



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

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## Relying Investigator Guidance and Checklist

As Principal Investigator (PI) at UK (**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 UK IRB Reliance Staff to:

- Discuss whether ceding IRB oversight to an external IRB is appropriate.

- Provide UK IRB Reliance Staff with details about the study (including your study team's role), the proposed reviewing IRB, and the lead PI's name and institution by completing a Reliance Request Form. This document can be found on UK ORI's Reliance/sIRB Webpage.

- Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with the UK Reliance Staff and the IRB.

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

- Provide the UK IRB with:

- Protocol-specific information by submitting an Abbreviated Application (AA) for Reliance in E-IRB.

- 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.

- Register the study at UK according to local processes (such as creating an abbreviated application in the E-IRB, or submitting pertinent study documents via e-mail). See "*Steps to Creating an Abbreviated sIRB...*"

- 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 UK 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.

- Ensure completion of all local reviews and sign offs 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 UK's IRB/HRPP 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 OSPA with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Notify UK ORI Reliance Staff of any staff changes 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.

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 UK HRPP/IRB, the Reviewing IRB's institution, and other regulatory or monitoring entities.