**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:

1. 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)](https://csrc.nist.gov/publications/detail/sp/800-52/rev-1/final) and NIST [800-131A (Rev 1)](https://csrc.nist.gov/publications/detail/sp/800-131a/rev-1/final). (Please provide an email or other documentation from your local ISSO verifying the non-VA entity web system/portal’s conformance to FIPS 140-2 compliance for transmission from VA to the system), and
2. 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).

PLEASE NOTE THAT ORD WILL NOT PROCESS THE APPLICATION UNTIL DOCUMENTATION IS RECEIVED FOR THE ABOVE TWO ITEMS

1. **VA Facility Information:**

VA Facility: Click or tap here to enter text.

Physical Address: Click or tap here to enter text.

City: Click or tap here to enter text.

State: Click or tap here to enter text.

Zip Code: Click or tap here to enter text.

1. **VA Facility Medical Director/Institutional Official (IO) Information:**

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

1. **ACOS/R&D Information:**

Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

**Information about the IRB:**

1. **Is the IRB a VA facility IRB?** [ ]  Yes [ ]  No

If yes, which VA facility IRB do you plan to rely upon? Please provide:

1. Name of VA facility: Click or tap here to enter text.
2. FWA #: Click or tap here to enter text.
3. IRB Registration Number: Click or tap here to enter text.
4. Registration Expiration Date: Click or tap here to enter text.
5. Primary contact Name: Click or tap here to enter text.
6. Primary contact’s Role: Click or tap here to enter text.
7. Primary contact’s Email: Click or tap here to enter text.
8. Primary Contact’s Phone: Click or tap here to enter text.
9. **Is the IRB a non-VA IRB?** [ ]  Yes [ ]  No

If yes, which non-VA IRB do you plan to rely upon? Please provide:

1. Name of non-VA IRB: Click or tap here to enter text.
2. FWA #: Click or tap here to enter text.
3. IRB Registration Number: Click or tap here to enter text.
4. Registration Expiration Date: Click or tap here to enter text.
5. Primary contact Name: Click or tap here to enter text.
6. Primary contact’s Role: Click or tap here to enter text.
7. Primary contact’s Email: Click or tap here to enter text.
8. Primary Contact’s Phone: Click or tap here to enter text.
9. **A current IRB roster must accompany this reliance request form.**

A current roster is included: [ ]  Yes [ ]  No

If not, provide a justification as to why the roster is not included at this time: Click or tap here to enter text.

**8. The IRB’s Standard Operating Procedures (SOPs) are required to be submitted for vetting.** Provide the website where the IRB SOP(s) is located. If IRB SOP is not publicly available, include a copy of the IRB SOP with the submission of this form.

**9. Does the IRB identified currently hold an accreditation?** [ ]  Yes [ ]  No

If yes, please name the accreditation organization: Click or tap here to enter text.

Date of issued Accreditation: Click or tap here to enter text.

Expiration Date of Accreditation: Click or tap here to enter text.

**10. Will your institution be required to pay for IRB review services?**

[ ]  Yes [ ]  No

**11. Has the IRB identified received any warning, restriction, suspension, or disqualification letters** from the Office for Human Research Protections (OHRP), US Food and Drug Administration (FDA) or any other auditing agency within the last 10 years?

[ ]  Yes\* [ ]  No

\*If yes, provide a copy of the letter(s) issued with the submission of this form.

**12. What type of system does the IRB use for receiving, processing, reviewing and communicating with Investigators and institutions?** (Check all that apply)

[ ] Paper

[ ] SharePoint

[ ] Cloud-based

[ ] Commercial Software (e.g. IRBNet, IRB Manager) [ ] IRB Software Name:
[ ] Other: Click or tap here to enter text.

**13. Does the IRB you wish to rely perform the Health Insurance Portability and**

**Accountability Act (HIPAA) related functions in accordance with 45 CFR 146 on behalf of the VHA facility?**

 [ ]  Yes [ ]  No\*

\*If no, which IRB/Privacy Board will you rely upon for the review and approval of HIPAA related functions?

1. Name of facility: Click or tap here to enter text.
2. Primary contact Name: Click or tap here to enter text.
3. Primary contact’s Role: Click or tap here to enter text.
4. Primary contact’s Email: Click or tap here to enter text.

**14. Has the VA facility contacted the appropriate official(s) at the IRB to verify that the IRB will agree to be the IRB of Record for your VA facility?**

 [ ]  Yes [ ]  No

**15. Has the external IRB been given a copy of the model VA IRB Reliance Agreement MOU (Model VA IRB Reliance Agreement)?**

 [ ]  Yes [ ]  No

**16. IRB Point of Contact:**

Name: Click or tap here to enter text.

Title/Position: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

**17. VA Facility Requester(s)**

Provide the Name(s), Role(s) and Contact Information for the primary contact(s) at your VA facility for questions about this application:

Name: Click or tap here to enter text.

Role: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

Name: Click or tap here to enter text.

Role: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

Name: Click or tap here to enter text.

Role: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

**Signature of the Individual Completing the Form:**

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**Title:** Click or tap here to enter text. **Date**