



# Suggestions for Implementing Standard I-9: AAHRPP Tip Sheet 24



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Association for the Accreditation of  
Human Research Protection Programs, Inc.<sup>®</sup>

# Single IRB Review Working Group

- Developed new Standard and revised Tip Sheet
- Extensive input from an advisory group established by AAHRPP
  - Met from June 2016 – May 2017
  - Additional input from external peer reviewers
- Variety of perspectives from many different types of organizations
  - Independent IRBs
  - Academic health centers
  - Hospitals
  - Research networks

## Standard I-9

- Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.
- Standard and Tip Sheet are located on AAHRPP's main web page



# **Part A: General Considerations**

## General considerations

- Describe the process for entering into agreements (MOUs, attestation, reliance agreements – what is negotiable, what is fixed).
- Process for adding new research sites.
- Process to ensure organization maintains record of all open research.
- Process for ensuring all relevant approvals (e.g., biosafety, radiation safety) are in place before research starts.

## Examples of additional materials

- Websites, tip sheets, researcher manuals – resources to ensure compliance with requirements of both organizations
- Decision trees, matrices, or other tools based on types of research, funding sources to decide whether to enter into reliance agreements
- Template reliance agreements and checklists
- Guidance documents and website information that are readily available to sponsors and researchers
- Checklists, databases, or other tools to aid researchers in tracking their responsibilities



## **Part B: Role of the Reviewing IRB or EC**

## Role of reviewing IRB or EC

- How general information about other organizations or research sites is collected and made accessible to the reviewing IRB or EC.
  - FWA, contact information for organizational official, accreditation status, whether ancillary reviews are needed before IRB or EC review.
- Site specific information (e.g., consent template language).
- International sites – relevant laws (age of majority, who can serve as LAR) – See AAHRPP Tip Sheet 19.
- Describe how study-specific information is collected.
- Adding study sites – as minor changes vs new studies.

## Role of reviewing IRB or EC – examples of materials

- Research initiation checklists.
- Consent and assent templates.
- How general information about other organizations or research sites is collected and made accessible to the IRB.
- Checklists for reviewing continuing review, reports of potential unanticipated problems involving risks to subjects or others, and reports of noncompliance or deviations from relying sites.
- Reporting templates for approval documentation, regulatory reporting, and routine communication with relying sites.

## **Role of reviewing IRB or EC – information collection tools**

- An application form specifically for single IRB review.
- Site-specific application forms for submission from each site or through a central PI or Coordinating Center.
- Tracking and documentation tools such as spreadsheets, matrices, databases.
- Mechanisms to track reliance agreement terms applicable to each research study.
- If local context information is collected separately from IRB or EC application forms, checklists or worksheets to provide this to the IRB or EC.



## **Part B: Role of the Relying Organization**

## Role of the relying organization

- Workflow for relying on external IRBs, including any approvals by the researcher's own organization.
- Who decides whether to rely upon an external IRB or EC.
- Identifying general areas where reliance is commonly used (independent IRBs for industry-sponsored research).
- Process for reporting suspensions, terminations, or study closures
- How to provide any site-specific language to the IRB.
- How to provide the reviewing IRB with local context information.

## Role of the relying organization – examples of materials

- Listing or checklists of terms required in reliance agreements.
- Local consent language.
- Checklist of local regulations, laws or policies.
- Checklists to document ancillary reviews (radiation safety, biosafety).
- A description of the local organizational structure that describes the relationship between various legal components where human subjects research is conducted and FWA coverage.

## **Role of the relying organization – information collection**

- An administrative application or study file for each research study.
- Reporting tools for communicating results of any HRPP reviews such as monitoring reports and conflict of interest management plans.
- Document reliance agreement terms applicable to each study.
- Develop methods to document key administrative and IRB or EC officials at each reviewing IRB (spreadsheet, table)



## **Part D: Relying on Non-accredited IRBs**

## Relying on non-accredited IRBs or ECs

- Organizations may rely upon non-accredited IRBs or ECs for a portion of research.
- Should take reasonable steps, based on risks in research, to ensure participants are protected
  - Attestations for not greater than minimal risk research
  - Potentially greater oversight of higher risk research

# Questions

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