
SINGLE IRB REVIEW:

Responsibilities Associated with the Review of Study Personnel



Review of Study Personnel Working Group
of the SMART IRB Harmonization Steering Committee

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INTRODUCTION

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board for Multi-Site Research and the Common Rule change, effective January 21, 2020, requiring single IRB review of multi-site studies means that Institutional Review Boards (IRBs) at many institutions may take on the role of serving as a reviewing (or single) IRB. Likewise, many institutions will now have to rely on an external IRB for review of studies in which their institution is a participating site. These new roles require that institutions develop processes for standard local functions to ensure studies are properly reviewed under the single IRB model.

The NIH policy cites the use of single IRBs to increase efficiencies, decrease time to start of research, and reduce costs while still maintaining or even improving human subjects protections. It is expected that some processes, such as review and approval of research sites and amendments and continuing reviews, will be more efficient under the single IRB model. However, other processes are not as well-suited to the single IRB review process and may actually become more cumbersome. One such process is evaluating the qualifications of study personnel.

Ensuring study personnel are adequately trained is a joint responsibility of institutions, sponsors, investigators, and IRBs. Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations require that IRBs have a role in reviewing investigators qualifications; however, they do not stipulate how IRBs must ascertain these qualifications. For the purposes of the HHS regulations, the Office of Human Research Protections (OHRP) interprets an “investigator” to be any individual who is involved in conducting human subjects research studies¹, and the FDA and HHS “Written Procedures Checklist” includes “[re]viewing the qualifications of the investigator(s) and study staff...” as a topic for which an institution should have a written procedure to facilitate compliance.

It is clear that single IRBs must evaluate the qualifications of Principal Investigators (PI) as part of their regulatory responsibilities; however, it is not clear whether other study personnel also require review by the single IRB. Traditionally, IRBs review and approve all study personnel, and, as use of single IRBs has become more prevalent, that responsibility has typically been taken on by the Reviewing IRBs. Changes in study personnel are common study amendments, and, while the initial review of study personnel is not that onerous, ongoing review of personnel changes consumes significant resources for single IRBs, and can overwhelm those overseeing large multi-site studies.

To address the challenges presented by the single IRB model, this SMART IRB guidance makes recommendations on how to establish mechanisms for institutions, investigators, and IRBs to work together to ensure study personnel are trained in human subjects protections and are qualified to conduct the research under review.

1. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>

IRB REVIEW OF STUDY PERSONNEL

FDA and HHS human subject protection regulations do not provide clear instructions on what IRBs, institutions, and investigators need to consider when evaluating personnel conducting human subjects research. In the absence of specific regulations governing IRB review of personnel, IRBs have generally evaluated study personnel to ensure:

- 1) They have completed human subjects protection training required by their institution.**
- 2) They are qualified to conduct the research under review.**
- 3) Relevant financial conflicts of interest (COI) are identified, assessed regarding their potential impact on the research, managed to minimize risk to subjects, and disclosed to subjects when appropriate.**

Lack of clarity in the regulations has led to variation across IRBs and institutions regarding:

- **Which study personnel must be listed on an IRB application and whether their role(s) must be identified.**
- **What types of training are required or expected for different personnel.**
- **What personnel changes (adding or removing personnel) are communicated to the IRB.**
- **How and when updates to personnel are submitted to the IRB.**
- **What the IRB considers in its review of personnel, and which responsibilities for ensuring the qualifications of study personnel are overseen by institutional personnel or processes.**
- **The IRB review process for personnel changes (e.g., convened board, expedited review, or other approach).**

Institutions often require additional training or vetting of research personnel for various reasons, such as for credentialing, conflict of interest, research misconduct, access to protected health information (PHI), and background checks. In some cases, IRBs monitor compliance with these requirements, but institutions frequently have other offices or processes (e.g., human resources, HIPAA privacy officers, other administrative reviews) to address these requirements.

The FDA guidance, *IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed*, provides a basis from which to derive a harmonized framework for the expectations for the review of personnel engaged in human subjects research. It suggests the rationale for IRB review of investigator qualifications is twofold:

- **To “ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.” [from 21 CFR 56.107(a)]**
- **To ensure that risks to subjects are minimized and reasonable in relation to anticipated benefits, if any, to subjects. [from 21 CFR 56.111]**

In short, the FDA guidance asserts that, in order to determine research risks to subjects are adequately minimized, IRBs must ensure clinical investigators are adequately qualified to conduct and supervise the research.

The concept of qualified within this guidance encompasses training and experience. While social, behavioral, and educational research (SBER) research may not be regulated by the FDA, the expectations outlined in the guidance would also be applicable to non-FDA regulated research.

Other key points within the FDA guidance include:

- **IRBs should assess qualifications based on both the research-related role individuals fulfill (e.g., Principal Investigator vs. other research team members) and the study- specific activities they perform (e.g., obtaining informed consent, administering study instruments, executing invasive study interventions).**
- **The necessary information for assessing investigator qualifications, and the methods for obtaining that information, will vary “depending upon the nature and risks of the proposed research and the relationship between the IRB and the investigator or the institution where the proposed research is being conducted...”**
- **IRBs can rely on other resources to confirm investigator qualifications.**

Of note, the FDA guidance generally references “investigators,” and does not directly address expectations for personnel other than investigators. However, as noted above, OHRP interprets an “investigator” to be any individual who is involved in conducting human subjects research studies.

Although the above-referenced FDA guidance does not address IRB review of research personnel COIs, the FDA, in conjunction with the Department of Health and Human Services (DHHS), issued “IRB Written Procedures: Guidance for Institutions and IRBs,” which specifies that IRBs should have written procedures to identify and manage “an investigator with a conflicting interest”. Further, “Financial Conflict of Interest: HHS Guidance (2004)” establishes expectations that IRBs have a responsibility to ensure that financial interests do not compromise the rights and welfare of human research subjects, and that they should specifically determine:

- **Whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.**
- **Whether other actions are necessary to minimize risks to subjects.**
- **The kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.**

Additionally, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) standards for accreditation include the expectation that IRBs have the final authority to determine whether the research in which an investigator has a financial conflict of interest— and the management plan of that conflict, if any—allow the research to be approved.

IMPACT OF THE SINGLE IRB MODEL ON THE REVIEW OF STUDY PERSONNEL

Before widespread adoption of single IRB review, research personnel training, qualifications, and COI were often assessed by IRBs that functioned within the same institutions as the research personnel they oversaw. Often inherent in this arrangement was local knowledge of researchers, including their training, qualifications, and COI, which facilitated IRBs' ability to assess personnel as part of their reviews. Thus, evaluation of personnel was embedded within IRB responsibilities and processes (e.g., linking internal training databases to IRB applications to allow monitoring of human subjects protection training) or mechanisms set up to share information within the institution (e.g., COI committees sharing management plans with IRBs or having IRB personnel serve as representatives on COI committees).

The use of external IRBs to review research generally eliminates the local knowledge of personnel and thus requires IRBs serving as Reviewing IRBs for other institutions to consider how they will be able to ensure research personnel have adequate training and qualifications to carry out their roles and study activities as well as how the IRB will receive information about relevant COIs.

To address these challenges, we make the following recommendations:

- 1. Relying Institutions and investigators assume the primary responsibility to assess study personnel training and qualifications both initially and throughout the course of the study.**
- 2. Relying Institutions develop mechanisms to identify and communicate relevant COIs and proposed management plans to the Reviewing IRB throughout the course of the study.**

Relying Institutions may assign some or all these responsibilities to a coordinating center, but this should be documented and clearly communicated to relevant parties, such as through a communication plan. We outline this division of responsibilities below.

DOCUMENTING AND COMMUNICATING ROLES & RESPONSIBILITIES

The division of responsibilities for the review and oversight of personnel qualifications and potential financial COIs between a Reviewing IRB and Relying Institution should be formally outlined in a reliance agreement, such as the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement ([SMART IRB Agreement](#)). The division of responsibilities should continue throughout the life of a study. Any delegation of responsibilities to a study-wide Principal or Lead Investigator or to a site investigator should be outlined clearly in policies, procedures, and/or communication plan. [The SMART IRB template communication plan](#) can be completed by the Reviewing IRB, with input from Relying Institutions and study teams, and distributed to capture and communicate a variety of responsibilities, including responsibilities related to requirements for study personnel.

REVIEWING IRB RESPONSIBILITIES

Under the single IRB model, we recommend that Reviewing IRBs implement processes to ensure that study personnel from Relying Institutions are adequately trained and qualified to conduct the research and to obtain information from Relying Institutions about relevant COIs. The Reviewing IRB should ensure Relying Institutions are aware of their obligations for assuring personnel training and qualifications and providing information regarding relevant financial COIs throughout the life of the study. In addition, Reviewing IRBs should clearly identify and communicate to Relying Institutions the mechanism that should be used to communicate this personnel-related information and the expected timing for doing so. Reviewing IRBs may obtain some information from coordinating centers rather than directly from the Relying Institutions, such as in research consortia. When using a coordinating center to monitor for and provide certain information related to personnel, this should be documented and communicated to relevant parties (e.g., in a communication plan).

One means for Reviewing IRBs to document their expectations of the Relying Institution is by using the SMART IRB Agreement. The SMART IRB Agreement obligates Participating Institutions to ensure that their research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of research subjects. Further, the SMART IRB Agreement clarifies that this responsibility includes having any institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subjects protections, and background checks for their assigned role in the research. The Agreement also obligates Participating Institutions to provide information or documentation regarding their research personnel's education, training, and qualifications when requested by the Reviewing IRB. Finally, unless the Reviewing IRB and the Relying Institution agree to an alternate approach in advance, the SMART IRB Agreement requires each Relying Institution to perform its own COI analysis under its relevant policies and to provide any resulting COI determinations, prohibitions, and management plans to the Reviewing IRB, including any updates.

By delegating to Relying Institutions the responsibility to ensure research personnel have adequate education, training, and qualifications to perform the research, the Reviewing IRB can then limit what it considers in its review of personnel. We recommend Reviewing IRBs obtain the names of certain personnel in order to facilitate communication of key information between the IRB and research teams and ensure that each site has a responsible investigator in place. Specifically, we recommend the Reviewing IRB obtain information for any Overall (or Lead) PI, Relying Site PIs, and a study team Point of Contact (POC) for each relying site, if different from the Relying Site Investigator (or Relying Site PI). The study team POC should be someone knowledgeable about the research study and its local implementation. Under this model, the Reviewing IRB would not be responsible for reviewing and approving non-PI study personnel from Relying Institutions. If information about a relying site PI or relying site study team POC changes during the time the study is open, the Reviewing IRB must be informed of the change.

Reviewing IRBs should also have policies and procedures to collect from Relying Institutions information about all engaged research personnel's potential financial COIs, in sufficient detail to be able to make the assessments recommended by HHS as noted above, namely:

- **Whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.**
- **Whether other actions are necessary to minimize risks to subjects.**
- **The kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.**

RELYING INSTITUTIONS RESPONSIBILITIES

The recommendation to shift responsibility for the review of study personnel away from Reviewing IRBs means the responsibilities for the review of personnel training and qualifications and the communication of relevant COIs and their management would fall to Relying Institutions. These responsibilities would include ensuring the following, initially and throughout the life of the study:

- **All study personnel who will be engaged in human subjects research under the institution's purview are appropriately trained and qualified to conduct the proposed research study; this includes ensuring personnel have completed institutionally-required trainings at the sites in which they conduct research activities, such as training in human subjects protection, HIPAA Privacy Rule, and Good Clinical Practice, as well as study-specific training.**
- **Relevant study personnel have met institutional requirements related to their assigned research role before engaging in research activities, such as professional staff appointments, credentialing, insurance or other liability coverage, background checks, or other requirements.**
- **COI determinations, prohibitions, and management plans are monitored and communicated to the Reviewing IRB.**
- **Research personnel are notified of their responsibilities related to information that should be provided to the Reviewing IRB, Overall PI, the Lead Study Team (when one exists), and/or local human research protection program (HRPP) to fulfill oversight obligations.**
- **Research personnel are in compliance with the requirements of the Reviewing IRB.**

Relying Institutions may meet these obligations in a variety of ways. For example, a Relying Institution might use a combination of the following approaches:

- **Delegate some or all responsibilities to a coordinating center and document this arrangement.**
- **Require local site PIs to track personnel updates, ensure study personnel are trained (both to conduct research and the specific study), and communicate certain personnel changes (e.g., changes in personnel COIs, changes in local site PI) to their HRPP.**
- **Use a departmental sign-off process to verify that the local site PI has adequate training and resources to conduct the proposed research.**
- **Leverage credentialing or human resources processes to ensure the local research personnel have the professional staff appointments, credentialing, insurance or other liability coverage, and background checks for their assigned role in the research.**

If a Relying Institution delegates any responsibilities to study teams or coordinating centers, the institution should consider periodic monitoring to ensure that these obligations are being met.

STUDY TEAM RESPONSIBILITIES

FDA guidance “Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects” indicates that investigators are responsible for ensuring that all personnel participating in the conduct of a study are appropriately qualified by education, training, and experience to perform study-related tasks. The guidance also states that the investigator should maintain a list of the appropriately qualified persons that identifies the training these individuals have received that qualifies them to perform delegated tasks. Although SBER research may not be regulated by the FDA, the expectations outlined in the guidance would also be applicable to non-FDA regulated research.

Overall PIs, when they exist, and relying site PIs are responsible for ensuring that they and their team have the training and qualifications to conduct the research and for disclosing COIs relevant to the research.

Relying site PIs are responsible for ensuring:

- **All research personnel meet the minimum training, experience, and credential requirements set by the institution to conduct their assigned research duties.**
- **All personnel are appropriately trained, including study-/procedure-specific training, before engaging in research activities.**
- **They have assessed the research workload for all engaged study personnel to ensure they have adequate time and resources to decrease risks to subjects.**
- **They provide information regarding possible COI relevant to the research for all engaged study personnel via the appropriate channels, so that the Relying Institution and Reviewing IRB can make an appropriate assessment and determination.**
- **They comply with institutional requirements regarding oversight of personnel, which may include tracking personnel and their training and communicating personnel changes to the local HRPP for assessment.**

If following the [SMART IRB Standard Operating Procedures \(SOPs\)](#), the Overall PI is responsible for designating a Lead Study Team. The Lead Study Team would be responsible for ensuring:

- **Local site PIs are aware of what information they are required to provide to the Reviewing IRB related to personnel, as well as the mechanism and the timeframe for providing that information.**
- **The names of the relying site PIs, as well as the study team POC (if different), are communicated to the Reviewing IRB.**

OTHER FACTORS TO CONSIDER

The recommendations above envision multi-site research conducted at institutions with established human research protection programs and previous experience conducting human subjects research. However, on occasion a research project will involve sites that have little or no research infrastructure or experience conducting human subjects research. Examples include community health centers, dentist offices, and speech therapy offices. Often these types of sites will only participate in a single research project. When research is conducted in these settings, many of the presumptions above will not hold. For instance, the institution will not have the resources to ensure that there are appropriate research training programs in place, or a process for identifying and managing COI. Similarly, the site PI might not have training or experience in conducting research, and may not have a good idea of the duties that the personnel will take on. In these situations, the Reviewing IRB may need take on some of the duties that this guidance assigns to Relying Institutions and study teams. Often that may be accomplished through supplemental submission form questions. For example, when a Relying Institution does not have an established process for reviewing COI, it may negotiate terms with the Reviewing IRB so that the Reviewing IRB is responsible for the COI review and management plan.

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