Human Research Protection Updates in VA Research

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VHA Office of Research and Development (ORD)

May 13, 2022

- ✓ A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar

- ✓ An archive of all ORPP&E webinars can be found here: https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm

- ✓ Please use the Q&A feature to submit questions.
  - ✓ **Please do not use Chat to send in questions.**
  - ✓ **Be sure to send questions to "All panelists".**

- ✓ We would be ever so grateful if you would complete the post-webinar evaluation survey that pops up once you exit the webinar.

- ✓ Experiencing sound issues – you can call in using the number included on the handouts and on your registration confirmation email that you received.

Objectives

- Describe recent changes in VA informed consent documentation for the National Cancer Institute Central Institutional Review Board (NCI CIRB).
- Identify new process for submission of applications for proactive calling (“cold calling)” using the new Proactive Calling SharePoint portal.
- Describe the rationale why written guidance was recently issued on California state law applicability for separation of the written IRB-approved informed consent document (ICD) and written HIPAA authorization for VA research.
- Differentiate myth vs. fact on issues involving:
  - DocuSign and
  - Commercial IRBs used in VA research.

Recent Changes in VA Informed Consent Documentation for the NCI CIRB

National Cancer Institute Central IRB: NCI CIRB

- The NCI CIRB oversees multi-site studies sponsored by the National Cancer Institute.
- Forty-six (46) VA Facilities have VA approved IRB reliance agreements with the NCI CIRB.
- The NCI IRB (which has over 2700 institutions with executed IRB reliance agreements) has a VA boilerplate informed consent form (ICF) used as the template for all VA participating sites.
- When VHA Directive 1200.05 was published on January 7, 2019, two VA specific informed consent policy requirements related to Certificates of Confidentiality Paragraph 22 were required to be included in the NCI CIRB VA boilerplate.

VHA Directive 1200.05(2): Paragraph 22.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.

NCI CIRB: Rationale for Creation of the VA Informed Consent Addendum

- The existing NCI CIRB VA boilerplate ICF at that time did not contain the ORD national policy requirements.
- Modifications to the NCI CIRB VA boilerplate require review processes by the NCI CIRB administration.
- The NCI CIRB approved the “Department of Veterans Affairs Informed Consent Addendum” on December 22, 2019.
- ORD published written guidance on January 3, 2020 stating that the Addendum was to be used for all new NCI studies approved after January 6, 2020 by the NCI CIRB until revisions were approved by the NCI CIRB to the VA boilerplate language containing the VA specific requirements for informed consent documents.

VA Informed Consent Addendum for NCI CIRB Studies – 12-22-2019

Department of Veterans Affairs Informed Consent Addendum

Name of Study: _____

As a VA subject participant, you are also being provided additional information about what is placed in your medical record:

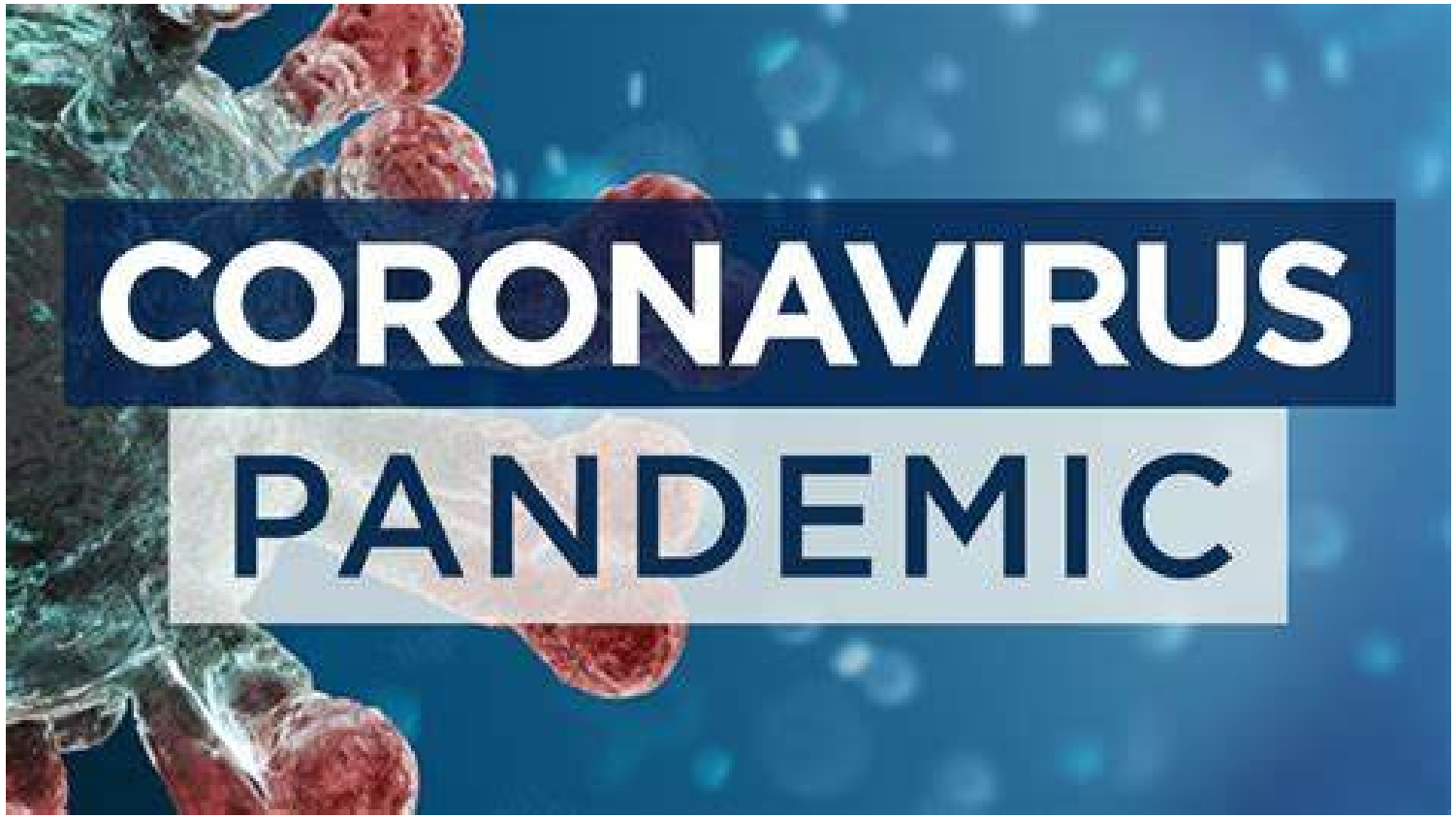
Who will See My Medical Information?

Information has been provided to you that the study doctors have a privacy permit. This privacy permit is called a Certificate of Confidentiality. In addition to help protecting your study records if there is a court case, the Certificate of Confidentiality also does not allow researchers to release research information identifying you to other people not connected with the study unless you allow it except in a few situations, such as if is required by law. However, your study doctors will put information about your participation in this study in your VA medical record for your safety. It is important for other health care providers taking care of you to know any study drugs or study treatments you are receiving.

_____
Participant's signature

_____
Date of signature

Events Occurred Impacting the Approval of the Revisions in the VA Boilerplate Language



Current Status of the Revised NCI CIRB VA Boilerplate Language

VA Boilerplate Language Revisions

- Contains additional language for the section, “Who will see my medical information?”
  - Addresses ORD policy requirements in Paragraph 22.c. regarding certificates of confidentiality.
  - Adds the VA Office of Research Oversight (ORO) and the VA Office of the Inspector General (OIG) as agencies that may see records.
  - Clarifies the signature section to reinforce that while the consent form signature lines cannot be replaced, additional lines may be added.

How Does a VA Facility Implement the Revised NCI CIRB VA Boilerplate Language?

Actions Required to Implement the Revised VA Boilerplate

1. Revise the Annual Signatory Institution Worksheet to include the language in the revised VA NCI template boilerplate language with a date of 04-21-2022.
2. VA Facilities will continue to use the VA Addendum until the new boilerplate document has been approved for their site.
3. Once the language has been approved for your VA Facility by the NCI CIRB, update as applicable your local standard operating procedures to include a statement that the NCI CIRB VA Informed Consent Addendum will not be used.

Questions can be sent to the NCI CIRB Help Desk at ncicirbcontact@emmes.com

Common Question #1: Revised NCI CIRB VA Boilerplate Language

- When the VA Addendum was initiated in Jan. 2020, it was to be used for new studies approved by NCI CIRB after 1/6/20. Do older studies require the addendum or boilerplate language?

Do older studies require the addendum or boilerplate language?

Common Question #1: Revised NCI CIRB VA Boilerplate Language

- **When the VA Addendum was initiated in Jan. 2020, it was to be used for new studies approved by NCI CIRB after 1/6/20. Do older studies require the addendum or boilerplate language?**

- **Answer**: Any NCI CIRB study approved on or prior to 01-06-2020 did not and do not require the addendum or changes to be made in the prior approved VNCI CIRB VA boilerplate language utilized for those studies.

Common Question #2: Revised NCI CIRB VA Boilerplate Language

- Do VA Facilities add all optional signatures (such as witness, “print name”, legally authorized representative) to the VA Facility’s boilerplate if not in the NCI template consent form?

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Common Question #2: Revised NCI CIRB VA Boilerplate Language

- **Do VA Facilities add all optional signatures (such as witness, “print name”, legally authorized representative) to the VA Facility’s boilerplate if not in the NCI template consent form?**

- **Answer**: Yes, signature lines can be added to the boilerplate and used as needed in the informed consent.

Common Question #3: Revised NCI CIRB VA Boilerplate Language

- **What is the corrective action if the NCI CIRB VA Informed Consent addendum was not implemented for NCI trials approved after 1/6/2020?**

Common Question #3: Revised NCI CIRB VA Boilerplate Language

- **What is the corrective action if the NCI CIRB VA Informed Consent addendum was not implemented for NCI trials approved after 1/6/2020?**

- **Answer**: Report it to the NCI CIRB as it falls in the category of apparent serious or continuing Noncompliance involving VA Non-Exempt Human Subjects Research (VHA Directive 1058.01, Paragraph 7.c.) in addition to any other required local VA Facility reporting as per local human research protection program policies and procedures.

Common Question #4: Revised NCI CIRB VA Boilerplate Language

- What is the submission deadline to have the site's updated boilerplate language approved by NCI CIRB and subsequently updated in all active NCI CIRB informed consent documents following approval of the VA Facility's revised boilerplate language?

Common Question #4: Revised NCI CIRB VA Boilerplate Language

- **What is the submission deadline to have the site's updated boilerplate language approved by NCI CIRB and subsequently updated in all active NCI CIRB informed consent documents following approval of the VA Facility's revised boilerplate language?**

- **Answer**: Boilerplate language should be updated now at the next protocol amendment or per Institutional policy if more stringent.

Process for Adding the NCI CIRB as an IRB of Record

1. Contact ORD at irbrelianceandsirbexceptions@va.gov and ORO (Priscilla Craig at priscilla.craig@va.gov and Elizabeth Clark at Elizabeth.clark3@va.gov). Your VA Facility will be guided through each step.
2. Develop local standard operating procedures to be reviewed by ORO (template on VA NCI CIRB SharePoint site).
3. Submit an Institutional Enrollment Form located on the NCI CIRB website. For VA Facilities without a local IRB, an additional questionnaire (Oversight Questionnaire) will be included with the Enrollment Form.
4. Submit an Authorization Agreement to the NCI CIRB.

Process for Adding the NCI CIRB as an IRB of Record (cont.)

5. Following receipt of the Authorization Agreement and final version of the NCI IRB SOPs, the NCI CIRB will grant the VA Facility access to the NCI CIRB Workshops to establish the VA Facility's local context.

- The NCI CIRB Help Desk has VA specialists to assist with this process.

- ORD and ORO have established a VA NCI CIRB SharePoint site with samples SOPs and other documents at Home - NCI Central IRB (sharepoint.com)

New Process for Submission of Applications for Proactive Calling (“Cold Calling)” using the New Proactive Calling SharePoint Portal

Current ORD Policy: VHA Directive 1200.05(2)

VHA Directive 1200.05(2), Paragraph 5(g)(8) states that each VA Investigator is responsible for the following:

"(8) During the recruitment process, making initial contact with potential subjects in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study."

Letter: Refers to hardcopy or electronic

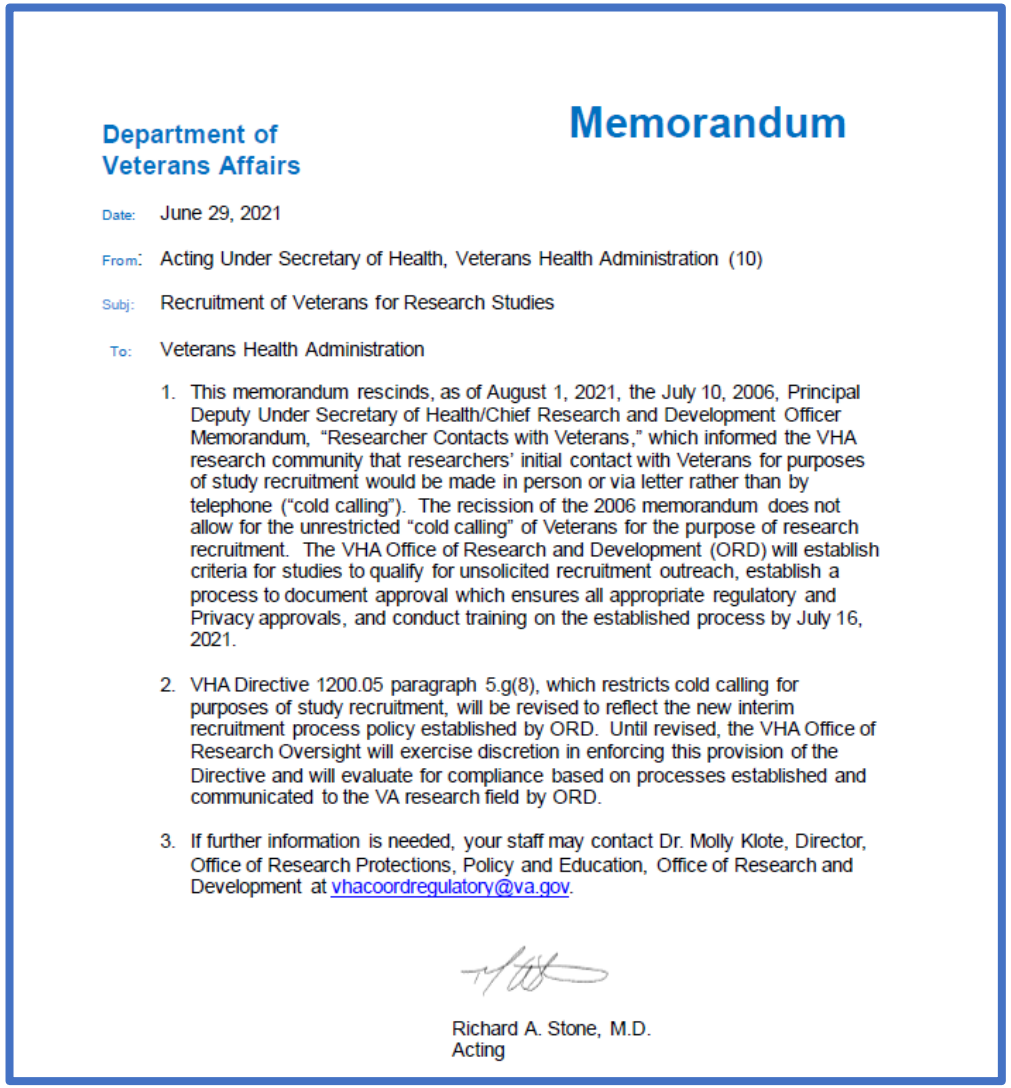
Current ORD Policy: VHA Directive 1200.05(2): Notes

- *NOTE: If existing information from sources such as a medical record or database (research or non-research) are used to identify human subjects, there must be an IRB-approved waiver of HIPAA authorization for this activity in the new protocol;*
  - *(a) Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research;*
  - *(b) If a contractor makes the initial contact by letter, the VA investigator must sign the letter;*
- *NOTE: This section does not apply when a Veteran calls in response to an advertisement;"*

Reference: VHA Directive 1200.05, Paragraph 5(g)(8)

Policy Change

The acting Under Secretary of Health (USH) signed a policy memorandum on June 29, 2021 allowing for the proactive calling of VA subjects for recruitment **only within the parameters that ORD establishes for an ORD approval process.**



Department of Veterans Affairs

Memorandum

Date: June 29, 2021

From: Acting Under Secretary of Health, Veterans Health Administration (10)

Subj: Recruitment of Veterans for Research Studies

To: Veterans Health Administration

1. This memorandum rescinds, as of August 1, 2021, the July 10, 2006, Principal Deputy Under Secretary of Health/Chief Research and Development Officer Memorandum, "Researcher Contacts with Veterans," which informed the VHA research community that researchers' initial contact with Veterans for purposes of study recruitment would be made in person or via letter rather than by telephone ("cold calling"). The recission of the 2006 memorandum does not allow for the unrestricted "cold calling" of Veterans for the purpose of research recruitment. The VHA Office of Research and Development (ORD) will establish criteria for studies to qualify for unsolicited recruitment outreach, establish a process to document approval which ensures all appropriate regulatory and Privacy approvals, and conduct training on the established process by July 16, 2021.

2. VHA Directive 1200.05 paragraph 5.g(8), which restricts cold calling for purposes of study recruitment, will be revised to reflect the new interim recruitment process policy established by ORD. Until revised, the VHA Office of Research Oversight will exercise discretion in enforcing this provision of the Directive and will evaluate for compliance based on processes established and communicated to the VA research field by ORD.

3. If further information is needed, your staff may contact Dr. Molly Klote, Director, Office of Research Protections, Policy and Education, Office of Research and Development at vhacoordregulatory@va.gov.

Richard A. Stone, M.D.
Acting

June 29, 2021 USH Memorandum:
"Recruitment of Veterans for Research Studies"

- Rescinds, as of August 1, 2021, the July 10, 2006, Principal Deputy Under Secretary of Health/Chief Research and Development Officer Memorandum, "Researcher Contacts with Veterans".
- Does not allow for the unrestricted "cold calling" of Veterans for the purpose of research recruitment.
- Requires ORD to establish criteria for studies to qualify for unsolicited recruitment outreach and establish a process to document approval which ensures all appropriate regulatory and Privacy approvals.
- States that the Office of Research Oversight (ORO) will exercise discretion in enforcing ORD policy in VHA Directive 1200.05, Paragraph 5.(g)(8) based on processes established and communicated to the VA research field by ORD until VHA Directive 1200.05 is revised.

August 24, 2021: Proactive Calling Webinar

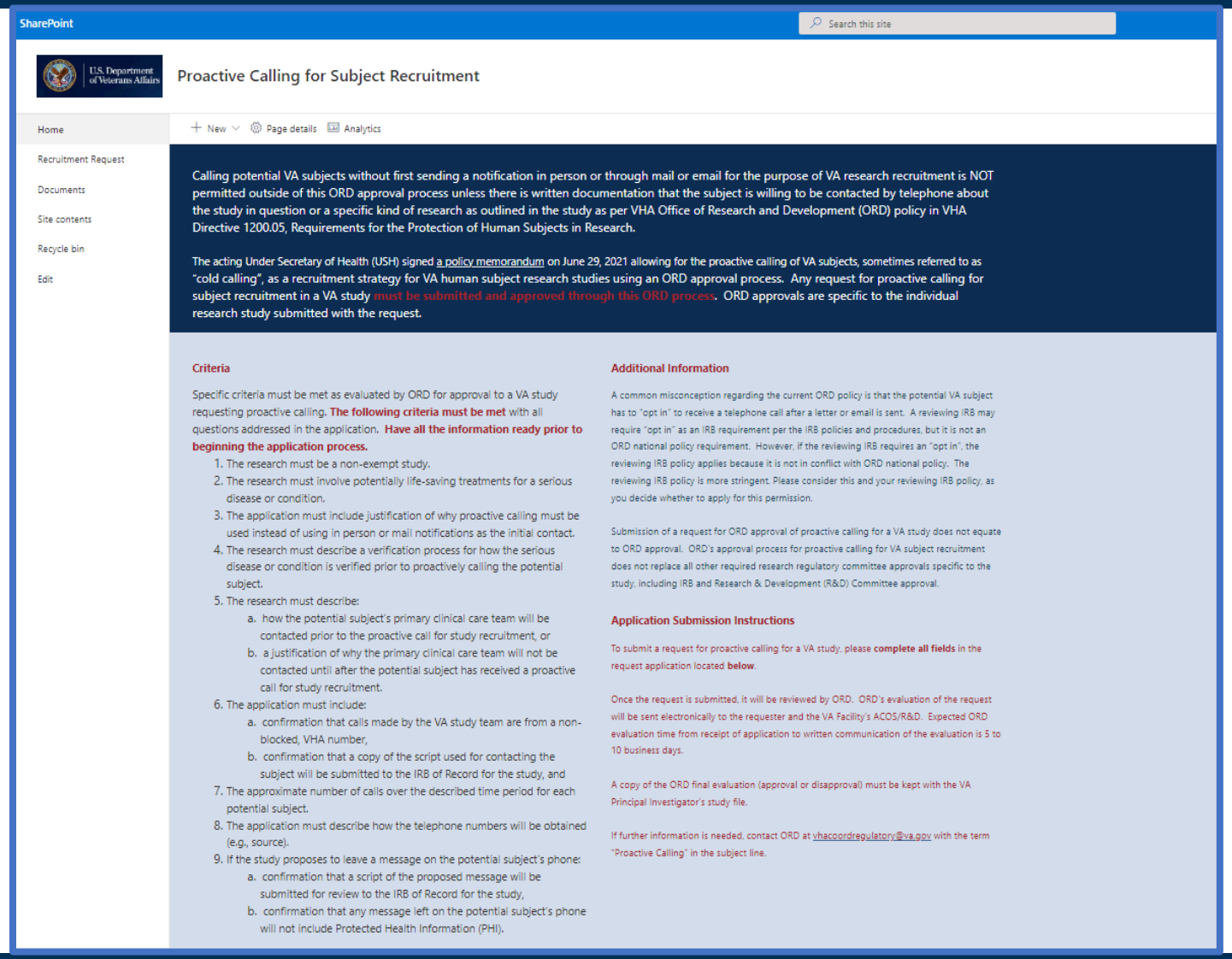
- ORD conducted a webinar on August 24, 2021 titled, “Recruitment by Phone” describing the process for submission and evaluation of requests submitted for ORD approval to proactively call VA subjects for recruitment.
- Criteria and process for evaluating proactive calling applications were described, including creation of a dedicated SharePoint site.
- The Proactive Calling SharePoint site has now been launched allowing submission of a streamlined application.
- Applications should be submitted prior to IRB approval.
- Application requests processed within 5-10 business days after receipt.

ORD Proacting Calling Application SharePoint Site

Proactive Calling for Subject Recruitment - Home (sharepoint.com) at https://dvagov.sharepoint.com/sites/VHAORPPE/RecruitmentRequests

Link will also be located on ORD's Policy and Webpage at: Human Research (va.gov)

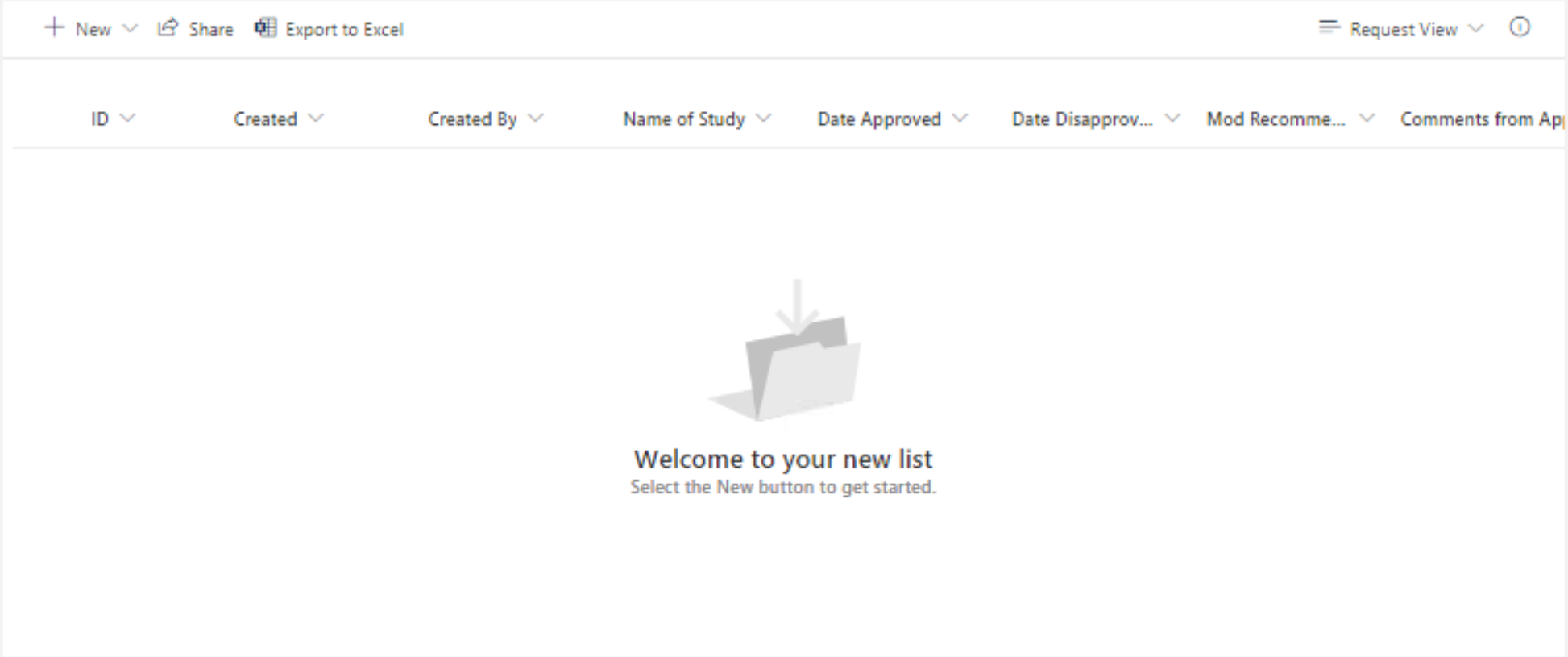
ORD Proactive Calling Application Portal



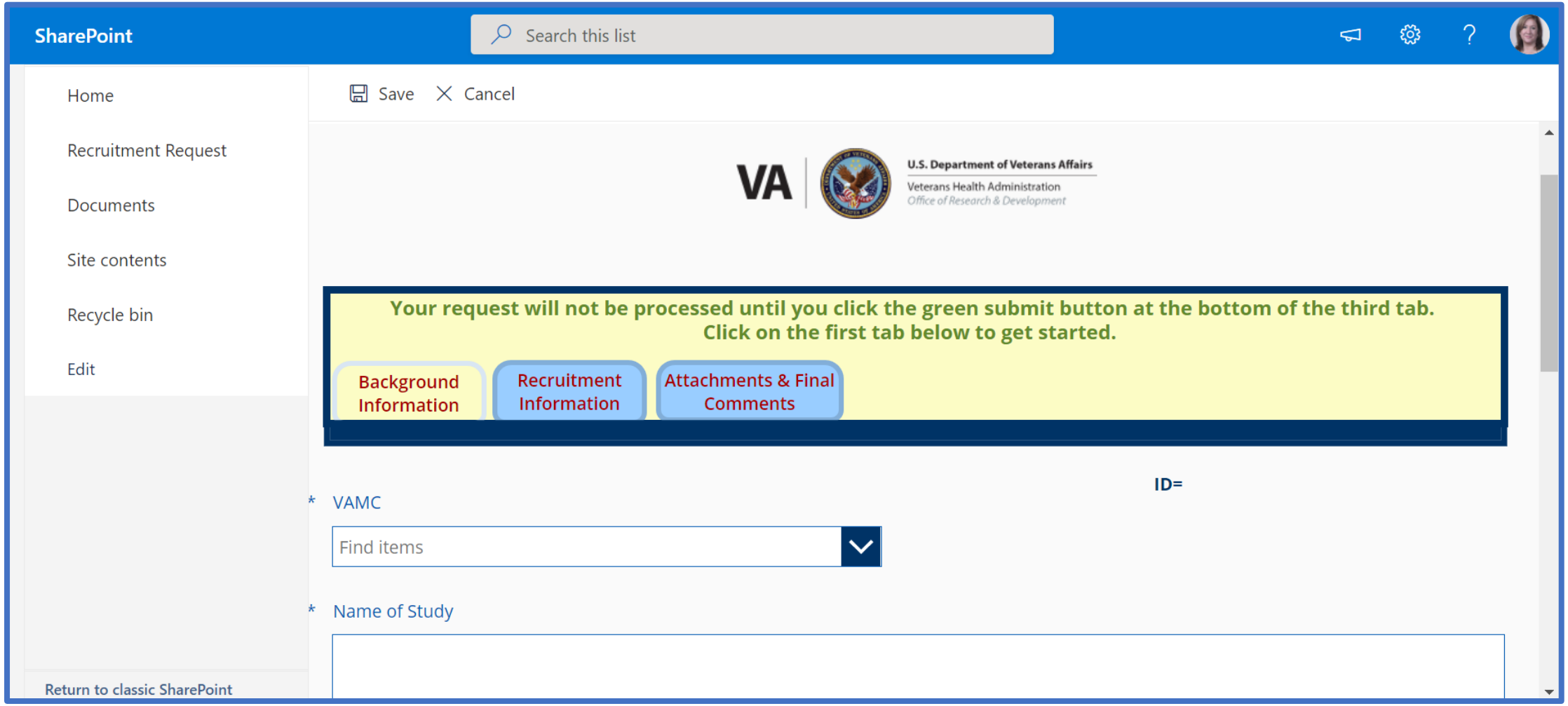
ORD Proactive Calling Application Portal

To make a new request, click on the "+New" button under the sub header "Recruitment Request".
To make an edit/update to a previous request, click on the "ID" number in the list below.

Recruitment Request



ORD Proactive Calling Application Portal



ORD Proactive Calling Criteria

1. The research must be a non-exempt study.
2. The research must involve potentially life-saving treatments for a serious disease or condition.
3. The application must include justification of why proactive calling must be used instead of using in person or mail notifications as the initial contact.
4. The research must describe a verification process for how the serious disease or condition is verified prior to proactively calling the potential subject.

ORD Proactive Calling Criteria (cont.)

5. The research must describe:
    a. how the potential subject's primary clinical care team will be contacted prior to the proactive call for study recruitment, or
    b. a justification of why the primary clinical care team will not be contacted until after the potential subject has received a proactive call for study recruitment.
6. The application must include:
    a. confirmation that calls made by the VA study team are from a non-blocked, VHA number,
    b. confirmation that a copy of the script used for contacting the subject will be submitted to the IRB of Record for the study, and
7. The approximate number of calls over the described time period for each potential subject.

ORD Proactive Calling Criteria (cont.)

8. The application must describe how the telephone numbers will be obtained (e.g., source).
   a. if the study proposes to leave a message on the potential subject's phone:
   b. confirmation that a script of the proposed message will be submitted for review to the IRB of Record for the study,
9. Confirmation that any message left on the potential subject's phone will not include Protected Health Information (PHI).

California State Law Applicability for Separation of the Written IRB-Approved Informed Consent Document (ICD) and Written HIPAA Authorization for VA Research

ORD and OGC STAR May 9, 2022 Guidance

On May 11, 2022, ORD and OGC STAR issued a Guidance titled, "Frequently Asked Question: California State Law Applicability for Separation of HIPAA Authorization for Research and Informed Consent Document" to address the following question:

Must VA separate the written IRB-approved consent and written HIPAA authorization for research language into separate documents, the latter of which required to be in at least 14-point font, for purposes of VA research conducted at VA sites in California?

ORD and OGC STAR May 9, 2022 Guidance

Must VA separate the written IRB-approved consent and written HIPAA authorization for research language into separate documents, the latter of which required to be in at least 14-point font, for purposes of VA research conducted at VA sites in California?

Answer: No. For this limited purpose, VA is not required to adhere to the California Confidentiality of Medical Information Act (CMIA; Cal. Civ. Code §§ 56 *et seq*.). The CMIA requires that an authorization for release of medical information be clearly separate from any other language present on the same page and executed by a signature which serves no other purpose than to execute the authorization. Additionally, this same California statute requires the written authorization language to be in a typeface no smaller than 14-point type.

Origin on May 9, 2022 Guidance

- Federal laws apply at VA facilities.
- VA looks to federal law to determine whether there is a basis to apply state law.
- VA, as a federal department, adopted the Federal Policy for the Protection of Human Subjects, also referred to as the "Common Rule. In 38 C.F.R. Part 16. Within the Common Rule, 38 C.F.R. § 16.101(f) reads:

  This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

Origin on May 9, 2022 Guidance (cont.)

- In the past, VA has interpreted implicated law and deferred to the CMIA by implementing a process that separated the written authorization from the IRB-approved informed consent form for research.
- VA has re-evaluated this policy and issued the May 9, 2022 Guidance.

What Action is Required from VA Facilities?

- No action is required for ongoing VA research.
- For VA research initiated at VA sites upon or after this guidance, VA shall have the flexibility to obtain written authorization, as applicable, by the means and as described in the May 9, 2022 Guidance:

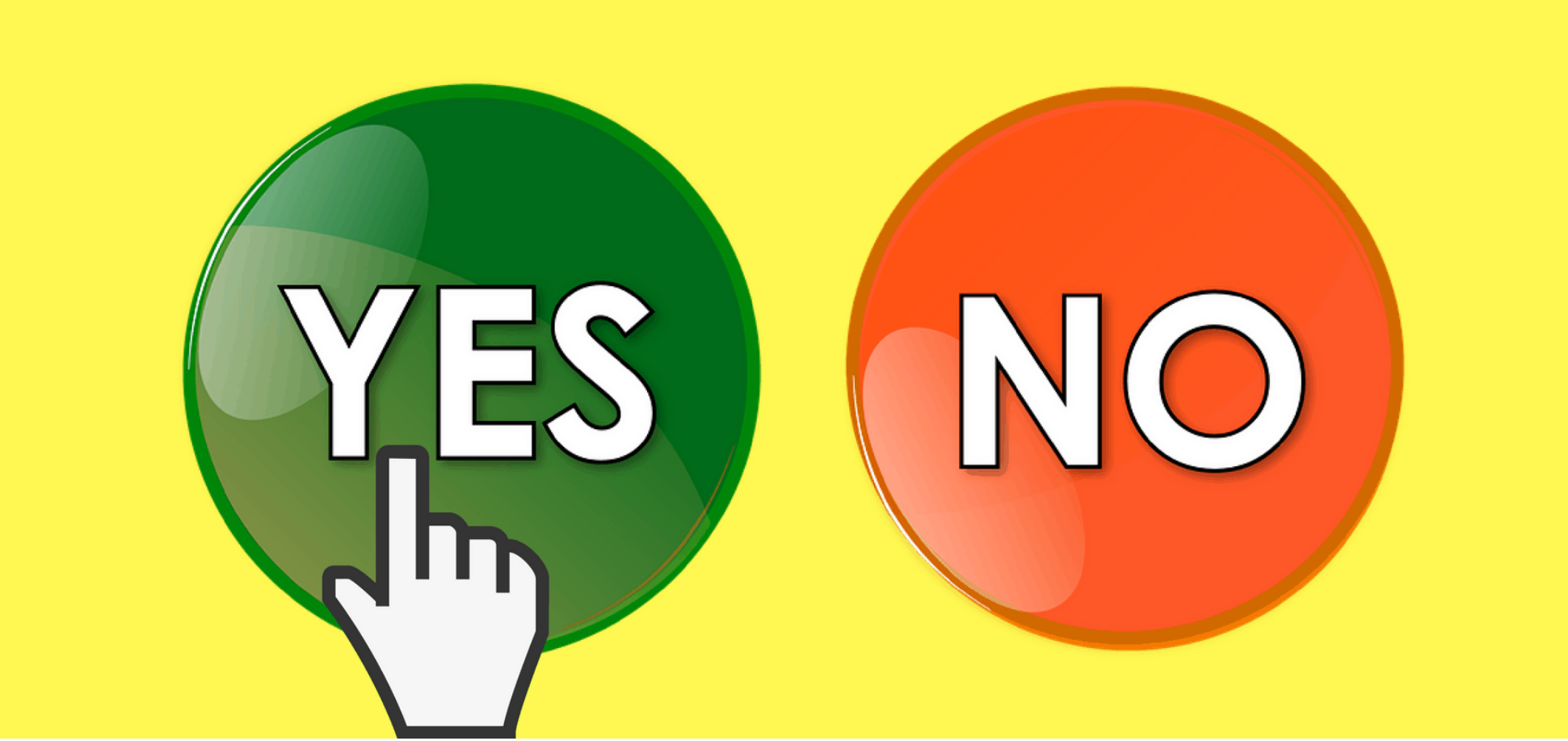
  "Frequently Asked Question: California State Law Applicability for Separation of HIPAA Authorization for Research and Informed Consent Document"


DocuSign

Common Question: DocuSign Eligibility

- Can my study apply for use of VA DocuSign if the total number of subjects to be entered into the study is less than 100?

Can My Study Apply for Use of VA DocuSign if the Total Number of Subjects to be Entered into the Study is Less than 100?



VA DocuSign Application Eligibility

- There is no longer a minimum requirement, but priority is given to studies that require more than 100 envelopes.
- If additional envelopes are needed after a study has been initiated, simply modify your original request.
- Please don’t ask for more than what is reasonable needed in a year in order to meet everyone’s needs.

True or False: Use of DocuSign in VA Research

1. DocuSign requires a special program in order for the subject to sign the documents sent to him/her in the DocuSign envelopes.
2. VA Investigators can use the University's instance of DocuSign interchangeably with the VA's instance of DocuSign for a VA study.
3. VA Investigators must obtain IRB approval for a study prior to submitting an application for VA DocuSign.
4. Industry-sponsored studies cannot apply for use of VA DocuSign.

All Four Statements are False

Truths: Use of DocuSign in VA Research

1. DocuSign does not require a special program in order for the subject to sign the documents sent to him/her in the DocuSign envelopes. If the VA subject can access email, DocuSign can be used anywhere.
2. VA Investigators cannot use the University's instance of DocuSign for a VA study.
3. VA Investigators must obtain IRB approval for a non-exempt human subjects study, but the VA DocuSign application should be submitted prior to IRB review and approval.
4. VA studies that are funded by industry or funded by non-VA sources (e.g., National Institute of Health, Department of Defense) can apply for use for use of VA DocuSign.

VA DocuSign Contract and Privacy Requirements

- VA's Office of Information Technology (OI&T) contract with Adobe DocuSign is managed by the VA Identity Access Management (IAM) Program Office.
- VHA must have legal authority under the HIPAA Privacy Rule to provide PII/PHI to VA OIT and its contractor, Adobe DocuSign, in order for the prospective VA research subject to be provided electronically an ICF and/or HIPAA Authorization for electronic signature.
- The only legal authority available prior to the signature of the HIPAA Authorization by the research subject is an IRB or Privacy Board-approved Waiver of HIPAA Authorization.
- The approved Waiver of HIPAA Authorization for research must include VA OIT and its contractor, Adobe DocuSign as entities to whom the Research Team will disclose PII/PHI for the purposes of the research, i.e., obtaining signed ICF and/or HIPAA Authorization.

Commercial IRBs

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VA's Use of Commercial (Independent) IRBs

- VHA Directive 1200.05 was amended March 3, 2020 to permit use of ORD-approved commercial IRBs for multi-site research.
- Master agreements have been executed between VA and each ORD-approved commercial IRB.
- There have been numerous issues addressed as the ORD-approved commercial IRBs have worked with the VA, but there are common themes.

ORD-Approved Commercial IRBs – Informed Consent

- ORD-approved commercial IRBs are required to include VA required informed consent language in the IRB-approved informed consent documents.
- VA specific requirements for language in the informed consent (and HIPAA authorization for combined documents) has been supplied at https://www.research.va.gov/programs/orppe/VA-Specific-Requirements-Informed-Consent-HIPAA-Commercial-IRB.pdf
- There is continuing confusion over who inserts the VA-specific required language.

VA Specific Requirements for Informed Consent and HIPAA Authorization When Using A Commercial IRB

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

VA Specific Requirements for Informed Consent and HIPAA Authorizations When Using a Commercial IRB
September 14, 2020

The following instructions with language for VA informed consent and VA HIPAA authorizations have been provided to commercial IRBs approved by the VHA Office of Research and Development to review and approve VA research. VA Facilities are to include VA informed consent language into the commercial IRB informed consent document, where applicable. It is the responsibility of the VA Facilities to include the language prior to uploading their local VA Facility informed consent documents and HIPAA authorizations as part of the application process.

Policy or Law	Citation and Topic	Policy Language	Language Provided to the Commercial IRBs	Comments
VHA Directive 1200.05	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.*	If you are 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***	This ORD policy requirement is a VA-specific element of informed consent. Do not 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.

It is the VA Study Team's Responsibility to Initially Insert the Language into the Provided Template

Insertion of VA Language for Informed Consent – Commercial IRB

- Commercial IRBs send the approved sponsor informed consent form template to the VA Investigator/VA Facility.
- The VA Investigator/study team is responsible for inserting the required VA language into the template, including the HIPAA authorization language when the informed consent is combined with the HIPAA authorization.
- If the language is not inserted upon submission, please inform the applicable commercial IRB that is serving as the IRB of Record for the study.
- Each commercial IRB has a quality improvement process to check that the VA specific language is inserted after submission.

Informed Consent Issues – Commercial IRB

- No submission will be processed unless the submission includes a VA Facility Commercial IRB Endorsement Letter.
  - This cannot be signed by the PI.
- The VA Facility's commercial IRB liaison should be copied if the VA Investigator/study team has issues regarding submission.

Commercial IRBs – Central or Local VA Facility PO and ISSO Review

- The commercial IRBs do not perform privacy and information security reviews.
- Some (not many) studies reviewed by an ORD-approved commercial IRB have a central privacy officer and information system security officer review:
  - Central privacy review: ORD's Privacy Officer
  - Central ISSO review: Research and Operational Technology Cybersecurity Division (ROTC-D)

Commercial IRBs – Central or Local VA Facility PO and ISSO Review

- The Partnered Research Program (PRP) is a program office within ORD that facilitates sponsors conducting multi-site clinical trial within VHA.
- If the study if being managed by PRP, the PRP consults with ORD and the Research and Operational Technology Cybersecurity Division (ROTC-D) regarding the feasibility of conducting a central PO and ISSO review.
- If a central PO and ISSO review is to be done for the applicable study, the PRP will inform the VA study site.

ORD-Approved Commercial IRBs: Annual Reports

- How does my VA Facility obtain a copy of the annual IRB evaluation conducted by the applicable commercial IRB?

How Does my VA Facility Obtain a Copy of the Annual IRB Evaluation Conducted by the Applicable Commercial IRB?

- The VA Facility's ORD Liaison contacts ORD at the following mailbox:

irbrelianceandsirbexceptions@va.gov

Commercial IRB Issues

- When does my VA Facility Need to contact ORD?

Commercial IRB Issues: When does my VA Facility Need to Contact ORD?

- If your VA Facility has questions regarding information being provided before or following the applicable commercial IRB's review, contact ORD at irbrelianceandsirbexceptions@va.gov.

- Please always include the VA Facility's commercial IRB liaison on communications.

Summary

- Multiple updates are being made to a variety of processes and guidance documents to reflect changes and improve efficiency.
- Multiple methods are being used to convey these updates.

Availability of Recording

- A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar
- An archive of all ORPP&E webinars can be found here: https://www.research.va.gov/programs/orppe/education/webinars/archives.cfm.

Contact Information

- C. Karen Jeans, PhD, CCRN, CIP
  Director of Regulatory Affairs, ORPP&E
  VHA Office of Research and Development
  c.karen.jeans@va.gov

- ORD Regulatory Box: VHACOORDREGULATORY@VA.GOV

References

- VA Specific Requirements for Informed Consent and HIPAA Authorizations When Using a Commercial IRB (September 14, 2020)
- ORD's NCI CIRB webpage: https://www.research.va.gov/programs/orppe/nci_irb.cfm
- VA's NCI CIRB SharePoint site: https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/ncicirb/default.aspx
- VHA Directive 1200.05(2): Research and Development Committee (January 7, 2019) at VHA Publications
- ORD's Policies and Guidance Documents webpage at https://www.research.va.gov/resources/policies/
- ORD's Proactive Calling SharePoint Application site: https://dvagov.sharepoint.com/sites/VHAORPPE/RecruitmentRequests
- ORD's DocuSign SharePoint Application site:

  https://dvagov.sharepoint.com/sites/VHAORPPE/DocuSign