SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

This project has been funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

FYI

Questions for the presenter or SMART IRB Team are welcome! Please post these under ‘Q/A’

Questions for fellow attendees should be posted under ‘Chat’

A link to today’s recording will be emailed to attendees. A recording will be posted on the SMART IRB website

Your feedback is valued! Please complete the survey at the end of the SMART Talk! The survey will be emailed as well.

What Is SMART IRB?

SMART IRB is…

A federally funded project to support institutions and researchers in the implementation of single IRB

SMART IRB provides…

An IRB reliance agreement

An Online Reliance System to initiate and track reliance

Zero Cost Education, Guidance, and Resources

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

Reach out to a SMART IRB Ambassador

Aaron Kirby
Harvard Catalyst

Polly Goodman
Harvard Catalyst

Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

https://smartirb.org/ambassadors/

Carissa Minder
Washington University in St. Louis

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka
Medical University of South Carolina

Lubabah Helwani
University of California, Los Angeles

What We've Been Up To…

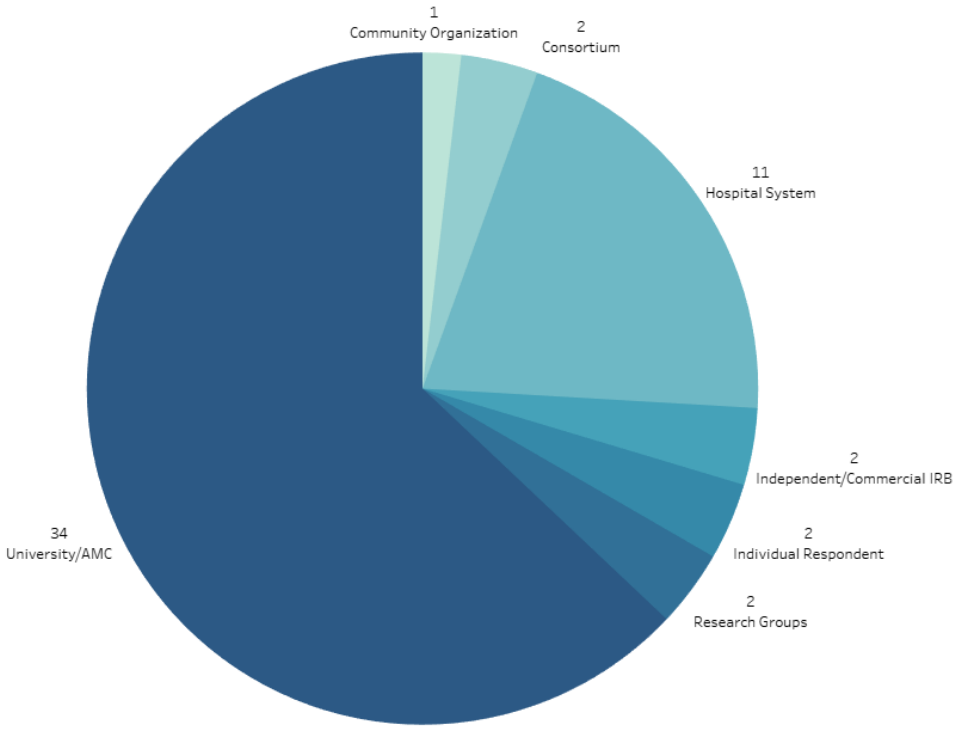
2024 Single IRB Boot Camp

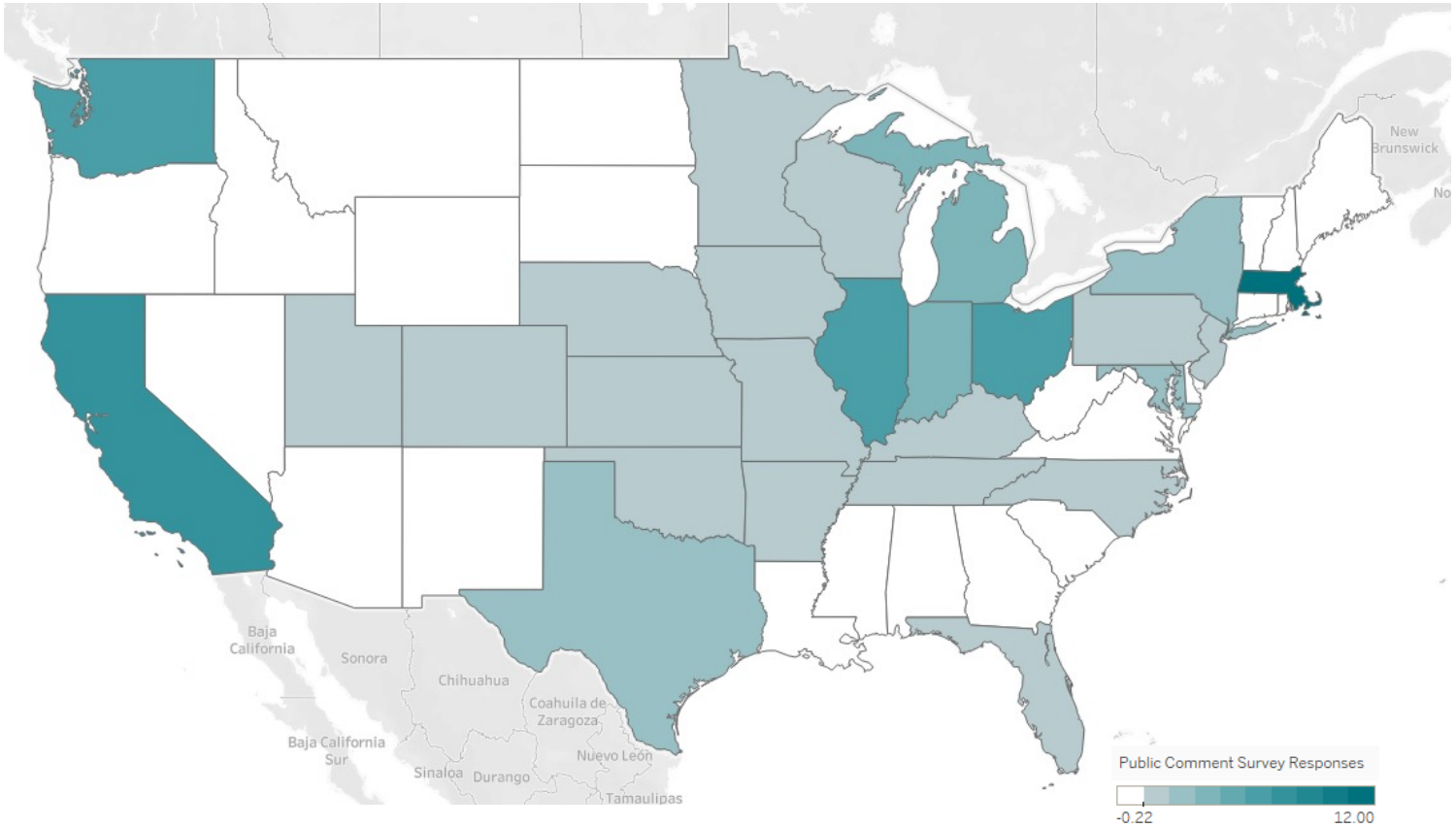
This beginner-level online session was held on February 7 & 8 to train IRB and HRPP personnel on successful implementation of the sIRB review model and how to leverage SMART IRB resources to achieve that success.

- 96% felt it met their educational needs
- 92% would recommend to colleagues, found the event “Extremely Helpful” or “Very Helpful”
- “Any new person involved in the SMART IRB process should go through a Bootcamp”
- “I believe that even if you have attended, one should take advantage of attending each time the bootcamp is provided. There is always something new to learn”

SMART IRB Agreement V3.0 Public Comments

THANK YOU for your feedback regarding the proposed SMART IRB Version 3.0 Agreement! Public comment period ended on February 15, 2024**. Stay Tuned for next steps!**





Understanding VA Specific Requirements for Single IRB Implementation

Today's presenter:

- **Karen Jeans,** Director for Regulatory Affairs for the Office of Research Protections, Policy, and Education in the Office of Research and Development, Department of Veterans Affairs

Moderators:

- **Jeremy Lavigne**, Senior Officer, SMART IRB Regulatory Affairs, Harvard Catalyst
- **Nichelle Cobb**, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs

SMARTIRB.org

Save the date for the next SMART Talk

The sIRB Process: Department of Defense, Department of Energy and SMART IRB V3.0

April 17, 2024
2:00-3:30 pm ET

Questions?
Contact
help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings

Understanding VA Specific Requirements for Single IRB Implementation

C. Karen Jeans, PhD, CCRN, CIP

Director of Regulatory Affairs, Enterprise Protections, Regulatory, Outreach, and Systems

VHA Office of Research and Development (ORD)

SMART Talk

March 20, 2024

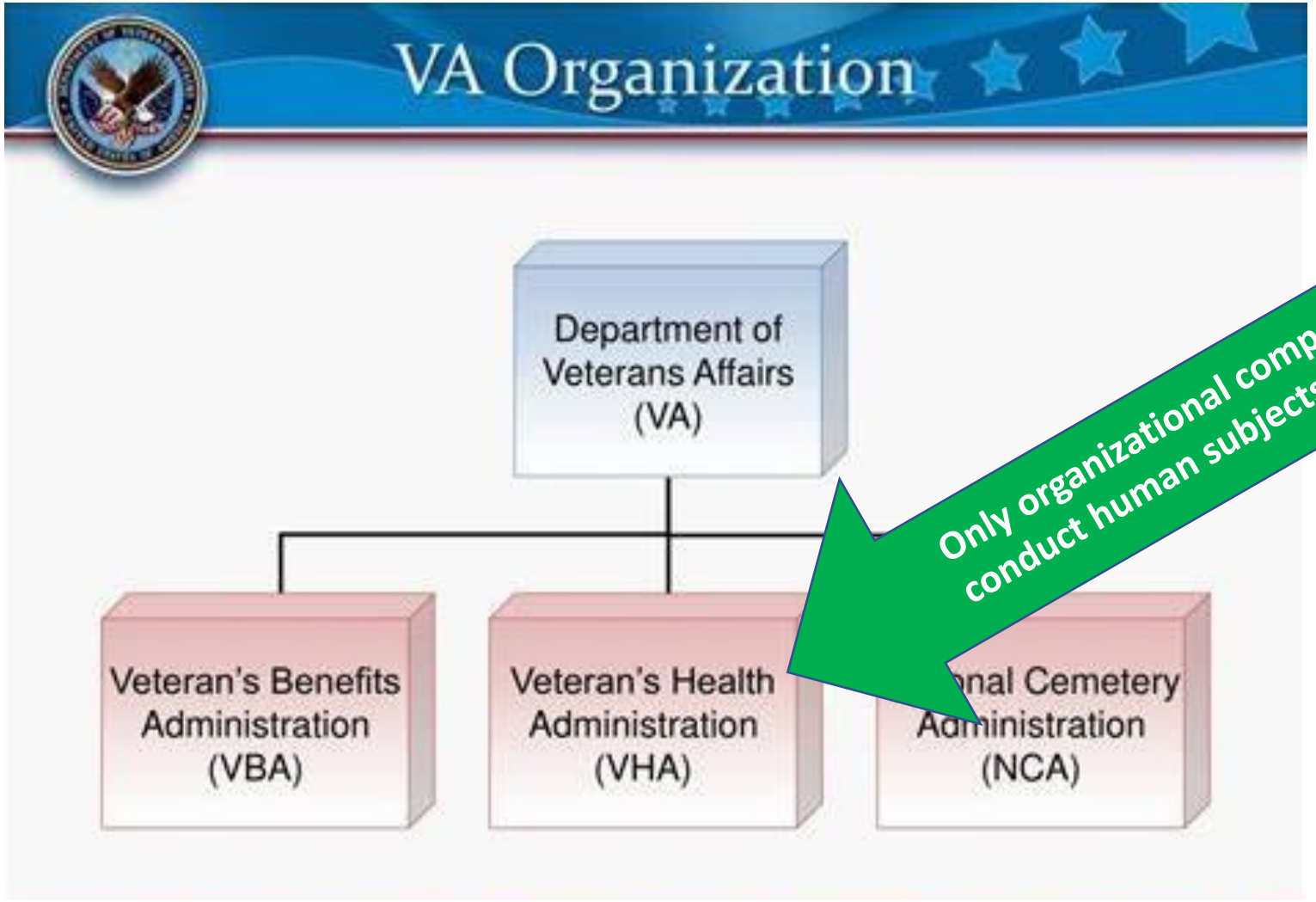
Objectives

- Describe why the Department of Veteran Affairs (VA) is committed to become part of SMART IRB.
- Identify key VA-specific policies and procedures applying to VA's implementation of the cooperative research provisions (e.g., single IRB mandate).
  - Types of IRBs currently allowed to be reviewing IRBs for VA Facilities,
  - Types of institutions a VA Facility's IRB or the VA Central IRB may currently serve as a reviewing IRB, and
  - Exception process for use of a single IRB utilized by the Office of Research and Development (ORD) when ORD determines it is not appropriate to use a single IRB for the specified study.
- Describe the process when a VA Facility wishes to add another IRB to its research program as a reviewing IRB.

Objectives (cont.)

- Identify and locate where to find VA specific requirements (“VA isms”) related to IRB reviews of VA research
  - Informed consent
  - The Privacy Rule (Health Insurance Portability and Accountability Act of 1996)
  - Other required reviews (e.g., information security, privacy)
  - VA Research and Development Committee


VA
U.S. Department
of Veterans Affairs


VA Organization
Department of Veterans Affairs (VA)
Veteran's Benefits Administration (VBA)
Veteran's Health Administration (VHA)
nal Cemetery Administration (NCA)
Only organizational component of VA that can conduct human subjects research

Background:
Veterans Health Administration and Human Subjects Research

- The Veterans Health Administration is America's largest integrated health care system, providing care at 1,321 health care facilities:
  - Includes 172 medical centers, and
  - 1,138 outpatient sites of care of varying complexity (VHA outpatient clinics).
- 110 VA Facilities are currently approved to conduct human subjects research by the Department of Veterans Affairs (VA).
- VHA has an intramural research program which is Veteran-centric.
  - The Agency does not have granting authority to fund non-VA investigators.
  - One must be a VA employee to be a VA Investigator.

Background (cont.): Veterans Health Administration and Human Subjects Research

- VA conducts thousands of collaborative research studies with Universities, other federal agencies and departments, and industry yearly.
  - VA-funded
  - Extramural funded
  - Unfunded
  - Domestic and international
- The VHA Office of Research and Development (ORD) is responsible for creation and publication of the majority of human research policies and guidance for the Agency, including Agency policies implementing the 2018 Common Rule
  - VHA Directive 1200.05(3): Requirements for the Protection of Human Subjects in Research is the VA's primary implementation policies for the 2018 Common Rule Requirements.
- VHA "generally" adheres to OHRP-developed guidance and other resources unless it conflicts with Agency policy.
- Reportable events are reported to OHRP even if the studies are not HHS-funded because all VA Facilities conducting non-exempt human subjects research must have a Federalwide Assurance (FWA).

How ORD First Became Associated with SMART IRB

Key VA-Specific Policies and Procedures Applying to VA's Implementation of the Cooperative Research Provisions

- Types of IRBs currently allowed to be reviewing IRBs for VA Facilities.
- Types of institutions a VA Facility's IRB or the VA Central IRB may currently serve as a reviewing IRB, and
- Exception process for use of a single IRB utilized by the Office of Research and Development (ORD) when ORD determines it is not appropriate to use a single IRB for the specified study.

Common Question Asked by ORD: "Is VA Required to Follow the 2018 Common Rule Cooperative Research Provisions (e.g., Single IRB Requirement)?

YES

VA's Implementation of the Cooperative Research Provisions

- ORD supports use of a single IRB whenever it is possible.
- Even prior to the 2018 Common Rule, ORD established a VA Central IRB for ORD-funded multisite studies in 2008 to facilitate single IRB use within VA for ORD-funded multi-site studies.
- VA codified the 2018 Common Rule requirements as 38 CFR Part 16.
- VA as a Common Rule signatory agency applies the Common Rule to all human subjects research meeting the definitions of research and human subject under the Common Rule.

Why Does VA Apply the Common Rule to All Human Subjects Research Meeting the Definition of “Research” and “Human Subject”?

The Reason why IRBs reviewing VA Research Must Apply the Common Rule to VA Research Regardless of Funding

The Common Rule requires it:

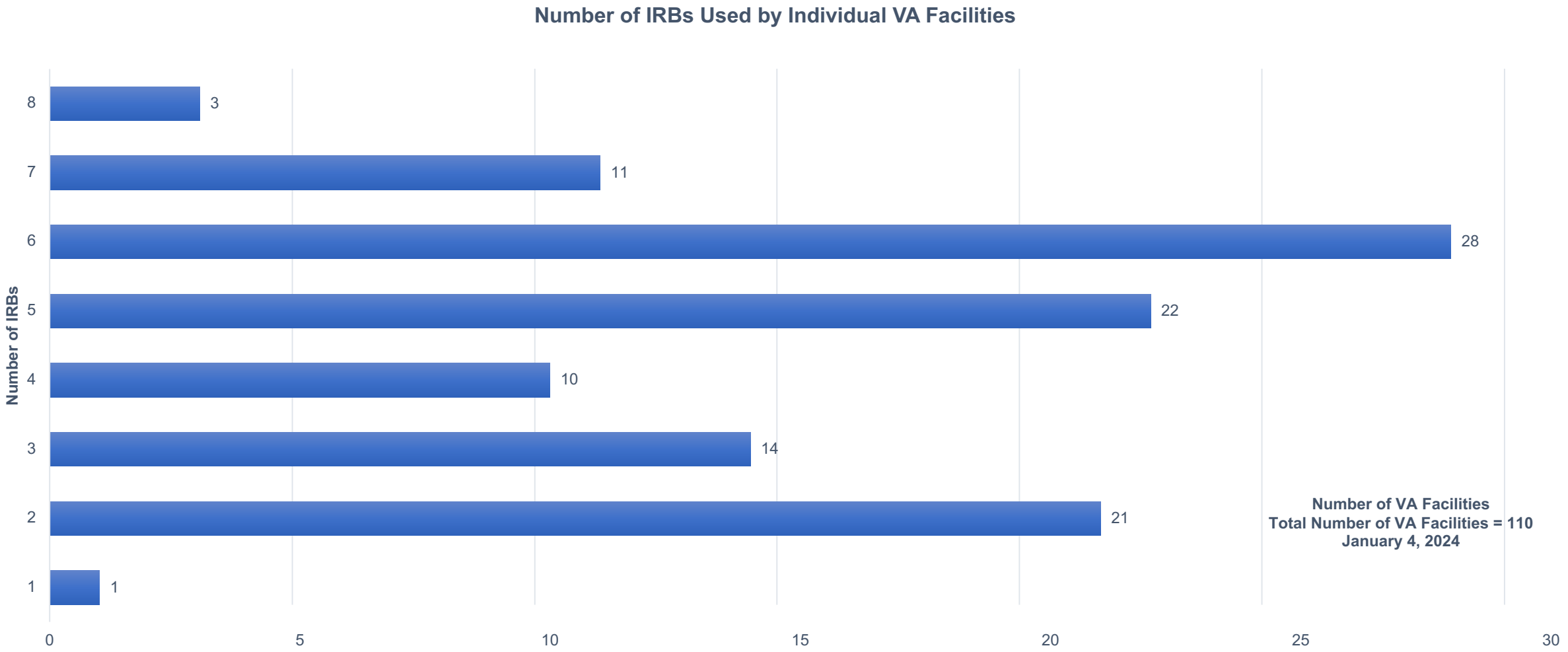
§16.101 To what does this policy apply?

(a) Except as detailed in §46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

Types of IRBs Currently Allowed to be Reviewing IRBs for VA Facilities

- VA Facilities with approved research programs may rely upon:
  - the VA Facility's IRB(s) of Record (if the VA Facility chooses to have one);
  - VHA Central Office IRB (VA Central IRB);
  - an IRB of another VA facility;
  - the IRB(s) of a medical or dental school;
  - the IRB of another Federal agency;
  - an IRB for multi-site protocols that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities; and
  - ORD-designated commercial IRBs.

Number of IRBs Used by Individual VA Facilities



Types of Institutions a VA Facility's IRB or the VA Central IRB May Currently Serve as a Reviewing IRB

- A VA facility's own IRB, also known as an internal IRB, and the VA Central IRB, cannot serve as an IRB of Record for any non-VA entity except:
  - Department of Defense (DoD) facility,
  - Department of Energy laboratory, or a
  - VA Nonprofit Corporation.
- ORD has the ability to obtain a waiver to allow a VA IRB to be the IRB of Record for another federal entity.

Will VA Facility IRBs or the VA Central IRB Be Able to Serve as Reviewing IRBs for Universities?

VA's Use of Exceptions to the Cooperative Research Provisions

Cooperative Research Provisions

§16.114 Cooperative Research.

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

> (i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
> (ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

VA's Process for Determining and Documenting When an Exception from the "Single IRB" Requirement Applies

- The VA Facility research leadership (not the investigator) must make the request.
- Only ORD can approve the request if an exception to use of a single IRB for non-exempt multisite research is granted for applicable studies.
- If ORD grants a single IRB exception, it applies to all VA sites in the study, but it does not apply to any non-VA sites.
- ORD never grants an exception to use of a single IRB because of "site preferences".

Can ORD Approve a Single IRB Exception for VA Sites in a Non-Exempt Multi-Site study Funded by Another Federal Agency (e.g., NIH, DoD)?

The Common Rule Agencies recognize each other's authority to grant exceptions for those institutions under that Agency's authority.

Frequently Asked Question: Single IRB Policy for Multi-Site Research: National Institute of Health

Question: Can Department of Veterans Affairs (VA) and Department of Defense (DoD) sites participate in NIH-funded multisite studies if the VA or DoD makes a determination that the use of a single IRB for the VA or DoD site(s) is not appropriate?

Answer: Yes. NIH will accept determinations by the VA or the DoD that the use of a single IRB is not appropriate for specified VA or DOD site(s) participating in NIH-funded multisite studies. A special exception request issued by NIH is not necessary. All remaining sites in NIH-funded multisite studies are expected to comply with the single IRB requirement unless they have received an exception issued by NIH or HHS.

Source: Frequently Asked Questions (FAQs) | grants.nih.gov

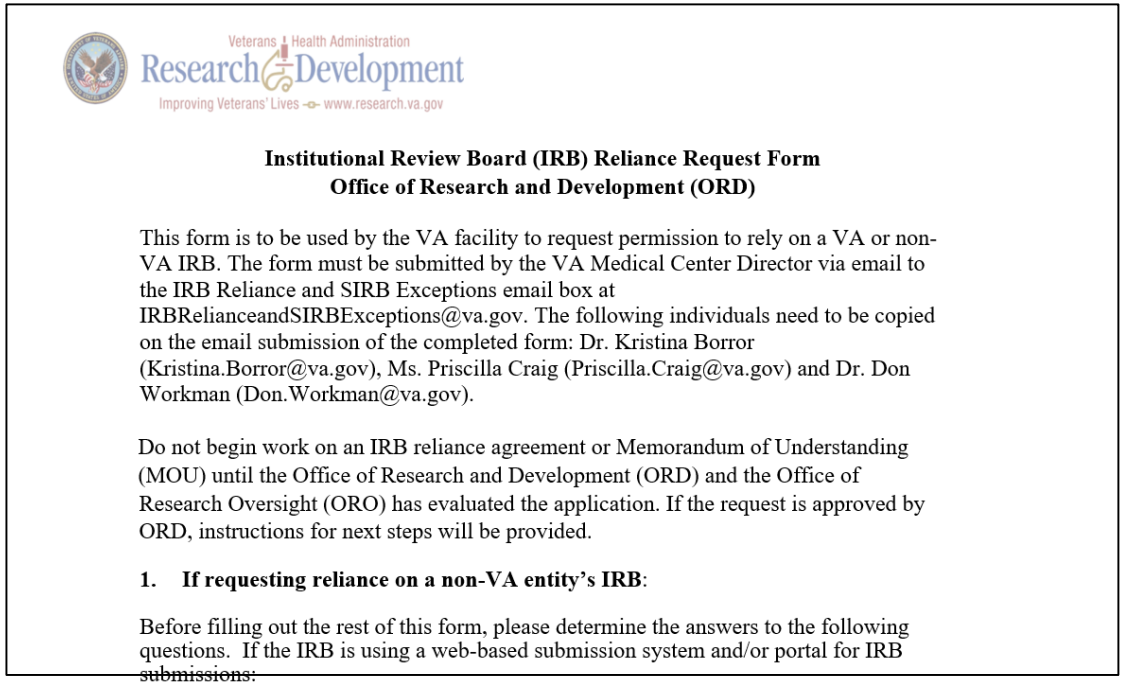
Requesting Changes in IRB Arrangements: New IRB Reliance

What Happens When a VA Facility Requests to Add Another IRB to its Research Program as a Reviewing IRB?

- ORD national policy requires the VA Facility Director to request approval from ORD when a VA Facility wishes to change (add or remove) an IRB from its VA Facility research program.
- ORD has standardized processes in place for VA Facilities requesting to seek an IRB reliance to ensure that:
  - Information security requirements are met to allow the VA Facility to use the institution's electronic IRB platform (if the institution utilizes an electronic platform);
  - Both the VA Facility and the requested institution's IRB both wish to obtain the IRB reliance;
  - Vetting of the institution's IRB policies occur;
  - The VA Facility has written procedures in place to allow the reliance to occur; and
  - The IRB reliance agreement is executed prior to studies being reviewed.

The Initial Step for a VA Facility Seeking a Reliance on a Non-Commercial IRB is to Complete the Application

- VA Facilities wishing to change IRB arrangements for a single or multiple studies must submit the ORD application form: *Institutional Review Board (IRB) Reliance Request Form*.



Veterans Health Administration
Research Development
Improving Veterans' Lives www.research.va.gov

Institutional Review Board (IRB) Reliance Request Form
Office of Research and Development (ORD)

This form is to be used by the VA facility to request permission to rely on a VA or non-VA IRB. The form must be submitted by the VA Medical Center Director via email to the IRB Reliance and SIRB Exceptions email box at IRBRelianceandSIRBExceptions@va.gov. The following individuals need to be copied on the email submission of the completed form: Dr. Kristina Borror (Kristina.Borror@va.gov), Ms. Priscilla Craig (Priscilla.Craig@va.gov) and Dr. Don Workman (Don.Workman@va.gov).

Do not begin work on an IRB reliance agreement or Memorandum of Understanding (MOU) until the Office of Research and Development (ORD) and the Office of Research Oversight (ORO) has evaluated the application. If the request is approved by ORD, instructions for next steps will be provided.

1. **If requesting reliance on a non-VA entity's IRB**:

Before filling out the rest of this form, please determine the answers to the following questions. If the IRB is using a web-based submission system and/or portal for IRB submissions:

Five Basic Steps When a VA Facility Requests an IRB Reliance on a University IRB

VA Facility Application to ORD for IRB Reliance

IRB Reliance Agreement Negotiated and Executed as VA Facility and Institutional IRB develop implementation SOPs

ORD Review of Application with Initial Documentation of Information Security Issues Before Proceeding

ORD Issues Approval or Disapproval of IRB Reliance to VA Facility Director

Meeting Between ORD, VA Facility and Institutional IRB Key Personnel to Address Issues if Applicable After ORD Review of IRB SOPs

How Long Does This Process Take?

Two Key Issues Directly Impacting the IRB Reliance Request Related to Use of the Institution IRB's Electronic Platform

1. The method of electronic transmission between the VA Facility and the Reviewing Institution's IRB must meet federal information security requirements.
    - Application Question: Does the web application and/or portal meet FIPS 140-2 requirements for transmission of information from VA to the system? (The web application and/or portal must implement encryption for TLS transmission using FIPS 140-2 validated cryptographic ciphers in accordance with NIST 800-52 (Rev 1) and NIST 800-131A (Rev 1)).
2. The VA Investigator must be able to have access to the institution IRB's electronic platform.
    - Application Question: Are VA Investigators able to log directly into the IRB's system for submission and retrieval of documents and IRB correspondence using their va.gov email address? (Please provide an email or other documentation verifying that access will be granted to VA Investigators using a va.gov address or access independent of the VA Investigator being an employee of the non-VA entity).

Other Key Factors Impacting IRB Reliance

- Reliance requested for single study vs. multiple studies
- Communication between Institutions
- Timeline for needed reliance
- Available resources

VA Specific Requirements

- VA specific requirements (“VA isms”) related to IRB reviews of VA research
  - Informed consent
  - The Privacy Rule (Health Insurance Portability and Accountability Act of 1996)
  - Other required reviews (e.g., information security, privacy)
  - VA Research and Development Committee

VA Specific Requirements: IRB Review of VA Studies

In 2010 ORD's primary policy for implementation of the Common Rule for VA research was 144 pages long.

In 2019, ORD substantially reduced its primary policy for implementation of the Common Rule for VA research with the revision of the Common Rule ("the 2018 Requirements") into a 45-page policy document.

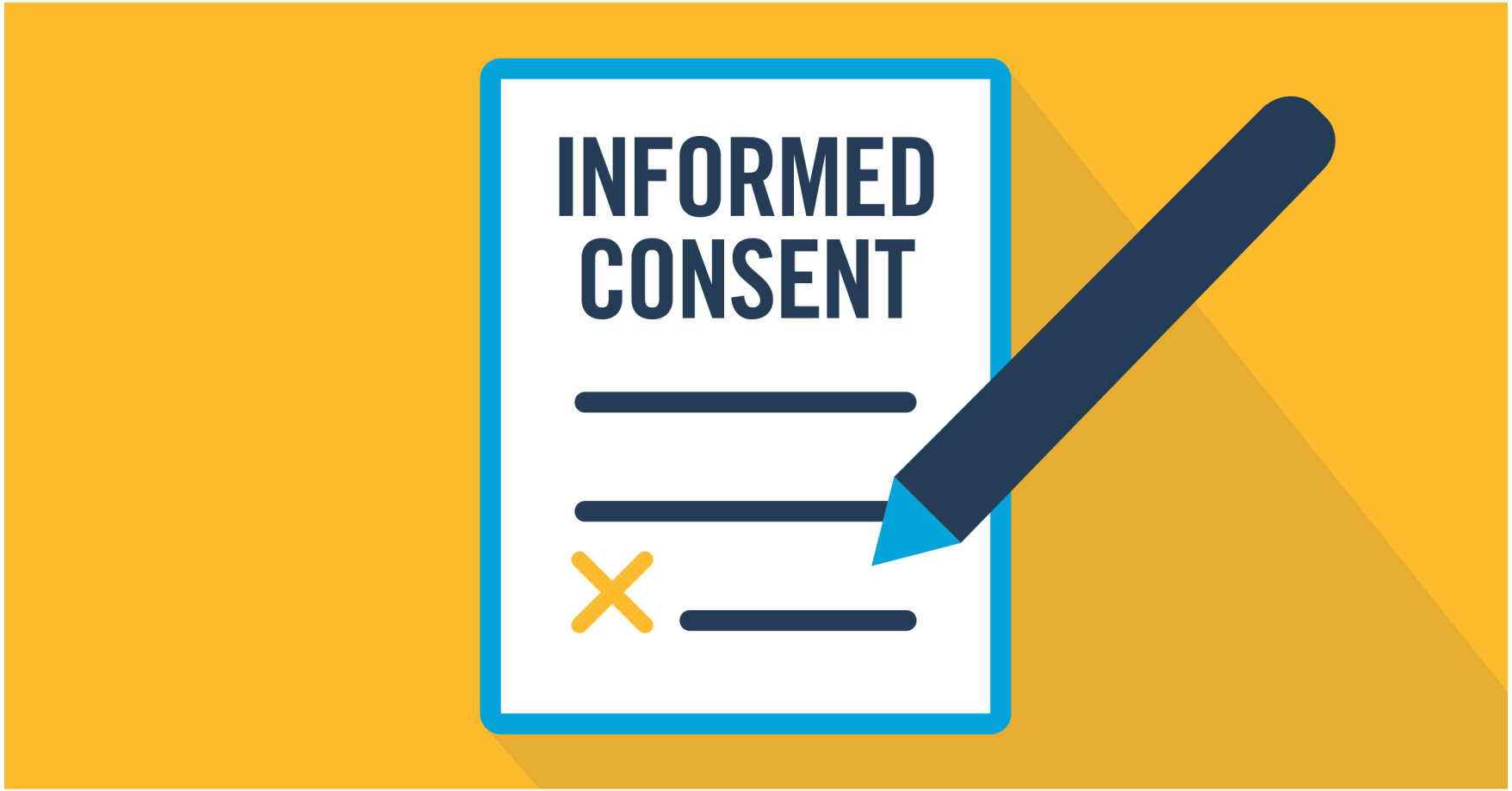
Origin or Basis for the Majority of the VA Specific Requirements Related to VA Research

- Most VA specific requirements related to review of VA Research are based on:
  - VA specific law,
  - VA specific regulations,
  - An Executive order, or
  - A sentinel event or Agency need.
- With the above stated, there are still a few VA specific requirements that are based on past legacy.

What are some VA Requirements that NO Longer Exist as of 2019 (including the present) Related to IRB Review?

- It is no longer a VA requirement that:
  - A VA paid employee of a relying VA Facility must be a voting member of the reviewing IRB;
  - The reviewing IRB must vote to approve IRB minutes;
  - The person obtaining consent must also sign and date the IRB-approved informed consent document when obtaining consent from the subject's (or subject's legally authorized representative);
  - The reviewing IRB must apply VA specific policy criteria when reviewing VA studies involving subjects with impaired decision-making capacity;
  - The reviewing IRB must approve the inclusion of non-Veterans; and
  - The reviewing IRB must "stamp" the IRB approval date of informed consent forms.
- There is also no longer a requirement to use a VA specific form (VA Form 10-1086) as the VA template for informed consent.

What are Some of the VA Specific Requirements for IRBs Reviewing VA Research?


INFORMED
CONSENT

VA Specific Requirements – Informed Consent

- VA requires informed consent documents approved by an IRB to be both dated and signed by the subject or the subject's legally authorized representative.
- Documentation of consent may be obtained electronically if it contains the required information to long as the informed consent process meets all of ORD's requirements for informed consent and VA requirements for use of electronic signatures.
  - VA's requirements for use of electronic signatures must meet government requirements for authentication and identification.
- Broad consent can only be used in VA research when identifiable data or biospecimens are collected solely for research purposes.

VA Specific Elements: Informed Consent

- ORD policy has four (4) VA specific informed consent information requirements which may or may not be applicable depending upon the study:
  - VA Treatment for Research-Related Injuries,
  - Costs for Study Participation Paragraph,
  - Consent for Photographs, Video, or Audio Recordings, and
  - Certificates of Confidentiality (CoCs).

VA Treatment for Research-Related Injury

- ORD policy (VHA Directive 1200.05(3), Paragraph 17.d.(10)) requires that the following be provided:
  - A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85 (see section 24 of this directive). NOTE: VA's statutory requirements in 38 CFR 17.85 apply regardless of inclusion of the information as part of the informed consent process.
- VA as an Agency has a commitment that no VA subject will be responsible if injured in a research study (with a few exceptions).

Costs for Study Participation

- ORD policy (VHA Directive 1200.05(3), Paragraph 17.e.(10)) requires the following information be provided:
  - When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. NOTE: Some Veterans are required to pay copayments for medical care and services specifically related to their medical care provided by VA. These co-payment requirements will continue to apply to medical care and services that are not part of the research procedures or interventions.
- The Agency has a commitment that no VA subject will pay for costs directly related to participating in a research study.

Consent for Photographs, Audio, or Video Recordings

- ORD policy (VHA Directive 1200.05(3), Paragraph 17.k.) requires informed consent language to be included when photographs, video, and/or audio recordings are taken or obtained exclusively (solely) for research purpose:
  - A description of any photographs, video, and/or audio recordings to be taken or obtained for research purposes;
  - How the photographs, video, and/or audio recordings will be used for the research; and
  - Whether the photographs, video, and/or audio recordings will be disclosed outside VA.

Certificates of Confidentiality (CoC)

- Any National Institute of Health (NIH) funded study submitted to an IRB will automatically have a CoC.
- VA does not have authority to issue CoCs for its own studies.
- If a VA Principal Investigator (PI) conducting a VA study wishes to seek obtaining a CoC, an application must be submitted to the NIH for review and determination of approval or disapproval.
- If an IRB requires the multi-site study to have a CoC, an individual VA participating site (not the lead site) cannot apply for a CoC because that specific site PI wishes to have a CoC.

Certificates of Confidentiality Statement Requirements for VA Informed Consents

- ORD policy (VHA Directive 1200.05(3), Paragraph 22) requires the following information to be provided for VA studies with a CoC:
  - c. When VA conducts a study that is protected by a Certificate of Confidentiality, the following requirements apply:

    (1) For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record; and

    (2) For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. NOTE: The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included in informed consent documents describing Certificates of Confidentiality.

ORD Specific Tools for Informed Consent

- To facilitate review of VA studies sponsored by industry and facilitate inclusion of VA specific elements of informed consent into the ICDs during submission to commercial IRBs, ORD developed tools to assist VA study teams and facilitate reviews.
- These Tools are available for any IRB reviewing VA studies:
  - VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using an Independent-Commercial IRB Revised 06/28/2023
  - VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB Revised 06/28/2023
  - Checklist for VA Facilities Using Independent Commercial IRBs-ICDs and Combined ICD-HIPAA Authorizations Revised 06/28/2023

Tool: VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using an Independent Commercial IRB)

VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using an Independent (Commercial) IRB
June 28, 2023

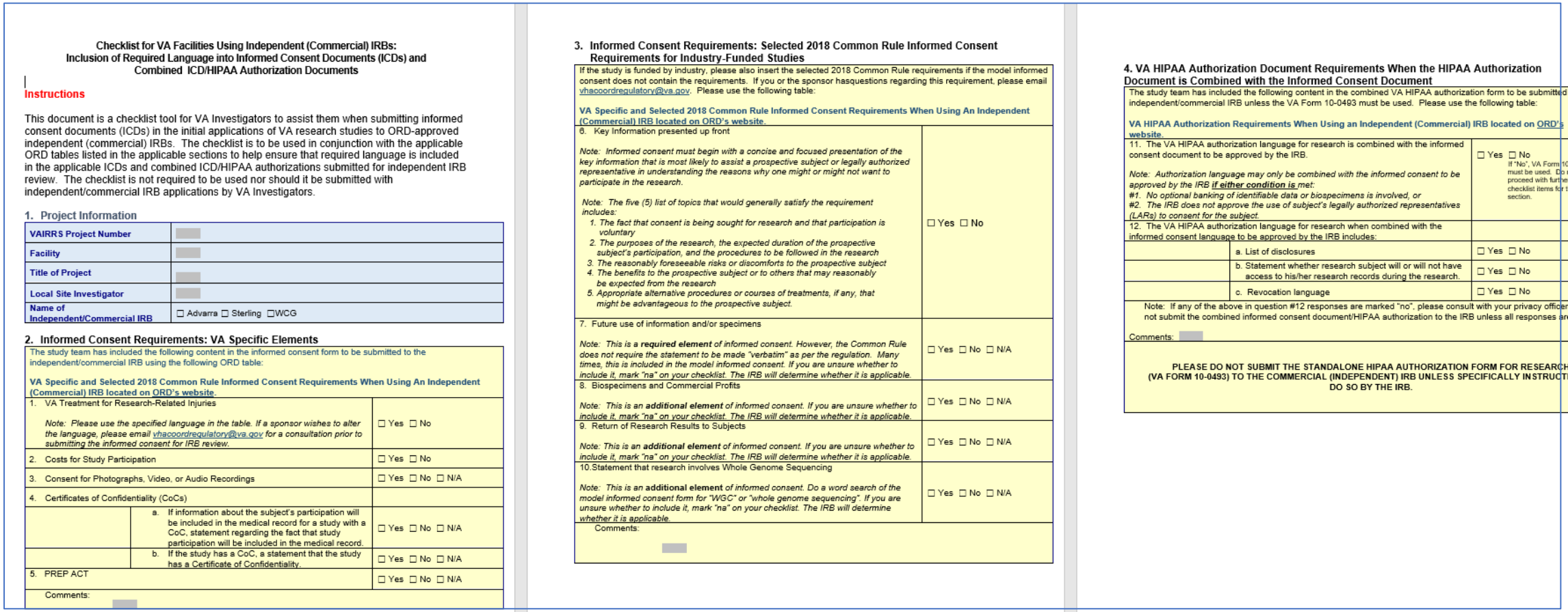
The following instructions with language for VA informed consent documents (ICDs) are provided in this table.

VA specific informed consent requirements, as applicable, must be included in all ICDs submitted during the application submission to the independent IRBs.

If the study is funded by industry, please also insert the applicable selected 2018 Common Rule requirements if the model informed consent does not contain the requirements.

Policy or Law	Citation and Topic	Policy Language	Language Provided to the Commercial IRBs	Comments
VHA Directive 1200.05(2)	Paragraph 17.d.(10) VA Treatment for Research-Related Injuries	A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85. **NOTE:** *VA's statutory requirement in 38 CFR 17.85 apply regardless of inclusion of the information as part of the informed consent process.*	As a VA study participant, the VA (not you or your insurance) will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the (***insert local name***) VAMC or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at (***insert phone number***). If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call (***fill in numbers***).	**The study is not required to include this language if the VA informed consent document is required to include the VA required language consistent with the PREP Act; the PREP Act informed consent language addresses this policy requirement for COVID-19 related research involving medical countermeasures.** Please note that the terms of the current PREP Act declaration for COVID -19 countermeasures, PREP Act coverage will end if the public health emergency and all other emergency declarations end, and there is no federal agreement relevant to the activity. It is preferred (but not required by ORD policy) that sponsors remove their template language addressing research-related injuries if present.

Checklist for VA Facilities Using Independent (Commercial) IRBs: Inclusion of Required Language into Informed Consent Documents (ICDs) and Combined ICD/HIPAA Authorization Documents



Checklist for VA Facilities Using Independent (Commercial) IRBs: Inclusion of Required Language into Informed Consent Documents (ICDs) and Combined ICD/HIPAA Authorization Documents

Instructions

This document is a checklist tool for VA Investigators to assist them when submitting informed consent documents (ICDs) in the initial applications of VA research studies to ORD-approved independent (commercial) IRBs. The checklist is to be used in conjunction with the applicable ORD tables listed in the applicable sections to help ensure that required language is included in the applicable ICDs and combined ICD/HIPAA authorizations submitted for independent IRB review. The checklist is not required to be used nor should it be submitted with independent/commercial IRB applications by VA Investigators.

1. Project Information

VAIRRS Project Number	
Facility	
Title of Project	
Local Site Investigator	
Name of Independent/Commercial IRB	☐ Advarra ☐ Sterling ☐WCG

2. Informed Consent Requirements: VA Specific Elements

The study team has included the following content in the informed consent form to be submitted to the independent/commercial IRB using the following ORD table:

VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using An Independent (Commercial) IRB located on ORD's website.

1. VA Treatment for Research-Related Injuries *Note: Please use the specified language in the table. If a sponsor wishes to alter the language, please email vhacoordregulatory@va.gov for a consultation prior to submitting the informed consent for IRB review.*		☐ Yes ☐ No
2. Costs for Study Participation		☐ Yes ☐ No
3. Consent for Photographs, Video, or Audio Recordings		☐ Yes ☐ No ☐ N/A
4. Certificates of Confidentiality (CoCs)		
	a. If information about the subject's participation will be included in the medical record for a study with a CoC, statement regarding the fact that study participation will be included in the medical record.	☐ Yes ☐ No ☐ N/A
	b. If the study has a CoC, a statement that the study has a Certificate of Confidentiality.	☐ Yes ☐ No ☐ N/A
5. PREP ACT		☐ Yes ☐ No ☐ N/A
Comments:		

3. Informed Consent Requirements: Selected 2018 Common Rule Informed Consent Requirements for Industry-Funded Studies

If the study is funded by industry, please also insert the selected 2018 Common Rule requirements if the model informed consent does not contain the requirements. If you or the sponsor hasquestions regarding this requirement, please email vhacoordregulatory@va.gov. Please use the following table:

VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using An Independent (Commercial) IRB located on ORD's website.

6. Key Information presented up front *Note: Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.* *Note: The five (5) list of topics that would generally satisfy the requirement includes:* *1. The fact that consent is being sought for research and that participation is voluntary* *2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research* *3. The reasonably foreseeable risks or discomforts to the prospective subject* *4. The benefits to the prospective subject or to others that may reasonably be expected from the research* *5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.*	☐ Yes ☐ No
7. Future use of information and/or specimens *Note: This is a **required element** of informed consent. However, the Common Rule does not require the statement to be made "verbatim" as per the regulation. Many times, this is included in the model informed consent. If you are unsure whether to include it, mark "na" on your checklist. The IRB will determine whether it is applicable.*	☐ Yes ☐ No ☐ N/A
8. Biospecimens and Commercial Profits *Note: This is an **additional element** of informed consent. If you are unsure whether to include it, mark "na" on your checklist. The IRB will determine whether it is applicable.*	☐ Yes ☐ No ☐ N/A
9. Return of Research Results to Subjects *Note: This is an **additional element** of informed consent. If you are unsure whether to include it, mark "na" on your checklist. The IRB will determine whether it is applicable.*	☐ Yes ☐ No ☐ N/A
10.Statement that research involves Whole Genome Sequencing *Note: This is an **additional element** of informed consent. Do a word search of the model informed consent form for "WGC" or "whole genome sequencing". If you are unsure whether to include it, mark "na" on your checklist. The IRB will determine whether it is applicable.*	☐ Yes ☐ No ☐ N/A
Comments:	

4. VA HIPAA Authorization Document Requirements When the HIPAA Authorization Document is Combined with the Informed Consent Document

The study team has included the following content in the combined VA HIPAA authorization form to be submitted to the independent/commercial IRB unless the VA Form 10-0493 must be used. Please use the following table:

VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB located on ORD's website.

11. The VA HIPAA authorization language for research is combined with the informed consent document to be approved by the IRB. *Note: Authorization language may only be combined with the informed consent to be approved by the IRB **if either condition is** met:* *#1. No optional banking of identifiable data or biospecimens is involved, or* *#2. The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject.*		☐ Yes ☐ No If "No", VA Form 10-0493 must be used. Do not proceed with further checklist items for this section.
12. The VA HIPAA authorization language for research when combined with the informed consent language to be approved by the IRB includes:		
	a. List of disclosures	☐ Yes ☐ No
	b. Statement whether research subject will or will not have access to his/her research records during the research.	☐ Yes ☐ No
	c. Revocation language	☐ Yes ☐ No

Note: If any of the above in question #12 responses are marked "no", please consult with your privacy officer. Do not submit the combined informed consent document/HIPAA authorization to the IRB unless all responses are "yes".

Comments:

PLEASE DO NOT SUBMIT THE STANDALONE HIPAA AUTHORIZATION FORM FOR RESEARCH (VA FORM 10-0493) TO THE COMMERCIAL (INDEPENDENT) IRB UNLESS SPECIFICALLY INSTRUCTED TO DO SO BY THE IRB.

VA and HIPAA

VA Specific Requirements: Combining the HIPAA Authorization with the Informed Consent Document

- VHA is a covered entity and has some VA specific requirements regarding authorizations for research.
- VHA does not allow an alteration of a waiver of HIPAA authorization to be approved by an IRB or Privacy Board for VA research.
- HIPAA authorization for research language may only be combined with the informed consent to be approved by the IRB if either condition is met:
  - No optional banking of identifiable data or biospecimens is involved, or
  - The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject.
- VA Form 10-0493 must be used if a standalone HIPAA authorization document is required.

Who is Responsible for Ensuring the HIPAA Authorization Meets the Agency's Requirements?

- It is the responsibility of the VA Facility (not the IRB) to ensure the authorization language meets the requirements for a valid HIPAA authorization.
- To facilitate review of VA studies sponsored by industry and facilitate privacy officer reviews during submission to commercial IRBs, ORD developed tools to assist VA study teams and facilitate reviews.
- These tools are available on the web for all IRBs reviewing VA research.

Tool: VA HIPAA Authorization Requirements

Veterans Health Administration
Research & Development
Improving Veterans' Lives -- www.research.va.gov

VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB
June 28, 2023

The following instructions with language for VA HIPAA authorizations for research when combined with the informed consent document (ICD) have been provided in this table. Please use this table to also determine if a standalone written HIPAA authorization for research (VA Form 10-0493) is required or whether the authorization language can be combined with the ICD.

VA Facilities must include the VA authorization language into the informed consent document as a replacement for the model authorization language where applicable or use the VA Form 10-0493 as part of independent IRB application requirements. If there are questions regarding this language, please email vhacoordregulatory@va.gov.

If the study involves a standalone written HIPAA authorization (VA Form 10-0493), do not submit the VA Form 10-0493 to the independent (commercial IRB)

Policy or Law	Citation and Topic	Policy Language	Language Provided to the Independent IRBs	Comments
VHA Directive 1200.05(2) VHA Directive 1605.03 (2)	Paragraph 23.a.(1) Appendix D, Paragraph 1.k.(5)(b)(2)(f) Authorization Requirements and Authorization language when the ICD and authorization is combined: entities for use or disclosure of protected health information.	(1) Authorization must meet all VHA Privacy requirements detailed in VHA Directive 1605.01. The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research located at http://vaww.va.gov/vaforms/medical/pdf/10-0493-fill.pdf must be used (NOTE: This is an internal VA Web site that is not available to the public.	When the Authorization Language is combined with the informed consent to be approved by the IRB, the following authorization language is provided: There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule. The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.	Authorization language may only be combined with the informed consent to be approved by the IRB if either condition is met: #1. No optional banking of identifiable data or biospecimens is involved, OR #2. The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject. **If there is optional banking of identifiable data or biospecimens, the HIPAA authorization language for research cannot be combined with the informed consent document.** **If the IRB has approved the use of subjects' LARs to consent, the HIPAA authorization language for research cannot be combined with the informed consent document.**

Information Security and Privacy Reviews

Required Information Security and Privacy Review

- VA requires both an initial privacy review and information security review prior to IRB review.
- It is not the responsibility of the reviewing IRB to ensure these reviews occur prior to the IRB's review; it is the responsibility of the VA Facility research program.
- A final privacy and information security review occurs prior to the VA Research and Development Committee approval.

Committee

VA Research and Development Committee

- The VA Research and Development (R&D) Committee is a VA-specific committee.
- A study is not VA research unless it is approved by the VA Facility's Research and Development committee.
- The R&D Committee serves as an institutional governance committee for purposes of research approved by an IRB.
- The R&D Committee is not constituted by an IRB, and does not serve as an IRB in its review.

Most Common Question ORD Receives About R&D Committees and IRBs: Informed Consent

Question: A study has received initial approval by the IRB of Record for the study. The study has received all approvals, including VA R&D Committee approval. Three months after the study has been initiated, the study requires amending to revise the number of study visits and schedule of assessments, including an informed consent modification. The IRB of Record approves the amendment.

Is the R&D Committee required to approve the amendment, including approval of the informed consent modification before the VA Investigator can initiate the amendment?

Is the R&D Committee required to approve the amendment, including approval of the informed consent modification before the VA Investigator can initiate the amendment?

- ORD policy (VHA Directive 1200.01(1), Paragraph 9.b.(4)) does not require the R&D Committee to review amendments of a study under the oversight of another committee UNLESS it is for inclusion of non-Veterans.

VA Research and Development Committee

- The R&D Committee is responsible for conducting an annual review each year of all research related committees and subcommittees utilized by the VA Facility.
- When a VA facility uses an IRB other than its own internal IRB the role of the R&D Committee is to review and evaluate facility-specific aspects of these relationships, rather than the subcommittee itself, to ensure the obligations as detailed in the IRB Reliance Agreement are being met.

Summary

- This presentation has focused on some key VA specific requirements related to IRB review of VA research.
- VA has eliminated or modified many VA specific requirements over the last five years to meet the needs of the Agency, including facilitating research.
- ORD as the primary policy office responsible for most of the VA's policies impacting IRB review of VA research is continually working to facilitate relationships between our VA Facilities and IRBs by developing tools and conducting educational activities.
- SMART IRB is an important part of the Agency's commitment to facilitating collaborative research and single IRB implementation.

References

- Frequently Asked Questions (FAQs) | grants.nih.gov
- ORD webpage: IRB Relationships in the VA: Single IRB Exceptions, Independent (Commercial) IRBs, and changing IRB reliance by the VA Facility
  - VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using an Independent-Commercial IRB (Revised 04/03/2023)
  - VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB (Revised 04/03/2023)
  - Checklist for VA Facilities Using Independent Commercial IRBs-ICDs and Combined ICD-HIPAA Authorizations (New 04/03/2023)
- VHA Directive 1200.01(1): Research and Development Committee (issued January 24, 2019) at VHA Publications
- VHA Directive 1200.05(3): Requirements for the Protection of Human Subjects in Research (issued January 7, 2019) at VHA Publications.

Questions