PREPARE YOUR IRB OPERATIONS FOR THE REVISED COMMON RULE

JULY 19, 2017

AGENDA: PREPARE YOUR IRB OPERATIONS FOR THE REVISED COMMON RULE

1. Introductions & Information
2. Making the Switch
3. Broad Consent
4. Continuing Review & Follow-Up
5. Planning Ahead
6. Questions

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INTRODUCTIONS & INFORMATION

HURON

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.

HURON

TODAY'S MODERATOR

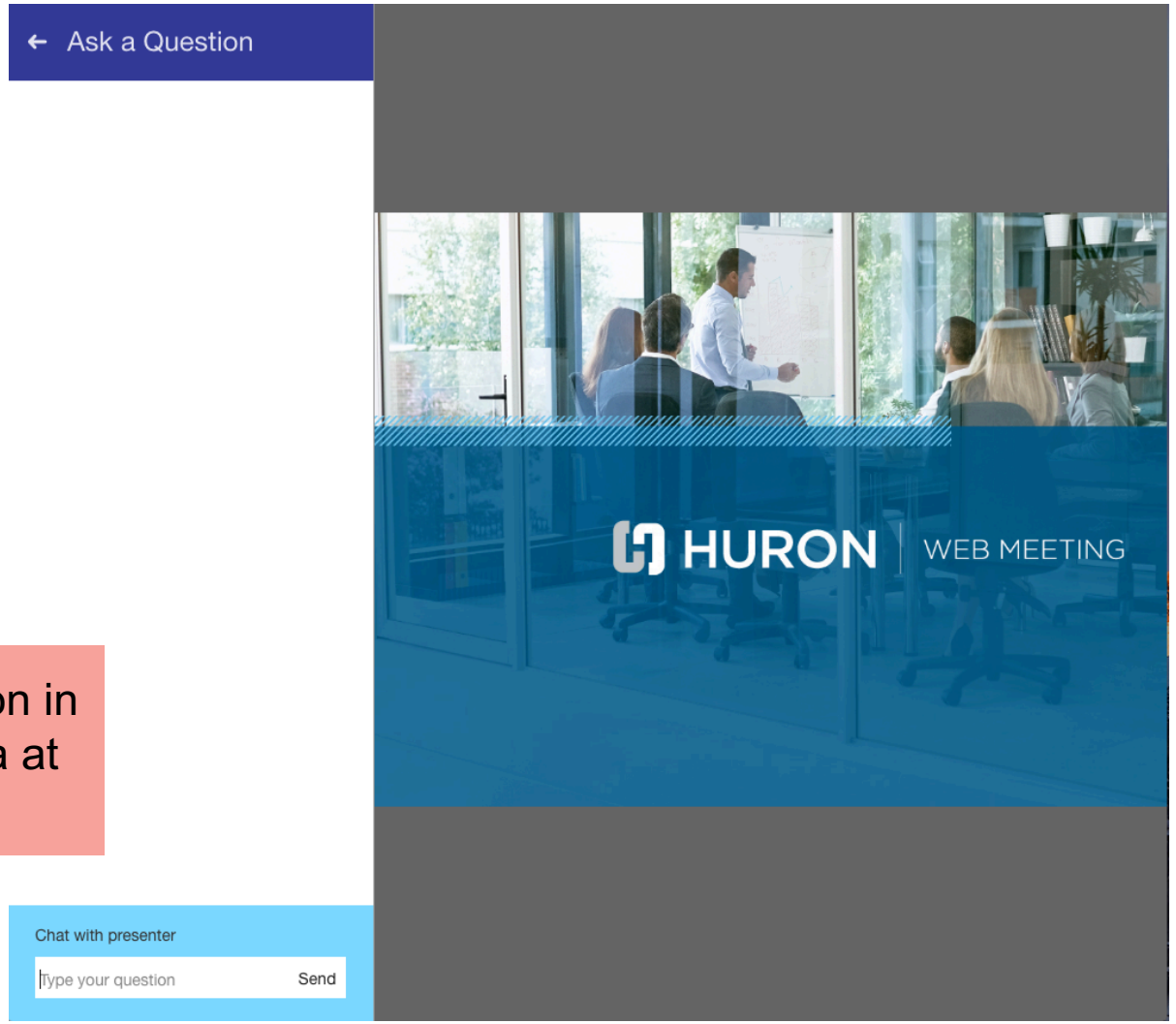
+ **GARY WHITNEY**
+ Managing Director
+ **Huron's Education and Life Sciences Practice**

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.

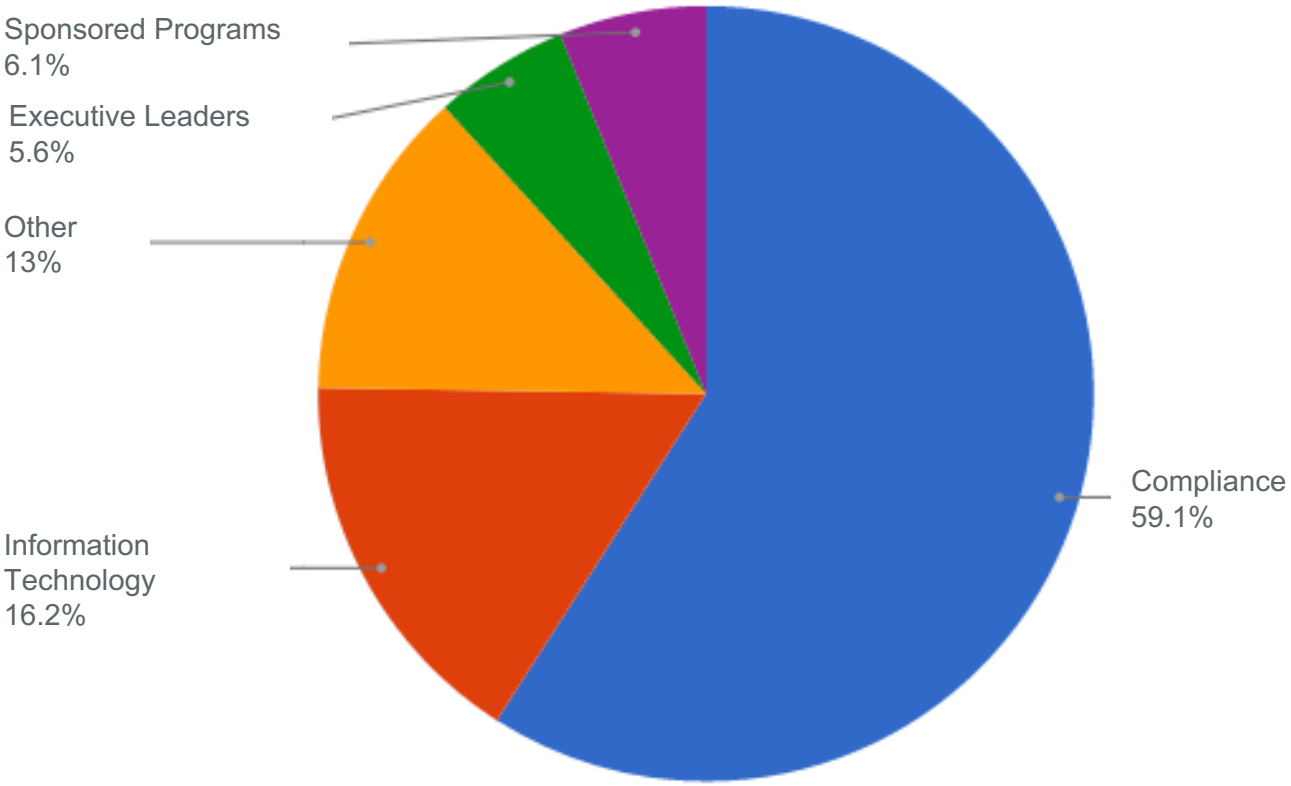
JOIN THE CONVERSATION!

#HuronResearchSuite

Keep the conversation going during and after the webinar.

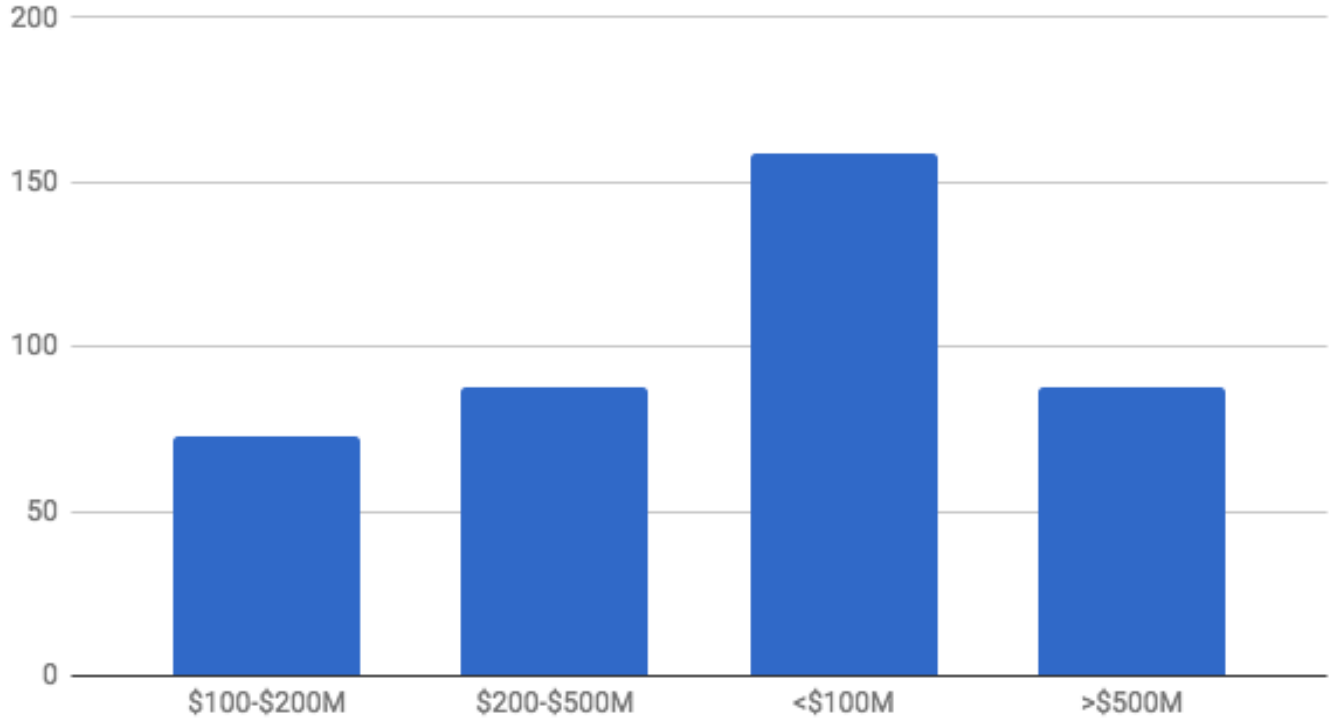
WHO IS ATTENDING THE WEBINAR TODAY?

What is your primary job function?

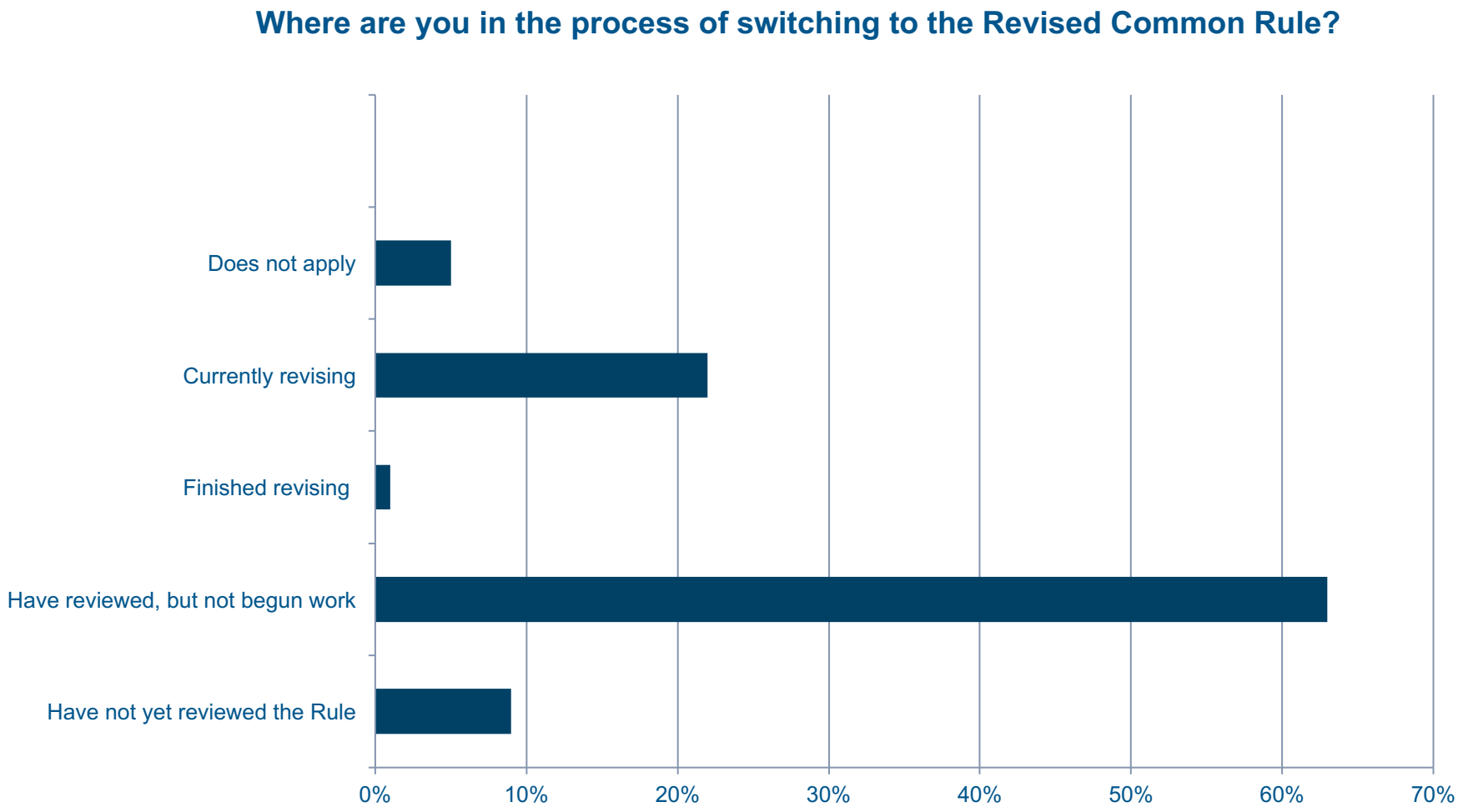


WHO IS ATTENDING THE WEBINAR TODAY?

What level were your research expenditures last year?



POLLING QUESTION 1



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MAKING THE SWITCH

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REVISED COMMON RULE:
GENERAL 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

REVISED COMMON RULE:
GENERAL IMPLEMENTATION NOTES

- The **effective date** and the **compliance date** are the same date.
  - Several organizations have requested an extension of the **compliance date**.
  - For example, the AAMC, AAU, APLU, and COGR jointly requested a one year extension of the **compliance date** to January 19, 2019.
- The current version of the Common Rule still governs Human Research until the **effective date** of the Revised Common Rule.
  - We understand that there is no provision for adopting the Revised Common Rule early.
- On the **effective date**, all *new* research will be subject to Revised Common Rule provisions.
  - *New* research means research for which a determination has not been made prior to January 19, 2018. (45 CFR 46.101(l)(4)

REVISED COMMON RULE:
TIMELINE

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

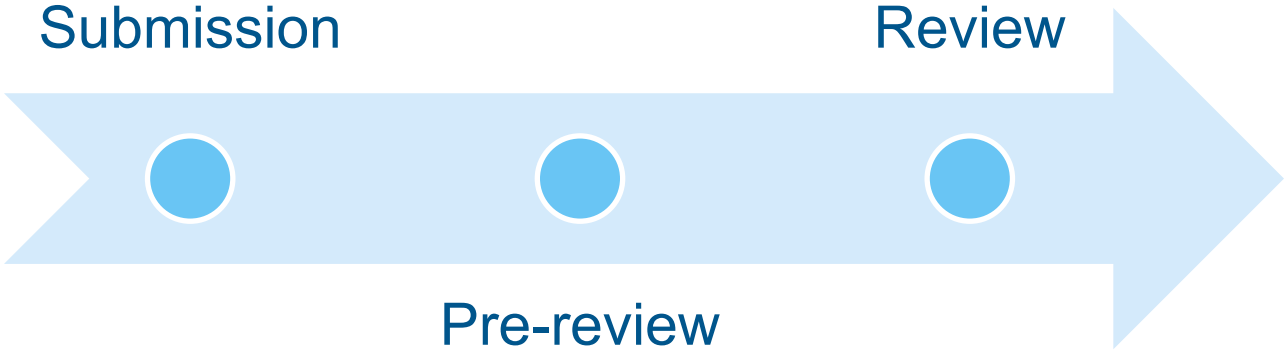
1/19/18
- Effective AND Compliance date for the Final Rule
- All research APPROVED on/after this date must follow the Final Rule

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

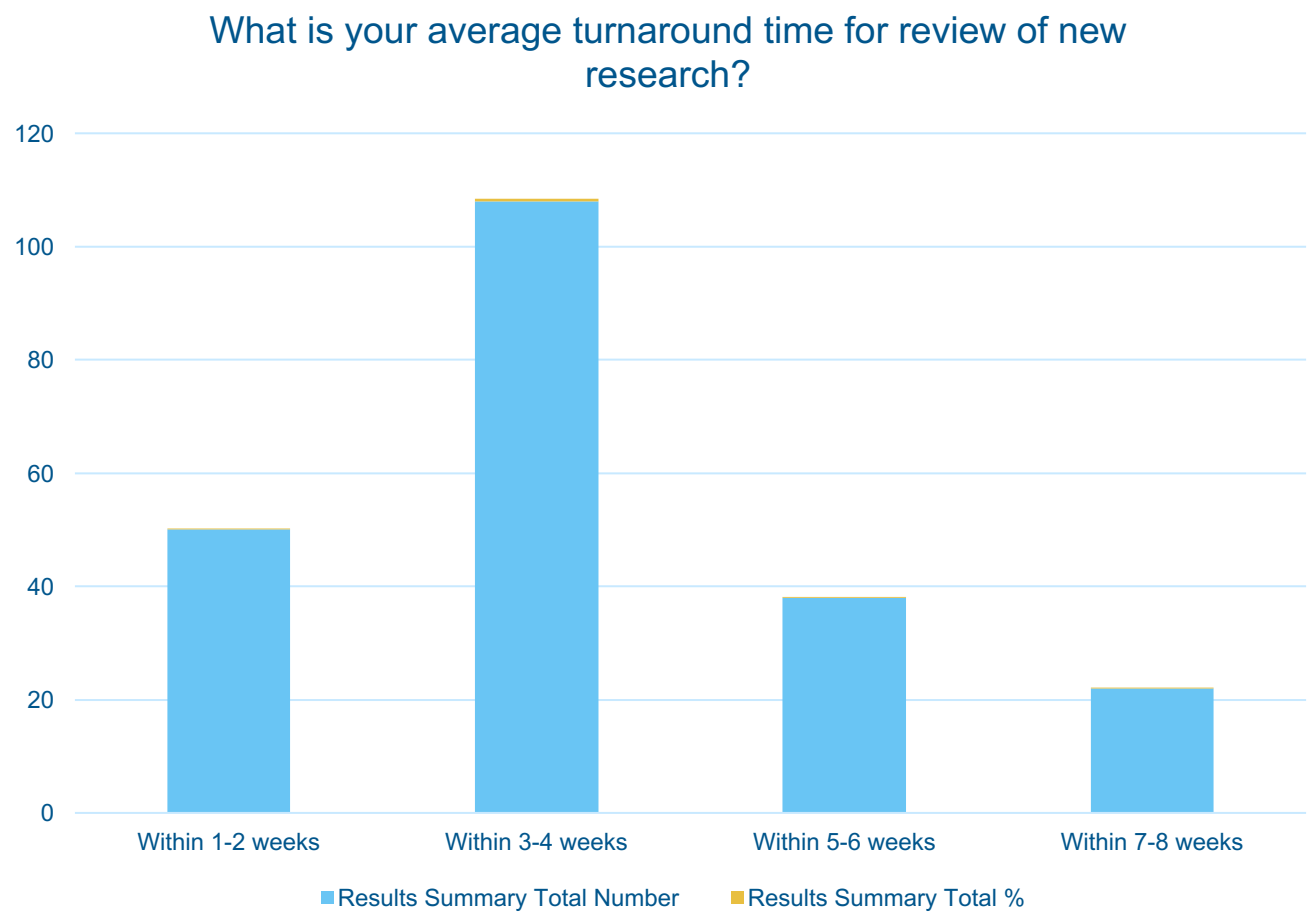
HHS.gov
Office for Human Research Protections

MAKING THE SWITCH:
NEW RESEARCH



- If new research has been **submitted** prior to January 19, 2018, but not **reviewed** by that date, then the Revised Common Rule would apply to that research.
  - For example, research submitted on December 4, 2017 would be reviewed under the Current Rule if that review takes place on December 8, 2017.
  - The same research would be reviewed under the Revised Common Rule if that review takes place on January 24, 2018.
- You should honestly evaluate review turnaround times to understand how the switch to the Revised Common Rule will impact submitted research.

POLLING QUESTION 2



MAKING THE SWITCH:
NEW RESEARCH EXAMPLE

Big State University IRB System

1. Study Title

   A Survey of IRB Administrators on the Impact of the Revised Common Rule on IRB Operations

2. Is this activity Human Research?

   ☒ Yes
   ☐ No

3. Is this Human Research Exempt?

   ☒ Yes
   ☐ No

4. Under which category is this Human Research Exempt?

   ☐ Exempt 1
   ☒ Exempt 2
   ☐ Exempt 3
   ☐ Exempt 4
   ☐ Exempt 5
   ☐ Exempt 6

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4. Under which category is this Human Research Exempt?

   ☐ Exempt 1
   ☒ Exempt 2
   ☐ Exempt 3
   ☐ Exempt 4
   ☐ Exempt 5
   ☐ Exempt 6

MAKING THE SWITCH:
NEW RESEARCH TAKEAWAYS

If your new submission application is similar to Big State's, you will need to update that application to reflect the components of the Revised Common Rule.

- For example, Big State will need to update the exempt categories investigators select.

If new research has not been reviewed before January 19, 2018 and your new submission application is similar to Big State's, 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?

MAKING THE SWITCH:
NEW RESEARCH TAKEAWAYS

Consider removing routing or review level questions from your new submission application in advance of the effective date.

- Instead, ask basic questions about the proposed activity and then leave all review level decisions to IRB staff/members.
- This will create flexibility around the effective date for how you review the new research.

Review tools, e.g., reviewer checklists, will need to be updated as well to reflect the components of the Revised Common Rule.

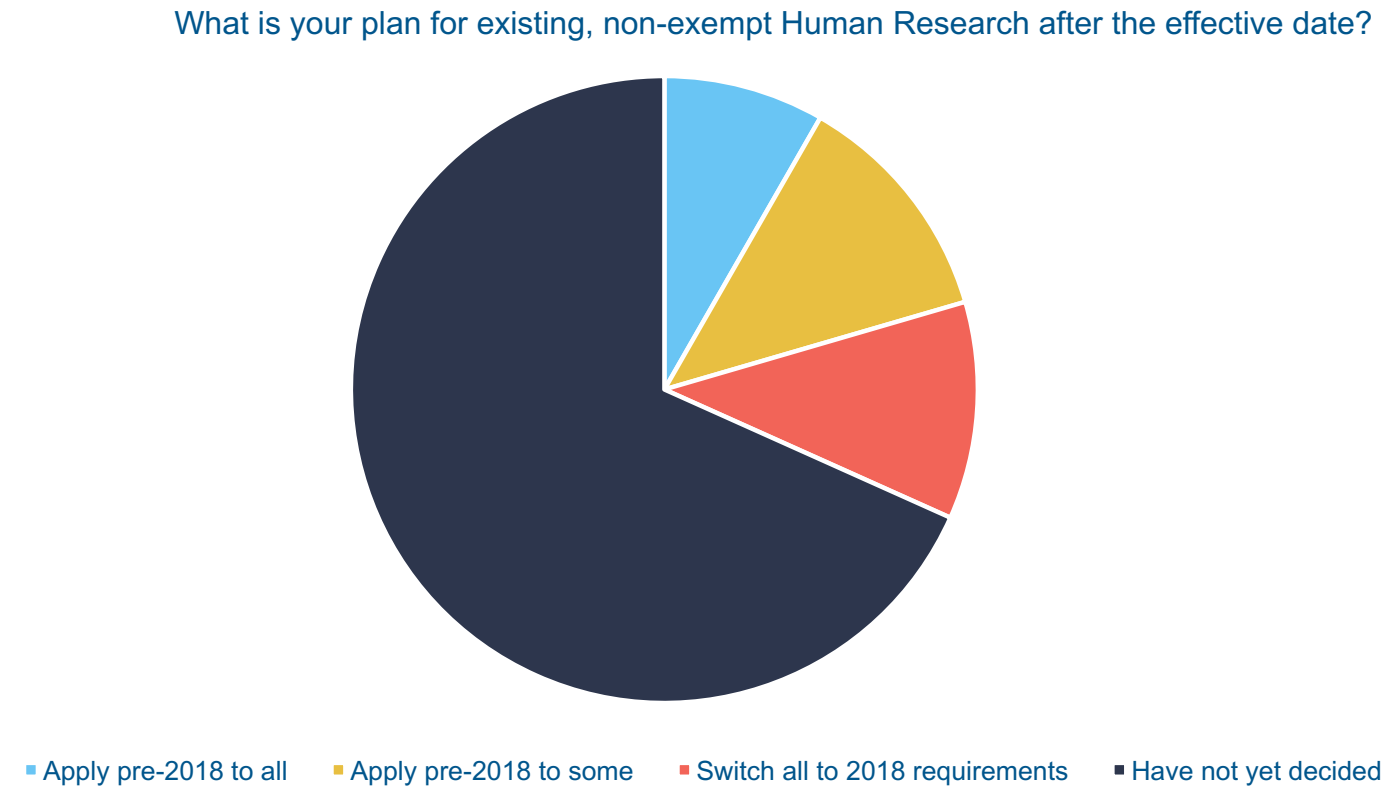
- For those institutions that have reviewer checklists hard-coded in an IRB system, you will need to be sure that functionality is updated as well.

MAKING THE SWITCH:
EXISTING RESEARCH

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)).

POLLING QUESTION 3



MAKING THE SWITCH:
EXISTING RESEARCH

QUESTION:
If an institution elects to apply 2018 requirements to previously initiated research, is this a blanket decision or decided on a case-by-case basis?

ANSWER:
"§_.101(l)(3) permits institutions engaged in ongoing research that was initially approved by an IRB, waived pursuant to §ll.101(i), or determined to be exempted before January 19, 2018, to choose, on a ***study-by-study basis****, whether such research will be subject to the pre-2018 requirements (the rule in place before January 19, 2018, or the final rule"* (Federal Register, p. 7161).

MAKING THE SWITCH:
EXISTING RESEARCH

If your institution chooses to switch existing research to the 2018 requirements, you need to establish a plan.

- ✓ **Evaluate your research portfolio**
  - For example, how many expedited category 5 or 7 studies are currently approved?
- ✓ **Consider the process to determine which existing research will be switched**
  - Will the VP for Research decide? Will the IRB Director decide? Will the decision be investigator-driven?
- ✓ **Consider when you will make the switch.**
- ✓ **Consider the downstream impacts of making the switch.**

MAKING THE SWITCH:
EXISTING RESEARCH TAKEAWAYS

For previously approved non-Exempt Human Research which you choose to switch to the 2018 requirements, we recommend switching at a “natural” touch point in the review cycle.

- For example, since you are evaluating the entire research study at the time of Continuing Review, this would be a good time to evaluate for a possible switch.
- Also, Continuing Review submission volume and timing is much more predictable than Modification submission volume, so you can plan ahead.

You must document your decision to make the switch.

- You should record the switch in your IRB system or another tracking tool.
- You should be able to report on which pre-2018 initiated research you have switched to the 2018 requirements.

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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:
EXEMPT CATEGORIES

- **Exempt categories 7 and 8 address broad consent.**
  - Exempt category 7 is for storage or maintenance for future secondary research use.
  - Exempt category 8 is for secondary research use of information or biospecimens stored under exempt category 7.

- **These exempt categories do not cover primary collection or use of either identifiable private information or identifiable biospecimens.**
  - An investigator who wants to collect information or biospecimens directly from research subjects would not be covered by these exemptions

BROAD CONSENT:
LIMITED IRB REVIEW

- In order to understand broad consent, you need to understand limited IRB review.

- Limited IRB review is paired with several of the updated exempt categories.
  - For exempt categories 2(iii), 3(i)(C), or 8, “limited IRB review” means that, in addition to satisfying the terms of the exempt category, the privacy and confidentiality requirement at 45 CFR 46.111(a)(7) must be satisfied.
  - For exempt category 7, “limited IRB review” means that 45 CFR 46.111(a)(8) must be satisfied.

BROAD CONSENT:
LIMITED IRB REVIEW TAKEAWAYS

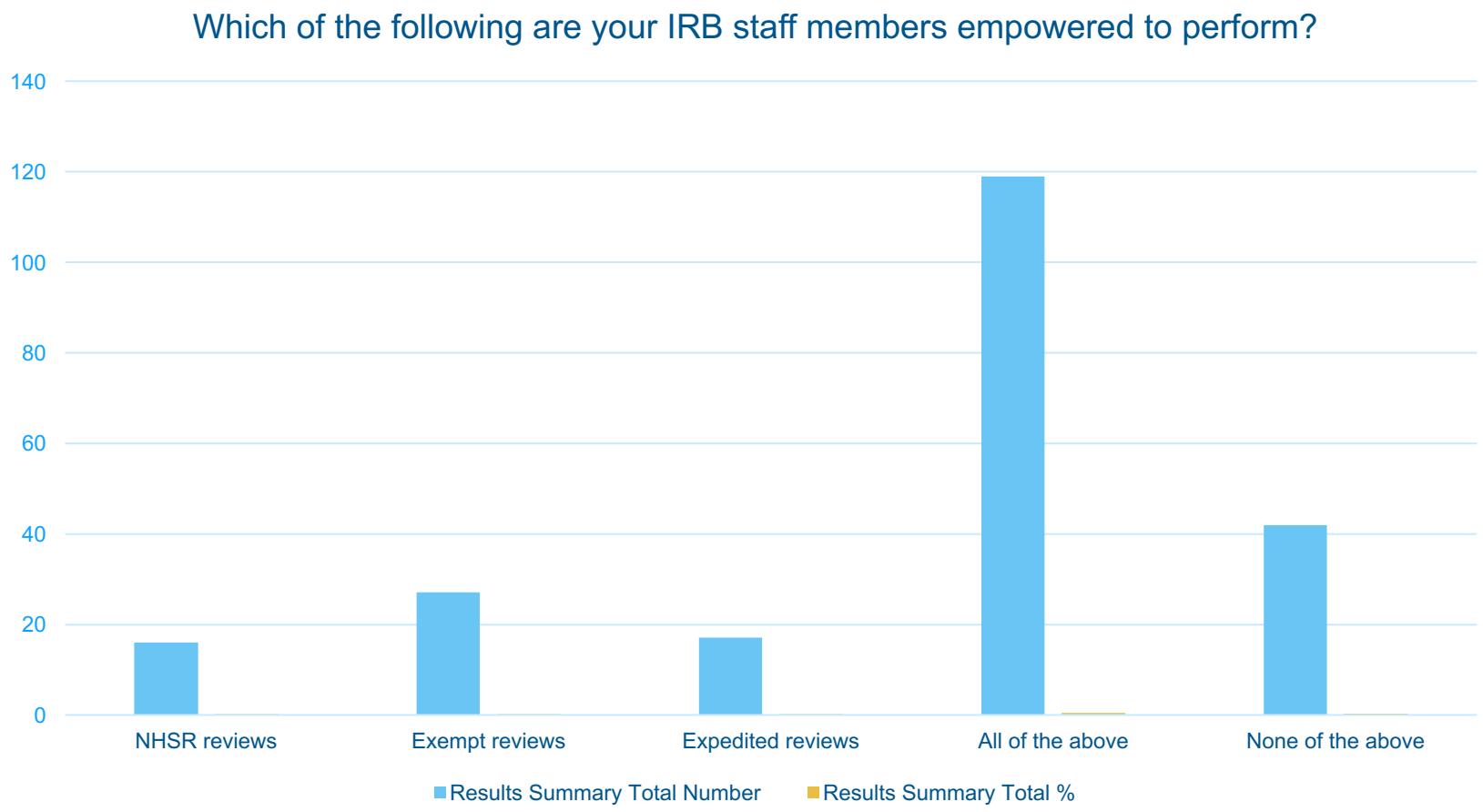
- Our understanding of these exempt categories is that limited IRB review is an essential component of each determination.
  - Since it is an essential component, limited IRB review does not need to be documented separately from the exempt determination itself.
  - That said, your review tools, e.g., reviewer checklists, should make it very clear what is packed into the determination.

- Limited IRB review is IRB review…just without *all* of the criteria for approval.
  - Because of this, limited IRB review must be conducted by an IRB member.
  - If you want for IRB staff members to make exemption determinations where limited IRB review is required, those staff members will need to be IRB members as well.

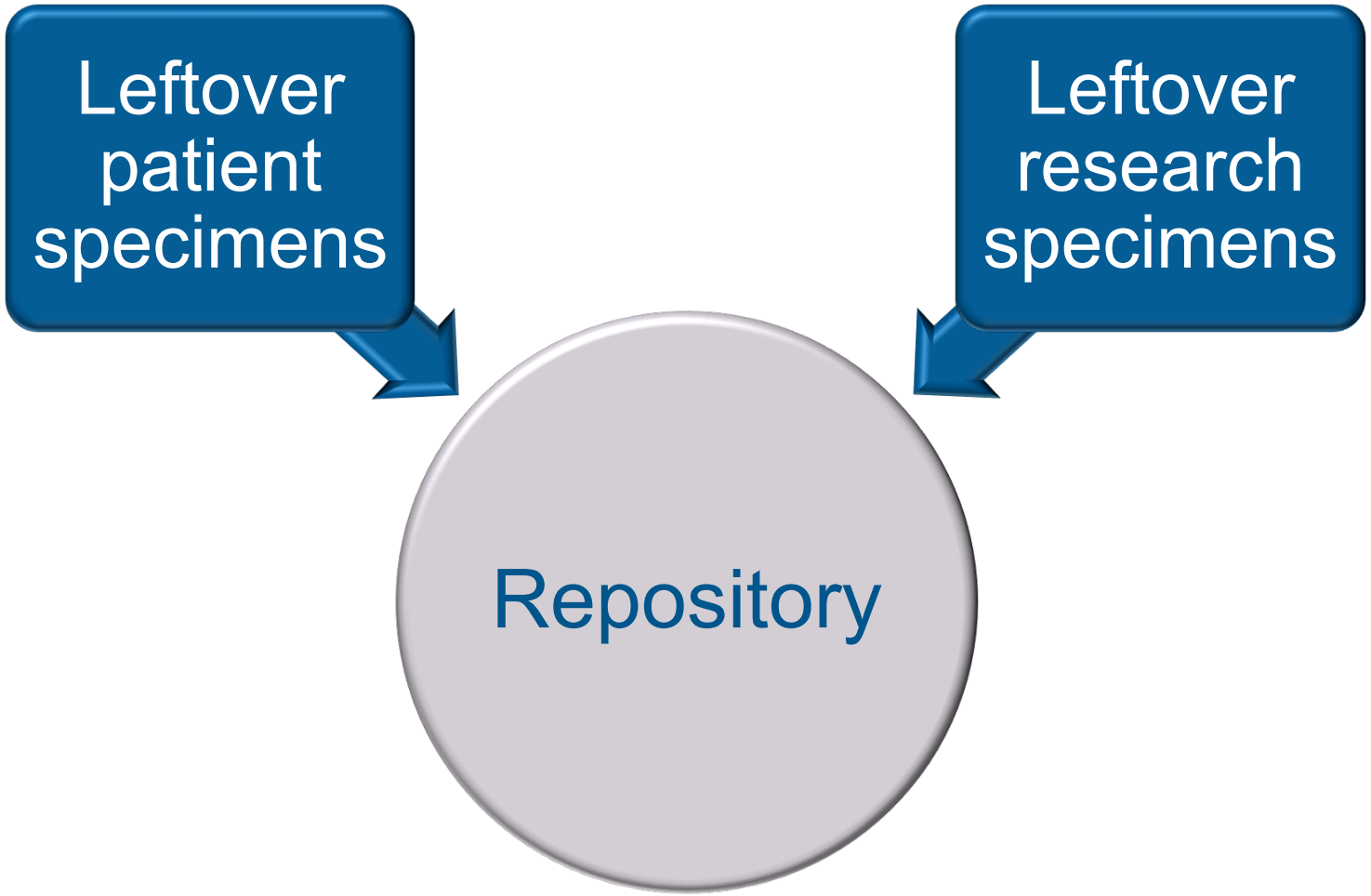
- Limited IRB Review can be conducted under the expedited procedure (45 CFR 46.110(b)(1)(iii)) and 45 CFR 46.110(b)(2).

- Continuing review is not required where limited IRB review is conducted.

POLLING QUESTION 4



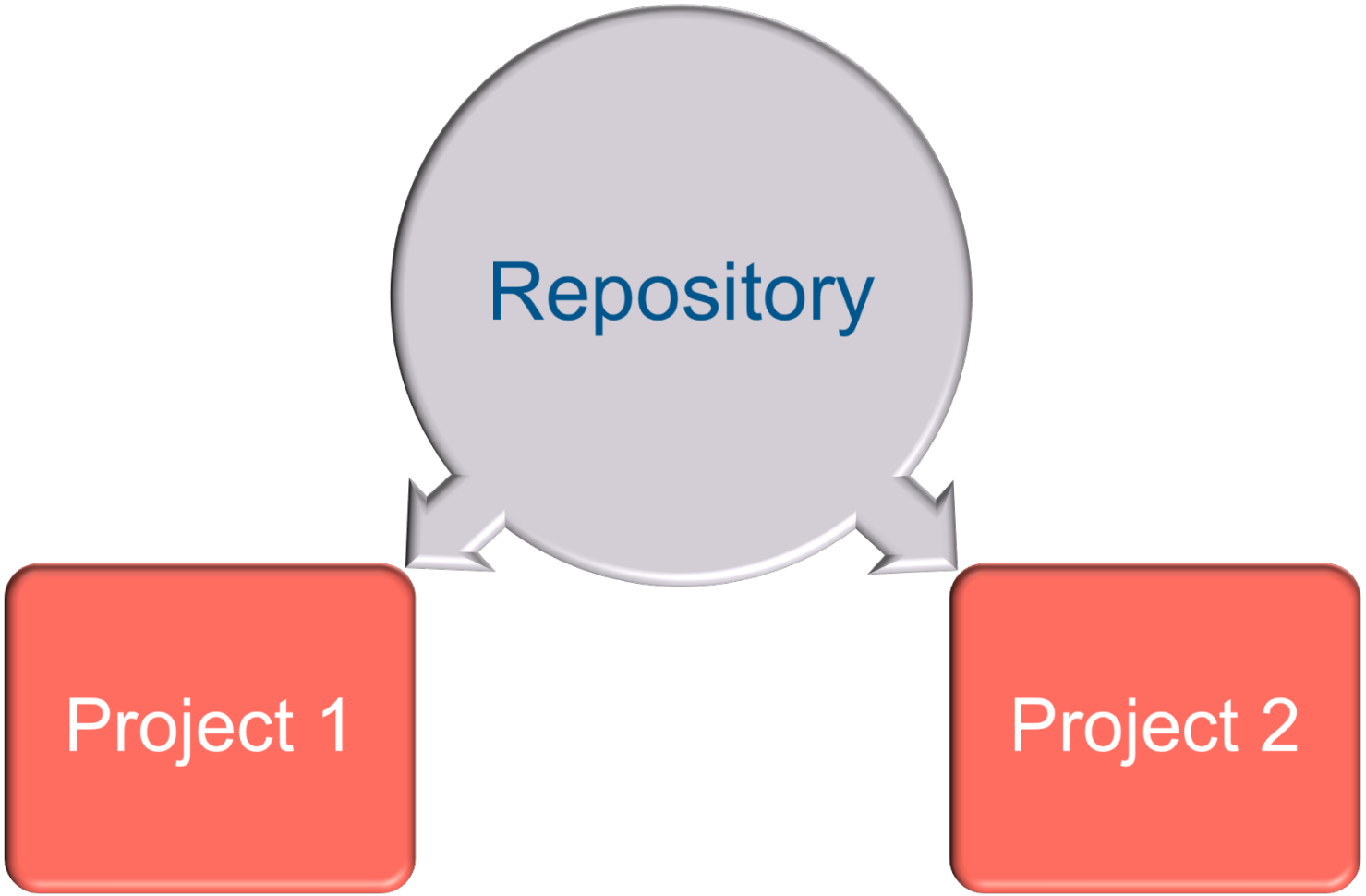
BROAD CONSENT:
STORAGE AND MAINTENANCE



BROAD CONSENT:
STORAGE AND MAINTENANCE

- Consider how your institution currently stores or maintains identifiable private information or identifiable biospecimens for secondary research use.
  - Often, individual investigators or departments will store biospecimens in local labs for their own secondary research uses.
  - An individual patient's biospecimens could be stored in more than one local lab depending on that patient's particular condition and visit history.
- Consider how your institution ensures that specimens are used for clinical purposes prior to being stored for secondary research use.
- Consider how consent is currently obtained throughout your institution and how consent is noted in institutional records, if at all.

BROAD CONSENT:
SECONDARY RESEARCH USE



BROAD CONSENT:
SECONDARY RESEARCH USE

- Consider how secondary research use of identifiable information or identifiable biospecimens is currently reviewed and approved at your institution.
  - Investigators will reference another project under which consent for secondary research use was obtained.
  - Often, IRBs will grant waivers of consent for such use.

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.

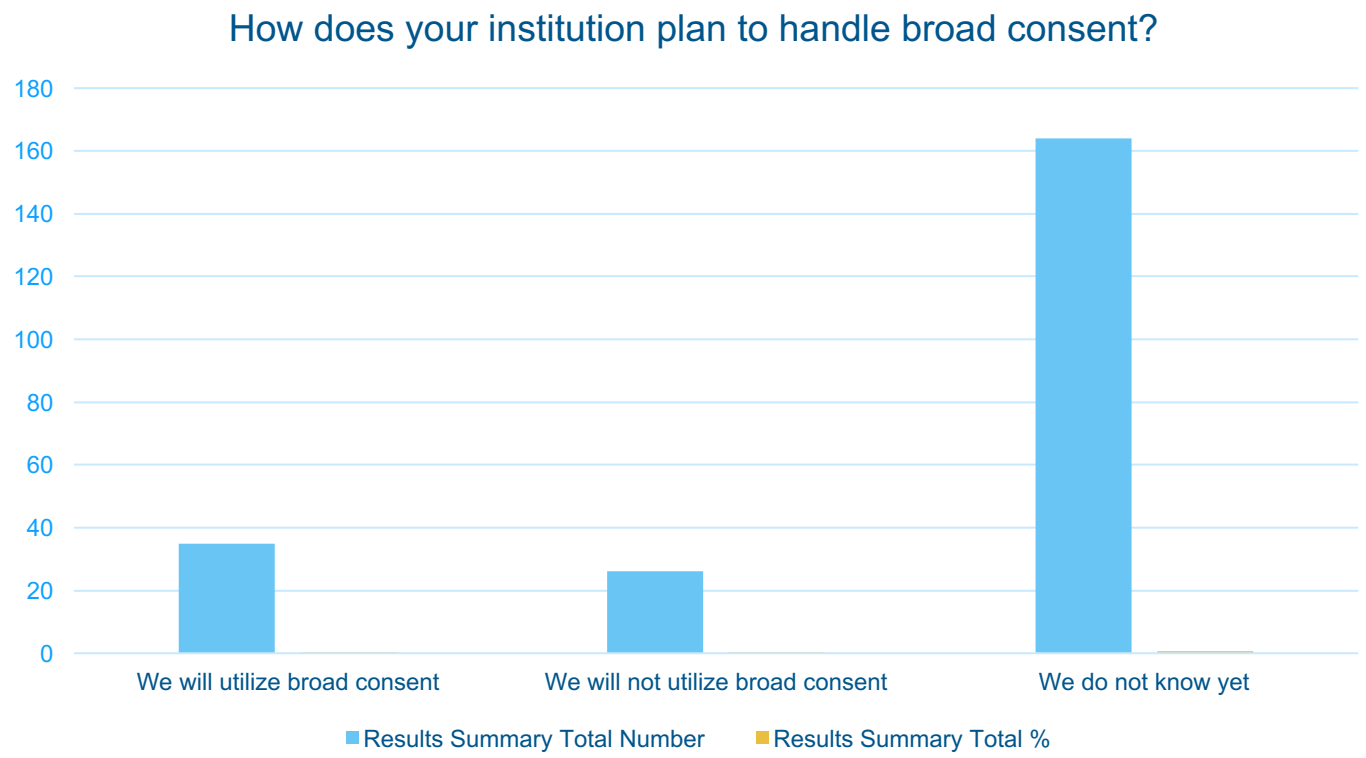
- For institutions that provide clinical care, is broad consent obtained at admission?
- For institutions that do not provide clinical care, is there a single point of entry for approaching potential subjects for broad consent?
- Who obtains broad consent?

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?

POLLING QUESTION 5



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CONTINUING REVIEW & FOLLOW-UP

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CONTINUING REVIEW: RATIONALE FOR REQUIREMENT

- Continuing Review is not or is no longer a requirement for certain research as stated at 45 CFR 46.109(f)(1).
- However, you will need to record rationale for when you require Continuing Review for that research as stated in 45 CFR 46.115(a)(3).
- Because of this, you will need a mechanism to track whether or not Continuing Review is required. And when required, you need to record the rationale.

CONTINUING REVIEW: FOLLOW-UP TAKEAWAYS

- **Even when Continuing Review is not required, you will still 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 that 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."

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PLANNING AHEAD

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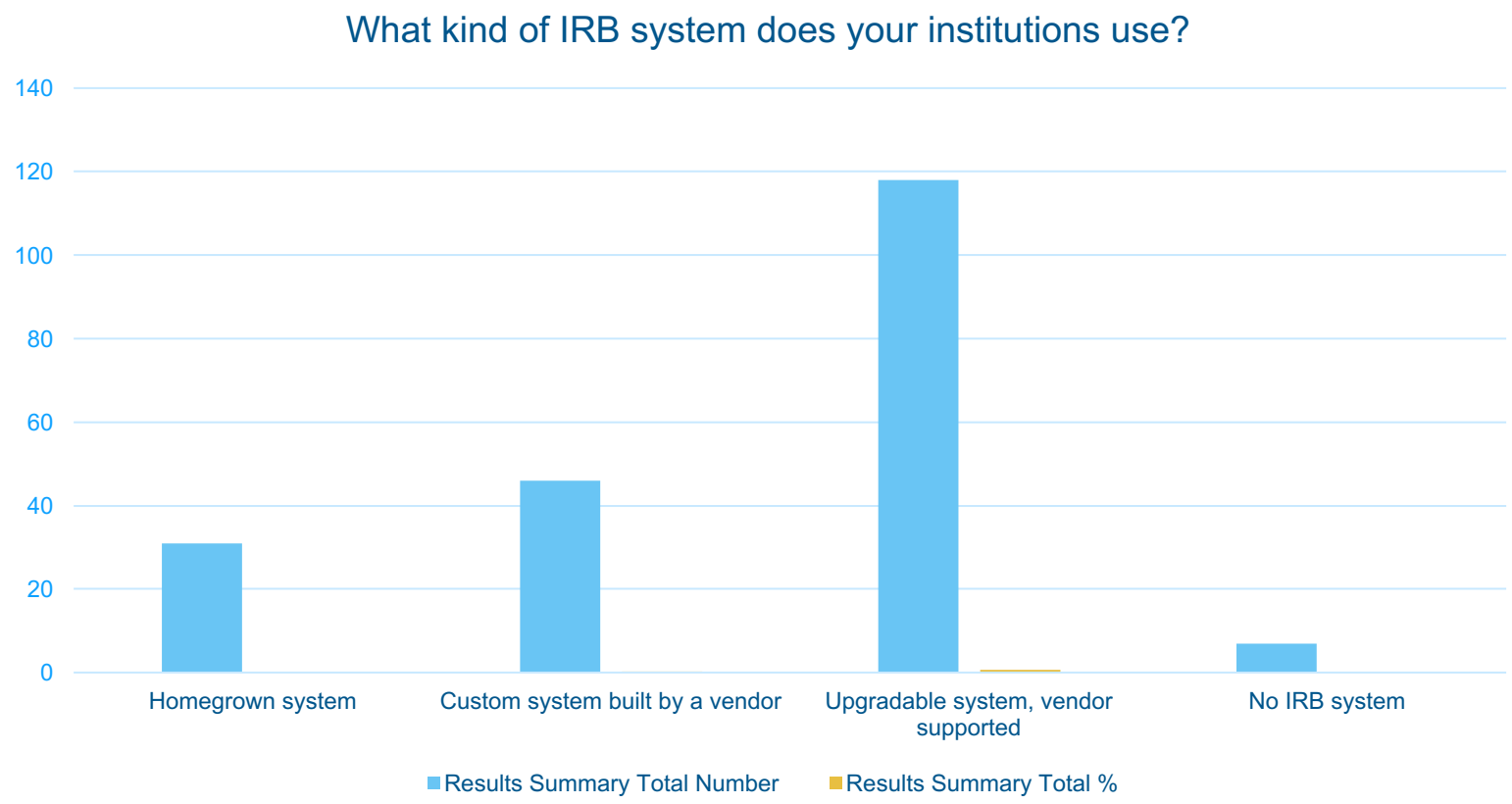
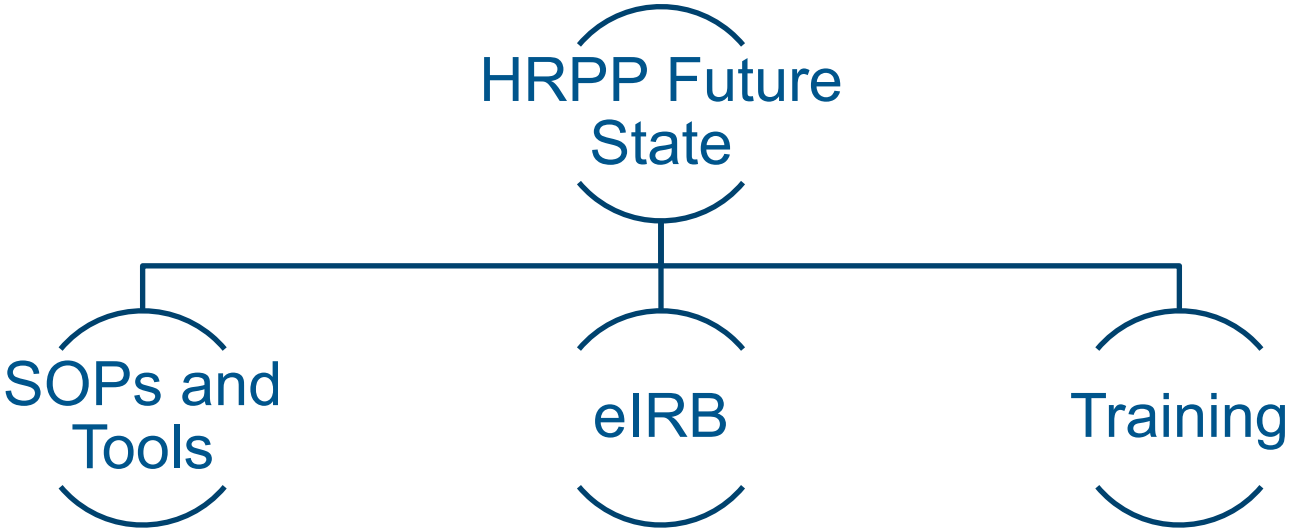
POLLING QUESTION 6

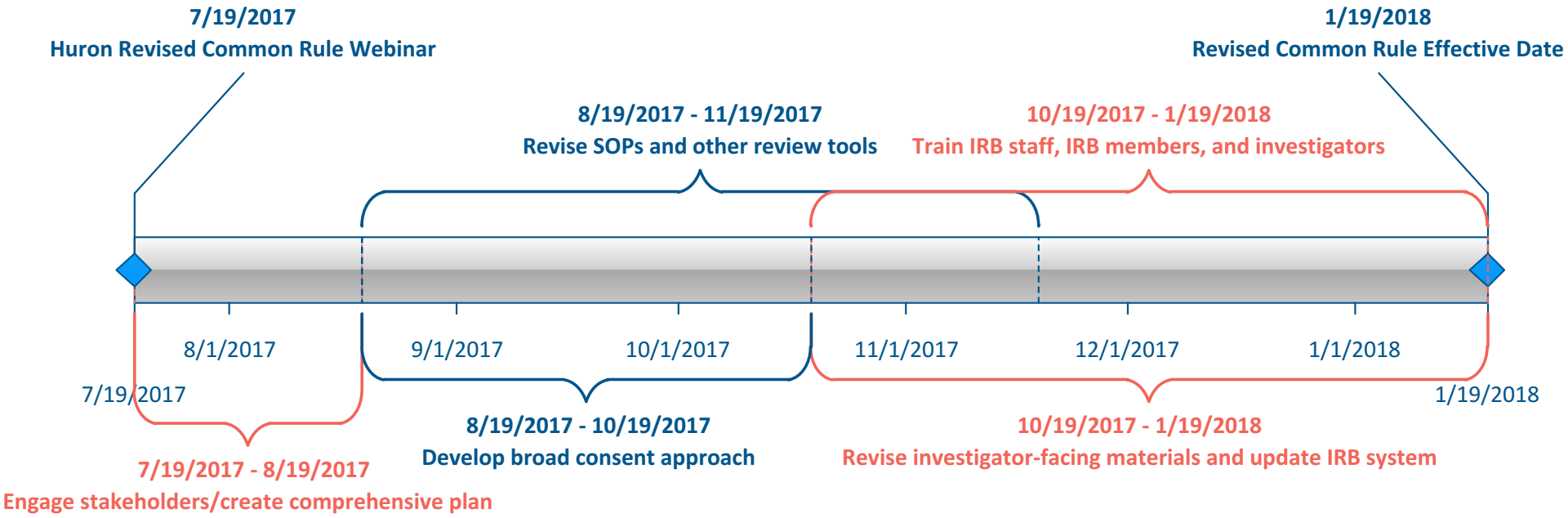


PLANNING AHEAD:
HRPP PROCESS CHANGE



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



Q&A

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RESOURCES:

- Huron IRB Transformation Services: https://www.huronconsultinggroup.com/-/media/Resource-Media-Content/Education/RES_IRB-Transformation-Sell-Sheet.pdf?la=en
- Huron IRB Product Information: https://www.huronconsultinggroup.com/irbexchange
- 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.*

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THANK YOU!