



Welcome to ORO back to Basics.

This is an ORO P&E workshop series that will have multiple sessions and cover several research topics.

This session and the whole series is meant to be an introduction to VA research. The goal is to cover foundational knowledge needed for the RCO role.

In this series we want to carefully step through handbooks and Directives that are important RCO base knowledge. We will point out the policy and how it relates to audit requirements.

Some sessions will be presented by P&E staff and others by external subject matter experts..

The key attendees will be new RCOs, and the primary goal will be new RCO education. However, any RCO with any level of experience is welcome to attend the sessions as a refresher.

They should just understand that the information will be presented in a manner that presumes little to no previous understanding of the concepts.

ORO Back to Basics RCO Workshop:  
**Research 101**

**Objectives:**

[Introduction to research that includes information]

VHA Directive 1200.02(1)  
Research Business Operations  
March 10, 2017

Choose VA U.S. Department of Veterans Affairs

Here are the initial Directives that will be covered in the back to basics series. These are the Office of Research and Development Directives – series 1200

The links to these documents are at the end of the slide set.

I won't go over what each of these discusses since we are going to look at each individually throughout the workshop series.

(click) The Directive under the lense today is Directive 1200.02(1).

# Research in the Department of Veterans Affairs

## There are three Administrations within VA

### VA Medical Centers

The Veterans Health Administration is home to the United States' largest integrated health care system consisting of 171 medical centers.

Veterans Health Administration (VHA),

VA » Veterans Benefits Administration

Veterans Benefits Administration

Veterans Benefits Administration (VBA),



National Cemetery Administration (NCA).

VA research can be done by any of these departments, but only VHA has been granted authority by the agency to conduct human subjects research.



But before we step into the Directive specifics lets first take a step back and talk in general about VA research.

If you are new to the VA you might not yet know that are three separate entities that make up the VA.

You will often here VA refereed to as if the VA medical centers make up the entirety of the VA system but there are three separate entities with in the VA.

1- The first is the VHA – Veterans health administration. The VHA is the largest health care system in the United States and provides care to over 9 million enrolled veterans. There are over 1,200 health care facilities which includes 171 medical centers, approximately 1,100 outpatient centers .

2- Veterans Benefits Administration- They handle a multitude of things related to Veteran benefits including compensation and pension for service, education, loans, employment resources, insurance.

3-National Cemetery Administration. – They assist service members, veterans and their

families with burial services. This includes such things as burial planning, paying for burial, and memorial items such as flags and headstones in non-national cemeteries.

It is important to note that all 3 can do research. Only the VHA has been granted authority to do human subject research.

RCOs only audit VHA research typically only at their VA facility but may also in certain approved situations cover more than one facility.

## Research in the Department of Veterans Affairs

- VHA Research offers Veterans opportunities to participate in high-quality, ethical research studies that offer cutting edge therapies. In some disciplines, to be in research studies is the treatment (such as oncology) because of lack of approved therapies for specific conditions. COVID-19 itself was a great example.



Research in general advances medical care and disease understanding.

You will hear a lot in this and upcoming sessions about the importance of VA research and the RCO's role in auditing the research.

We all must do our best to ensure that VA research is conducted correctly for the good of the veterans, future veterans needing care and society in general.

People, especially outside the VA, don't often understand the impact VA research has had and continues to have on healthcare. The VA has been doing research since the 1920s and cooperative research since the 1950s.

### **A few examples:**

VA Research led to discoveries of effective TB treatments

VA researchers developed the concept of CT scanning

First liver transplant

Demonstration of the relationship between smoking and lung cancer which led to the first surgeon general packaging warnings.

So you can easily see how VA research touches not only the veteran but far beyond the VA to all health care.

VA research is important and a RCOs role in VHA research is important as a means to ensure protections are in place.

As is noted here in some cases the research project may be the only treatment hope for that participant. Conducting these studies in the VA allows the Veterans options that otherwise might not be available to them.

|                        |  |
|------------------------|--|
| <b>VA<br/>Research</b> | VA carries out four specific health-related missions: health care, education, <b>research</b> and emergency response.  |
|                        | The VA has been improving the lives of veterans through research for over 95 years.  |
|                        | VA scientists seek new and innovative ways to improve care for Veterans and all of society.  |
|                        | VA research is a key element in attracting the best Clinicians and Non clinicians to its facilities, as well as a tool for retaining the individuals.  |
|                        | There are many teams and staff that comprise the Research Administration and make it possible to fulfill the research mission.   |
|                        | The mission starts in the office of Research and Development (ORD) in the Veterans Health Administration located in the VA Central Office and is managed by the local Research Service Office by overseeing the research infrastructure necessary for local investigators to conduct research studies. |

A few more notes about VA research-

The VA in general has 4 health related missions- veteran healthcare of course, education, research and emergency response. We saw all 4 of these in action during covid.

As we discussed the VA has been doing research since the 20s and cooperative research since the 50s

Frequently we see that bright young clinicians want to work where there are strong opportunities to continue or begin their research and where their scholarly activities are supported.

There are a lot of staff that make research happen. This varies by facility. We will go over the most common shortly.

The bottom line is that this is a team process and many play their part in making VA research successful. From first inception through publication and beyond to translation to care.



This is the task.

Here is the office of research and development's mission statement. It is 4 fold.

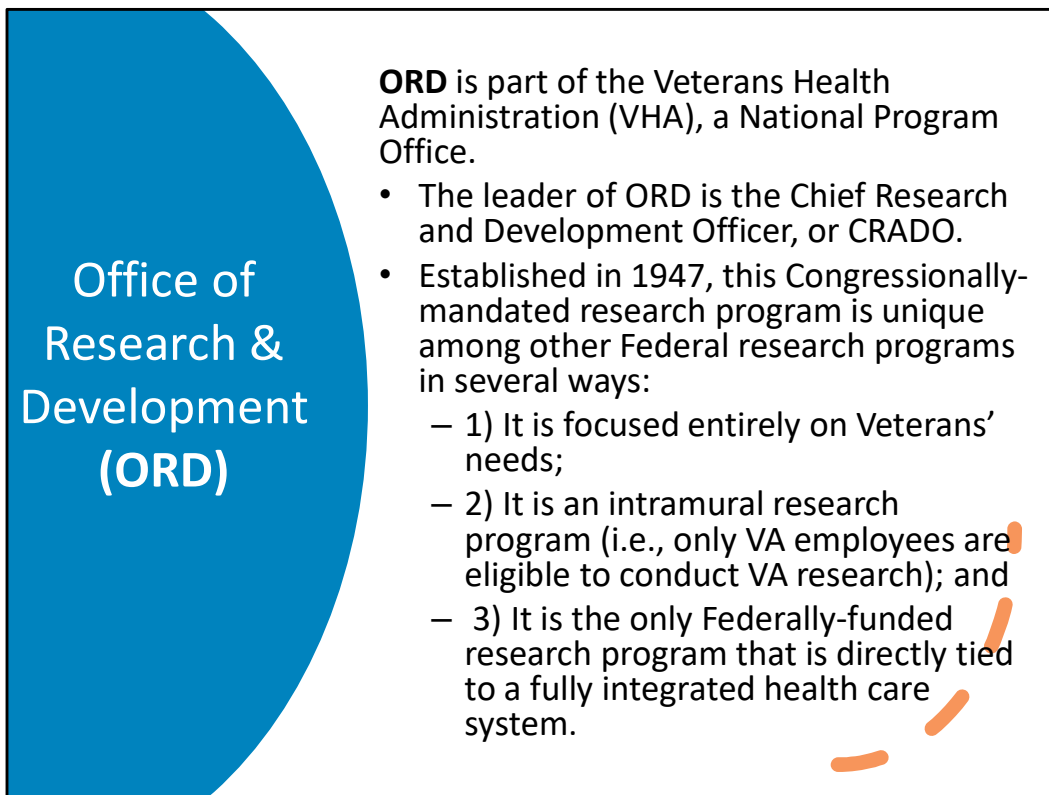
1- To ultimately improve veterans health and well-being through research. Just as past accomplishments have changed peoples' health, the hope is that the ongoing research will continue to do the same.

2- To make this happen we need the best and the brightest, so we have a mission to attract and train them to be leaders.

3. But to do this there will be no sacrifices or short cuts so it must be done in a culture of professionalism, collaboration, accountability and the highest regard for research volunteers' safety and privacy (you can see the RCO role in this mission)

4. And then importantly we can't keep it to ourselves there must be mechanisms that this knowledge translate back to improving veteran health.



A graphic for the Office of Research & Development (ORD). On the left, a blue curved shape contains the text "Office of Research & Development (ORD)" in white. To the right, a white box contains text and a bulleted list. The text states that ORD is part of the Veterans Health Administration (VHA), a National Program Office. The list includes: the leader is the Chief Research and Development Officer (CRADO); established in 1947, it is a unique Congressionally-mandated research program; and it is focused on Veterans' needs, is an intramural research program (only VA employees are eligible), and is the only Federally-funded research program directly tied to a fully integrated health care system. There are some orange decorative dashes at the bottom right of the white box.

**Office of Research & Development (ORD)**

**ORD** is part of the Veterans Health Administration (VHA), a National Program Office.

- The leader of ORD is the Chief Research and Development Officer, or CRADO.
- Established in 1947, this Congressionally-mandated research program is unique among other Federal research programs in several ways:
  - 1) It is focused entirely on Veterans' needs;
  - 2) It is an intramural research program (i.e., only VA employees are eligible to conduct VA research); and
  - 3) It is the only Federally-funded research program that is directly tied to a fully integrated health care system.

So how is all this research funded and managed?

The national program office over VA research is the Office of Research and Development. You will typically hear the office referred to by their acronym ORD.

ORD is the primary office for establishing VA research policies in the VA.

The leader of the program office is the Chief Research and Development Officer. Called also by the acronym of CRADO. Currently this is Rachel Ramoni.

Dr. Ramoni started in 2017. She is responsible for managing the VHA program and developing and executing VA's research strategy.

If you would like to learn more about Dr. Ramoni you can find her bio on the ORD website under leadership.

ORD has been in existence since 1947.

It is the only federal research program that is a direct part of the health care system. This situates the VA in the position to do all types of research from lab to the patient bedside and as we saw in covid, the unique position to rapidly access health information for analysis.

## VA Research

- VA research is an intramural program not only because only VA employees can conduct VA research but also because of funding - that is the money statement that is critical - VA does not fund external investigators



You will hear the terms intramural versus extramural research.

VA research is intramural research which means only VA employees can receive VA research funding.

Even though at times due to space or equipment needs the research may be done outside the VA walls it is still considered within the institution.

Extramural research is research that is funded by a source other than the institution conducting the research.

An example of extramural is when NIH grants funding to researchers outside of the NIH to conduct research.

While VA research is intramural it cultivates close collaborations with other federal agencies, academic institutions, non-profit organizations and private industry. These relationships help further increase the impact of VA research by making specialized resources available and speeding study completion and translation to practice.

## VHA ORD Four Funding Services

### BLRD

- Biomedical Laboratory Research and Development (BLRD) supports and conducts preclinical research to understand life processes from the molecular, genomic, and physiological levels for the purpose of advancing science and the understanding of how diseases affect Veterans, humans or animals through intramural funding mechanisms and career development programs that support talented individual researchers who are working in areas of particular importance to improving the well-being of our nation's Veterans.
- BLRD supported research includes pre-clinical models and investigations of tissues, blood or other biologic specimens from humans. It supports tissue banking, and the development of substantial medical databases through national voluntary research studies such as the Million Veteran Program (MVP)



The VHA Office of research and development Funds VA research VA through 4 mechanisms.

I'm going to go through these quickly because ORD is undertaking a major revision in this approach, and these will be changing soon.

In October of 2022 the individual funding services were moved under a new umbrella called ISRM (Investigations, Scientific Review and Management) but for now will continue to operate as they currently do. The transition will occur in phases over the next 1-2 years.

The overall goal of the funding reorganization is to fund portfolios of Veteran needs rather than disciplines or methods.

Some test portfolios have been established in precision oncology, health services research, and pain and opioid use disorders.

BLRD- biomedical laboratory Research and Development.

Biomedical research is typically lab research that may include animals. The service sets the funding requirements and submission deadlines.

## ORD Four Funding Services CSRD

- Clinical Science Research and Development (CSRD) is focused on moving ideas along the translational pathway from scientific discovery to clinical application in order to advance the healthcare of our Veterans.
- CSRD supports research focusing on human beings as the unit of examination. Examples include interventional and effectiveness studies, clinical, epidemiological and technological studies.



The next ORD funding service is Clinical Science Research and Development - CSRD

These are studies that come out of the lab and test on actual human subjects. Often involve a drug or other intervention with a participant. This research is typically human subject research.

## ORD Four Funding Services HSR&D

- The VA Health Services Research and Development (HSR&D) supports research that encompasses all aspects of VA healthcare, focusing on patient care, cost, and quality. The main mission of HSR&D research is to identify, evaluate, and rapidly implement evidence-based strategies that improve the quality and safety of care delivered to Veterans.
- Investigations look at topics including suicide prevention, opioid management, mental health, complex chronic diseases, health informatics, and implementation science, among others. All HSR&D research proposals are merit-reviewed and subject to strict standards regarding scientific merit and relevance to Veterans' healthcare needs.



Health Services research and Development – HSR&D

Covers all aspects of healthcare. It focuses on moving to the bedside and includes research on healthcare specific patient care, costs and quality of care. This is important in the goal of how new discoveries get implemented.

Looks at multiple aspects of care and the best way to manage the care.

## ORD Four Funding Services

### RR&D

- The Rehabilitation Research and Development (RR&D) Service funds research into treatments and technologies that returns functional independence back to Veterans to improve the quality of life of impaired and disabled veterans.
- RR&D funds a full spectrum of research from approved rehabilitation research projects, through evaluation and technology transfer to final clinical application. The Veterans' needs define the research goals, and they participate in the research efforts, often testing the outcomes and ultimate usefulness of research results in their daily lives.

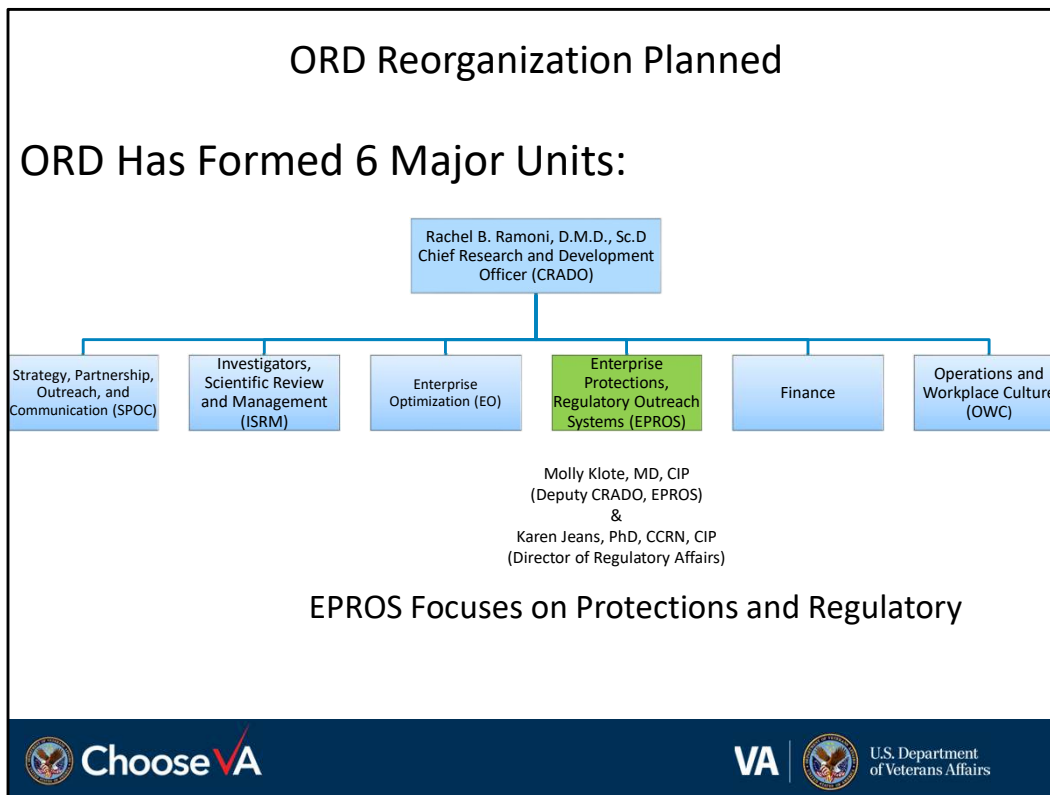


The Rehabilitation Research and Development - RR&D

It is specifically focused on a key veteran need – Rehab

Covers a wide spectrum of study types and veteran needs related to rehab. It focuses on assisting veterans be as independent as possible while preserving quality of life.

There is a large scope of projects under RRD all related to serving veterans rehab needs.



Looking a bit more at the ORD reorg you can see there are 6 major units.

First is - Strategy, Partnership, Outreach and Communication

The next is again the - Investigators, Scientific Review and Management that we just touched on.

Enterprise Optimization

Enterprise Protections, Regulatory Outreach – this unit is highlighted because as RCOs you will likely have the most interaction with this group.

Finance

Operations and Workplace Culture

There will be a lot more information to come directly from ORD on this transformation.

We wanted to make you aware so you can watch for updates from ORD.

There is detailed information on the ORD Website

## Active VA Funded Research by the numbers

| VA Research by the Numbers  | Fiscal Year 2021 | Fiscal Year 2022 |
|---|------------------|------------------|
| Active research sites nationwide  | <b>102</b>       | <b>104</b>       |
| Active funded principal investigators (with funding from VA or other sources) | <b>3,642</b>     | <b>3,699</b>     |
| Active funded research projects (including VA funding and other sources)      | <b>7,304</b>     | <b>7,260</b>     |
| Total congressional appropriation for VA medical and prosthetic research      | <b>\$795M</b>    | <b>\$882M</b>    |
| Total research budget (including other VA and non-VA sources, such as NIH)    | <b>\$2.09B</b>   | <b>\$2.26B</b>   |
| Published research articles authored or co-authored by VA investigators       | <b>13,873</b>    | <b>13,315</b>    |



To give you just a touch of an idea of the funding that ORD provides here are some numbers from 2021/ 2022.

ORD defines an active research site as a site with at least one active research protocol. ORO defines an



active research site as one that holds a valid Federalwide Assurance which you will hear in detail in the VHA Directive 1058.03 session.

If you were not already aware you can easily see here that VA research is a huge multifaceted billion-dollar enterprise. And by the number of publications, you can again see why it is so crucial that VA research is done by the highest standards.

## Office of Research Oversight (ORO)

**ORO** is within the VHA and was mandated Public Law 108-170 signed by the President on December 6, 2003.

- Reports directly to the Under Secretary for Health and serves as the primary office for advising the Under Secretary on matters of research compliance. Functions independently of entities within VHA that have responsibility for the conduct of medical research programs.
- The leader of ORO is the ORO Executive Director, or ORO ED

### **Mission:**

- Promote responsible conduct of 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 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 provides training to facility Research Compliance Officers (RCO) and oversight of RCO auditing programs.



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The Office of Research Oversight or ORO is the primary VHA office responsible for oversight of the research program compliance with VA and other federal requirements.

ORO reports directly to the under secretary for health.

and functions independently of the entities that manage and conduct VA research.

The ORO executive Director is Doug Bannerman who assumed this position in 2017. You can see his bio on the ORO website.

ORO's Mission:

Promote responsible conduct of VA research- just as you saw with the overall research mission.

The mission is to ensure that not only the veterans and others that volunteer but those that will ultimately be touched by the research are protected by ensuring the research is sound and conducted ethically.

ORO provides oversight for the protection of Human subject research, animal welfare,

research safety, research lab safety, research information security and research misconduct.

As you are all aware ORO also provides training to RCOs.



## Key VA Research Facility Leadership

- **Medical Center Director (MCD)** – The facility director is the CEO of the Medical Center. They are also the **Institutional Official** for research.
- **Deputy or Associate Director** – Oversees Operations/Security/HR/ Labor – oversees all of the day-to-day operational, employment, HR, and physical plant issues, and industrial hygiene that support patient care services.
- **Chief of Staff (COS)** – Oversees the clinical policies, daily service issues that directly impact on patient care: safety, census, emergencies and crisis management, appointment, and credentialing of all clinicians. The ACOS/R&D generally reports directly to the COS.
- **Associate Chief of Staff/Research and Development (ACOS/R&D) Or a Research Coordinator at smaller sites** – This position heads the research program at the facility, and helps in the recruiting, training, and development of research investigators.



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Let's now look at some of the key VA research leadership at the individual facilities.

The facility Director is what in the private sector might be called the CEO. The Director is the leader of the medical center.

There can be several different titles for this role and different leadership organization. The most common used historically is the Medical Center Director, the Directives are now using the term medical facility director some use executive director.

Next is the Deputy associate Director-

Depending on the size of the VA there can be one or a few individuals serving in a similar title. Including deputy or associate Director.

Chief of Staff is typically a physician and handles the daily clinical management of the hospital. Most clinical service chiefs are under the COS.

The Associate Chief of Staff for Research (ACOS/R) is also usually under the COS. Keep in mind the arrangement may be different at your facility depending on the size and set up.

Associate Chief of Staff for research and Development is comparable to a section chief or Department head at private facilities.

There are ACOSs for multiple services within the hospital. ACOS of cardiology or ACOS

Hematology for example. The ACOS/R&D can be called lots of short cuts ( ACOS or ACOS R or ACOS RD.)

Sometimes at VAs with smaller research the research program leader may be called the Research Coordinator. Typically, when there is not enough research to warrant a fulltime ACOS/R an individual that might also have another role in the hospital such as the mentioned ACOS/of cardiology may also serve as the research coordinator.

If it is a large program the research service may also have a Deputy ACOS/R&D



## Key VA Research Facility Leadership (cont'd)

- **Administrative Officer/Research and Development (AO/R&D)** – The AO/R&D manages the business operations of the program and carries out the day-to-day program and office management activities of the research service.
- **Research Committee Manager** – Manages committee activity, including agendas, minutes, rosters, filing of protocol documentation, training of committee members, COI disclosures and follow-up tasks.
- **Budget Analyst** – A budget analyst manages money sent from ORD for research and administrative use, ensuring that it is properly spent, and that none is left when the funding expires.
- **Procurement Technician** – Orders supplies for research and research administration.
- **Program Support Assistants** - Assist in a variety of tasks including HR, procurement, tracking Without Compensation (WOC) appointments, contract management.



More research personnel-

The Administrative Officer for Research and Development or AO/R&D handles the daily operations, HR, staff management.

Committee manager- these can be arranged in many ways depending on the program. Some facilities have a committee manager for each committee some cover more than one committee and sometimes there will be more than one for a committee, if the committee handles a lot of protocols.

The key is to learn the arrangement at your facility because you will need to be on good terms and work closely together.

Sometimes also called Committee administrators but ORD is recommending the term Research Committee Manager because that is the title on the standard performance description.

Budget analyst handles ORD funding. Some facilities also have budget technicians working with the budget analyst to order and track supplies and other budget management tasks.

Program support assistants- multiple tasks. Education tracking, scheduling, assistant to

ACOS/R&D, Tracking staff on Without compensation appointments.

WOC appointments are appointments of individuals who will provide services to VA facilities without payment or remuneration.



## Key VA Research Facility Leadership (cont'd)

- **Information System Security Officer (ISSO)** – SME for all information security matters at the VA Facility including compliance with VA OI&T requirements for securing and transmitting VA sensitive data. Advises on protection of research information.
- **Privacy Officer (PO)** – SME for all VA Facility Privacy and confidentiality of information, reviews research protocols for HIPAA, privacy and confidentiality concerns. At some facilities is responsible for managing FOIA requests.
- **Radiation Safety Officer** – Liaison between Research Service and the Medical Center's Radiation Safety Program and the Radiation Safety Committee regarding all aspects of use of radioisotopes and radiation producing machines in research.



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Listed here are some key staff that are outside of research that act as subject matter experts for VA research.

The information system security Officer- is the subject matter expert for all information security matters at the facility. The ISSO advises on the protection of research information.

Privacy officer or PO- is the subject matter expert for all VA facility privacy and confidentiality.

Radiation Safety officer- protocols may include use of radiation this must be reviewed by the radiation safety officer. Each facility will have one. If a smaller facility it may be shared amongst more than one facility.





## Key Research Documents

- Guidelines, policy and regulations for VA research are found in a series of Handbooks, Directives, and Program Guides.
- VA-Wide Handbooks and Directives cover the entire VA, such as VA Handbook 6500 VA Cyber Security Program.
- VHA research policies are published in the VHA Handbook, Directive and Program Guide series begin with the digits 1200.XX.

VHA Policy Documents from ORO begin with the digits 1058.XX.

- In this workshop series Handbooks and Directives related to research and RCO responsibilities will be reviewed in depth.



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I have thrown around a lot of terms related to documents so let's talk a bit about them.

We talked about important research history, key offices, key personnel let's now talk about key documents. What documents tell us how research should be managed and conducted.

You will see that there are different types of documents. Policy and regulation for VA research are found in a series of Handbooks, Directives and Program Guides.

Handbooks prescribe mandatory Department wide procedures or operational requirements in implementing policies that are contained in directives.

Directives provide mandatory department wide policies.

ORD research policy begins with 1200 – the 1200 series

ORO documents begin with the digits 1058.XX

In this back to basic series, we will be looking at both handbooks and directives.



## Key Research Documents

- Numbered Handbooks and Directives describe the regulatory and VA/VHA Policy –What must or must not be done in a particular research enterprise.
- Numbered Program Guides such as 1200.21 “VHA Operations Activities That May Constitute Research” describe how a program or policy is managed or operated.
- ORD also provides guidance documents in response to targeted topics. For example: the guidance documents issued in response to Covid 19.

[ORD VHA Directive, Handbooks, and Program Guides -- 1200 series \(va.gov\)](#)



Together the Research-related handbooks and directives provide the regulatory policy for research.

Program guides- describe how a program or policy should be managed.

ORO and ORD also provide multiple resources referred to as guidance documents . These are not numbered and are topic specific.

What is VA Research?  
VHA Directive 1200.01(1)

**VA Research.** VA research is research conducted by VA investigators (serving on 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. The research must be approved by the R&D Committee 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. NOTE: Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.



So, I have probably said VA research 50 times so far in this presentation but what is that? Well, we know so far that it is intramural research, may be funded by the VA itself or NIH or many other outside sources but what makes something VA research?

The VHA Directive 1200.01(1) definition is here for you. You already know or will soon see that almost every directive defines research and VA research but for today we are using the definition in 1200.01(1) because it is a broader definition.

What does it tell us? Let's break it down. There are

several distinct requirements here and each is an important factor when determining if something is VA research.

1-VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property.

2- The research may be funded by VA, by other sponsors, or be unfunded.

3-The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated.

4-All research activities approved by the R&D Committee are considered VA Research.

5-NOTE: Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.

1200.05- Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive.

## What is VA Research? VHA Directive 1200.05(2)

**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.

NOTE: Any emergency use of a test article does not require R&D Committee approval but is VA research under this policy.



Here is the 1200.05(2) definition.

1200.05 is related only to human subject research

## Research Defined in VHA Directive 1200.07 VA Research With Animals

Animal Research or Research with Animals.

Animal research, or research with animals, is any activity in which animals are the subjects of procedures that are necessary for specific research or teaching projects.



We won't spend much time on the definition of animal research because it will be reviewed in detail in the 1200.07.

1200.07 refers to any use of lab or animals in research, testing or training.

VHA Directive 1200.08(1)  
Safety of Personnel and Security of Laboratories  
Involved in VA Research

- VA Research Laboratories: VA research laboratories are research laboratories under the control of VA and/or used for VA research within VA facilities or a space occupied by VA under a legal agreement (e.g., lease).
- NOTE: Laboratories within the VA facility in space leased to a non-VA entity should have in the leasing agreement requirements for managing safety and security.



The same for VA research laboratories it will be covered in 1200.08.

VA research laboratories under the control of and/or used for VA research within the facility or can be space occupied under a legal agreements

What is a VA investigator?  
VHA Directive 1200.01(1)

- **A VA investigator** is an individual who conducts research approved by the R&D Committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 et seq.). As a VA investigator, that individual represents the interests of the VA in conducting the study.
- **NOTE:** Individuals working under a contract with VA cannot be given a WOC appointment to conduct research on their contract time. Contractors can provide clinical services or other activities in support of VA research in accordance with their contract.



You can see from the definitions that the definition of VA research refers to a VA investigator. What is a VA investigator?

Here we are looking at the definition from 1200.01.

VA investigator conducts research approved by the R&D committee. Since the definition of VA research is any research approved by the R&D it would follow that anyone conducting this research would be a VA investigator.

An important flag to watch for that can sometimes be overlooked is the “on VA time”. If the individual is doing an activity during their VA time, then they are a VA investigator. This is no matter what type of VA appointment they have. If they are doing it on VA time, then they are representing the VA in that study.

If someone is working under a contract with the VA they can’t be provided a WOC to conduct research on their contract time. They can provide services or activities that are specifically described in the contract.



What is a VA investigator?  
VHA Directive 1200.05(2)

- **VA Investigator:** A VA investigator is any individual who conducts research while acting under a VA appointment, including full and part-time employees, without compensation (WOC) employees, or individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 et seq.). Individuals working under a contract with VA cannot conduct research as VA Investigators under a WOC appointment while simultaneously working as a contractor.
- **NOTE:** Students/Trainees may serve as co- or sub-investigators but must have a VA PI sufficiently experienced in the area of the trainee's research interest to serve as the PI. Trainee/ Student research activities are further discussed in VHA Directive 1200.02(1), Research Business Operations, dated March 10, 2017.



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Let's look at the VA investigator as defined in 1200.05 Directive. Recall again that this is related to human subject research.

A VA Investigator is any individual who conducts research while acting under a VA appointment,- again we see clarification that this includes full and parttime employees, WOC, IPA.

Again, with a bit different wording we see that individuals working under a contract with the VA cannot conduct research under a WOC appointment at the same time working as a contractor.

And then an added note here that is not part of the definition but extremely important. Students and Trainees may serve as a co- or sub investigator but must have a VA PI in that area of the research to serve as PI. You can see more details related to trainee research in 1200.02.

And note further that this says students may serve as a sub or co investigator but not every student or trainee will be qualified to serve as an investigator. There are requirements to be met to be an investigator and not all students will qualify.

Priscilla will be going into more detail on this when we get into the 1200.02 specifics. Also immediately following this webinar ORD is holding their HRPP bimonthly Updates

in VA research where one of the topics will be student research issues. Strongly recommend you attend that conference, and if you can't they are always recorded.

## What is a Research Protocol? VHA Directive 1200.05(2)

**Research Protocol:** A research protocol details the aims and objectives of a research study, scientific rationale, the methods used to carry out the research, and how data will be analyzed. For human subjects research it also entails how subjects will be accessed/recruited, any foreseeable risks, and how these risks will be mitigated. NOTE: The protocol for social or behavioral research is sometimes referred to as the Research Plan or Research Purpose and Methodology.

You will also hear words like "study" or "project" for human and other research.



The next definition to look at is Research Protocol. For that we turn again to Directive 1200.05

In summary the research protocol details the research study. It provides the objectives, rationale, methods and how the data will be analyzed. If humans are involved, it will also provide information about the participants involvement. How they will be accessed/recruited, risks, how the risks will be mitigated.

In social or behavioral research, the protocol is sometimes referred to as the research plan or research purpose and methodology.

You will also hear the research protocol referred to by many other names as well. For example, study protocol, project protocol,

What Is a Research Protocol?  
VHA Directive 1200.07 VA Research With Animals

- Animal Component of Research Protocol (ACORP): The ACORP, the official VA animal protocol form, is the set of questions that must be considered during a review of animal protocols. It must be used by VA Institutional Animal Care and Use Committees (IACUC) when a project involving animal research is submitted for consideration of VA funding. We will discuss the ACORP in detail when we present VHA Directive 1200.07



We can also look at research protocol in 1200.07 that discusses that the animal component of the research protocol (ACORP) is the official animal protocol form and must be used by the IACUC when a project involving animal research is submitted.

A teaser for you to stay tuned for the 1200.07 session.

## 1200.02(1) topics we will cover today



Some Selected  
Definitions



Required  
Research  
Program  
Infrastructure



Required  
Personnel



Students and  
Trainees  
Conducting  
Research



Required  
research  
committees



Required  
management  
processes



Formal  
Communication



Responsibilities  
of the VA  
Facility Officials  
and  
Investigators

In a moment I will pass it to Priscilla Craig who will cover these topics specific to 1200.02(1).

As you can see there are a lot of topics to cover with just this one Directive.

## VHA Directive 1200.02(1) Other Topics

Topics you can read about in the Directive, but we won't cover in depth today

New or  
Reactivated  
Research Programs

Financial  
Management  
Processes

VA Nonprofit  
Foundations

All the Business  
Responsibilities of  
those involved in  
research.

However, you will see there is a lot to 1200.02 so it is important to do a full review of the all the topics.

Some things we won't be covering today that we encourage you to read on your own are-

New or reactivated research programs.

Financial management processes

VA nonprofit foundations

Then details on business responsibilities of those involved in research.

I will pass now to my colleague Priscilla Craig.

VHA Directive 1200.02(1)  
March 10, 2017  
Research Business Operations

This Veterans Health Administration (VHA) directive provides policy requirements and some guidance for the successful administration and operational management of Research Offices in VA medical facilities. In addition, it also addresses issues related to research staff and research conducted within VHA.

## Important Definitions in Directive 1200.02



- **Academic Affiliate.** An academic affiliate is an academic institution that has a relationship for the purpose of education, research, or enhanced patient care with a VA medical center documented by a formal Affiliation Agreement in conformance with VA requirements.
- **Site Investigator or Local Site Investigator.** A Site Investigator or Local Site Investigator (LSI) is the Investigator at one of the participating sites in a VA multi-site study that is responsible for the conduct of the study at the local site. The LSI serves as the PI at that local site.



Let's start with some selected definitions. Please note that definitions written in a Directive are for that Directive, but it doesn't mean that other Handbooks and Directives aren't applicable.



## Important Definitions in the Directive

- **VA Information.** VA Information is information on any storage media or in any form or format, owned or in the possession of VA, or under control of VA or any entity acting for or on behalf of VA. The information may be identifiable, de-identified, sensitive, or non-sensitive
- **VA Sensitive Personal Information and Data.** VA sensitive information is all VA Information which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions (see Title 38 U.S.C. 5727).



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## Important Definitions in the Directive



- **Without Compensation.** A WOC employee is an individual that has an official VA appointment, but does not receive any salary or benefits from VA. See 38 U.S.C. §513; 38 U.S.C. §7405(a)(1).
- This appointment may allow the individual to support VA's research program in various capacities including, but not limited to, Investigator, research coordinator, and administrator while at VA for a defined period of time.
- Research WOC employees are subject to all laws and regulations pertaining to government personnel, including, but not limited to, Government ethics laws and Standards of Conduct and VHA, Credentialing and Privileging Directives.



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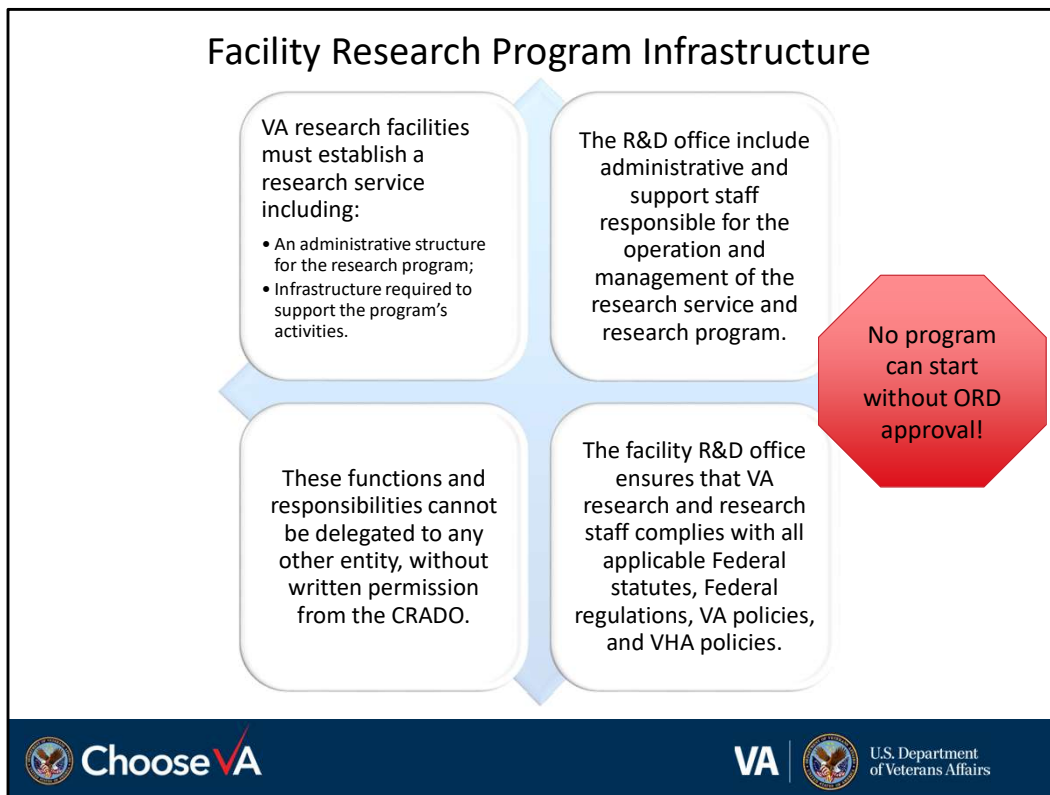


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## Intergovernmental Personnel Appointment (IPA)

- The Intergovernmental Personnel Act (IPA) allows for the temporary assignment via a detail or temporary appointment 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 defined in 5 U.S.C. §3371 and 5 CFR Part 334. The Office of Personnel Management (OPM) maintains the list of acceptable Institutions.
- Until recently 2-year IPAs could be renewed for an additional 2 years but couldn't exceed 4 years total. New legislation has been passed and ORD guidance is pending to remove the time limits.





- Each VA medical facility that conducts research is required to establish a research service that includes an administrative structure for the research program and the infrastructure that is required to support the program's activities. The R&D office within each VA medical facility conducting research is composed of administrative and support staff whose functions and responsibilities include the operation and management of the research service and the local research program.
- These functions and responsibilities cannot be delegated to any other entity or performed by any other entity on behalf of the VA medical facility, without written permission from the Chief Research and Development Officer (CRADO). The facility R&D office also ensures that VA research conducted by the VA medical facility and the programs' research staff complies with all applicable Federal statutes, Federal regulations, VA and VHA policies.
- No research program may begin without ORD approval.

## Research Office Functions

The Research Office and its personnel are responsible for ensuring the effectiveness of the research program. The Research Office must establish tracking systems that allow for easy retrieval of information to assist in assessing compliance with applicable requirements and the status of each program activity or element, including but not limited to:

- Research Protocols/Studies
- Research Review Committee (RRC) Actions
- Contracts, Agreements, Memoranda
- Personnel Matters
- Financial Management
- Training of Committees, Research Staff and Research Teams
- Management and Tracking of Research Data repositories
- Reporting required by all concerned VA and external parties like Congress



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The Research Office and its personnel are responsible for ensuring the effectiveness of the research program. The Research Office must establish tracking systems that allow for easy retrieval of information to assist in assessing compliance with applicable requirements and the status of each program activity or element, including but not limited to:

- Research Studies
- Committee Actions.
- Agreements. The system must track all local Cooperative Research and Development Agreements (CRADA), research contracts, research Memoranda Of Understanding (MOUs), and other written research agreements.
- Personnel.
- Training.
- Research Data repositories.
- Reporting. All regular R&D reporting is incorporated in the Research and Development Information System (RDIS). The RDIS database provides information needed by field facilities for managing the R&D program and for responding to inquiries from VHA ORD staff, Congress, and others.

Much of this is done through the new VAIRRS/IRBNet. VA facilities use other supporting systems, particularly when they use the IRB of their Academic Affiliate.

## Required Research Review Committees

The Research Service is assisted by the R&D Committee and its Research Review Committees.

- The R&D Committee is responsible for assisting the medical facility Director in fulfilling responsibilities for the facility's research program by making recommendations regarding personnel, space and other resource needs of the research program.
- VHA Directive 1200.01(1), Research and Development (R&D) Committee, addresses requirements for and management of the R&D Committee and its research review committees.

There is some "VA Speak" terminology associated with the research review committees. Research Review committees like the IRB and IACUC are considered "subcommittees" of the R&DC if they are internally operated by the VA facility. External committees established by MOUs or other agreements in lieu of required subcommittee(s) are not considered subcommittees and are governed by the agreement.



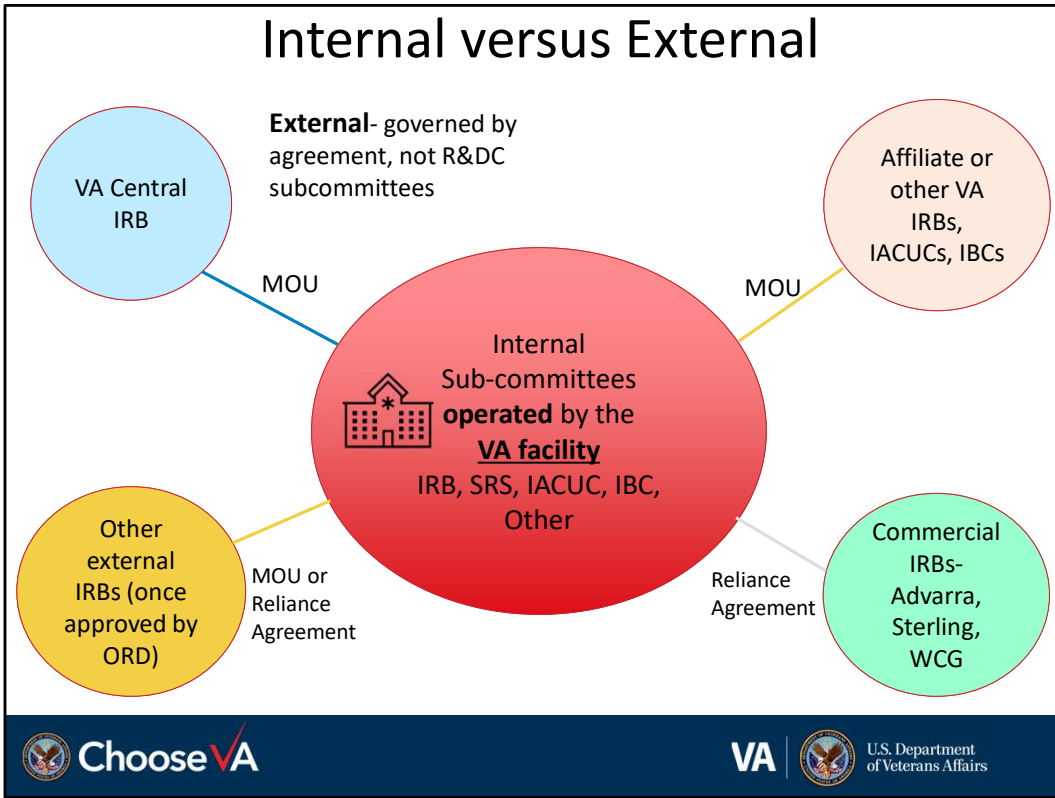
## Research Review Committees Required by Directive 1200.01(1)

VHA Directive 1200.01(1) distinguishes between Research Review Committees operated by the VA facility with the terminology as Internal “Subcommittees of the R&DC.” Where a VA facility uses the services of a Research Review Committee operated by another VA or another Institution permitted by ORD, Directive 1200.01(1) refers to these committees as External “Research Review Committees.” A Subcommittee on Research Safety is not required for research programs that do not conduct basic laboratory research. Research that only involves the collection and analysis of biospecimens by any VA personnel within clinical areas or clinical research areas, or the performance of standard clinical procedures in clinical areas or offices is exempt from the requirement for SRS review and approval. VHA Directive 1200.08(1) goes into detail about the SRS.

Also, an IACUC is not required if there is no animal research program.



# Internal versus External



## Required Appointments

- All VA Investigators and research team members must hold a VA appointment (Full time, Part Time, WOC, or Intergovernmental Personnel Appointment (IPA)) prior to conducting any aspect of VA research or being involved in research activities in any way.
- All VA research staff (clinical and non-clinical) conducting VA research must be credentialed and privileged (if applicable) as required by current local, VA, and VHA requirements (see VHA Directive 1100.21 Privileging, VHA Directive 1100.20 Credentialing of Health Care Providers and VA Handbook 5005 Staffing).
- Research staff may only perform those activities in a research study that are allowed by the job series to which they were appointed, have the relevant credentials and privileges, and are allowed by their research scope of practice or functional statement.



There is no requirement for a research scope of practice. However, if people have one, they must follow-it.

Please note that in Collaborative research with other institutions, collaborators are not required to have VA appointments.

## Required Credentials

**Credentials:** All research staff who are licensed health care professionals permitted by the VA medical facility to provide patient care services independently must be credentialed and privileged as defined in VHA Directive 1100.20, VHA Directive 1100.21 and VA Handbook 5005 apply to those Advanced Practice Registered Nurses, Physician Assistants, and clinical pharmacy specialists who do not practice as licensed independent practitioners, as well as physicians, dentists, and other practitioners assigned to research or administrative positions not involved in patient care.

ORD follows these publications.

Human Resources Management Service (HRMS) is responsible for credentialing all research employees prior to offering these individuals a VA appointment per VA Handbook 5005. There are a number of federal databases HRMS uses to do that. They are described in Directive 1200.02(1)



VHA Directive 1100.20 Credentialing of Health Care Providers  
VHA Directive 1100.21 Privileging

## Privileging Requirements are Specific to a VA Facility

- Only practitioners who are licensed and permitted by the VA medical facility to practice independently may be granted clinical privileges **at that VA Facility**.
- If the local VA medical facility where the research is to be performed requires privileging to perform a given duty (e.g., a procedure) in the clinical setting, the individual **must be privileged at that VA medical facility** to perform the clinical duty before the individual can perform that duty in the research setting.
- Some of the Human Research Processes for hiring research personnel are described further in 1200.02(1) Chapter 9. ORD does not establish HR policies.



## Trainee/Student Research

Trainees and Students are defined as a subset of employees who are:

- Appointed under trainee authority (38 U.S.C. 7405 or 7406), and
- Enrolled in one of two types of training programs:
  - Enrolled in an accredited training program sponsored by an affiliated educational institution under a formal current and existing academic affiliation agreement, or
  - Enrolled in a VA sponsored training program (either accredited or non-accredited).



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Trainees are defined as a subset of employees who are:  
(Appointed under trainee authority (38 U.S.C. 7405 or 7406), and

Enrolled in one of two types of training programs:

Enrolled in an accredited training program sponsored by an affiliated educational institution under a formal current and existing academic affiliation agreement, or

Enrolled in a VA sponsored training program (either accredited or non-accredited). Examples of these VA sponsored training programs include Office of Academic Affiliation (OAA)-funded advanced fellowship programs, OAA-funded Chief Residents in Quality and Safety, or OAA-funded and VA-sponsored accredited training programs.

Your Education Service and Research Service should consult on the type of training program and whether an individual student qualifies to conduct research at VA.

Such as Medical and Pharmacy residents or students in other allied health professions with your facility

academically affiliated schools.

## Student/Trainee Research (Continued)

- As defined in the previous slide, Trainees or Students may conduct research at a VA medical facility and serve as a co- or sub-investigator, use VA data, or use human biological specimens that have been collected within VA for clinical, administrative, or research purposes.
- Trainees and Students who do not fulfill the requirements specified in the previous slide cannot participate in VA research unless the VA medical facility Designated Education Officer (DEO) seeks a waiver from the Chief Academic Affiliations Officer or designee, and the Chief Research and Development Officer (CRADO), Dr. Ramoni.
- *Trainees/Students from unaffiliated academic institutions in the community may not be permitted to conduct student projects in VA or be given a WOC appointment for the sole purpose of conducting student research.*



Not every Student or Trainee is qualified to conduct research in VA. ORD is presenting a webinar this afternoon and I believe they will also discuss Student research. They may present updated information so stay tuned for that.

## Student/Trainee Research (Continued)

Trainees and students must have a VA Investigator sufficiently experienced in the area of the trainee's research interest to serve as the PI. The PI is responsible for ensuring that the trainee:

- Complies with all applicable local VA medical facility, VA, and other Federal requirements including those related to human subjects or animal safety, use of radioactive substances, information security, privacy, and other research processes;
- Completes or terminates the study in an orderly fashion prior to leaving VA in accordance with all applicable local, VA, and other Federal requirements;
- Provides the VA Research Office with an inventory of all research records to be retained at VA in accordance with the Record Control Schedule 10-1.





## Business Responsibilities of VA Facility Officials

VHA Directive 1200.02(1) describes the responsibilities of:

- Medical Facility Director (MFD)
- Associate Chief of Staff for Research (ACOS/R&D) or Coordinator for Research & Development (C/R&D)
- Administrative Officer
- Investigators



Somewhere in your VA facility there are organization charts for the facility and there should be an organization chart for Research.

## Medical Facility Director Responsibilities (Highlights)

Responsible for all aspects of the research program

Appointing an ACOS/R&D (must be at least 5/8 FTE) with the official concurrence of ORD or a C/R&D if the program is small.

Making Research Appointments

Appointing or hiring an Administrative Officer for Research (AO/R&D)

Operating the RRCs or securing services of RRC through an MOU

Appointing one or more RCOs but VHA Directive 1058.01 discusses this responsibility.

Appointing All VA members of the VA-operated Research Review Committees in writing.



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## Responsibilities of the ACOS/R&D (or the C/R&D)

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Responsible for the day-to-day activities of the research program and usually reports through the Chief of Staff (COS) to the VA medical facility Director. The ACOS/R&D also serves as the Executive Secretary of the R&D Committee.

**NOTE:** In small programs lacking an ACOS/R&D, the C/R&D assumes these responsibilities.

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Ensuring that all research personnel hold an official VA appointment from HRMS (as a compensated, full-time or part-time employee, a WOC, or under an IPA)

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Ensuring that all requests for WOC appointments for research have been appropriately justified and the appointments are in compliance with all applicable research, HRMS, and other VA policies. A VA supervisor must be officially appointed for each WOC employee

---

Ensures complete and accurate documentation/records of research program activities.



## Administrative Officer AO/R&D Highlights

- The AO/R&D supports the research program by administering and managing the business operations of the program. The AO/R&D reports to either the ACOS/R&D or C/R&D.
- The AO is often supervisory and manages the program activities listed in the Directive for finance, staffing, tracking education and training, appointments, and more. A few examples include:
  - Tracking all required activities or elements of the research program and reporting required fiscal and project information
  - Coordinating personnel issues
  - Coordinating or facilitating development of research policies
  - Coordinating any required site visits from VA or other agencies
- The responsibilities may be delegated to another qualified research staff member.



## Key Responsibilities of VA Investigators

**Hold**

the appropriate VA Appointment, credentials, privileges and ensure study staff holds the same.



**Prepare**

protocols that meet VA requirements.



**Conduct**

the research according to VA R&D Committee and Research Review Committee requirements and maintain required records.

Report Unanticipated problems, serious exposures, and noncompliance per requirements of VHA Directive 1058.01



**Supervise**

the Research Team and Follow the Protocol as approved

## Responsibilities of VA Investigators (Continued)

All research data and biological specimens generated during the conduct of a VA-approved Research Protocol are the property of VA and are not owned by the Investigator, unless there is a valid agreement (e.g., CRADA or other equivalent) that establishes that data collected by VA belong to the sponsor with a copy retained by VA.

VA Investigators must only conduct VA research in VHA medical facility space and/or in third party space that VA has the legal authority to use for the intended purpose, and for which the parties have entered into an appropriate agreement such as a real property agreement that complies with applicable law and VA policy.



## References

- ORD ACOS/R&D and AO Manual found at [General Administration \(va.gov\)](#)
- ORD Policies and Guidance 1200 Series [ORD VHA Directive, Handbooks, and Program Guides -- 1200 series \(va.gov\)](#)
- ORO Policies and Guidance [www.va.gov/ORO](http://www.va.gov/ORO)



# QUESTIONS

