INSTITUTION V. IRB RESPONSIBILITIES

A Guide for Reviewing IRBs and Relying Institutions Using the SMART IRB Agreement or Other IRB Reliance Agreements

Institution v. IRB Responsibilities Working Group
of the SMART IRB Harmonization Steering Committee

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Harmonized: This document underwent a review and input process from February 2017 to April 2018 and has now been finalized.

INTRODUCTION

This guidance delineates discrete roles for reviewing IRBs and relying institutions* by identifying and separating appropriate responsibilities of institutions from functions that are, by regulation, within the purview of the IRB. A responsibility is considered "flexible" if regulation is either non-existent or intentionally variable based on the type of research under review.

- **This guidance is congruent with *but not specific to* the SMART IRB Agreement. Use beyond SMART IRB is intended and encouraged.**
- While this guidance was designed to be applicable to a variety of entities, federal or state government agencies (e.g., U.S. Department of Veterans Affairs, Department of Defense, National Institutes of Health) may have additional considerations.
- This document provides institutions and IRBs guidance to comply with relevant regulations; however, there are multiple ways to fulfill these regulatory responsibilities.
- Related institutional responsibilities (e.g., regarding publication, data use and ownership, intellectual property), while important topics, were deemed outside of the scope of this effort and are not included in this guidance.

Click here for a glossary of relevant terms.

Click here for a checklist that can be used or adapted to document and communicate roles and responsibilities when implementing the SMART IRB Agreement.

**Many responsibilities of the relying institution may be delegated to the institution's IRB office, as a component of its human research protections program (HRPP), although these remain the institution's responsibility. Here we designate them as responsibilities of the institution.*

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

RESPONSIBILITIES	REVIEWING IRB	RELYING INSTITUTION*	REGULATORY FLEXIBILITY	ASSUMPTIONS/COMMENTS
Federalwide Assurance (FWA)		X		Each institution must ensure it maintains a current FWA as needed; an FWA is needed only for federally-supported research.
IRB registration	X			The reviewing IRB must ensure that their IRB is registered.
IRB membership	X			The reviewing IRB must ensure their IRB membership complies with federal requirements.
Decision to function as reviewing IRB	X			The appropriate organizational official decides whether to serve as the reviewing IRB for the study or studies.
Decision to cede IRB review		X		The appropriate organizational official decides whether to cede review; while decision-making authority may be delegated to IRB leadership, it remains an organizational responsibility.
IRB findings and determinations	X			The relying institution's IRB must abstain from conducting redundant regulatory reviews and providing determinations. This does not preclude a relying institution from performing quality checks of an IRB's review and providing feedback about the reviewing IRB's determinations (e.g., the determination does not appear to comply with state or local requirements).

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Notification of IRB findings and determinations	X			• The reviewing IRB or designee is responsible for communicating all IRB findings and determinations in writing to investigators and institutions. This includes decisions on protocols, changes, suspensions, terminations or subject continuation during lapses in approval, unanticipated problems involving risks to subjects or others, noncompliance, or complaints. • The reviewing IRB may communicate determinations to a designee (e.g. a coordinating entity responsible for communicating to the relying study teams).
HIPAA determinations			X	Refers to reviewing HIPAA waivers and alterations of authorizations: • The reviewing IRB may act as the privacy board. • If the informed consent and HIPAA authorization are combined, the IRB must review both; if separate, the IRB is only responsible for reviewing the informed consent. • May not apply to non-HIPAA covered entities (e.g., the Federal government operates under the Privacy Act of 1974). • An IRB within a non-HIPAA covered entity may still act as the privacy board.
HIPAA implementation		X		Refers to the process of managing waivers of authorization including tracking (e.g., of disclosures) and recordkeeping.
Ensure study is compliant with federal IRB requirements	X			Refers to the review of the protocol; if under an FWA, the relying institution routinely ensures that the reviewing IRB has written procedures for conducting the review(s).

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Identifying and providing local considerations		X		The relying institution must communicate state or local laws, regulations, institutional policies, and/or standards to the reviewing IRB.
Review of local considerations	X			After obtaining information from the relying institution, it is the responsibility of the reviewing IRB to incorporate the information into their review (including compliance with reported state or local laws, regulations, institutional policies and/or standards).
Congruence of federal grant application			X	Review of the congruence of any federal grant application or contract proposal with the research submitted for IRB review and approval, when such review is required by federal or oversight agencies.
IRB-initiated audits/ investigations	X			• The reviewing IRB may delegate responsibility; the relying institution must cooperate. • If a relying institution conducts the IRB-initiated investigation, the results must be communicated to the reviewing IRB. • A relying institution has the right to conduct its own auditing and must communicate for-cause audits and reportable events to the reviewing IRB.
Reporting to federal agencies and sponsors	X			• This refers to submitting mandatory reports to federal agencies as required for determinations (e.g., a determination that an event qualifies as an unanticipated problem involving risk to subjects or others or a finding of serious or continuing noncompliance). • Under a reliance agreement, the default should be the reviewing IRB's responsibility. Responsibility may be delegated or shared between the reviewing IRB and relying institution; both entities should have copies of the report.

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Identification and analysis of conflict of interest (COI)		X		Refers to the identification and analysis of COI and, as necessary, the proposed management plan prepared by the institution that has a conflict or that employs the researcher or research staff with a conflict. • The relying institution must assure the IRB that conflicts have or can be managed or resolved. • The reviewing IRB has the right to request additional information and to require additional management and opportunity to further review the case. • Relying institution's policies govern COI. If relying institution does not have a COI program, it may delegate responsibility to the reviewing IRB institution.
Review of COI and IRB determination	X			Refers to the review of identified COI: • The reviewing IRB has the responsibility to review the identified COI and management plan provided by the relying institution and, if needed, to require additional measures to reduce, manage, or eliminate conflict to ensure the study is approvable from a human subjects protections standpoint.
IRB COI considerations	X			Refers to management of IRB member COI for review of a specific protocol.
IRB recordkeeping	X			Federal/state government entities will have specific responsibilities.
QA/QI of the human research protections program		X		Institutions that are or have an IRB must have or have access to a QA/QI program.

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Quality assessment: post-approval monitoring of studies			X	Refers to periodic monitoring of studies after IRB approval, as appropriate: • In certain situations, institutions may agree that monitoring is unnecessary (e.g., a minimal-risk study or an externally-monitored study, or institution with a limited role related to the research). • If a relying institution does not have a QA program, it may delegate responsibility to the reviewing IRB.
Education/training of researcher personnel		X		Relying institution may be asked to provide information or documentation to reviewing IRB (e.g., conduct of clinical trials and human research protection training).
Qualifications of research personnel	X			Refers to the review of information about the qualifications of research personnel; relying institution may be asked to provide information or documentation to reviewing IRB.
Notification of institutional legal requests and claims		X		The relying institution must inform reviewing IRB when in connection with the ceded research.
Notification of IRB legal requests and claims	X			The reviewing IRB must inform a relying institution when in connection with the relying institution's ceded research.
Contract/clinical trial agreement (CTA) congruence		X		The relying institution must coordinate with their relevant contracts office to ensure that the informed consent is consistent with language in the CTA.

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Institutional Reviews: • **Scientific** • **Feasibility** • **Radiation safety** • **Bio/DNA safety** • **Chemical and environmental** • **Coverage analysis** • **Pharmacy** • **Nursing**		X		The relying institution must communicate findings that impact the risk-benefit analysis of the ceded research to the reviewing IRB.

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