# Relying on an External IRB: FAQs for Research Teams

The purpose of this document is to provide helpful hints for study teams when **West Virginia University** has agreed to rely on an external IRB.

### *What does relying on an external IRB mean?*

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

### *How do I know whether a study can be ceded to an external IRB?*

Please review our website and **complete/submit the Reliance Request Form at:** **https://human.research.wvu.edu/reliance** and wait for a response from the Reliance team to find out:

- what research qualifies for ceded review
- how to make requests for ceding IRB review, and
- what, if any, agreement may be in place to cover the specific IRB review arrangement.

### *What studies DO NOT qualify for a reliance agreement?*

- Projects that do not meet the definition of human subjects research
- Human subject research that qualifies as Exempt under 45 CFR 46.101(b)
- Projects that meet the criteria for Flex review under WVU OHRP policies
- Phase I clinical trials

Please email **reliance@mail.wvu.edu** with questions about reliance agreements.

### *Does my institution need to sign an agreement in order to rely on an external IRB?*

Generally, a written agreement between the institutions must be executed for an institution to rely on an external IRB. The agreement spells out the responsibilities of the institution providing IRB review as well as the institution relying on the external IRB.



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### *What is the SMART IRB agreement?*

The SMART IRB agreement is a national **master agreement** that allows institutions to avoid having to negotiate individual agreements per study or group of studies. The SMART IRB platform is NOT an IRB and does not conduct the review process. **West Virginia University** has signed onto the SMART IRB agreement. More information about SMART IRB is at https://smartirb.org and a list of institutions that have signed onto the agreement is at https://smartirb.org/participating-institutions/.

### *Do I need to obtain sign-off from my home institution, such as its IRB office, to use an external IRB?*

Generally, yes, because institutions need to be able to identify the research that falls under its purview, even if an IRB outside the institution oversees some or all of its research. At **West Virginia University** researchers obtain sign-off to use an external IRB by **completing and submitting a Reliance Request form to the OHRP for review and guidance.**

### *What is the role of my institution if research is ceded to an external IRB?*

Most reliance agreements, such as the SMART IRB Agreement, require institutions to communicate "local context" issues to the Reviewing IRB. Local context issues can include institutional requirements for informed consent language (e.g., compensation for injury language), attesting to the adequacy of research team training, qualifications of the research team and resources available to conduct the study, and providing any relevant conflict of interest management plans (or, in the case of federal agencies, assurances that that the participation of their research personnel is permissible and consistent with federal law). **Contact reliance@mail.wvu.edu for assistance with completing local context forms/communicating local context information to the reviewing IRB.**

### *How do I request my institution cede review for my study to an external IRB?*

Please **complete and submit the Reliance Request Form at** https://human.research.wvu.edu/guidance/cirb-smart-irb) **and wait for a response from the Reliance team at the WVU OHRP**. Once the WVU OHRP has informed you that a reliance agreement is appropriate for your project, study teams will **be instructed to submit a CIRB protocol through the WVU+kc electronic system. That submission should include: the study protocol (from sponsor or other reviewing institution), Reviewing IRB approved consent form(s), Reviewing IRB approval letter, WVU Data Protection certificate, and any other applicable documentation that will assist WVU in ceding review and acknowledging reliance on the external IRB.**

### *How do I submit my documents to the external IRB for review?*

A lead study team, coordinating center, or sponsor will submit documents to the IRB and provide you with documentation of that IRB's approval for your site.


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### *How do I know when I can start the research?*

Obtaining IRB approval is only one of often many approvals or sign-offs that study teams must have in place to activate a study. The same institutional requirements must be met for study activation when using an internal IRB. Examples include: reviews and approvals by other institutional committees (e.g., biosafety, radiation safety, pharmacy, conflict of interest, billing compliance) and executing any clinical trials agreements.

You will need to have documentation that:

- your site has ceded review to the external IRB; and
- the external IRB approval for the study covers your site
- acknowledged submission in WVU+kc

If the external IRB has approved the study before your site is ready to join, your site will need to be specifically reviewed and approved as a new site, which is usually accomplished via an amendment to the existing study. **Activities involving human subjects at your site cannot occur until the external IRB specifically approves your site's participation in the research and you have obtained all required institutional sign-offs and/or approvals.**

### *What are my obligations when an external IRB is responsible for reviewing my research study?*

The responsibilities of the research team remain largely the same, and include:

- Obtaining sign-off from your institution to use an external IRB
- Obtaining initial approval as a participating study site
- Communicating information about study progress to the Reviewing IRB via the mechanism established for such communications (e.g., either to the IRB directly or to the lead study team or to a coordinating center)
- Tracking personnel updates, ensuring personnel are qualified and appropriately trained to perform their roles, and providing information about relevant personnel changes to the Reviewing IRB (including confirming personnel are qualified and appropriately trained) to the Reviewing IRB when required and via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center)
- Reporting unanticipated problems, noncompliance, and significant new information to the Reviewing IRB via the mechanism established for such communications
- Complying with the Reviewing IRB's policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints)
- Complying with the determinations of the Reviewing IRB
- Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents
- Complying with applicable policies from the local institution (e.g., conflict of interest, training and education, research subject compensation processes, billing compliance, data protection/retention requirements)


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- Working with the lead investigator to make any local updates to the protocol or other approved documents (e.g., consent form or recruitment materials) and ensuring the Reviewing IRB approves these changes before they are implemented
- Communicating applicable study updates with other relevant local institution committees and/or offices (e.g., research billing, radiation safety committees, pharmacy, oncology review committees)


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