HURON SINGLE IRB REVIEW OPTIONS FOR CLICK RX SITES

11.29.16

SINGLE IRB REVIEW FOR RX

1. Introduction
2. Policy Overview
3. Considering your options for achieving compliance
4. Click® IRB 8.1 Overview
5. Custom Enhancement Options
6. Q&A and Next Steps

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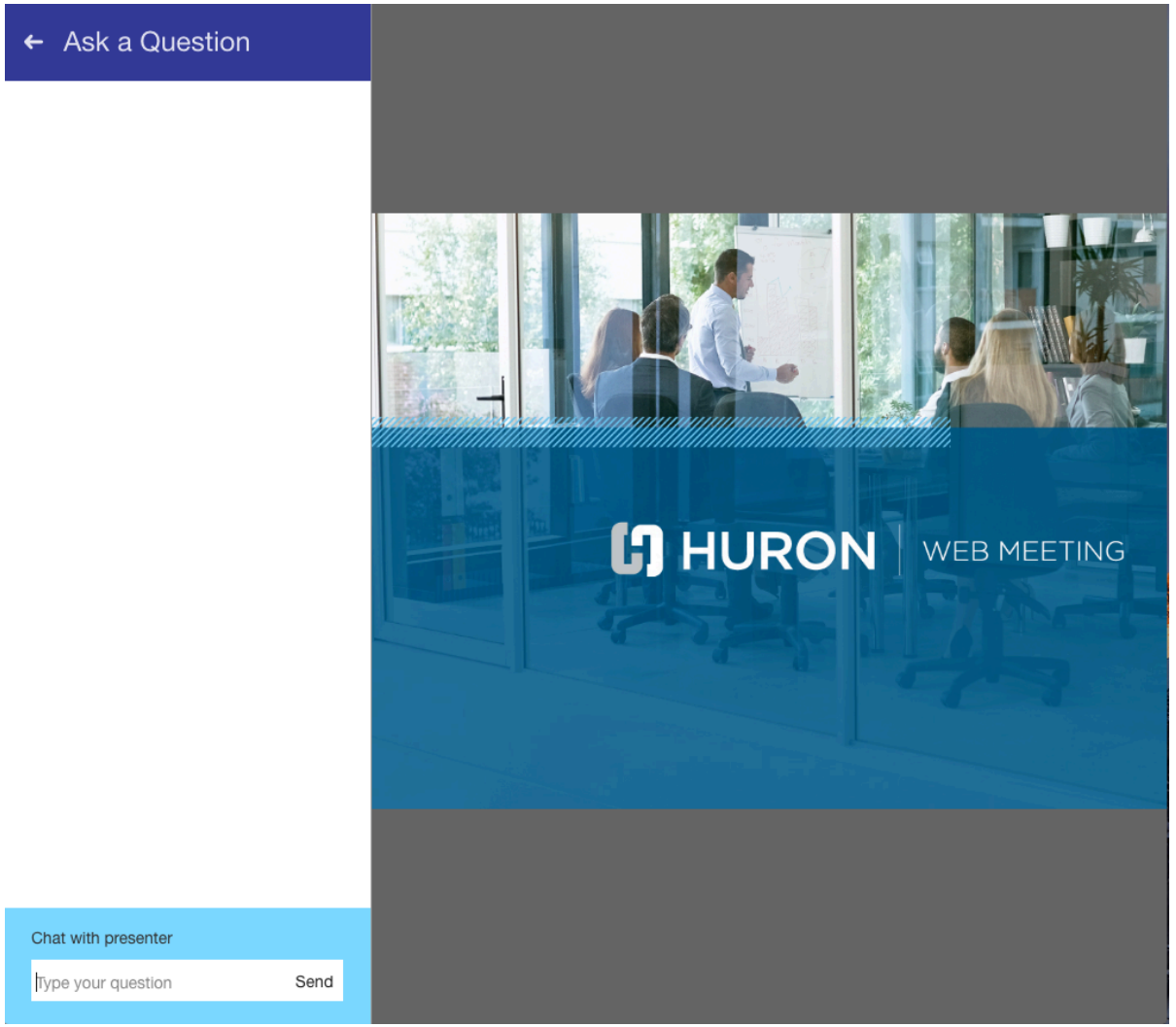
ASK US YOUR QUESTIONS: LEVEL 3 CHAT PANEL



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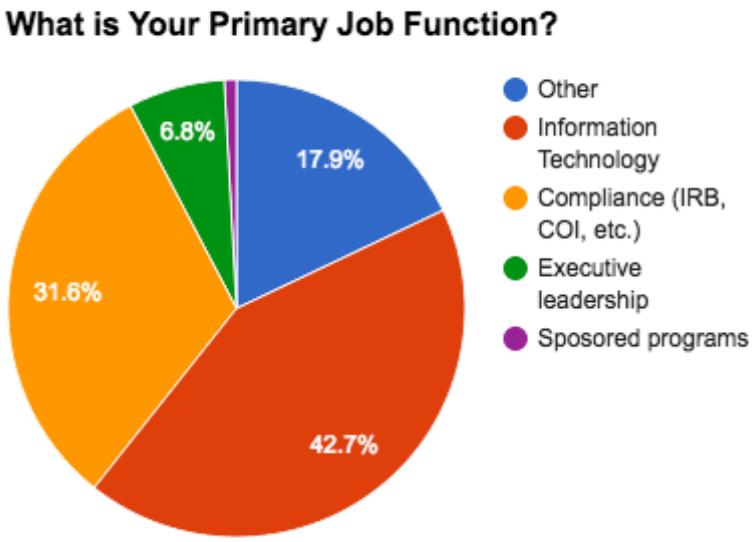
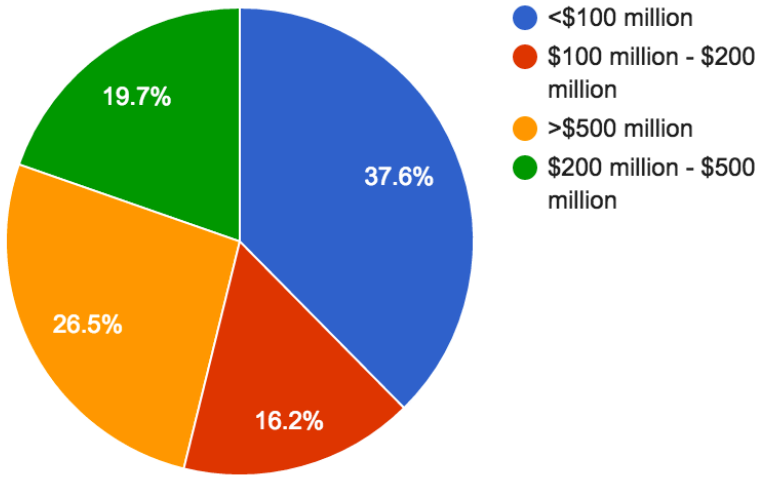


WHO IS ATTENDING THE WEBINAR TODAY?

What Level Were Your Research Expenditures Last Year?



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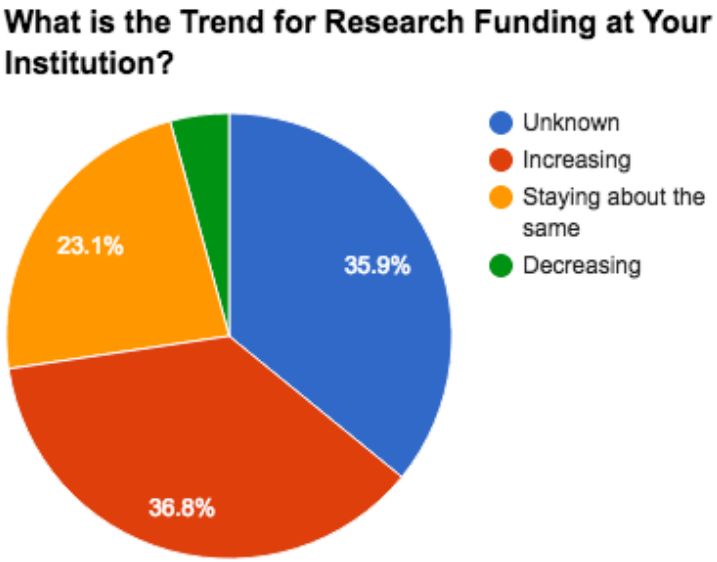
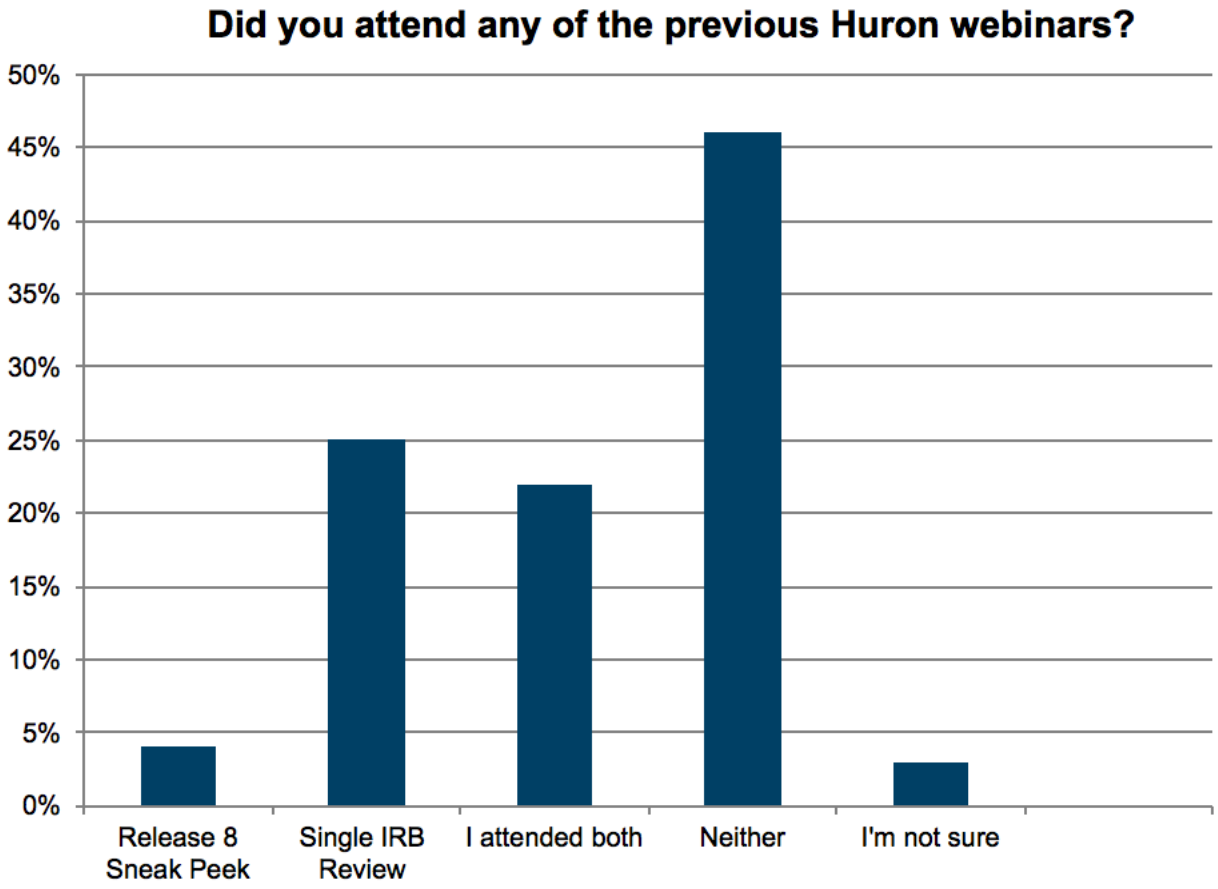


POLL #1



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SINGLE IRB REVIEW – POLICY OVERVIEW

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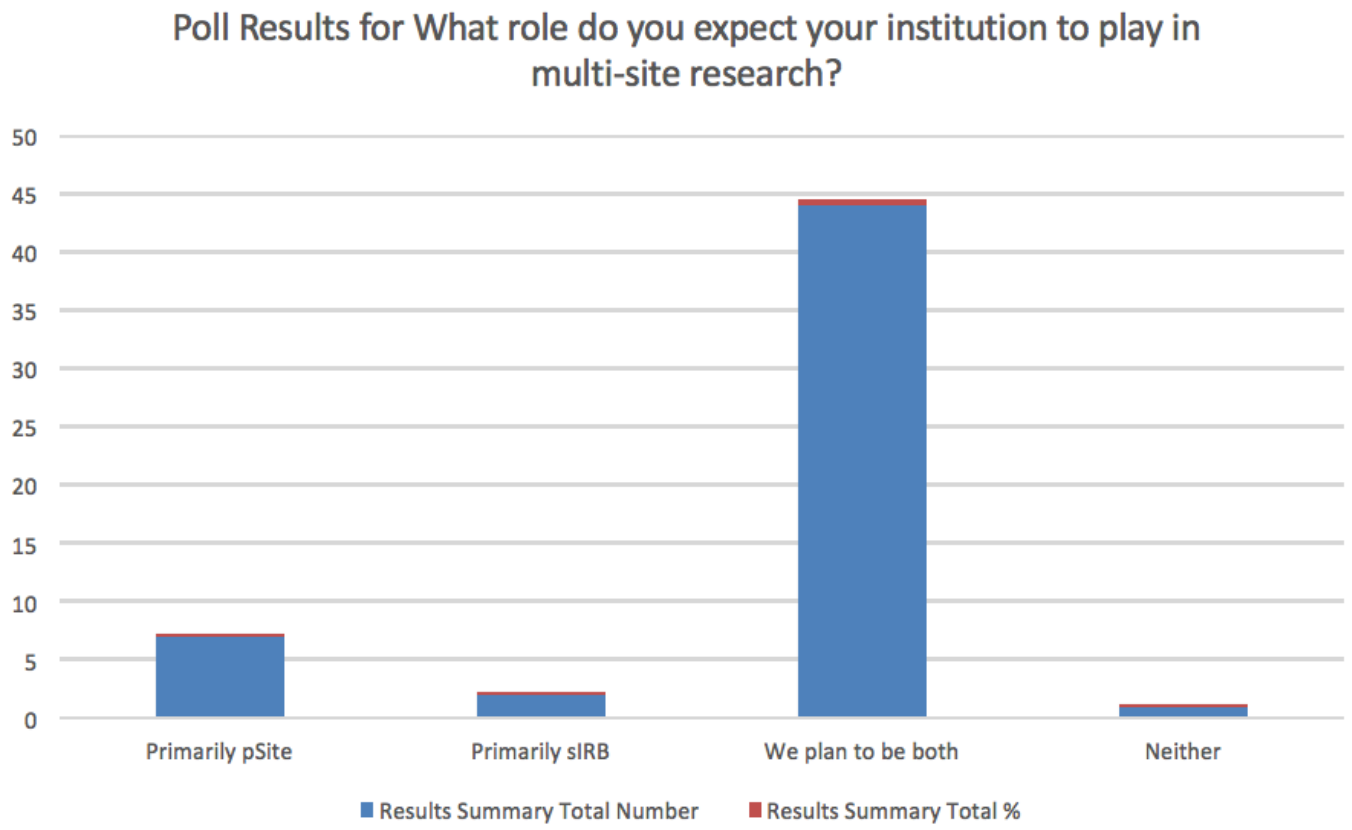
NIH POLICY UPDATE: SINGLE IRB REVIEW

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.

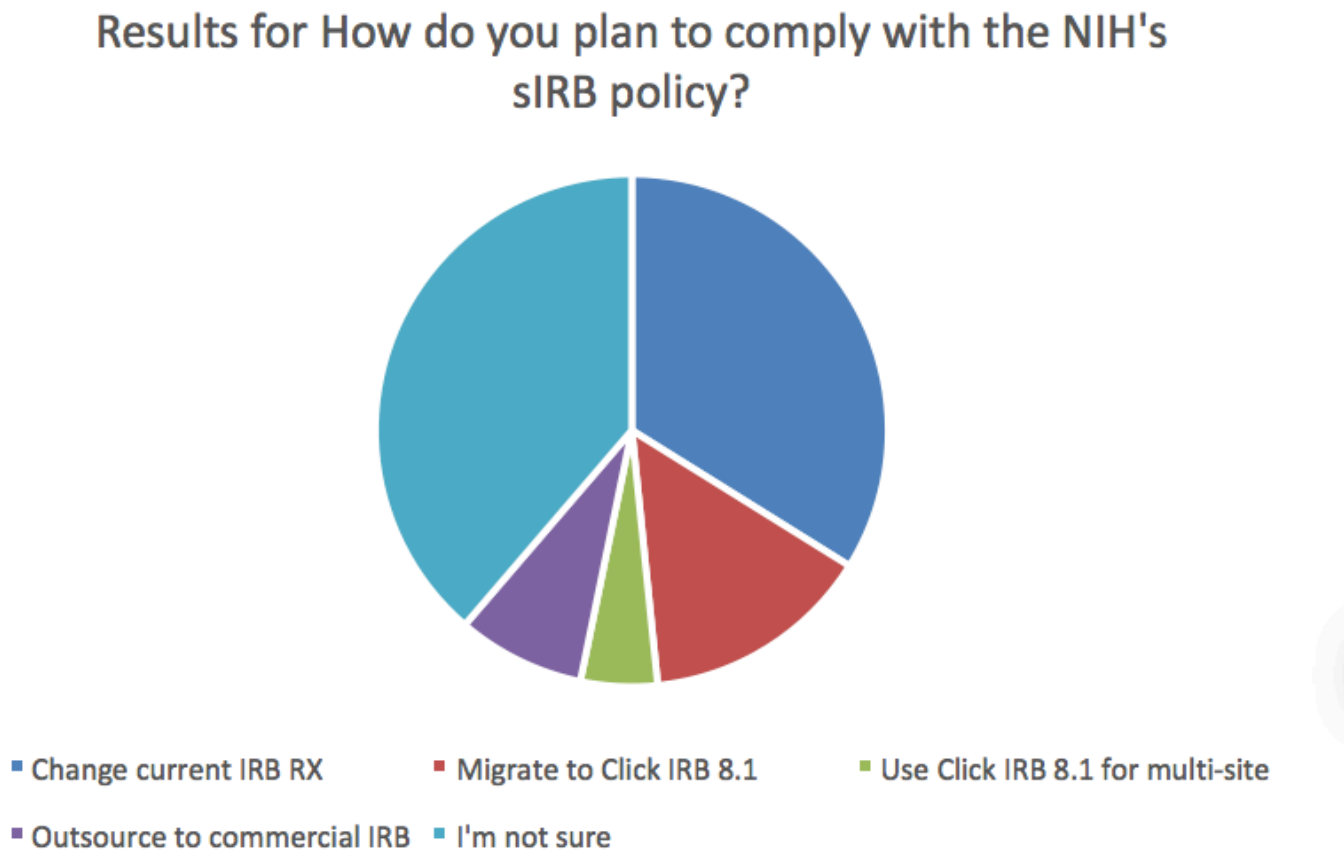
POLL #2



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

POLL #3



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

- **People**
  - Who decides whether or not to serve as the sIRB for a multi-site study?
  - With whom does the sIRB coordinate the submission and review process, with the lead site only or with all pSites?
  - Are IRB staff prepared to process information for the study and pSites?
- **Processes**
  - What business processes need to be reviewed and updated to serve as the sIRB?
  - What other ancillary reviews are required for multi-site studies?
- **Service**
  - What turnaround time commitments is the sIRB prepared to make?
  - How does the sIRB communicate with pSites?
- **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?

COMMON TERMINOLOGY

- **Authorization Agreement**
  An agreement between the sIRB of record and a participating site.
- **Lead Site**
  The site where the lead PI is located – is not necessarily located at the institution where the grant was awarded
- **Participating Site (pSite)**
  Site participating in the conduct of research for a study
- **Local Site**
  A site that is at the same institution as the sIRB
- **Single Institutional Review Board (sIRB)**
  The sIRB is the IRB of record for multi-site research. The NIH, per their final ruling, expects a sIRB of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the U.S.
- **Institutional Profile (IP)**
  A record of information about a participating site or sIRB
- **Multi-Site Study (MSS)**
  A single study, reviewed by a single IRB of record, and conducted by multiple pSites
- **Common Acronyms**
  - **CR** Continuing Review
  - **DCC** Data Coordinating Center
  - **FWA** Federalwide Assurance
  - **IB** Investigator's Brochure
  - **ICF** Informed Consent Form
  - **IRB** Institutional Review Board
  - **PI** Principal Investigator
- **New Software Service**
  - **Huron IRB Exchange**
    Click® IRB Exchange (exchange) is a cloud-hosted software component that leverages Click® Connector to enable data exchange between Click® IRB and pSites.

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CONSIDERING YOUR OPTIONS FOR ACHIEVING COMPLIANCE

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MINIMUM FEATURES OF A COMPLIANT SINGLE IRB SYSTEM

- Maintains relevant information on all eligible sites, including specific constraints, consent and recruitment language, and assurance agreement details
- Tracks multiple participating sites for a single Study, including Site specific Consent Forms, recruitment Materials and other relevant documents.
- Supports the ability to record enrollment numbers for each participating site in support of the Study Continuing Review process
- Supports Modifications for both Study and Site information
- Allows the reporting of incidents from all participating sites

HOW WILL INFORMATION BE SHARED?

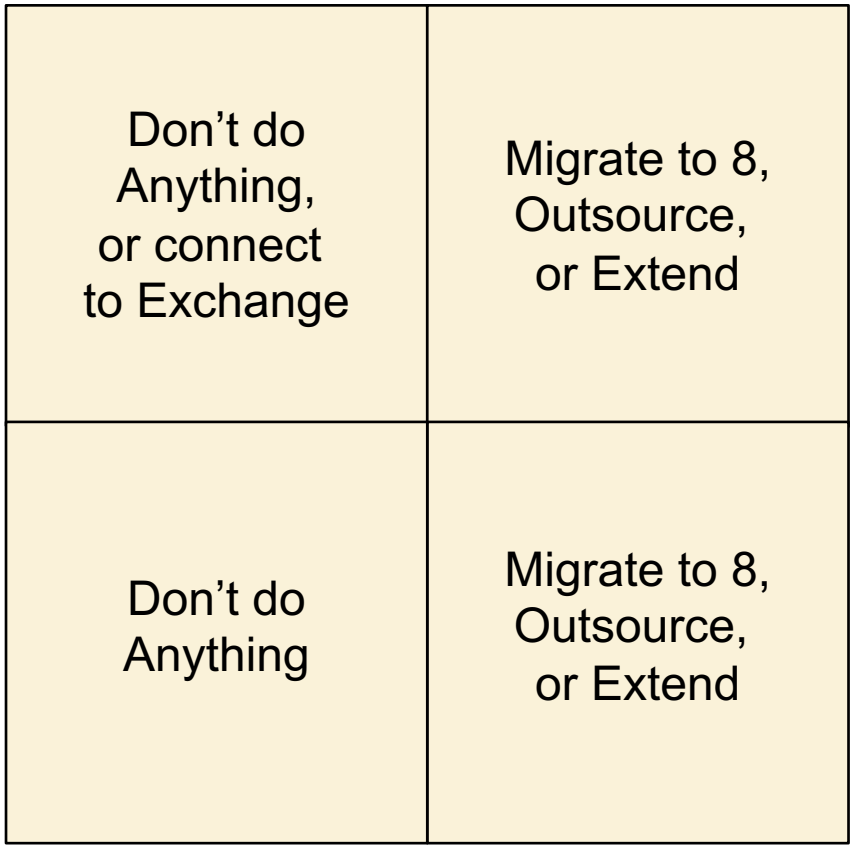
+ How will participating site information get recorded into the sIRB System?
+ How will pSites be able to conduct Site reviews according to local SOPs?

Approach	Advantages	Disadvantages
Self-Service	• Minimizes demand on sIRB Staff	• Provisioning access to users from other institutions may not be easily supported by central IT
Direct support by sIRB staff	• No need to provision access to external users	• Requires additional staff to support the needs of all Participating Sites
Facilitated approach using a separate internal group	• No need to provision access to external users • Minimizes demand on sIRB Staff	• Requires separate team • Requires updated SOPs by IRB to work with facilitators as PI proxies
Syndication (Sharing of information between institutional systems)	• Avoids need for account provisioning	• Requires additional development
Leverage a Commercial IRB for all Multi-Site Studies	• Shortest technical path to compliance	• Ongoing cost • Fragmented experience for local research staff

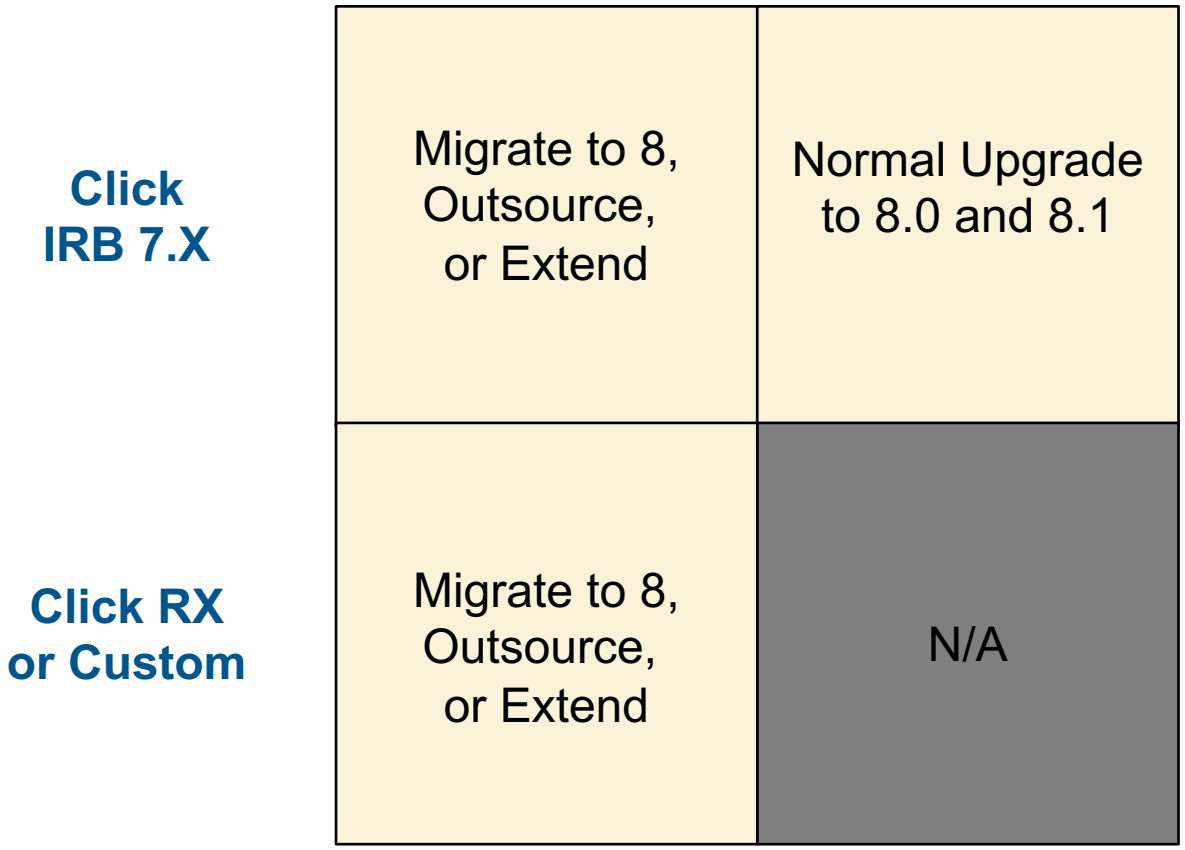
THREE POSSIBLE APPROACHES: YOUR CHOICE

- Outsource all Multi-Site Studies to a Commercial IRB
- Convert or Upgrade to IRB 8.1
- Leverage Hosted IRB 8.1 store for all MSS Studies
- Enhance your existing RX site through further customizations
- Do Nothing

DECISION CRITERIA #1
SINGLE IRB REVIEW IMPACT



DECISION CRITERIA #2
CURRENT IRB SOLUTION



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CLICK IRB 8.1 OVERVIEW

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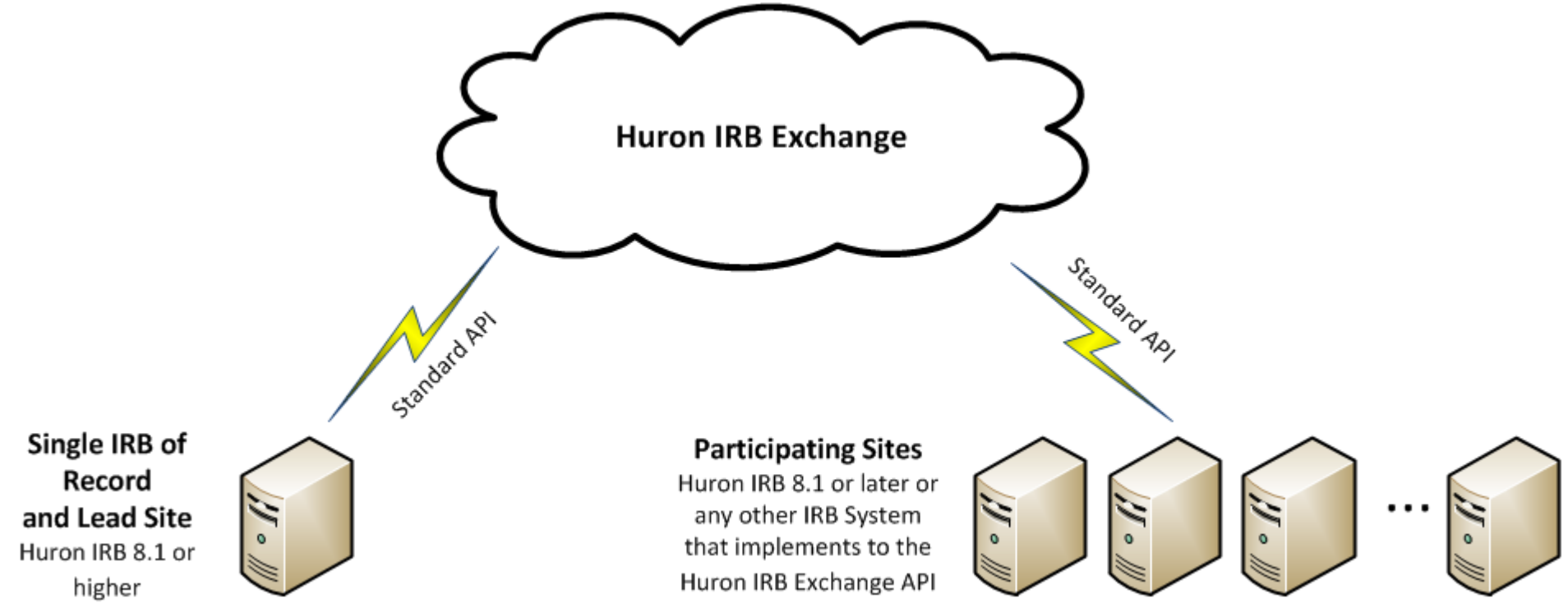
HURON IRB 8.1 WILL FULLY SUPPORT THE UPDATED POLICY

- ✓ Syndicated Information Exchange
- ✓ Site invitation and review process guided by Institutional Profiles
- ✓ Participating Site perform Site Reviews according to local SOPs
- ✓ Site Modifications in Parallel with Study Modification
- ✓ Support for sIRB Review of Site-specific consent forms and recruitment materials
- ✓ Support for Site Enrollment reporting

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

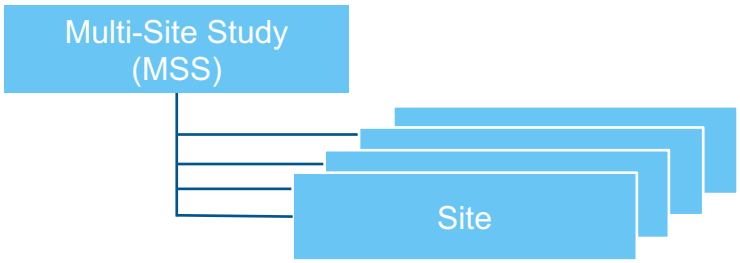
INSTITUTIONAL RELATIONSHIPS ARE TRACKED THROUGH THE INSTITUTIONAL PROFILE

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 template language be used by the Participating Site

MULTI-SITE STUDIES REQUIRE THE INTRODUCTION OF A PARTICIPATING SITE

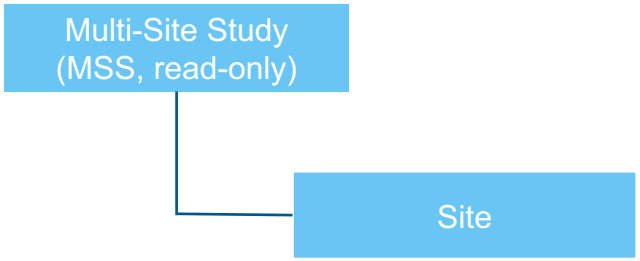
Single IRB of Record (sIRB) System:



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

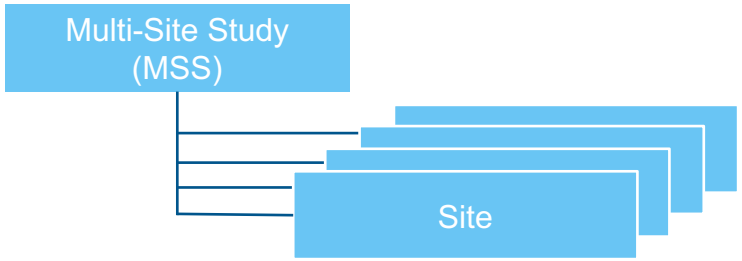
And maintain information on the Local Site

INFORMATION CAPTURED IN A SITE PROJECT

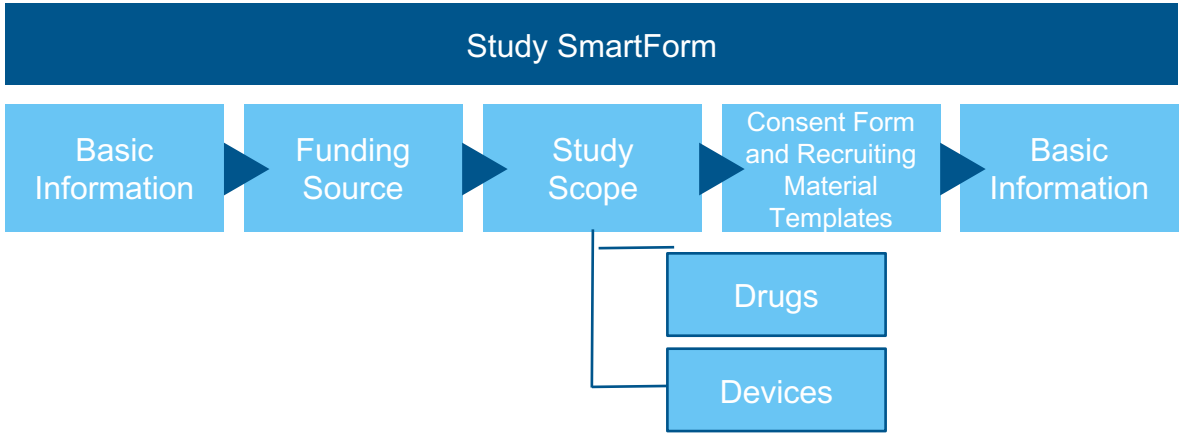
Each Site project will maintain the following information:

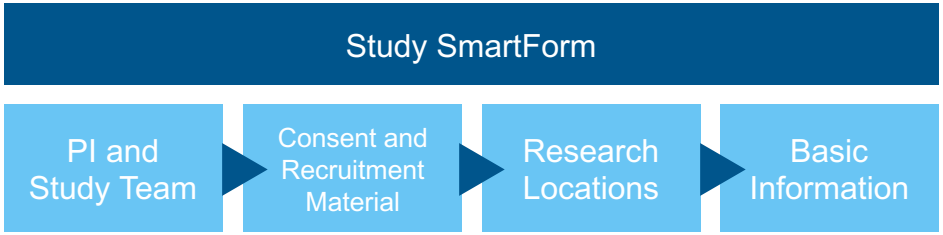
- A reference to the related Multi-Site Study (MSS)
- Principal Investigator (PI)
- Study team (for the local site only)
- Local, site-specific Informed Consent Forms
- Local, site-specific Recruitment Materials

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

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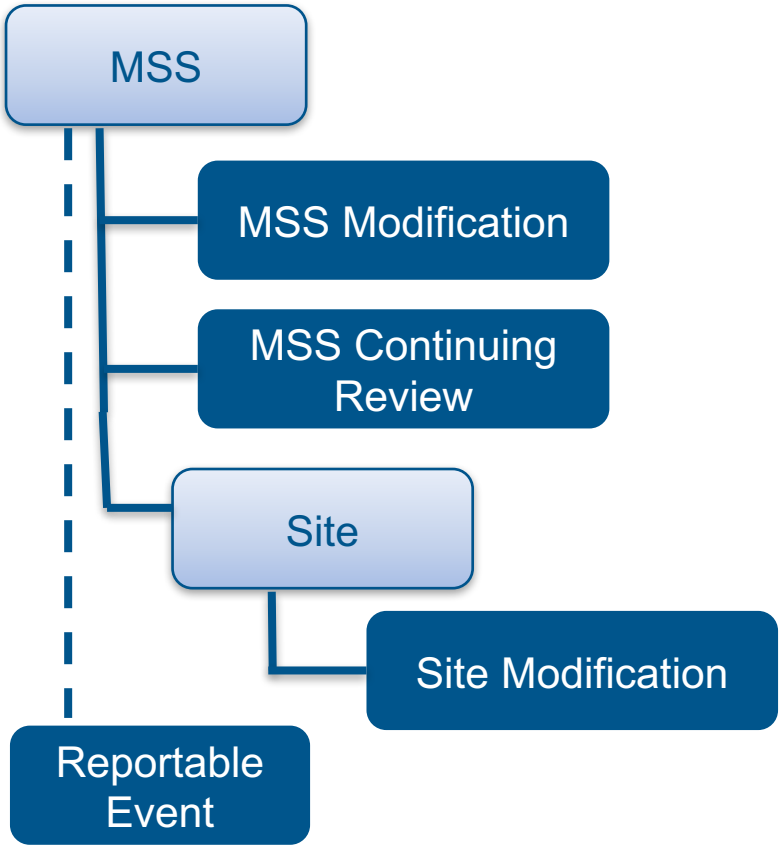
STUDY AND SITE REVIEWED SEPARATELY

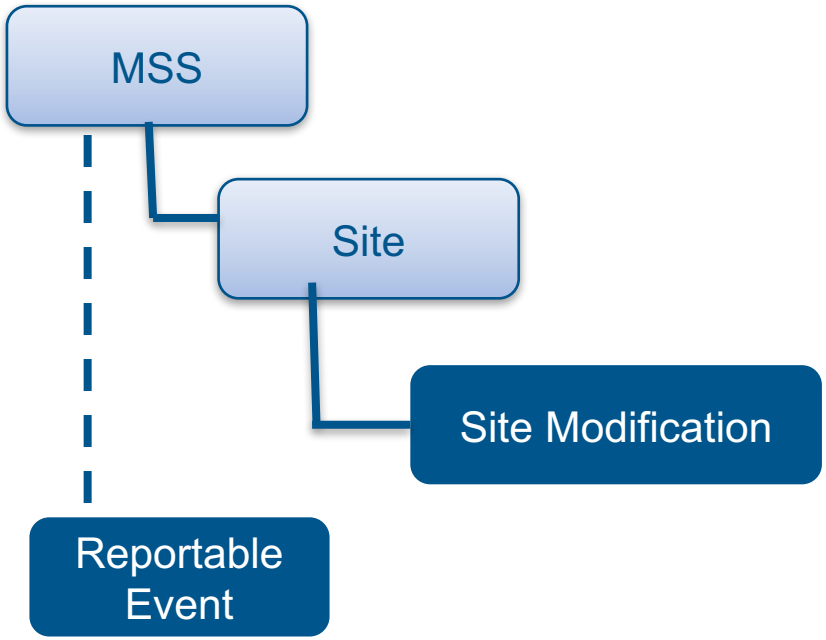
- Both Study and Site will follow a similar review process
- Both support Designated Review and Committee Review
- The only significant difference is the information captured during the review process

FULL SUPPORT FOR FOLLOW-ON SUBMISSIONS

Single IRB of Record:



Participating Site:



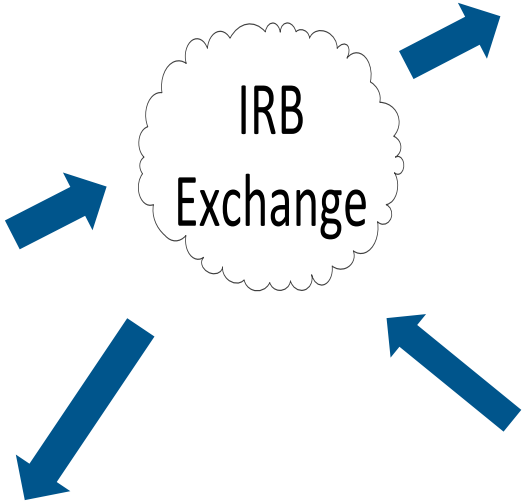
EXAMPLE:
NEW MSS SUBMISSION

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



8 pSite information is downloaded from the Exchange for final review by sIRB

9 sIRB reviews and approves pSite causing activation

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

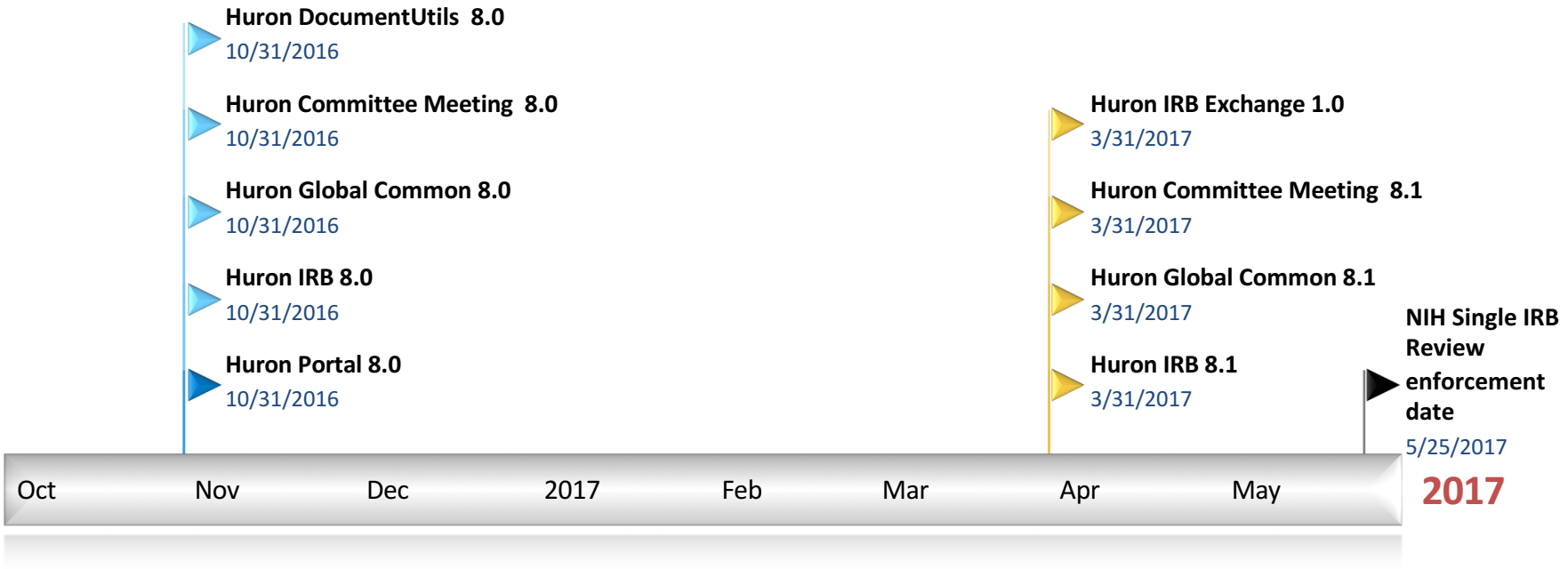
7 Approved Site information is published to the Exchange

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.

RELEASE TIMELINE



MIGRATING TO IRB 8.1

CONSIDERATIONS

- Full support to act as a sIRB and pSite
- Long-term support for the evolving environment, including industry best practices and regulatory changes provided via upgrades/patches
- May require changes in businesses processes/SOPs to adopt IRB product
- Loss of previously built customizations
- Upfront costs to migrate to IRB 8 but should help with long term maintenance

DATA RETENTION/CONVERSION IF MOVING TO IRB 8.1

1. **Convert** all approved studies (with or without documents). Old RX/starter site can still be maintained for read-only access.

2. **No Conversion:** Maintain RX site for read-only access. Use Click IRB 8.1 for all new studies. Users create new records at time of first annual review or modification.

This eliminates data cleanup, data conversion process and allows institution to be live on IRB 8.1 sooner. It may require accessing old system and new IRB 8.1 site in parallel for up to 12 months as studies transition into new IRB 8.1.

UPGRADING/CONVERTING TO IRB 8.1

OPTIONS

1. Migrate to IRB8/Portal 8 as soon as possible. Then do smaller upgrade from IRB 8.0 to IRB 8.1
2. Wait until Spring 2017 to go from Portal 6.x.x/IRB 7 to Portal 8/IRB8.1

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CUSTOM ENHANCEMENT OPTIONS

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RX/STARTER SITE ENHANCEMENT

CONSIDERATIONS

- Are multiple sites an extension of the Study or separately reviewed projects?
- What approach is the right one to enable sites to participate?
  - How are external users able to keep up to date?
  - How is the sIRB able to keep all information current?
- Should you take advantage of the IRB exchange to syndicate information?
- Potentially significant development cost
- Likely will still involve significant manual processes and workarounds, as the underlying starter sites do not support acting as a sIRB
- Supporting independent Site Modifications will require major changes
- Support Human Proxy model, external accounts, facilitated proxy, or leverage Huron IRB Exchange
- Maintain previous system enhancements

OUTSOURCING TO A COMMERCIAL IRB

CONSIDERATIONS

- The commercial IRB acts as the sIRB for your study and tracks all the site information too
- Need to consider additional training requirements for Research Teams initiating Multi-Site Studies
- Need to consider consolidated reporting expectations

HOSTING A VERSION OF CLICK IRB 8.1 IN THE CLOUD FOR MSS STUDIES

CONSIDERATIONS

- How to minimize end user confusion when using two IRB systems?
- How to reconcile reporting requirements?
- How to structure committees and meetings?
- Your IRB acts as the sIRB and tracks those protocols in the new 8.1 site in the cloud.
- These studies would be separate from the existing studies in your current IRB RX system, which would continue to be used for local studies

POLL #4

+ How do you plan to comply with NIH's sIRB policy?
  1. Make changes to our current IRB RX system
  2. Migrate to Click IRB 8.1
  3. Use Click IRB 8.1 for our multi-site trials only
  4. Outsource the oversight all multi-site studies to a commercial IRB
  5. I'm not sure

QUESTIONS?

NEXT STEPS

1. Estimate the impact of this policy on your institution with regards to people, processes, service and technology.
2. Determine the key drivers for your institution that may impact the option you take.
3. Contact your Client Services Manager to schedule a preliminary call and analysis.
4. Look for email invites for focused sessions on a) Migration to 8.0 from RX and b) Modifying RX to leverage the Huron IRB Exchange


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THANK YOU