ACHIEVE IRB OPERATIONAL SUCCESS FOR THE REVISED COMMON RULE

September 20, 2017

ACHIEVE IRB OPERATIONAL SUCCESS FOR THE REVISED COMMON RULE

1. Introductions & Information
2. General Notes
3. Key Takeaways from the July Webinar
4. System-Related Considerations
5. Broad Consent
6. Benign Behavioral Interventions
7. Planning Ahead
8. Q&A

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INTRODUCTIONS & INFORMATION

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TODAY'S PRESENTERS

FRANK CONTE

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+ Frank is a Director in Huron's Research Enterprise Solutions practice. He has more than fifteen years of project management experience in higher education. He focuses on assisting higher education and healthcare organizations with research administration initiatives including human research protection program and institutional review board (IRB) evaluation and process improvement, research administration system software selection, design and implementation and clinical research program evaluations. Frank is on the Huron IRB product advisory committee.

JONATHAN HUNTER

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+ Jonathan is a Manager in Huron's Research Enterprise Solutions practice. His work focuses on institutional review board (IRB) structure and function and human research protection program (HRPP) evaluation and accreditation. He has worked directly for or partnered with a wide range of institutions to implement policies and procedures designed to improve the efficiency and effectiveness of the IRB review process. Jonathan is also on the Huron IRB software solution product advisory committee, serves as the IRB Solution Lead for that product, and is part of the team responsible for maintaining Huron's HRPP Toolkit.

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TODAY'S MODERATOR

+ **GARY WHITNEY**
+ Managing Director
+ **Huron's Education and Life Sciences Practice**

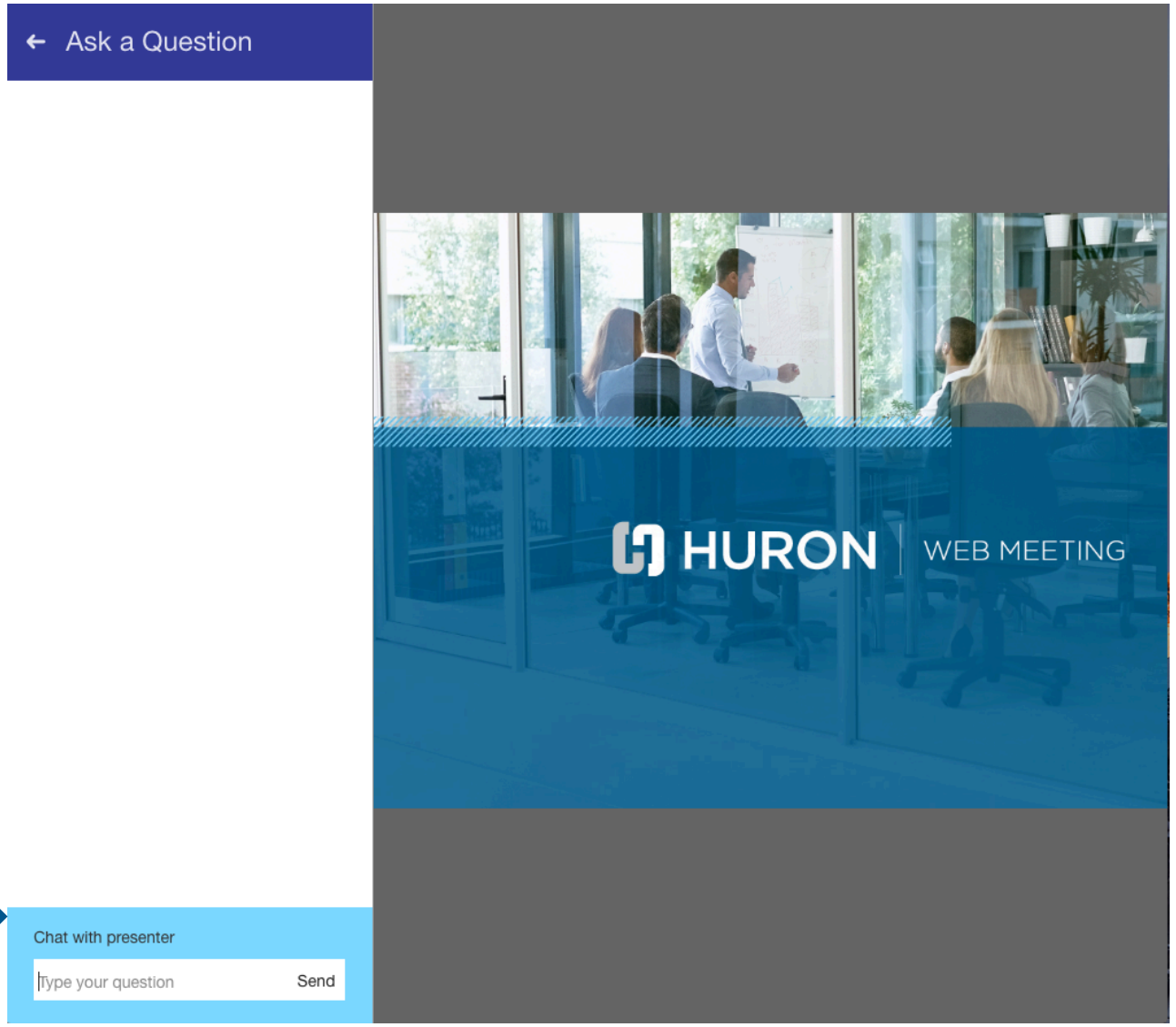
Experience:

Gary has 30+ years experience in software and technology products. He assists clients with automation and deployment strategies in the areas of research compliance, grants and contracts administration and clinical trials management.

Prior to joining Huron, Gary served as the VP of sales and marketing for Click Commerce. He co-founded Click Commerce's ".com" predecessor, Webridge, an enterprise web-based solutions startup.

ASK US YOUR QUESTIONS: LEVEL 3 CHAT PANEL

Enter a question in this dialog area at any time.



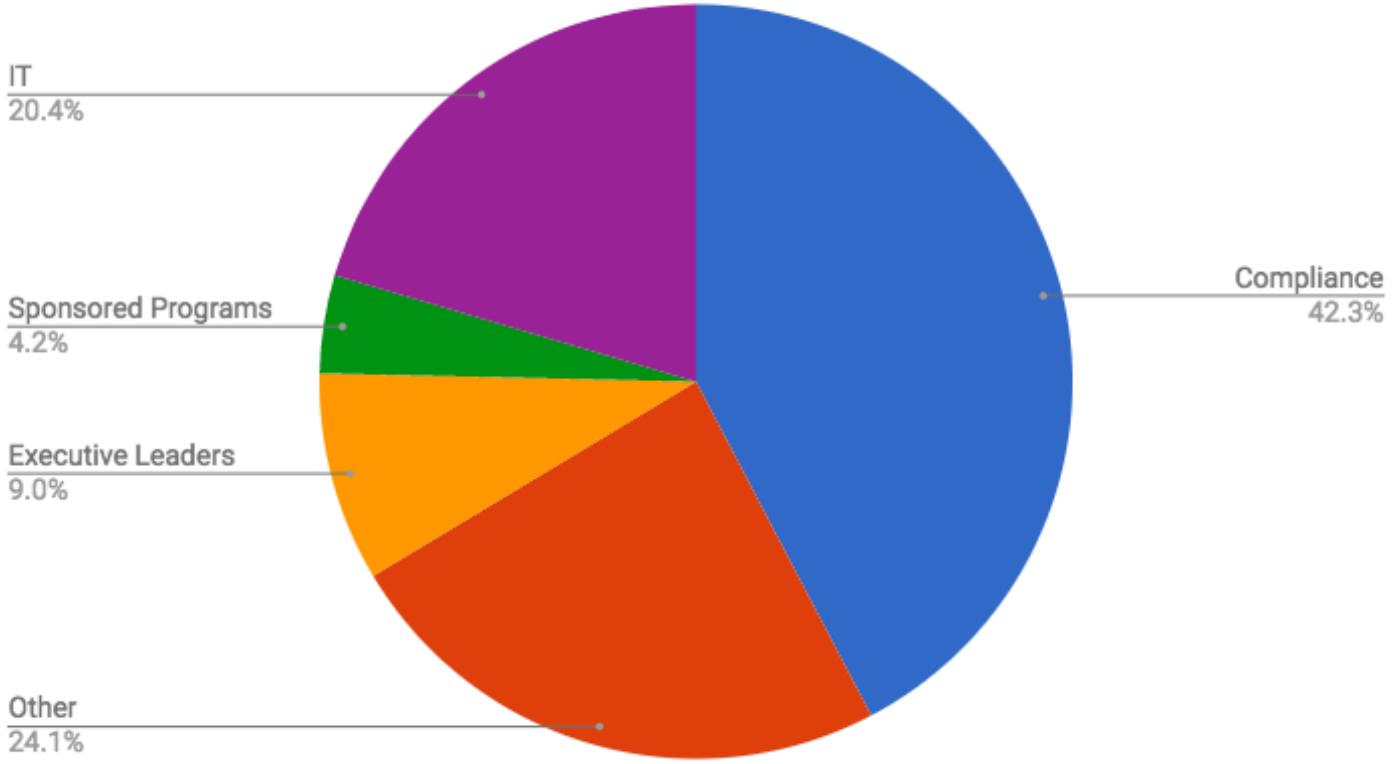
JOIN THE CONVERSATION!

#HuronResearchSuite

Keep the conversation going during and after the webinar.

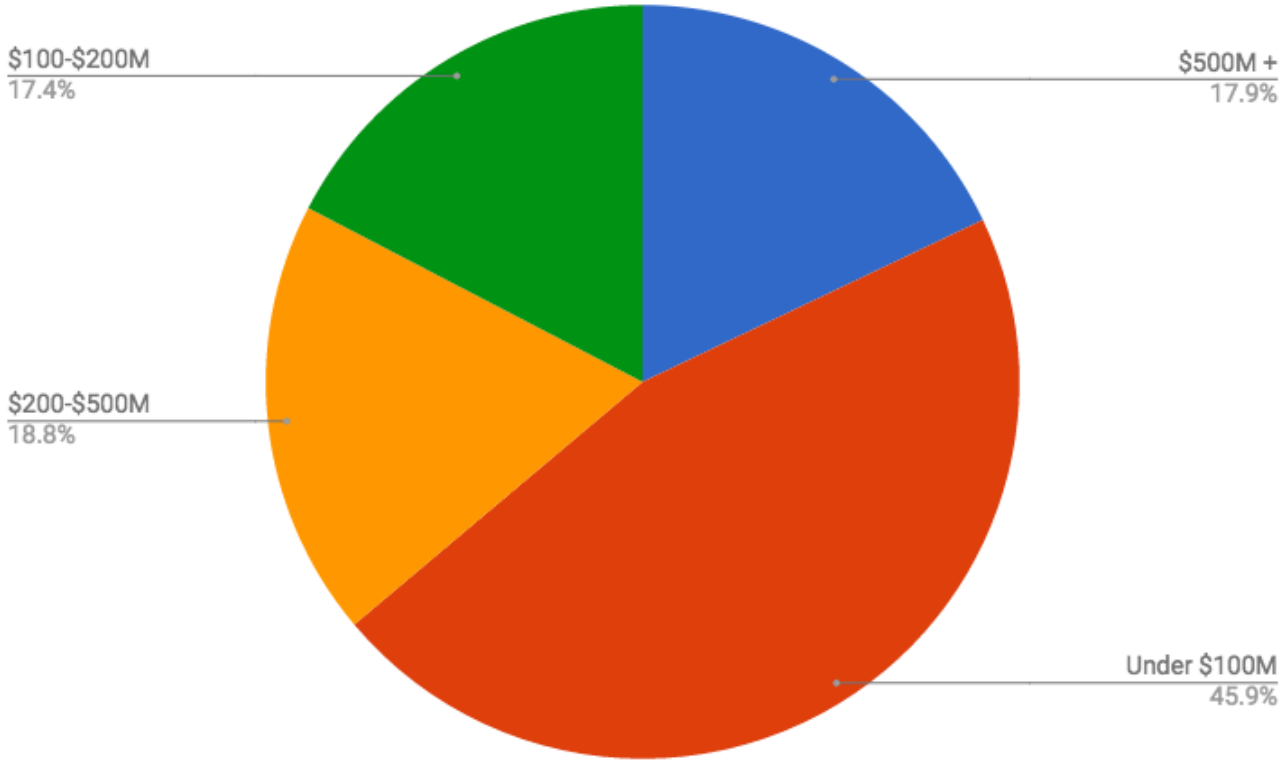
WHO IS ATTENDING THE WEBINAR TODAY?

Primary job function:



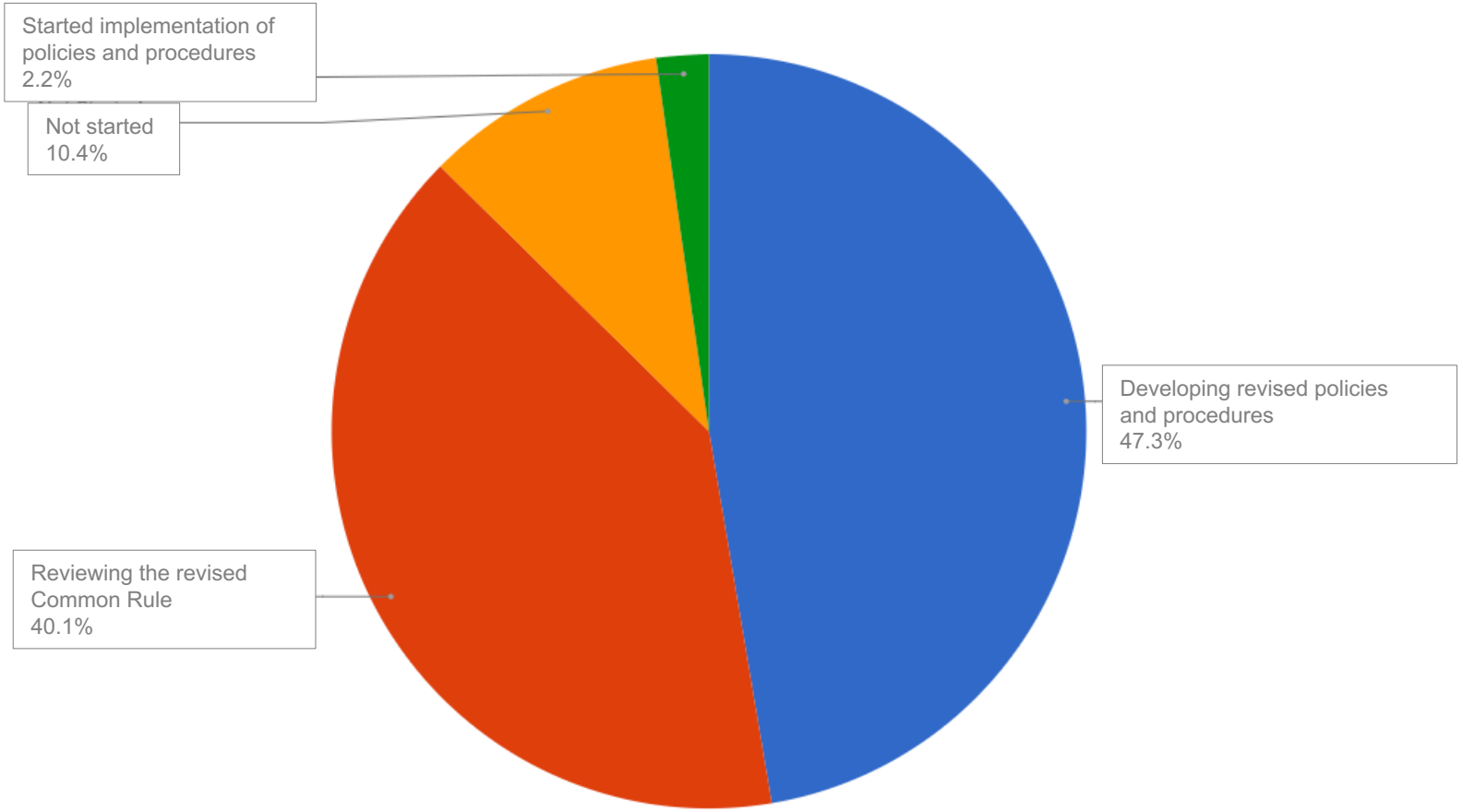
WHO IS ATTENDING THE WEBINAR TODAY?

Level of research expenditures last year:

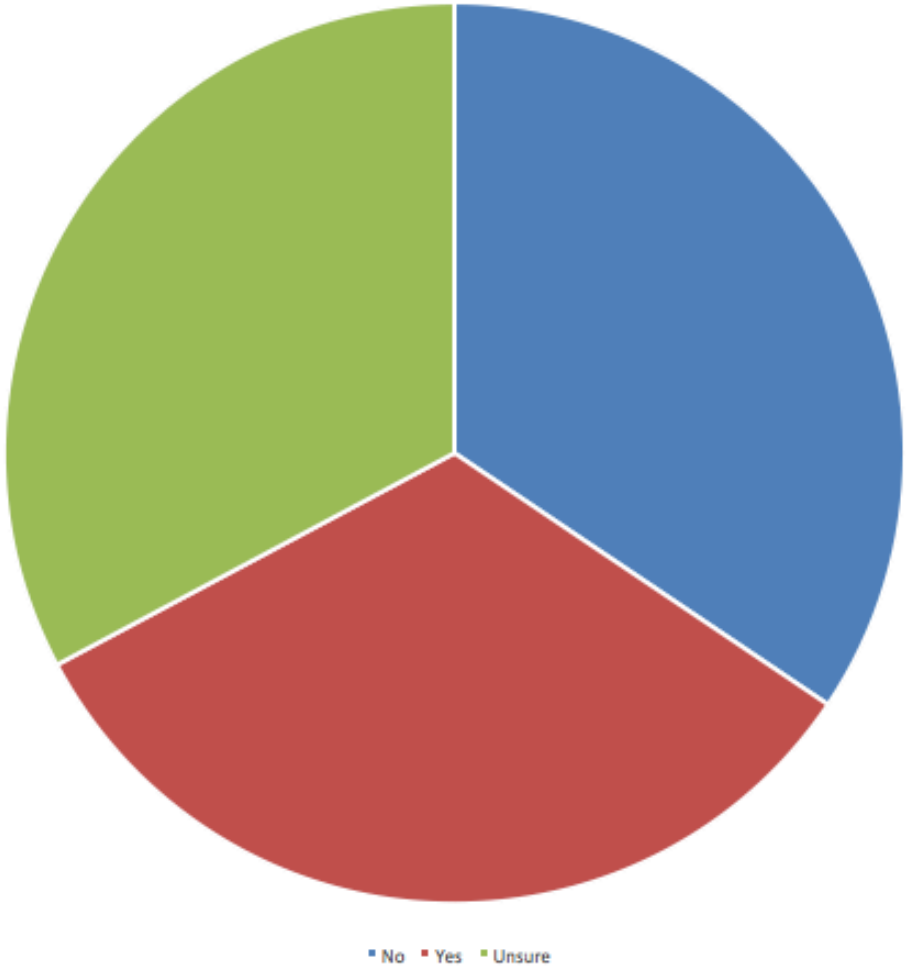


WHO IS ATTENDING THE WEBINAR TODAY?

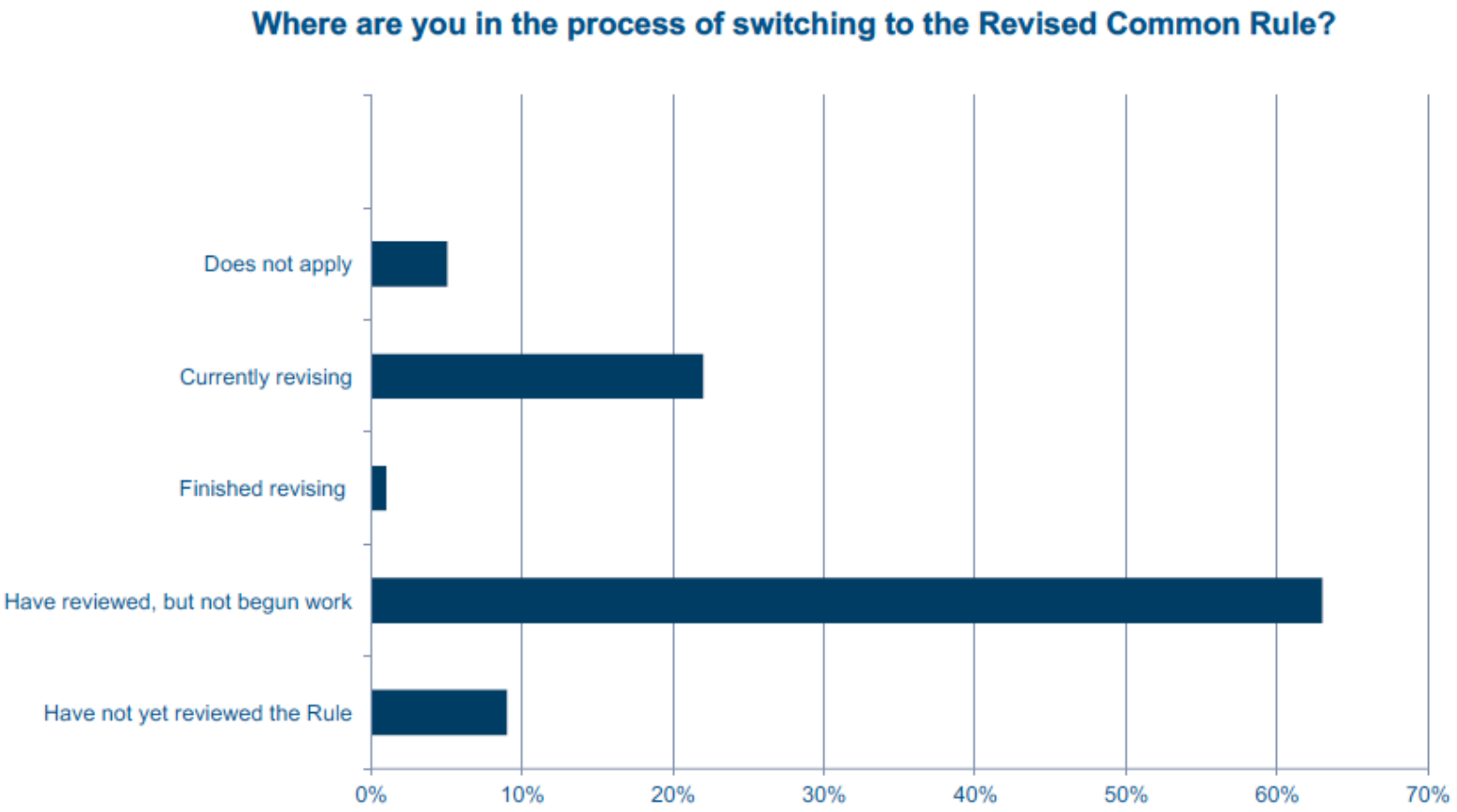
Where are you in the planning process for the revised Common Rule?



Do you believe the effective date of the January 19 will be delayed?



POLLING QUESTION RESULTS FROM PART 1



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GENERAL NOTES

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REVISED COMMON RULE: DISCLAIMER

The material presented today should be considered a work in progress, based upon our current understanding of the Revised Common Rule. We will continue to update our approach as guidance and other official information is released.

REVISED COMMON RULE
TERMINOLOGY

Terms	Definition
Current Rule; Pre-2018 Rule	Current set of Common Rule regulations that IRBs follow
Final Rule; New Rule; 2018 Rule; Revised Rule; Revised Common Rule	Updated Common Rule, effective January 19, 2018 (except for collaborative research, effective January 20, 2020)
NIH Single IRB Policy	Policy requiring Single IRB Review of multi-site research, effective January 25, 2018
NIH Certificate of Confidentiality Revised Policy	Effective 10/1/2017; all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this Policy is deemed to be issued a COC

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KEY TAKEAWAYS – PREVIOUS WEBINAR

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REVISED COMMON RULE TIMELINE

1/19/17
- Release of the Final Rule from OHRP
- First major update to the Common Rule since the '90s

1/19/18
- Effective *and* Compliance date for the Final Rule
- All research *approved* on or after this date must follow the Final Rule

1/25/18
- Effective Date for the NIH Single IRB of Record Policy

1/20/20
- Compliance Date for the Final Rule Single IRB of Record Requirement

HHS.gov
Office for Human Research Protections

MAKING THE SWITCH:
EXISTING PROJECTS

All research initiated prior to the effective date will remain subject to the pre-2018 requirements, unless switched to the 2018 requirements

Institutions “may instead comply with the 2018 requirements if the institution determines that such ongoing research will comply with the 2018 requirements and an IRB documents such determination” (45 CFR 46.101(l)(3))

Institutional Decision:

- Will existing studies move to the new rule at some point?
  - If so, what criteria will you use to make that decision?

MAKING THE SWITCH:
NEW PROJECTS

If your new submission application asks the investigator to select regulatory categories or answer questions about the regulatory criteria for approval:

- You will need to update that application to reflect the components of the Revised Common Rule.
- If new research has not been reviewed before January 19, 2018, you will need to require investigators to re-submit on your updated application.

Consider your turnaround times. If it is unlikely that research submitted on December 4, 2017 will be reviewed before January 19, 2018, then what is your plan?

- Do you have investigators submit using your updated application prior to the effective date knowing that you will not review prior to that date anyway?

Institutional Decision:
On what date will you require that investigators submit new projects on a revised submission form?

CONTINUING REVIEW

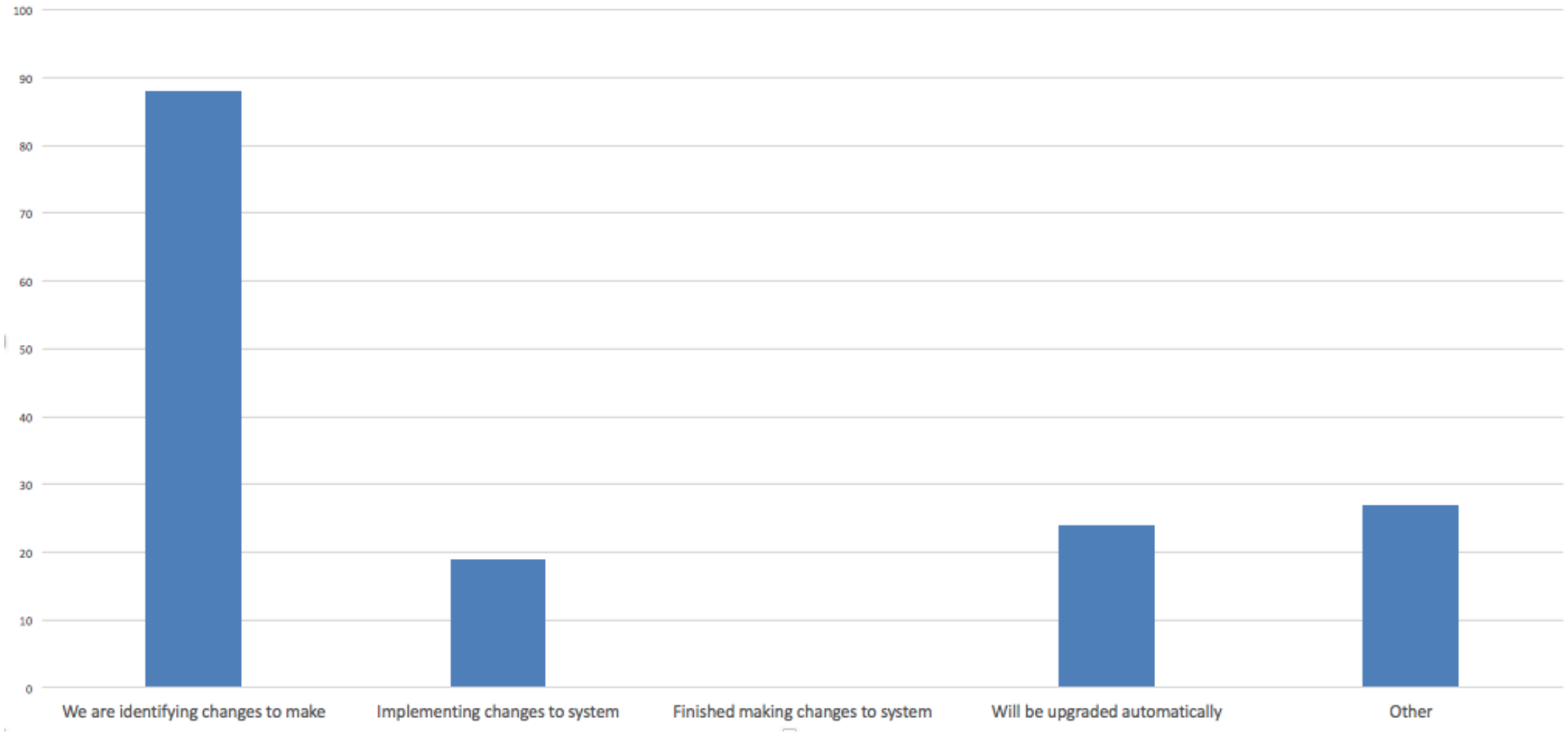
- The Final Rule indicates that Continuing Review is not required for minimal risk research projects, or for greater than minimal risk projects that have reached certain milestones;

- Even when Continuing Review is not required, you will may want to check in with investigators periodically.
  - Re-purpose the last day of approval as the date to send a reminder notification.
  - Remind investigators to submit modifications and to report new information.

- Remember the FDA has not yet aligned its regulations with the Revised Common Rule.
  - Continuing Review must continue for FDA-regulated studies. (This could be your rationale if there is overlap with Common Rule agency oversight.)

- What about expedited category 9?
  - You may need one Continuing Review cycle to determine that “no additional risks have been identified.”

If using an electronic IRB, which best describes its status relative to the revised Common Rule?



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SYSTEM-RELATED CONSIDERATIONS

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EXEMPT CATEGORIES

- A number of important considerations are required when working in an electronic eIRB management system

- Many of the Revised Common Rule changes will result in needed system enhancements, including:
  - Exempt Categories
    - If you ask investigators to indicate the category(ies) of review, your forms will need to be updated with the new exempt categories
    - If your reviewers select exempt categories within your system, those categories will need to be updated

Consideration:
You may need to modify your system in such a way that it preserves the current categories for existing research projects

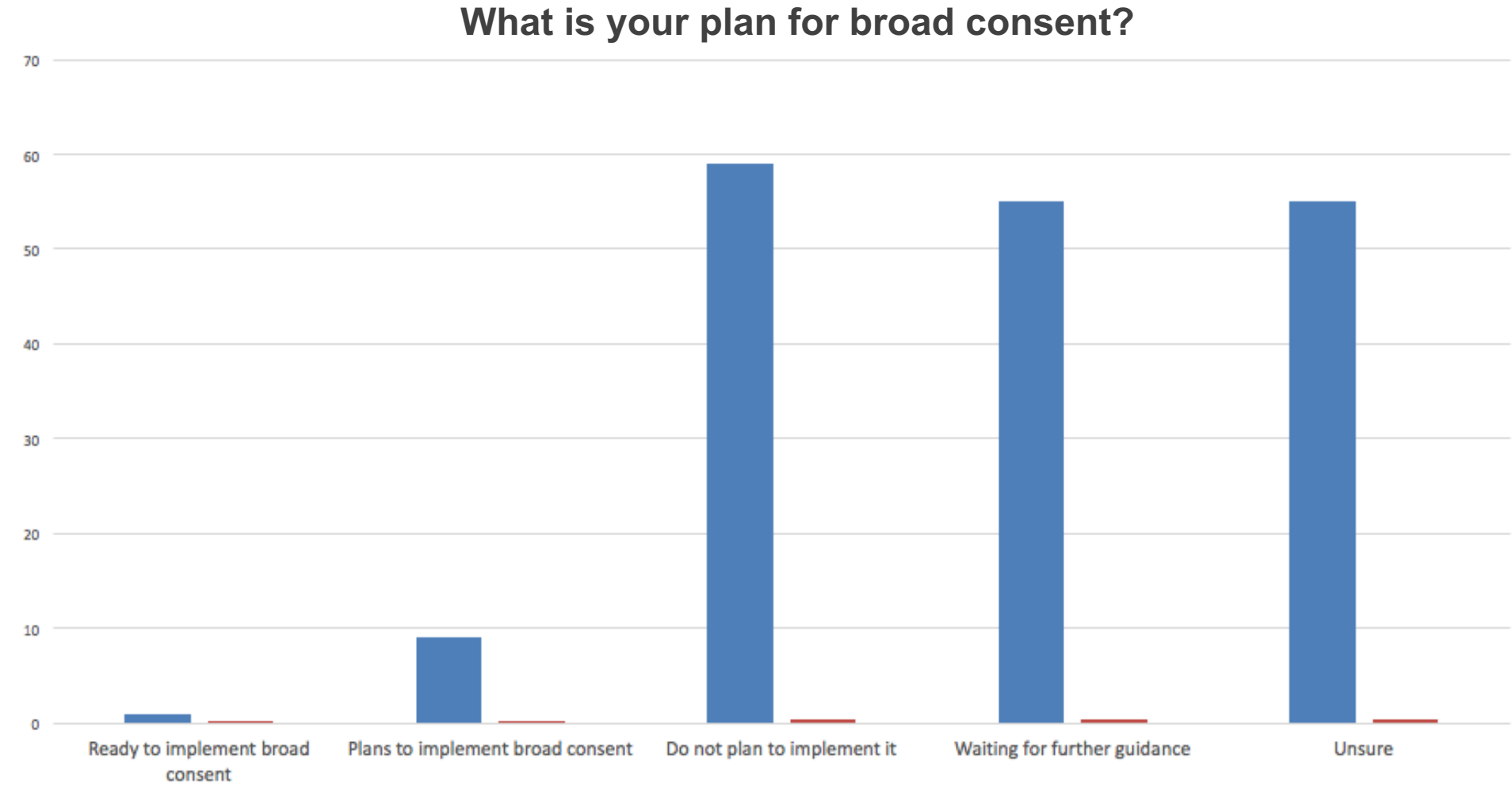
CONTINUING REVIEW & OTHER TRACKING

- Continuing Review is not always required under the revised rule.
- When a reviewer decides that CR is needed when it's not required by the new rule, the reviewer must provide a rationale for the decision.
- Most institutions will want to be able to track and report on projects that include:
  - Certificates of Confidentiality
  - Deception
  - Clinical Trials
  - Tribal Law

REGULATORY CRITERIA FOR APPROVAL

Regulatory criteria for approval have been updated, and apply in different circumstances.

- The new criterion at 45 CFR 46.111(a)(8) applies only to the new exempt category at 45 CFR 46.104(d)(7) when conducting Limited IRB Review.
- The criteria for the consent process and consent documentation 45 CFR 46.111(a)(4-5) relate to new elements of consent and the presentation of key information at 45 CFR 116.
- Review tools should be updated to reflect these criteria and other considerations.


What is your plan for broad consent?
70
60
50
40
30
20
10
0
Ready to implement broad consent
Plans to implement broad consent
Do not plan to implement it
Waiting for further guidance
Unsure

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BROAD CONSENT

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BROAD CONSENT:
A NEW REGULATORY CONCEPT

The Final Rule allows for the review and approval of Broad Consent in certain circumstances.

- Seeking **prospective consent to unspecified future research** from a subject for storage, maintenance, and **secondary research use** of identifiable private information and identifiable biospecimens.
- Broad consent will be an **optional alternative** that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.

BROAD CONSENT:
OPERATIONAL TAKEAWAYS

Institutions will need to have a plan for obtaining broad consent from potential subjects. This plan should include:

- How identifiable private information and identifiable biospecimens are stored.
  - Is it feasible to have a single institutional repository for all biospecimens, for example, so that all broad consent activity is housed under one project?

How broad consent is obtained.

- For institutions that provide clinical care, is broad consent obtained at admission?
- For institutions that do not provide clinical care, is there a single point of entry for approaching potential subjects for broad consent?
- Who obtains broad consent?

BROAD CONSENT: OPERATIONAL TAKEAWAYS

- **How broad consent is tracked**
  - Which patients were approached for broad consent?
  - How are investigators tracking whether each patient provides consent or declines?
  - For those who decline, will they ever be approached again for broad consent?
  - For those who decline, how are investigators ensuring that their biospecimens are not being utilized under a waiver of consent?
  - Suppose there is more than one project obtaining broad consent. What happens if a patient provides broad consent for one, but declines for the other?

- **Start having conversations now with stakeholders across your institution**
  - Will your institution utilize broad consent at all?
  - If not, why not?

BROAD CONSENT:
CONTINUING THE DISCUSSION

- Since the July webinar, SACHRP has posted recommendations for broad consent.
- SACHRP's recommendations letter contemplates the same tracking issue we discussed on the July webinar.

"Extensive and seamless IT system capacity will be necessary for any institution or health system to implement fully a broad consent tracking system, as both broad consents as well as refusals to consent (unless the materials are destroyed) must be tracked over the lifetimes of persons who give broad consent and persons who refuse to give such consent. Due to these systems requirements for electronic tracking processes, SACHRP expects that, practically speaking, institutions or systems without interconnected, interfacing and fully interoperable medical records systems will not be able to implement and benefit from the broad consent regimen established in the Final Rule. A "confederated," non-IT-unified health system will simply not be able, without significant error, to track these consents and refusals to consent. These logistical barriers will greatly limit the utility of the broad consent option."

BROAD CONSENT:
HURON'S RECOMMENDATION

- **The SACHRP recommendations cover several different areas in addition to tracking, including:**
  - The parties bound by an individual's refusal to provide broad consent.
  - Options for institutions when an individual refuses to provide broad consent.
  - The specificity of descriptions of future research use.

- **Huron recommends that institutions *not* implement broad consent at the present time.**
  - There is no requirement in the revised Common Rule for broad consent to be utilized.
  - Even if an institution opts to use broad consent, they do not have to do so by the effective date.
  - Many institutions will require substantial planning and effort to develop the infrastructure to support broad consent.
  - SACHRP's discussion is very helpful, but OHRP has provided no guidance on broad consent implementation.

POLLING QUESTION 4

Based on what you've learned since the July webinar, what is your plan for broad consent?

1. We are ready to implement broad consent.
2. We plan to implement broad consent, but we are not yet ready.
3. We do not plan to implement broad consent at all.
4. We are waiting on guidance before making a decision to implement broad consent.
5. We don't know.

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BENIGN BEHAVIORAL INTERVENTIONS

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EXEMPT CATEGORY 3

A new exempt category has been added for research involving benign behavioral interventions. At 45 CFR 46.104(D)(3):

+ (3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  - (A) The information obtained is recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;
  - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and **an IRB conducts a limited IRB review** to make the determination required by §__.111(a)(7).

BENIGN BEHAVIORAL INTERVENTIONS

Benign behavioral interventions are:

- Brief in duration,
- Harmless,
- Painless,
- Not physically invasive,
- Not likely to have a significant adverse lasting impact on the subjects, and
- The investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable **unless the subject authorizes the deception through a prospective agreement to participate in research** in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- Deception is defined as "*withholding the purpose of the research*"

LIMITED IRB REVIEW FOR EXEMPT 3

When the researcher is collecting identifiable data, **and** that data may reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation, then limited IRB review is required.

The IRB (a designee of the Chair), must determine that the research procedures meet the criteria for exempt category 3, and:

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  - **Note:** The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

OPERATIONALIZING EXEMPT 3

This exemption category was specifically designed to exclude the use of medical interventions (including medical tests, procedures and devices).

The exemption being finalized is specifically for research involving benign "behavioral" interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording

- Subjects must be adults, but the provision does not specify that they must be competent, and therefore tests of competency are not necessary

Authorized deception would be **prospective agreement** by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- Prospective agreement must be meaningful, but it is not the same as a requirement for explicit consent.

CAUTIONS

- Procedures and situations that may not qualify for this new exemption category include:
  - Biomedical procedures (blood pressure, blood draws, pulse measurements, etc.)
  - Risk of harm or pain or emotional distress for the subjects
  - “Brief” participation – will need additional guidance on how to define brief.

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PLANNING AHEAD

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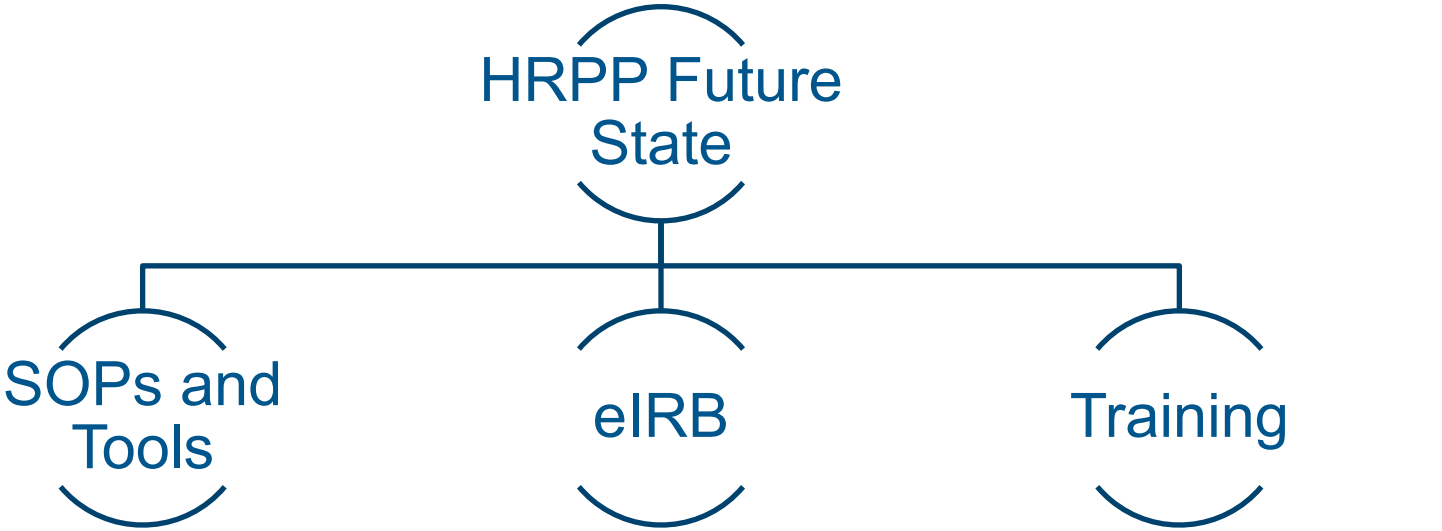
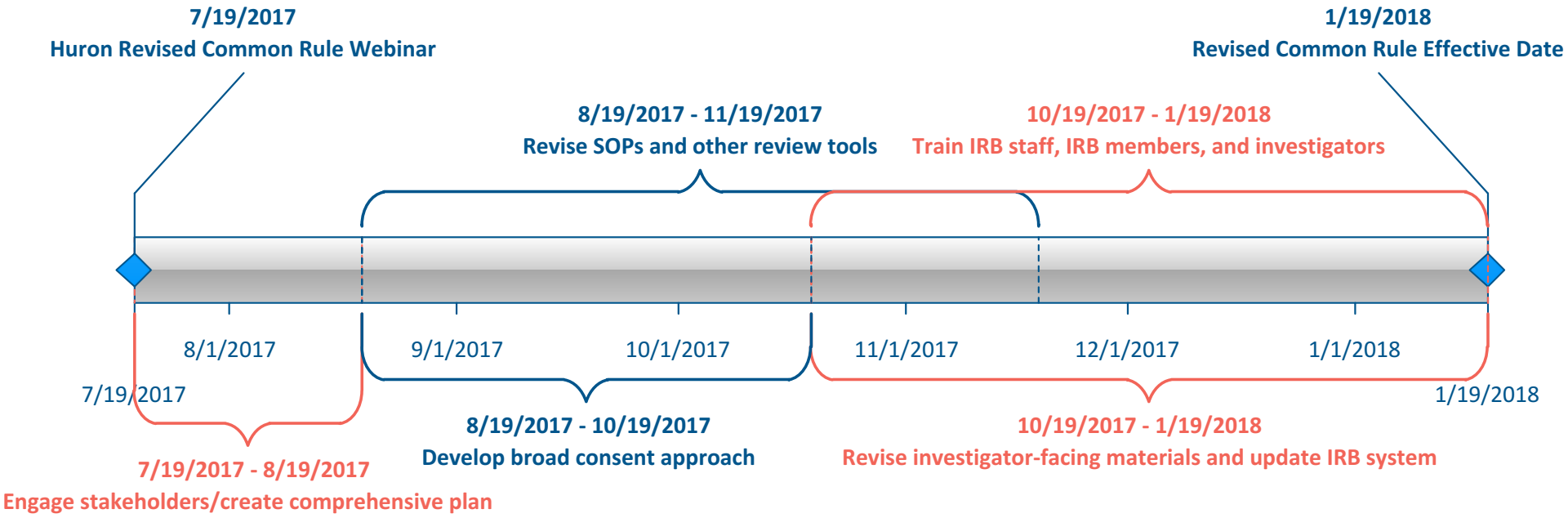
PLANNING AHEAD:
HRPP PROCESS CHANGE

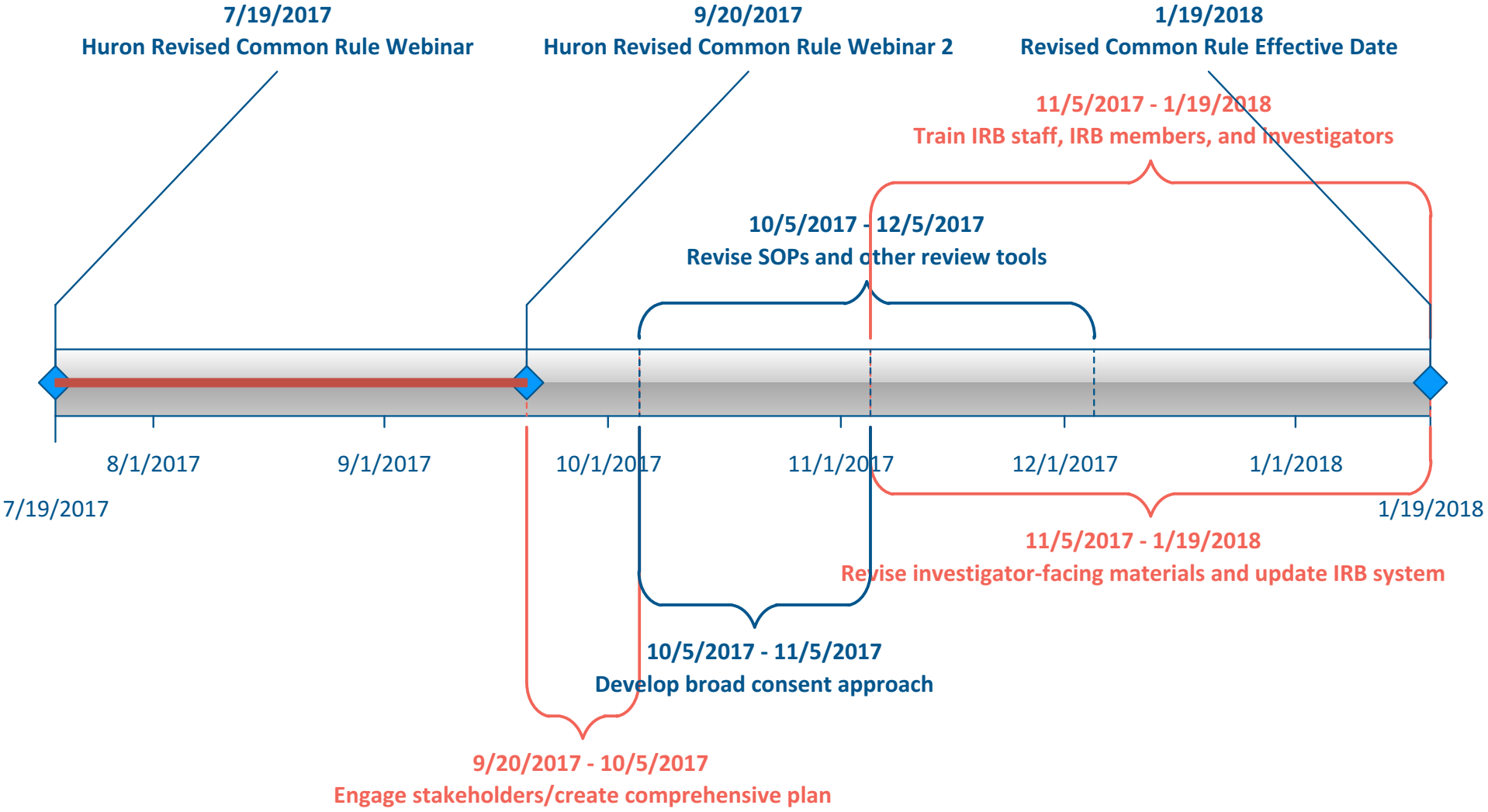


SOPs and Tools	eIRB	Training
Develop an approach to updating your SOPs and other Tools to accommodate the 2018 requirements.	Create a project plan for updating your IRB system; secure SME input and IT resources.	Determine which groups need what training, and who will develop the curriculum and lead it.

PLANNING AHEAD:
EXAMPLE TIMELINE – JULY WEBINAR



PLANNING AHEAD:
UPDATED EXAMPLE TIMELINE



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Q&A

RESOURCES:

- IRB Transformation Services & Product Information: https://www.huronconsultinggroup.com/expertise/technology/click-portal-solutions
- Huron NIH Single IRB Policy Thought Leadership: https://www.huronconsultinggroup.com/resources/higher-education/sirb-policy-steps-to-prepare
- Final revisions to the Common Rule: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html.
- "Trump Administration Seen Unlikely to Change Human Research Rule": https://www.bna.com/trump-administration-seen-n73014451606/.
  - *An article published on May 26, 2017 which quotes Jerry Menikoff of the Office for Human Research Protections.*
- SACHRP recommendations for broad consent, and draft template: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2017/index.html
- **Stop by our booth at the PRIM&R conference, November 6-8, in San Antonio!**

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THANK YOU!