PREPARE NOW FOR THE NIH'S SINGLE IRB REVIEW POLICY

11.10.2016

AGENDA

+ Introduction
+ NIH Policy Change
+ Support for Single IRB Review in Click® IRB 8.1
+ Q & A

PRESENTERS

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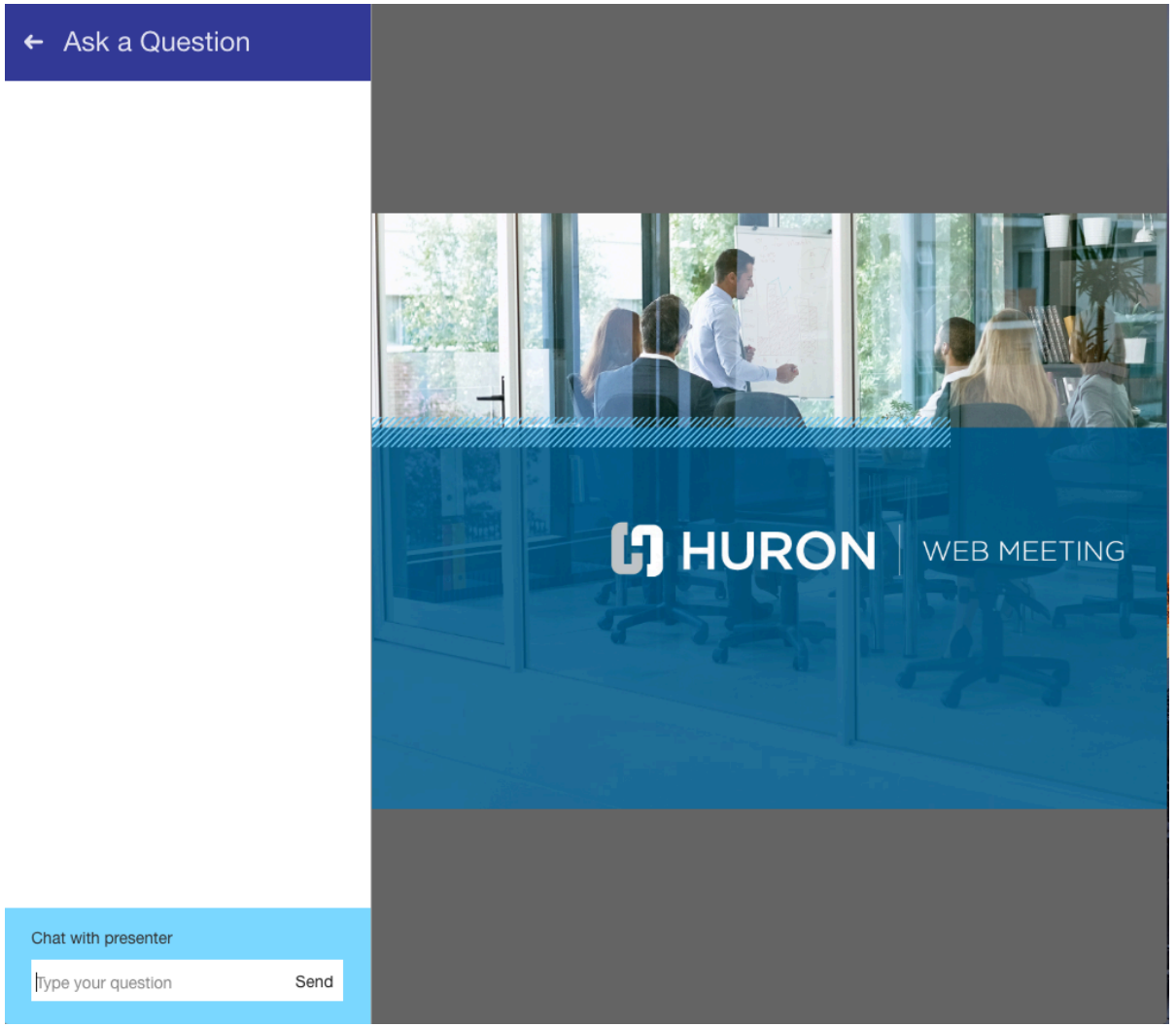
ASK US YOUR QUESTIONS: LEVEL 3 CHAT PANEL



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Keep the conversation going during and after the webinar.

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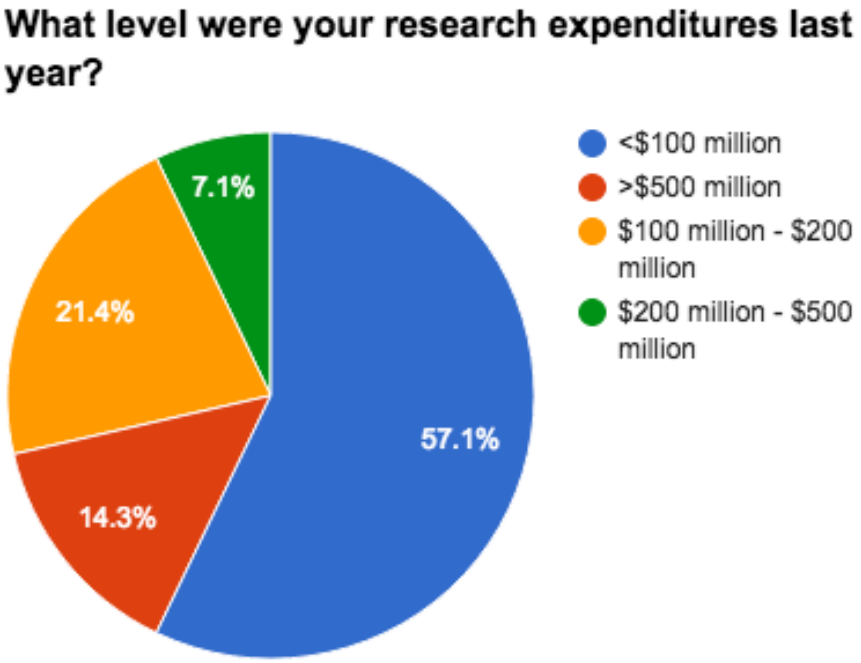

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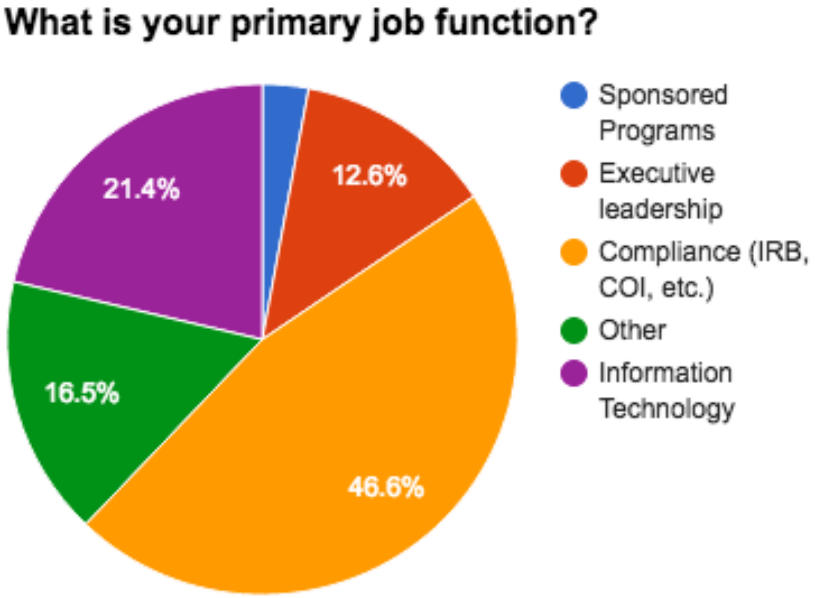

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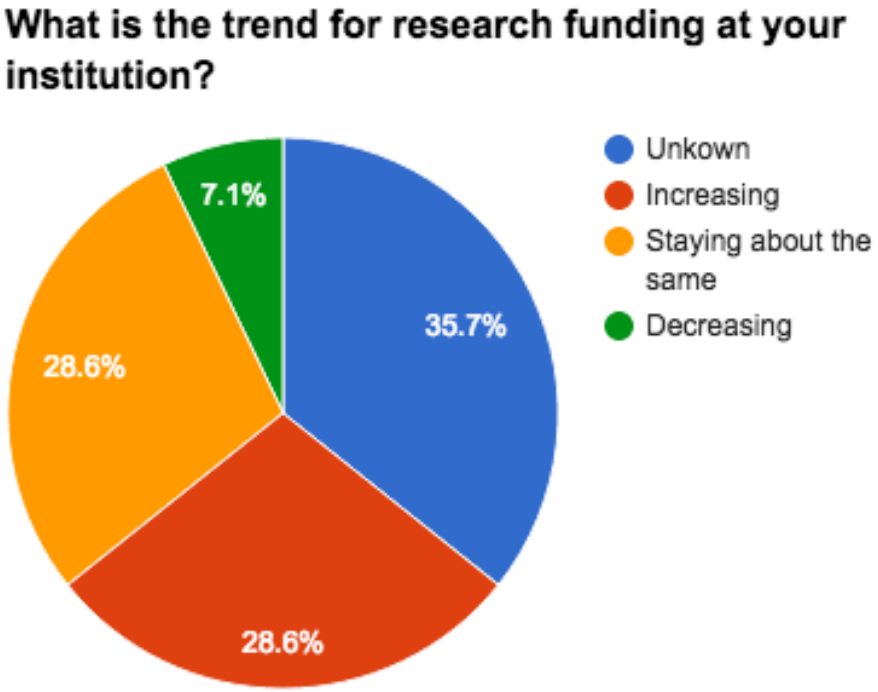

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NIH POLICY CHANGE

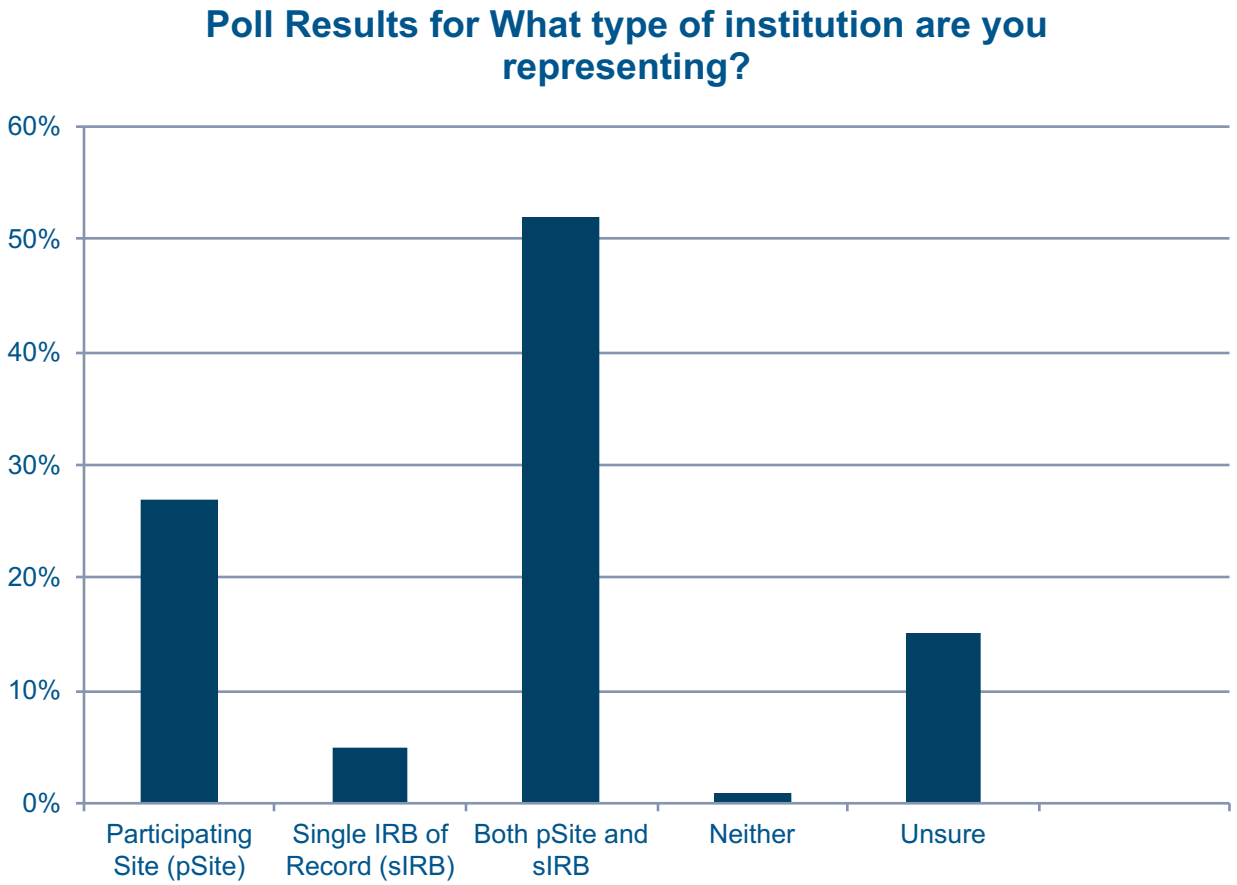
NIH POLICY UPDATE: SINGLE IRB REVIEW

The NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (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 May 25, 2017.

NIH National Institutes of Health
Turning Discovery Into Health

POLL #1



POLICY BACKGROUND: MULTIPLE IRB REVIEWS

- The “traditional” approach to ethical review of multi-site research has been for each participating site’s (pSite) IRB to review the research
- Challenges associated with the traditional approach include:
  - Duplication of effort
  - Inconsistency of IRB determinations
  - Delays in study start-up

POLICY BACKGROUND: MULTIPLE IRB REVIEWS

"For the majority of multi-site studies, the IRB at each participating site continues to conduct an independent review. This review adds time, but generally does not meaningfully enhance protections for the participants. This new NIH policy seeks to end duplicative reviews that slow down the start of the research."

- Francis Collins, NIH Director
June 20, 2016

- In the discussion of the policy, the NIH noted that there was not much evidence to support that multiple IRB reviews enhance protections for subjects involved in multi-site research
- The new NIH policy creates an expectation for a single IRB review arrangement that federal regulations have allowed on a voluntary basis

POLICY IMPLICATIONS:
PARADIGM SHIFT IN IRB REVIEW

- The NIH acknowledges that there may be “short-lived” challenges associated with the new policy
- Examples of implementation challenges include:
  - How costs associated with sIRB review may be charged as direct versus indirect costs
  - How the sIRB is selected
  - How IRB operations and electronic systems are adapted to facilitate the review process

POLICY IMPLICATIONS:
DIRECT VS. INDIRECT COSTS

+ The NIH has provided costing guidance* for the new policy for 12 scenarios

Scenario 1: ***Indirect***

- Institution A is the prime awardee, is conducting the study, and its IRB will serve as the sIRB

Scenario 3: ***Direct***

- Institution A is the prime awardee, is conducting the study, and is outsourcing sIRB responsibilities to an independent IRB

+ Huron's IRB and F&A teams are currently preparing additional guidance consistent with costing best practices

*Source: "Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research"

POLICY IMPLICATIONS: SELECTION OF THE sIRB

- The new policy requires the applicant to identify the sIRB in the grant application/proposal

- Considerations for sIRB selection include:
  - Experience and expertise represented on the proposed sIRB
  - Accreditation or standing of the proposed sIRB and/or sIRB's institution
  - Resources of the proposed sIRB
  - Utilization of an independent IRB as the sIRB
  - Execution of authorization agreements

POLICY IMPLICATIONS: AUTHORIZATION AGREEMENTS

- Authorization agreements should clearly define the responsibilities of the sIRB, the lead site, and pSites
- NCATS is developing a reliance platform called SMART IRB
  - Streamlined, Multisite, Accelerated Resources for Trials
  - SMART IRB is based on the IRBrely model; Huron IRB experts Maddie Williams and Tom Bechert were part of the IRBrely team
  - SMART IRB can be utilized to select the sIRB and facilitate the agreement process, but it *is not* an IRB review platform

POLICY IMPLICATIONS: IRB REVIEW

- Institutions should consider how the new policy impacts existing IRB operations and resourcing, including people, processes, service, and technology
  - The NIH has not yet released guidance on these topics
- There are different considerations for institutions serving as an sIRB and institutions ceding review to an sIRB

POLICY IMPLICATIONS: sIRB CONSIDERATIONS

1. People

- Who decides whether or not to serve as the sIRB for multi-site studies?
- With whom does the sIRB coordinate the submission and review process, with the lead site only or with all pSites?
- Do you have the staff needed to process an increased volume of information for the studies and pSites?

2. Processes

- What business processes need to be created and/or updated to serve as the sIRB?
- What other ancillary reviews are required for multi-site studies?

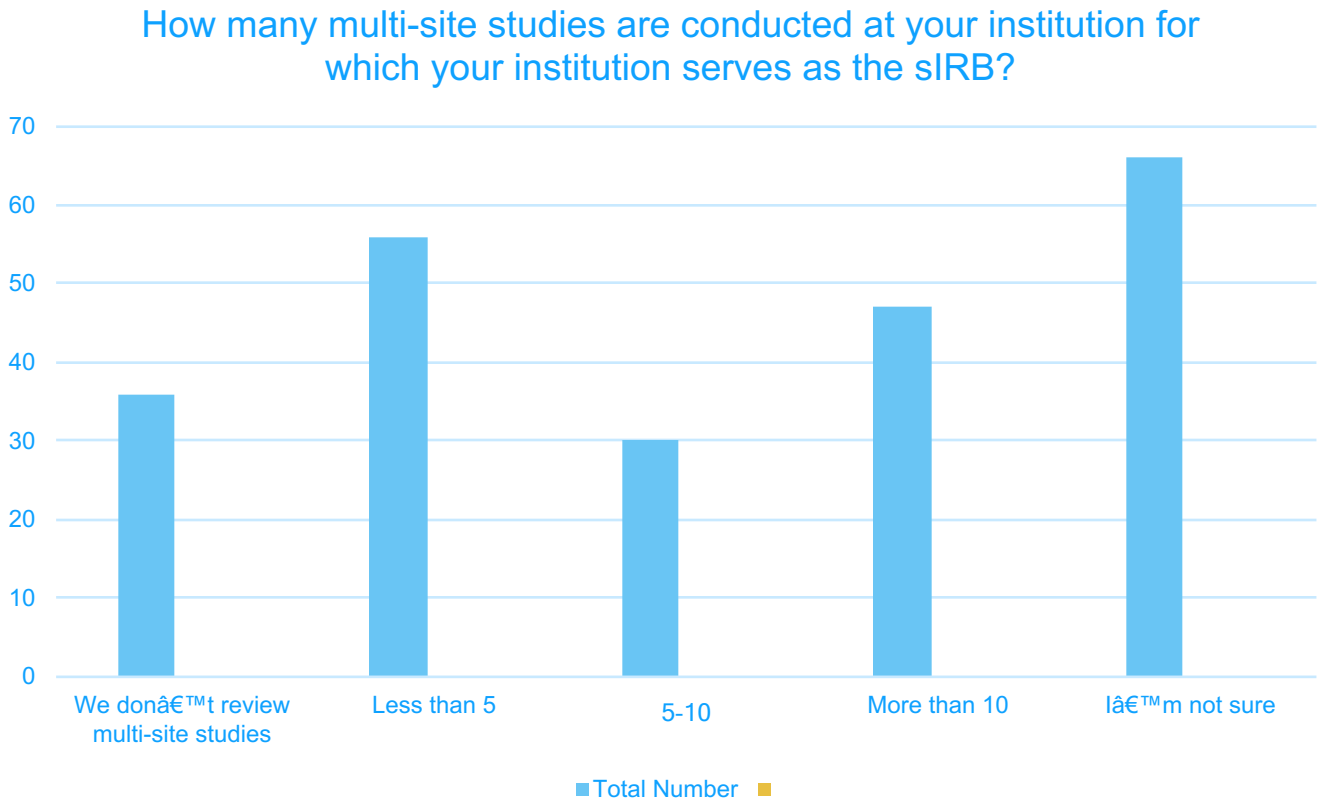
3. Service

- What turnaround time commitments is the sIRB prepared to make?
- How does the sIRB communicate with pSites?

4. Technology

- Does the sIRB have an electronic management system?
- What time, effort, and costs would be required to adapt that electronic management system to facilitate the review process?

POLL #2



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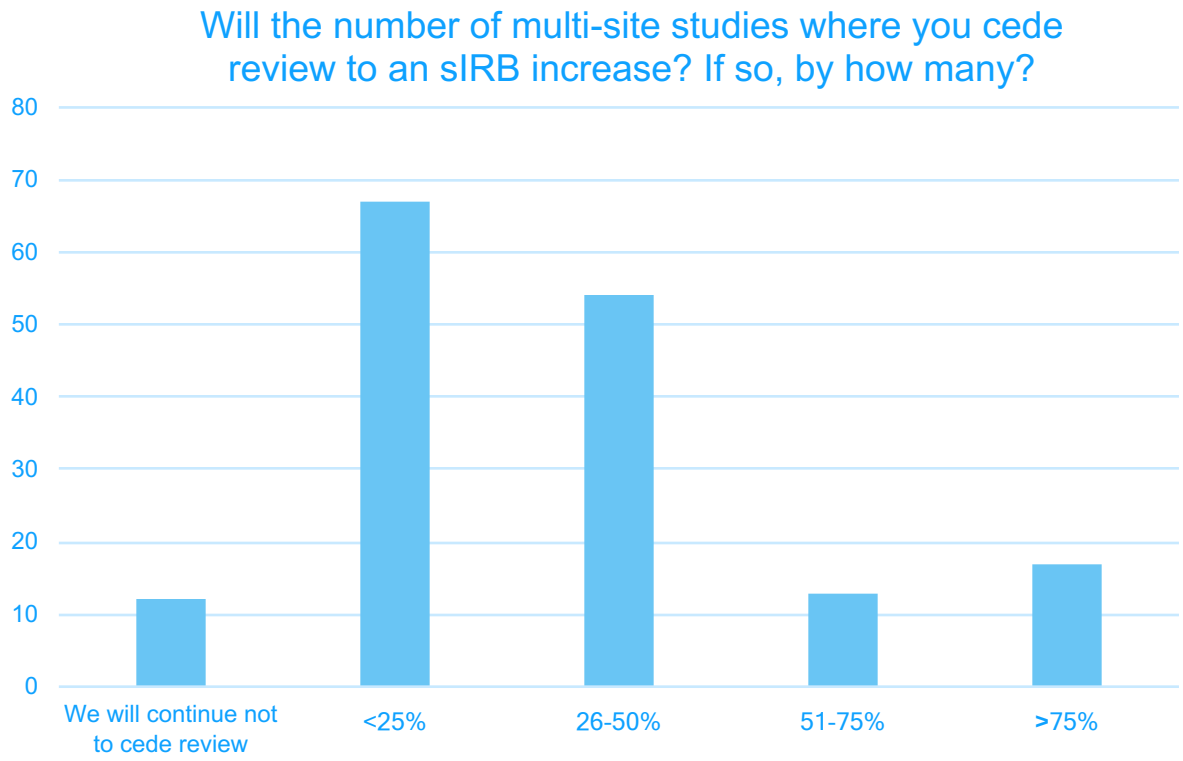

POLICY IMPLICATIONS:
pSITE CONSIDERATIONS

1. People

- Who will identify studies in which to participate?
- Who decides whether or not to rely on any particular sIRB?

2. Processes

- What business processes need to be created and/or updated to cede review to an sIRB?
  - Does volume impact how those processes are shaped?
- What responsibilities are retained by the pSite, e.g., COI management, other ancillary reviews?

3. Service

- What turnaround time expectations does the sIRB promise?
- How does the pSite communicate with the sIRB?
- What role does the pSite IRB play in facilitating the review process for ceded review, if any?

4. Technology

- Does the pSite have an electronic management system or another tracking tool?
- What time, effort, and costs would be required to adapt that electronic management system to facilitate the process of ceding review?

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SUPPORT FOR SINGLE IRB REVIEW IN CLICK® IRB 8.1

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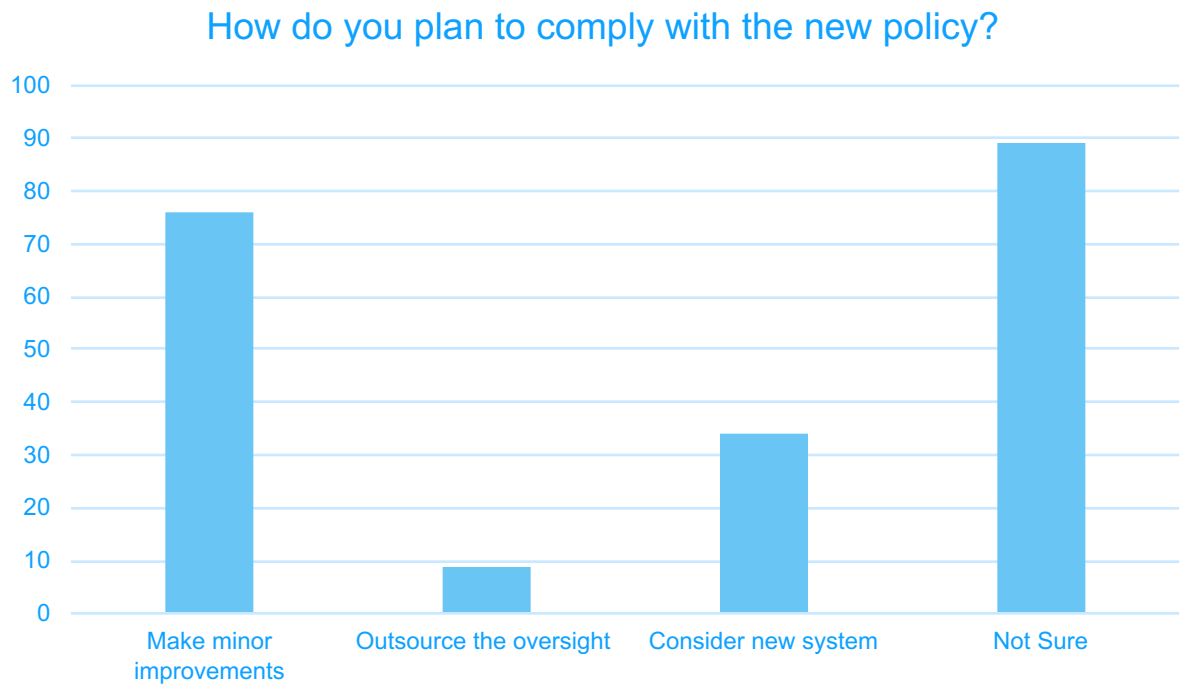
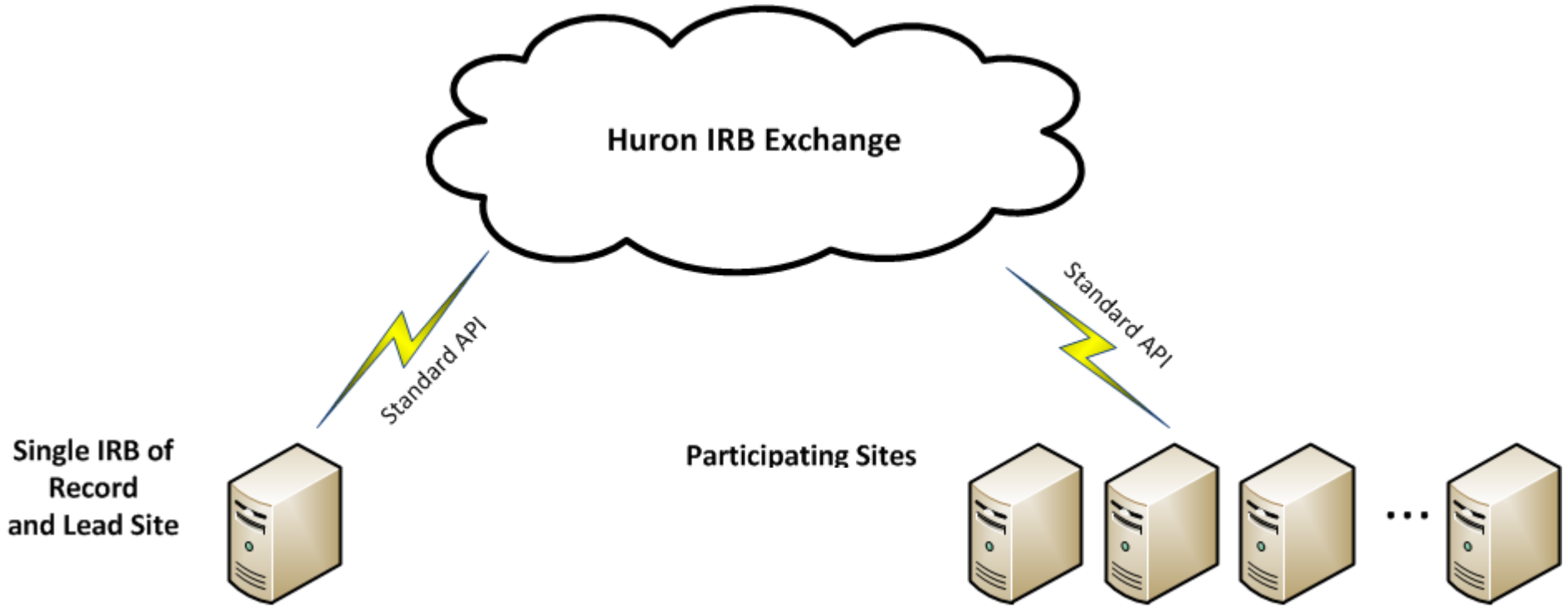
POLL #4



MULTI-SITE STUDIES REQUIRE CROSS-INSTITUTION COORDINATION



NEW CLOUD SERVICE
HURON IRB EXCHANGE

What is the Huron IRB Exchange?

+ The Huron IRB Exchange (aka “the Exchange”) is a cloud-based service, hosted by Huron, designed to facilitate the sharing of information between the sIRB and pSites

Why use the Exchange?

+ Though use of the Exchange will not be required, it addresses the critical need of timely exchange of data between different institutions
+ Use of the Exchange, allows institutions to avoid the troublesome task of provisioning user accounts for remote participants

Who can use the Exchange?

+ Any institution is able to sign up for the Huron IRB Exchange to exchange information according to a well-documented interface
+ Click® IRB 8.1 will deliver functionality that natively supports the use of the Huron IRB Exchange for both Single IRB’s of Record and Participating Sites

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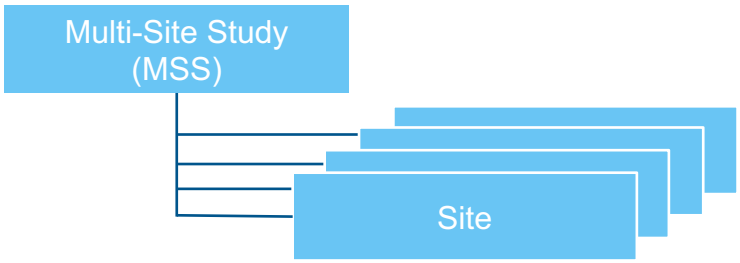
INSTITUTIONAL RELATIONSHIPS ARE TRACKED THROUGH THE INSTITUTIONAL PROFILE

What is the Institutional Profile (IP)?

- Each institution will maintain information about partner institutions in their local Huron IRB site that will allow for the tracking of
  - Contact Information
  - Authorization Agreement and effective status
  - Consent Form and Recruitment Material templates to be used by the Participating Site

MULTI-SITE STUDIES REQUIRE THE INTRODUCTION OF A PARTICIPATING SITE

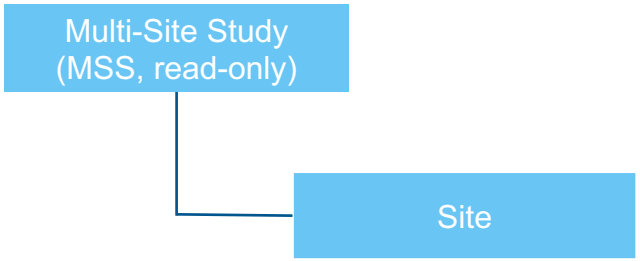
Single IRB of Record (sIRB) System:



The sIRB system will master information on the
- MSS
- Lead Site

And maintain lightweight information on all Participating Sites as received through the IRB Exchange or manually maintained

Participating Site (pSite) System:



The pSite system will keep a read-only copy of
+ MSS as delivered through the Exchange

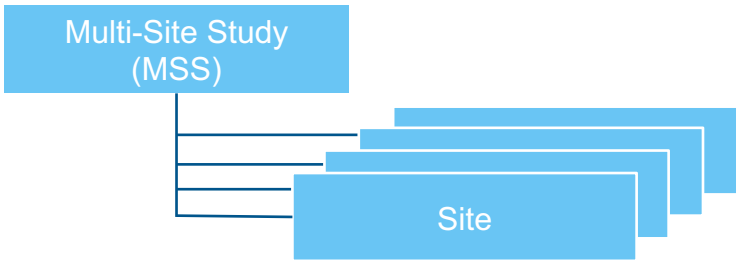
And maintain information on the Local Site

INFORMATION CAPTURED IN A SITE

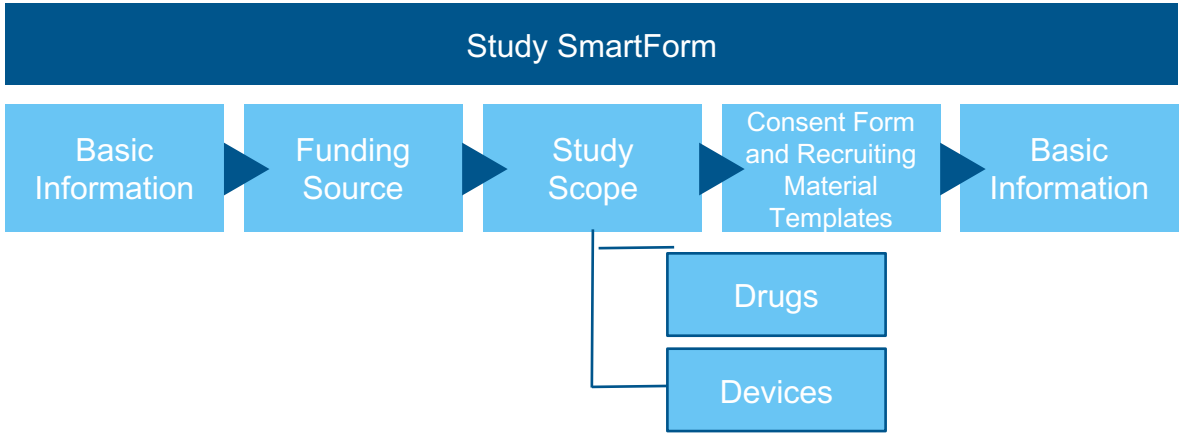
Each Site project will maintain the following information:

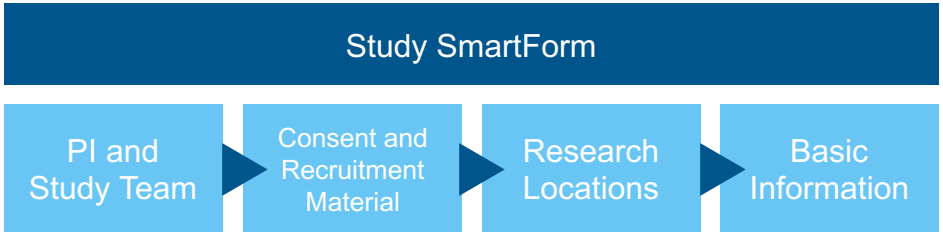
+ A reference to the related Multi-Site Study (MSS)
+ Principal Investigator (PI)
+ Study team (for the local site only)
+ Local, site-specific Informed Consent Forms
+ Local, site-specific Recruitment Materials

The MSS will not maintain site specific information and instead be related with one or more Sites



DATA CAPTURE:
2 PROJECTS, 1 EXPERIENCE





Study Team only collected for local site

+ **The Study**
  - Focuses on the research and method, not the team or locations
  - Will indicate if it is a MSS
  - Will keep the template consent form templates
  - is related to 1 or more sites

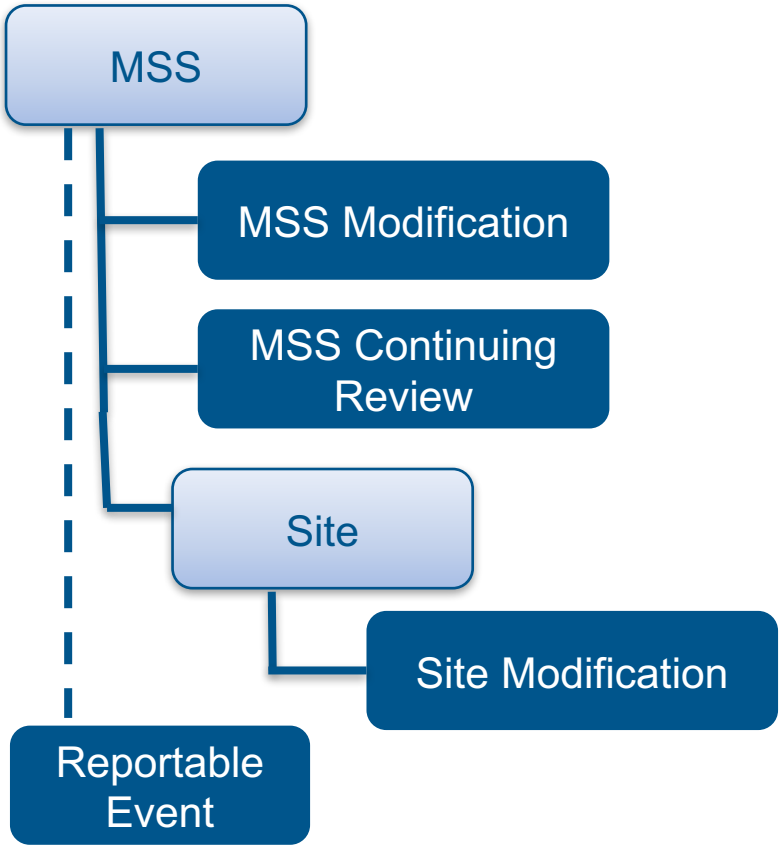
+ **The Site**
  - Focuses on the who and where of conducting the study
  - Will keep local consent forms and recruitment materials
  - Is related to one study

STUDY AND SITE REVIEWED SEPARATELY

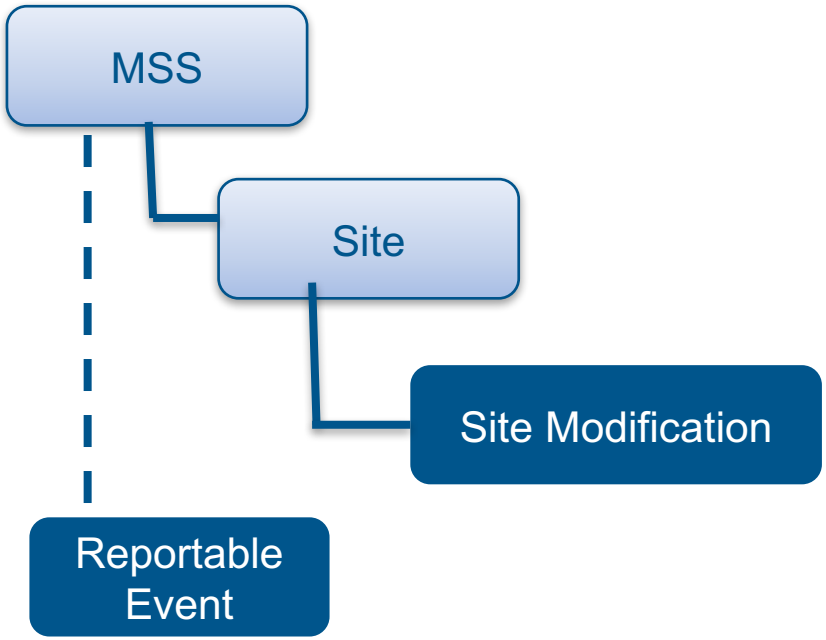
- Both Study and Site will follow a similar review process
- Both support Designated Review and Committee Review
- The only significant difference is the information captured during the review process

FULL SUPPORT FOR FOLLOW-ON SUBMISSIONS

Single IRB of Record:



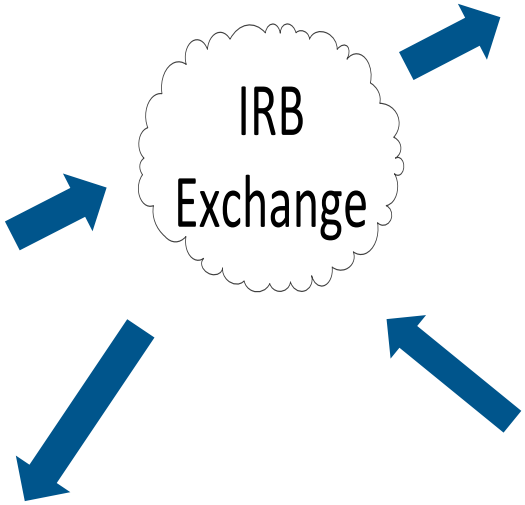
Participating Site:



EXAMPLE:
NEW MSS SUBMISSION

sIRB: Greenfields University

1. Lead Site PI submits MSS, Lead Site information for review by Local IRB
2. sIRB reviews and approves submissions triggering notifications
3. Study details published to the Exchange



pSite: Flatrock School of Medicine

4. pSite downloads study which automatically creates the local Site record
5. pSite PI completes the Site project and submits to pSite IRB for review
6. pSite IRB reviews and approves Site project triggering notification to pSite PI and Primary Contact, Lead Site PI and Primary Contact, and sIRB IRB Coordinator
7. Approved Site information is published to the Exchange

8. pSite information is downloaded from the Exchange for final review by sIRB
9. sIRB reviews and approves pSite causing activation

WHEN THE IRB EXCHANGE ISN'T USED, MANUAL UPDATES ARE APPLIED

- pSites without the ability to connect to the IRB Exchange can leverage a "human proxy" approach where updates from external sources can be manually applied to the local system.

- Multi-Site Studies may have participating sites that are unable to electronically transmit their information via the Huron IRB Exchange. In this case, the sIRB will have the ability to manually record pSite information into the system.

Q&A

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