Purpose: When a study is under the oversight of an IRB external to WVU, this document can be used to provide WVU's local study team with guidance regarding the investigator's responsibilities.

For more information about reliance agreements and terms used below, please see: https://human.research.wvu.edu/reliance and/or: https://human.research.wvu.edu/guidance/research-data-management/data-definitions.

Relying Investigator Guidance and Checklist

As Principal Investigator (PI) at WVU (**Relying Institution)** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and plan to use an external IRB for oversight of this study:

You should contact the WVU IRB Reliance Staff and/or submit a completed Reliance Request form and wait for a response from the Reliance team to:

- ☐ Determine whether ceding IRB oversight to an external IRB is appropriate.
- ☐ Provide WVU IRB Reliance Staff with details about the study (including your study team's role) and the proposed reviewing IRB by completing a Reliance Request Form. Information about this can be found on WVU OHRP's Reliance/sIRB Webpage: https://human.research.wvu.edu/when-wvu-relies-on-another-irb
  - ☐ Obtain a copy of the study-wide protocol and template consent document(s) and attach where requested on the Reliance Request form, which will help facilitate the discussion with the WVU Reliance Staff and the IRB.

If the WVU IRB agrees to cede review to an external IRB, you will be asked to:

Provide the WVU IRB with:

- ☐ Protocol-specific information by submitting a CIRB submission through WVU+kc. Include a copy of the Reviewing IRB approved protocol, approved site consent form(s), the reviewing IRB's approval letter, the WVU Data Protection Certificate and any other required documentation.
- ☐ Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

- ☐ Promptly respond to questions or requests for information from the Lead Study Team/PI/Reviewing IRB.
- ☐ Participate, as required, in conference calls regarding the study as requested by the Lead Study Team/PI, Reviewing IRB, or WVU IRB/HRPP.
- ☐ Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations/violations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required. REMINDER: Some events must also be submitted to your local institution.
- ☐ Ensure completion of all local reviews and signoffs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).
- ☐ Work with the Lead Study Team and the Reliance staff from WVU's IRB/OHRP to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.

- ☐ For externally funded studies, provide OSP with any required documentation that IRB oversight for a study has been ceded to and approved by an external IRB.
- ☐ Notify WVU OHRP Reliance Staff of any staff changes (via an amendment in WVU+kc) so they can confirm training is current and help ensure any relevant COI management plans are communicated to the Reviewing IRB.

Notify the lead PI of:

- ☐ Any reportable events that occur locally, according to regulations and the Reviewing IRB's policy.
- ☐ Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions. *Note: changes to the PI on the study should also be reported to the WVU IRB via an amendment.*
- ☐ Any management plans, including any updates to these plans, as relevant to the study.
- ☐ Any applicable information for continuing review progress reports in accordance with the Reviewing IRB's policies and procedures for timing and content of such submissions.

- ☐ Follow all determinations of the Reviewing IRB.
- ☐ Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.
- ☐ Provide, upon request, access to study records for audit by the WVU OHRP/IRB, the Reviewing IRB's institution, and other regulatory or monitoring entities.