4 ESSENTIAL STEPS TO PREPARE FOR THE NEW sIRB POLICY

The National Institutes of Health's (NIH) policy that mandates that multi-site research studies assign a single Institutional Review Board (sIRB) of record has set institutions on a course for change. The impact of the new policy will have significant ripple effects — from people and processes, to service and technology. And with a portion of over $2 billion annually in competing grant applications[1] at stake, many institutions are confronted with a new research imperative: adapt or risk future funding.

The goal behind the policy is to benefit all stakeholders: reduce duplication of work, increase consistency of IRB determinations, streamline communications and expedite study start-ups. The logistics—including reorganizing processes and workflow—however, pose unique challenges.

This brief helps research organizations assess the impacts of the policy, weigh the pros and cons of various compliance solutions and prepare for the change.

ABOUT THE POLICY

The NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research (sIRB) establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use an sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects.

This policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after September 25, 2017.

4 STEPS TO PREPARE FOR THE CHANGE

1. CONDUCT A PORTFOLIO REVIEW

Institutions should take stock of their current portfolios of multi-site studies to better quantify the scope of the policy's impacts. Ask yourself the following:

- How many multi-site studies does the institution currently participate in that are NIH funded?
- Of those, for which ones does it currently serve as the lead site or IRB of record?
- How many NIH multi-site studies will be up for renewal in 2017?
- How many new multi-site grant applications does the institution anticipate submitting to the NIH in the upcoming year?
- In what NIH-funded multi-site study does the institution foresee participating as a performance site?
- Does the institution have a strategy to grow its research portfolio significantly in the next five years?

An organization's path forward should be guided by the volume of studies impacted by the policy — whether it involves making minor modifications to a current process, or investing in a commercial solution.

2. DETERMINE WHO WILL SERVE AS THE sIRB

The sIRB of record will be required to coordinate IRB review processes on behalf of all sites participating in the study; consequently, the site will need the right resources to process an increased volume of information.

Key selection criteria for an sIRB include:

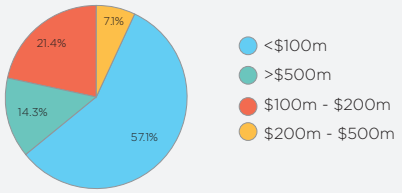
- Experience and expertise
- Accreditation or institutional standing
- Resources

In addition to existing IRBs, lead sites and participating sites (pSites), outside resources may also be considered for the sIRB role. Institutions that utilize commercial IRBs for industry-sponsored studies may realize efficiencies in using these same solutions for NIH-funded ones as well.

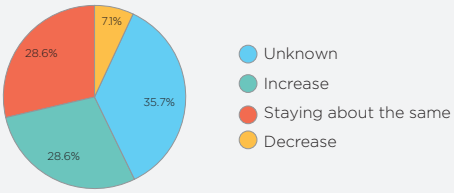
STATE OF RESEARCH FUNDING[2]

During a November 2016 webinar presented by Huron, participants were polled to gauge the prospective impact that the new policy may have on their institutions:

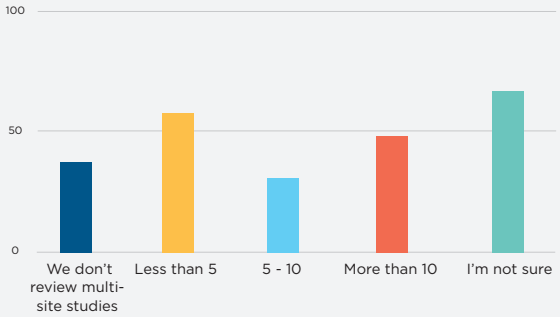
What level were your research expenditures last year?



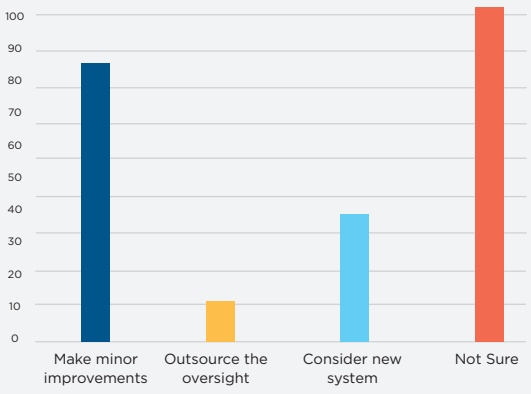
What is the trend for research funding at your institution?



How many multi-site studies are conducted at your institution for which your institution serves as the sIRB?



How do you plan to comply with the new policy?



Regardless of who is chosen as the sIRB of record, participating sites will continue to be responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of approved protocols, and reporting unanticipated problems to the sIRB.[3]

3. IDENTIFY THE BUSINESS PROCESSES THAT NEED TO BE CREATED AND/OR UPDATED

It's imperative that institutions thoroughly identify and document processes and service agreements between the sIRB and pSites that need to either be updated or created to ensure continuity of information, including:

- Authorization agreements
- Turnaround time commitments
- Communication processes

Authorization agreements should clearly define the responsibilities of the sIRB and pSites. The awardee institution for an NIH-funded, multi-site study should ensure that authorization agreements are executed with all pSites and ensure that communication channels are established between the sIRB and pSites. Additionally, the process for executing authorization agreements with all participating sites could be time-consuming if a template agreement is not accepted or used by all sites.

4. EVALUATE TECHNOLOGY OPTIONS

When a research institution's operational burden is lifted, productivity will dramatically increase, allowing it to focus on what matters most — its research mission.

Technology-driven automation strategies can deliver relief in the form of:

- Increased consistency across studies
- Streamlined and improved communications
- Reduced duplication of effort

There are pros and cons associated with various paths to NIH sIRB policy compliance:

- **Option A: Employ a manual process.** Although an institution may save budget in the short-term by avoiding a technology investment, the expense of

sIRB TECHNOLOGY SOLUTIONS

SMART IRB

- Developed by NIH NCATS
- Can be utilized to select the sIRB and facilitate the agreement process
- Provides authorization agreement templates that institutions may use
- Hosts a central list of IRBs of record
- Is not an IRB review platform

HURON IRB

- Developed by Huron
- Streamlines study workflow and facilitates compliance at the sIRB and pSites
- Built-in support for Huron IRB Exchange

HURON IRB EXCHANGE™

- Developed by Huron
- Cloud-based solution that facilitates cross-site communication and data exchange
- Enables secure institutional access to essential data, eliminating data-entry errors and increasing productivity

human resources (and risk of human error) may prove costly in the long run.

- **Option B: Modify an existing system.** An organization with an eIRB system has the ability to internally modify to accommodate serving as a sIRB; however, this may take significant effort and additional complexity if you allow pSite access to the sIRB system.
- **Option C: Outsource oversight to a commercial IRB.** Institutions running industry-sponsored studies using commercial IRBs may choose to use the same IRB for NIH-funded multi-site studies as well — increasing their ROIs and centralizing resources.
- **Option D: Move to a new system.** The process of cutting over to a new solution that supports sIRB functionality poses short-term challenges and added expenses, but could provide the infrastructure needed to ensure long-term success and cost savings.

While cost is a factor in weighing the best option for an institution, it's important to note the sIRB award applicant may also request direct cost funding to cover additional costs for pSite reviews related to the requirements of this policy, provided that NIH cost principles are followed.

CONCLUSION

Technology-driven solutions provide the greatest long-term benefit in handling the volume of multi-center trial interactions between research institutions seeking sIRB compliance — reducing operational burden, and increasing study effectiveness. With NIH funding at stake, organizations are incentivized to act quickly to meet the imminent deadline. Engaging in conversations early with all participating sites, thoroughly assessing the operational implications of the policy, and seeking the counsel of industry experts will enable institutions to put timely and effective processes in place without jeopardizing future studies.

ABOUT THE AUTHOR

Madeleine Williams, Senior Director, has 15 years of research experience and her work focuses on institutional review board (IRB) structure and function, regulatory compliance evaluations, human research protection program (HRPP) evaluation and accreditation, research biorepository design and development and research billing compliance. Prior to joining Huron, Madeleine served as a director for an independent IRB in addition to serving as a research coordinator in higher education and government settings.

THE HURON DIFFERENCE

Our experience stems from having actual practitioners who understand the issues facing research administrators at universities, academic medical centers, nonprofits and hospitals, and other clinical environments, as well as from having a strong technology implementation background.

- Huron's Education Research practice has partnered with 550+ institutions for a total of 3,500+ engagements — including 95+ of the top 100 research institutions.
- We have unmatched experience implementing enterprise software solutions for research, with a team of 250+ project managers, functional experts, business analysts and developers.
- We have proven implementation methodology, business process design and extensive experience with both academic medical centers and higher education institutions through our industry-leading software solutions — Huron's Research Suite (formerly known as Click TM).

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[1] National Institute of Health Research Portfolio Online Reporting Tools, https://report.nih.gov/budget_and_spending/index.aspx

[2] Polling results from 300+ participants of Huron webinar, "Prepare Now for the NIH's Single IRB Policy," November 2016

[3] Huron Consulting Group article, "NIH Releases Final Policy on the Use of a Single Institutional Review Board for Multi-site Research," https://www.huronconsultinggroup.com/resources/higher-education/nih-final-policy-single-irb