visit.

Creating an Encounter

To document a visit with a note, you must first create a new encounter in CPRS, which will serve as a link between the research visit and the research note. To create an encounter, navigate to the Notes tab in the participant’s CPRS record. From there, you will select the Encounter button.



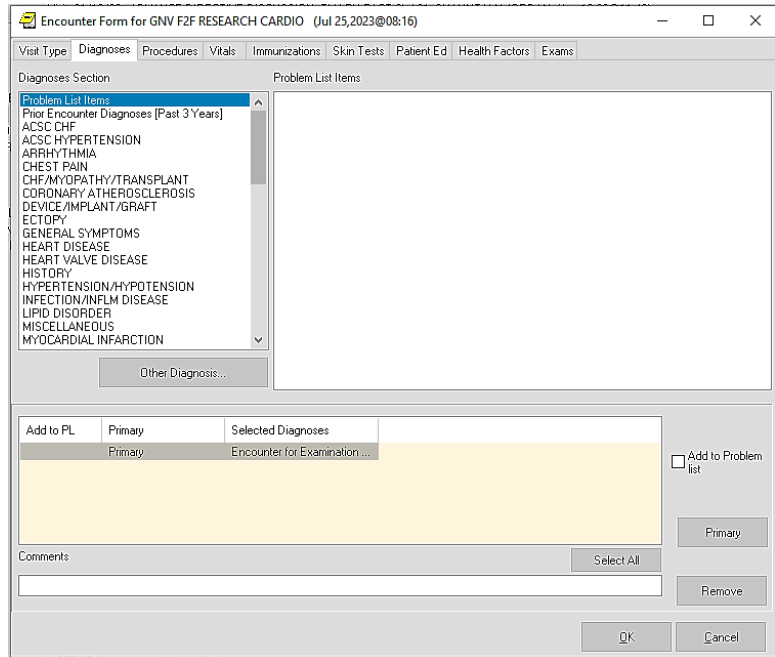
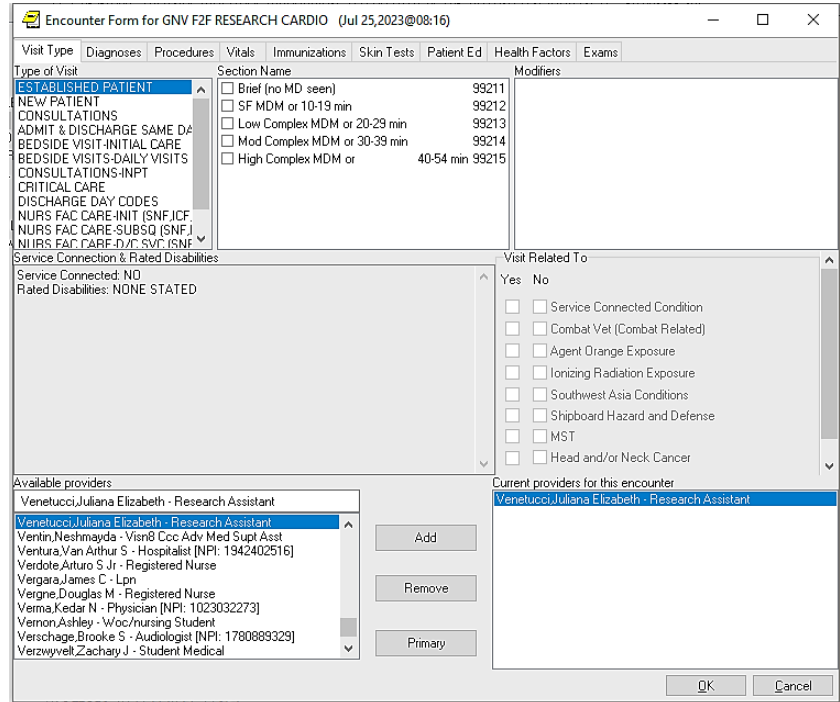
In the next window, select Create New Encounter. The next step will ask you for a location of the visit. For research encounter purposes, there will be 2 choices: Face to Face or phone visits (F2F or Ph).

Start typing: GNV F2F Research or GNV Ph Research

This will pull up 8 different research areas to choose from for each location. Select the clinic that best matches your research area. Select the correct date and time for the visit and check the “historical visit” box. The purpose of the “historical visit” is to ensure the Veteran is not charged for the visit encounter.

On the next screen (Encounter Form, at right, below), in the top left corner under Type of Visit, keep Established Patient. For the other fields, choose as follows:

- **Section Name:** This is for complexity of the encounter. When choosing one of these options, assess the participant based on **time commitment** to the visit.
- **Modifier:** DO NOT select a modifier.
- **Visit Related To:** In this field, you must select No for all bolded connections. In the example at right, none of the connections are in bold, so there is nothing to select.
- **Available Providers:** This is to indicate who was present at the visit; it is important to select the PI. To add a “provider,” search for the name, when it is highlighted in blue, click the button that says Add. Assign the PI as the “primary” designation.
- **Diagnosis Tab (2nd tab from left):** This takes you to the next page, where you must choose Other Diagnosis (under Diagnosis Section). In the search bar, type Research. This will bring up the option “Encounter for Examination for Normal Comparison and Control in Clinical Research Program.” Click this option and press OK. Click OK once more to complete the encounter.



Once the encounter is complete, you can create visit notes to be associated with the research encounter.

Research W(T) Note

A W(T) note is required to be entered when a participant is enrolled in a research study. The Research W(T) note is a pre-written template with required fields highlighted in yellow. The required fields confirm that important parts of the informed consent process have been completed at the research visit. You will be required to attest that the participant has met all inclusion/exclusion criteria, has had ample time to review the consent form and ask questions, and was capable of providing informed consent. The template will also ask for the name of the person obtaining consent and the contact information of the PI/Study Coordinator. If the study requires taking a drug, or having a device implanted, you must provide a 24hr emergency number in the space provided in the template. To enter a W(T) note, you will select the button “New Note” in the bottom right corner of the “Notes” tab. In the space labeled Progress Note Title, you will type Research, which will bring up a list of all available research notes. PLEASE NOTE: there are many research note templates available to you to use throughout your study duration

Select the RESEARCH-W(T) option. Update the date and the time as necessary and ensure you are the author. Click OK to move to on. The template should now appear on the screen for you to fill in the specifics of the consent process for your study. When you have finished filling in all of the information required, the OK button at the bottom right will pop up. When you click OK, all the information you put into the template will show up in the note page. You will be able to type in the note below the templated information. Please add the following required verbiage.

Veteran was provided with ample time to review the ICF and HIPAA and have questions answered. Veteran was provided with a signed copy of the ICF/HIPAA during this visit.

Once complete, sign the note by right clicking on the note and selecting Sign Note Now. You will be prompted to enter your password to provide electronic signature. Once you have signed the note, add the PI to the note as well as anyone else involved in the consent process by right clicking on the note and selecting the option Identify Additional Signers. Search for the names of the additional signers you would like to co-sign the note and select the add button. When you are finished adding signers, click OK. Their names should appear at the bottom of the note with the words Awaiting Signature.

The W(T) Note is now complete.

Joint Longitudinal Viewer

The Joint Longitudinal Viewer (JLV) provides an integrated view of a patient’s record from all sites and source systems in VA, DoD, Cerner, and the Veterans Health Information Exchange. JLV is a helpful tool if a potential research subject does not see VA doctors for their care.

Detailed information on how to access JLV and trainings available have been posted to the [Research Webpage](#).