Single IRB Review for Multicenter Research:
A Guide for Institutions

Single IRB review for multicenter research is becoming the norm in the US: initiatives like the NIH Single IRB (sIRB) policy, Common Rule revisions and the 21st Century Cures Act have made it clear that the federal agencies favor centralized review by a single IRB for multicenter research.

In this guide, we’ll discuss these new requirements and issues to consider as the research community evolves into this new landscape of mandated centralized IRB review.

### POLICIES

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<th>Policy</th>
<th>Requirements</th>
<th>Publish Date</th>
<th>Compliance Date</th>
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<td><strong>NIH Single IRB Policy</strong></td>
<td>Requires domestic awardees and domestic sites conducting NIH-funded multisite research to be overseen by a single IRB.</td>
<td>June 21, 2016</td>
<td>September 25, 2017</td>
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<td><strong>Final Revisions to “Common Rule”</strong></td>
<td>Requires single IRB review for federally funded multisite research with a few exceptions.</td>
<td>January 19, 2017</td>
<td>January 19, 2018</td>
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<td><strong>21st Century Cures Act</strong></td>
<td>Requires US government to reduce “duplication of effort” in human subject protections, suggesting centralized IRB review as one way to do that. Removes “local” from “institutional review board” references for device studies, aligning device regulations with established drug research regulations.</td>
<td>December 13, 2016</td>
<td>Deadline for harmonization of HHS (Common Rule) and FDA regulations to avoid regulatory duplication and unnecessary delays: December 13, 2019</td>
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In addition to the federal requirements, many industry sponsors prefer to rely on an sIRB for multisite studies.
RELYING ON AN OUTSIDE IRB

Institutions with a history of working exclusively with their local IRB will need to carefully examine local processes and requirements to determine how best to engage with an external IRB. Here are some key items to consider:

- **Number of IRB partnerships: Work with just one external IRB vs work with several (depending on the research opportunity)**
  - Institutions may find that limiting the number of sIRB partners also limits the type of research opportunities available to their investigators.

- **Which studies may be overseen by an sIRB vs which studies must remain with the local IRB**
  - The answer(s) here may vary based on the source of research funding.
  - Sample scenarios:
    - All industry-funded research goes to sIRB(s), investigator-initiated research stays with local IRB.
    - Only research in certain therapeutic areas (e.g., oncology, neurology, etc.) goes to sIRB.
    - Only late phase research goes to sIRB, early phase remains with local IRB.

- **Reliance agreements: Establish study-by-study reliance agreements vs global reliance agreement**
  - Global reliance agreements tend to be the proactive approach. They allow the institution to establish expectations and processes for working with the sIRB up front, so the review process can begin immediately whenever a new study arrives.
  - Study-by-study reliance agreements are usually established when a new study needs to be overseen by an sIRB. These agreements allow the institution to decide which IRBs it will work with on a per study basis.
  - Carefully evaluate any agreement that requires exclusivity. These often benefit the sIRB more than the institution, potentially locking the institution out of research being overseen by other sIRBs.

- **Compliance record**
  - Confirm the sIRB is registered with OHRP and FDA.
  - Inquire regarding AAHRPP accreditation status. An AAHRPP accredited sIRB has taken significant steps to demonstrate its regulatory compliance and quality, and these efforts have been validated by an established third party accreditation organization.
  - Request information on the sIRB’s FDA audit history (as applicable). If feasible, request an audit of the sIRB to evaluate the organization’s policies and processes according to the institution’s priorities and values.

- **Local requirements**
  - Define what institutional language must be included in each informed consent form.
  - Confirm whether only federally funded research is covered by the institution’s FWA, or if the FWA covers all institutional research (i.e., “checking the box”).
  - Evaluate how the local IRB review process will impact the sIRB review process (e.g., must the sIRB receive a completed cover sheet before proceeding with review?).
  - Identify any other local context requirements the sIRB should be aware of.
Communications with the sIRB
- Find out if the sIRB will be providing a primary point of contact for your institution.
- Determine who should receive communications from the sIRB: local research/HRPP office, principal investigator, and/or others.
- Determine who needs access to IRB documents from the sIRB.
- Determine the type and frequency of reporting the institution expects from the sIRB.
- Find out if the sIRB offers training resources for research staff.

Submission process: Centralized or decentralized
- Centralized sIRB Submission Process
  Institutional research oversight staff is responsible for all submissions to the sIRB

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<td>Offers institution complete control over which studies are submitted to sIRB and allows institution to confirm local requirements are addressed prior to sIRB submission.</td>
<td>More work for local research oversight staff.</td>
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<td>Institution is able to submit to sIRB more quickly, as only a handful of institutional staff need to be trained on sIRB submission process.</td>
<td>Limits communication between sIRB and specific study personnel.</td>
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Institutions choosing this process may wish to ask the sIRB for a primary point of contact to streamline communications.

- Decentralized sIRB Submission Process
  Researchers submit their own studies directly to the sIRB

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<td>Less work for local research oversight staff.</td>
<td>Not as much control over what is submitted to sIRB.</td>
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<td>Offers more communication between sIRB and study-specific staff at institution, which often leads to quicker responses to IRB-related inquiries.</td>
<td>More training is involved for the increased number of coordinators/research staff who need to learn on the sIRB submission system.</td>
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Institutions choosing a decentralized process may wish to require a cover page for the research office or HRPP to sign off on each submission, providing clear documentation of studies that may be reviewed by an external IRB.
SERVING AS AN SIRB

Serving as the IRB of record for multiple sites requires significantly more resources than serving as the IRB of record for a single site. Here are some key items to consider:

- **Technology**
  - Evaluate the institution’s current research management or IRB management software to determine if it can support multiple sites.
  - New software may be required to handle the additional relying sites.

- **SOPs**
  - Revise institutional SOPs to accommodate submissions from investigators outside the institution.

- **Resources**
  - Assess the capacity of current research office or HRPP staff. Can the existing staff support dozens of additional investigators, research staff and unique requirements from multiple institutions?

CONCLUSION

These federal initiatives seek to simplify the IRB review process and avoid duplicate efforts, and complying with the requirements necessitates a good deal of discussion and development at institutions and local IRBs. By proactively considering these issues and others, institutions and local IRBs will find themselves better prepared to comply with the requirements and better equipped to compete for future research.

Need specific guidance on how to comply with sIRB requirements? Contact Schulman IRB’s Institutions Team – having previously worked at institutions and local IRBs, we understand the challenges these policies present.