# STRATEGIES TO HELP FUTURE-PROOF YOUR IRB OPERATIONS

January 26, 2018

# STRATEGIES TO HELP FUTURE-PROOF YOUR IRB OPERATIONS

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5. What Can We Do Now?
6. Future-Proofing Strategies
7. Planning Ahead
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# INTRODUCTIONS & INFORMATION

# TODAY'S MODERATOR

+ **GARY WHITNEY**
+ Managing Director
+ **Huron's Education 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.

# 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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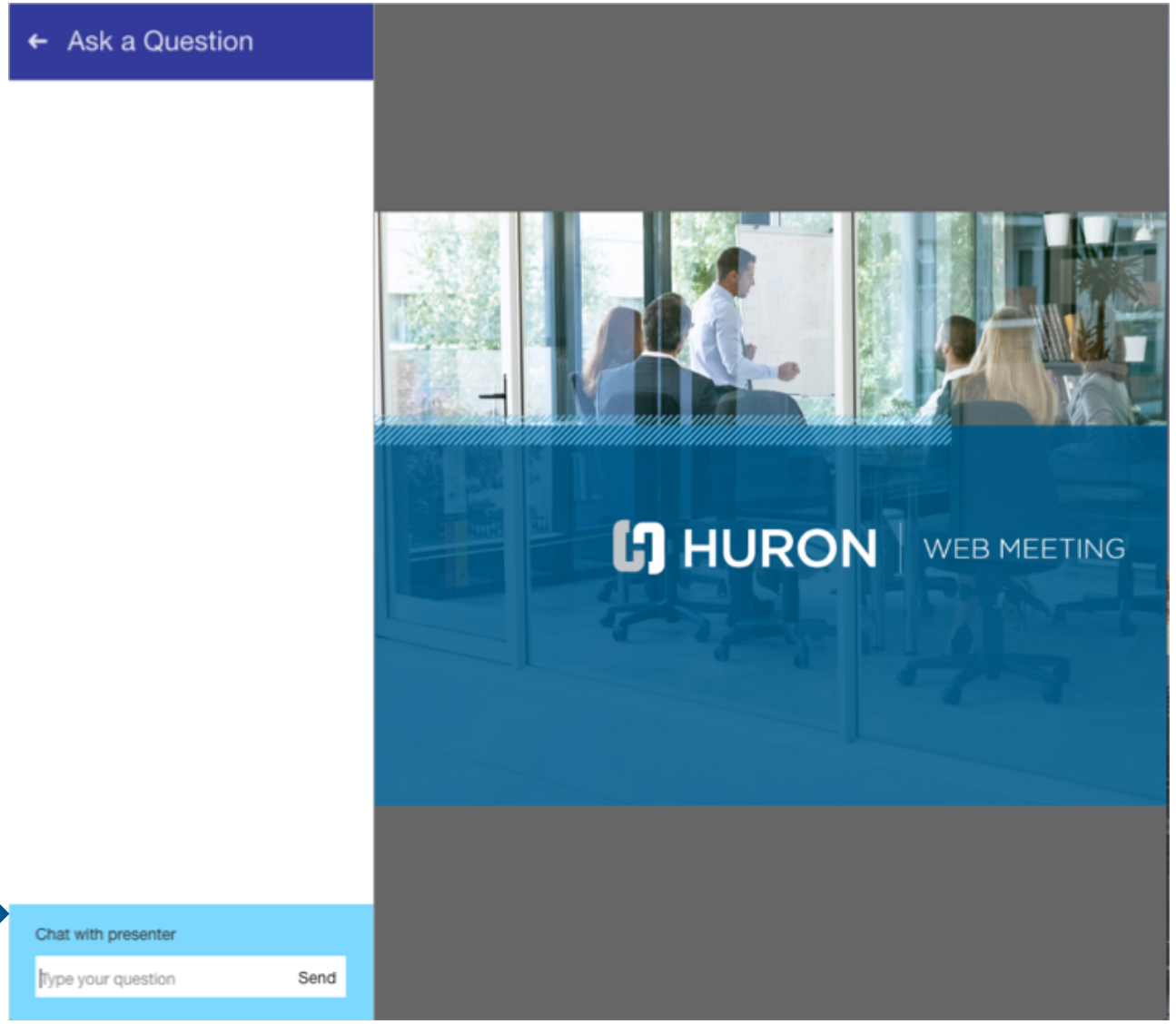
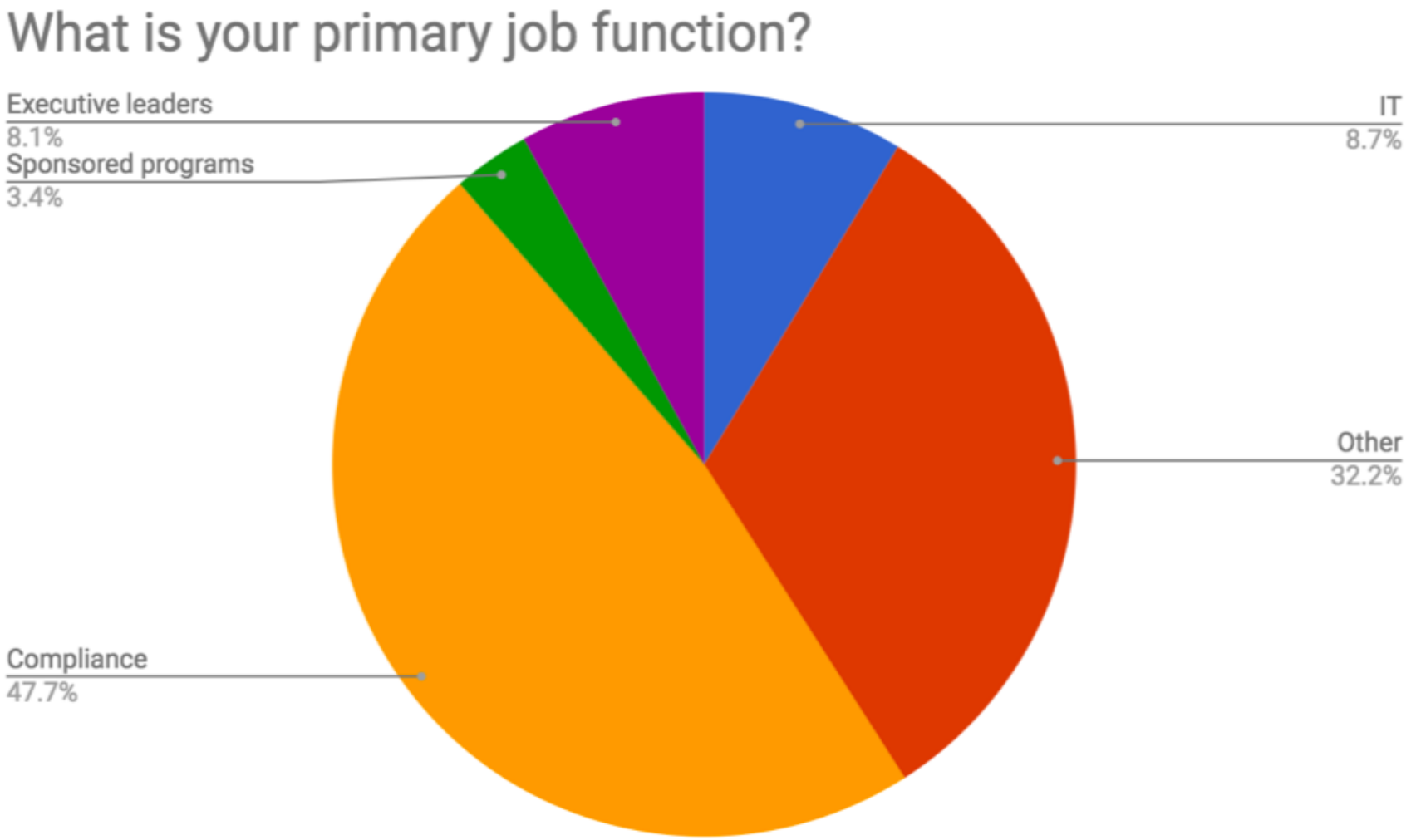
+ Jonathan is a Manager in Huron's Research Enterprise Solutions practice. His work focuses on institutional review board (IRB) structure and function and human research protection program (HRPP) evaluation and accreditation. He has worked directly for or partnered with a wide range of institutions to 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.

# ASK US YOUR QUESTIONS: LEVEL 3 CHAT PANEL




Enter a question in this dialog area at any time.

# WHO IS ATTENDING THE WEBINAR TODAY?



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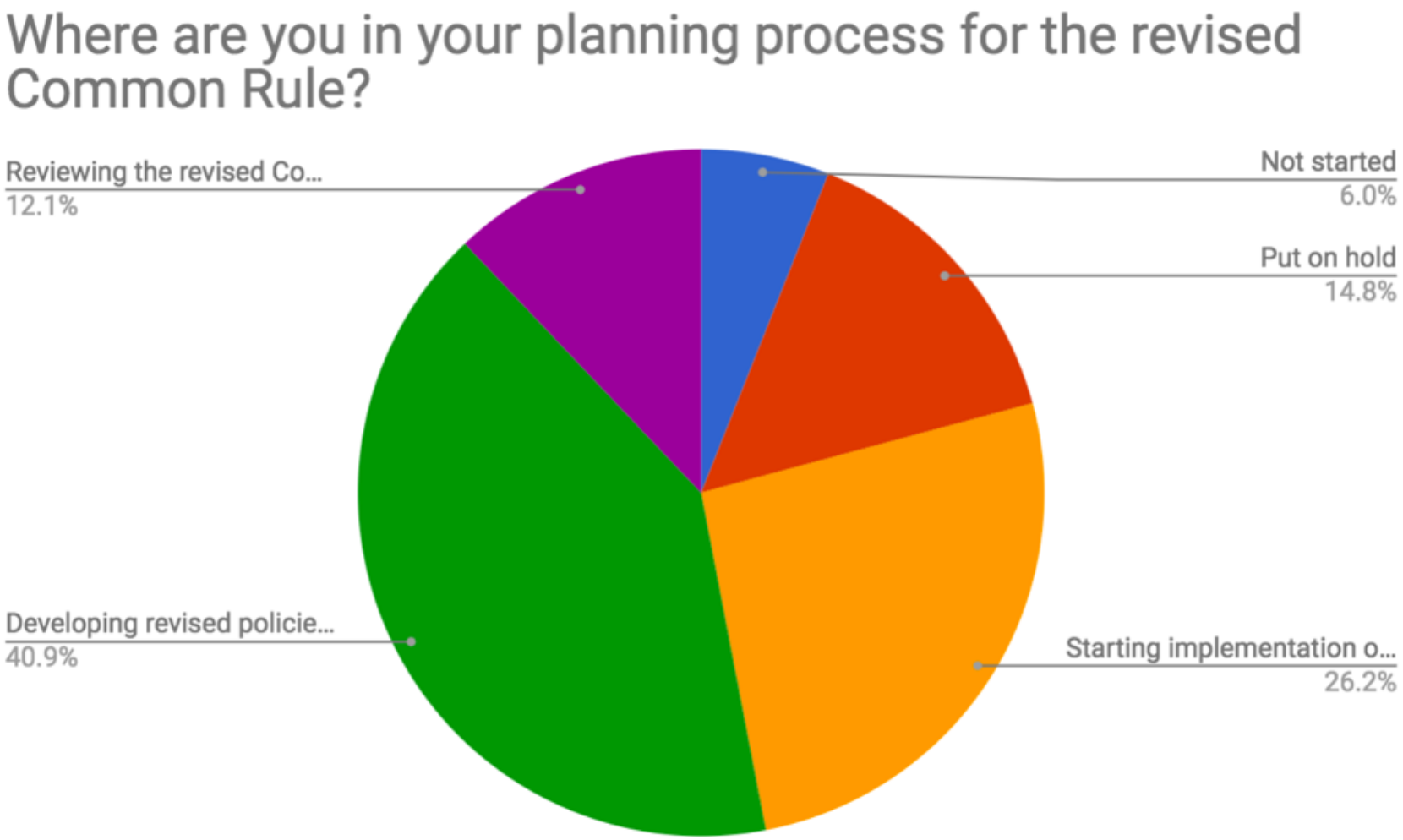

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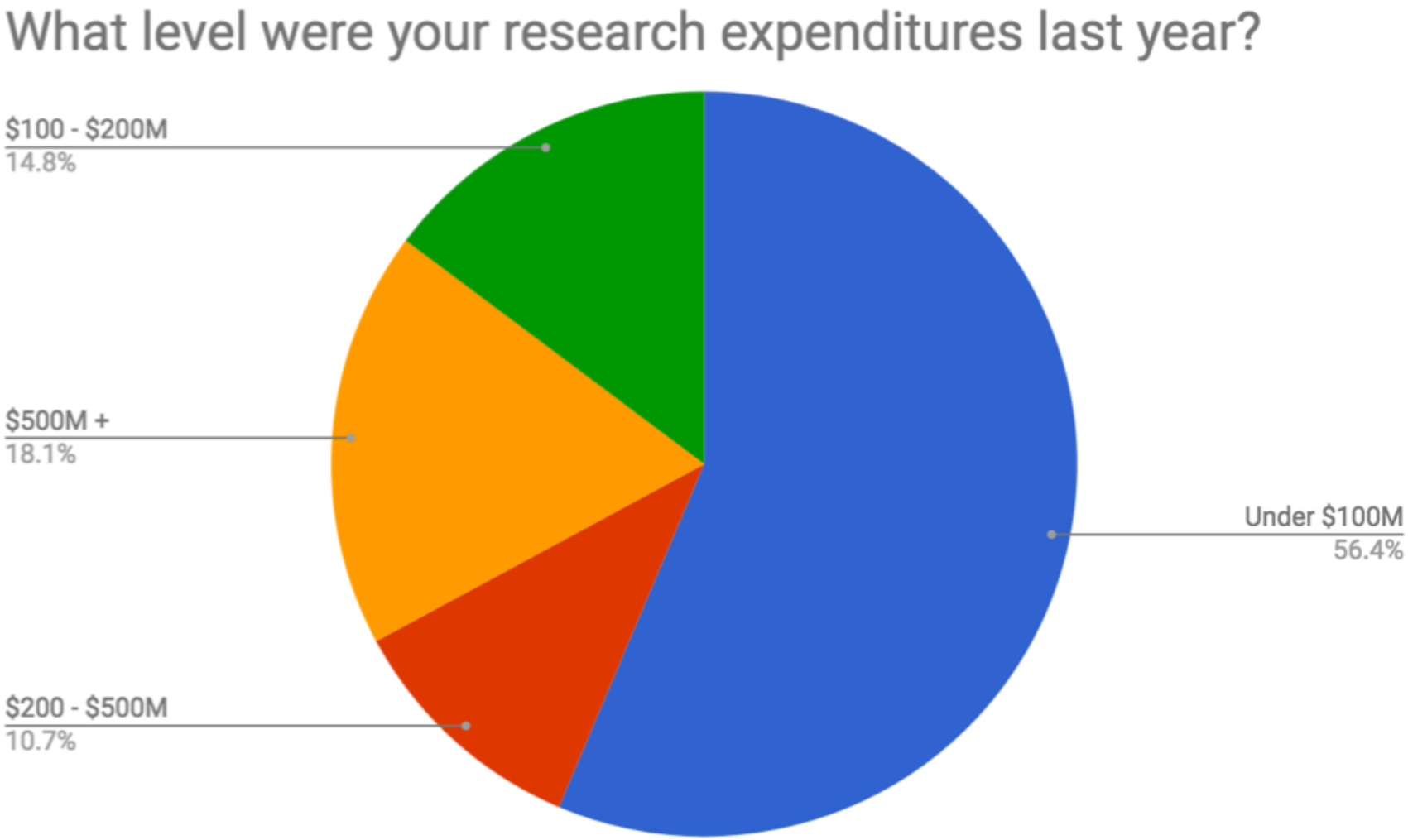
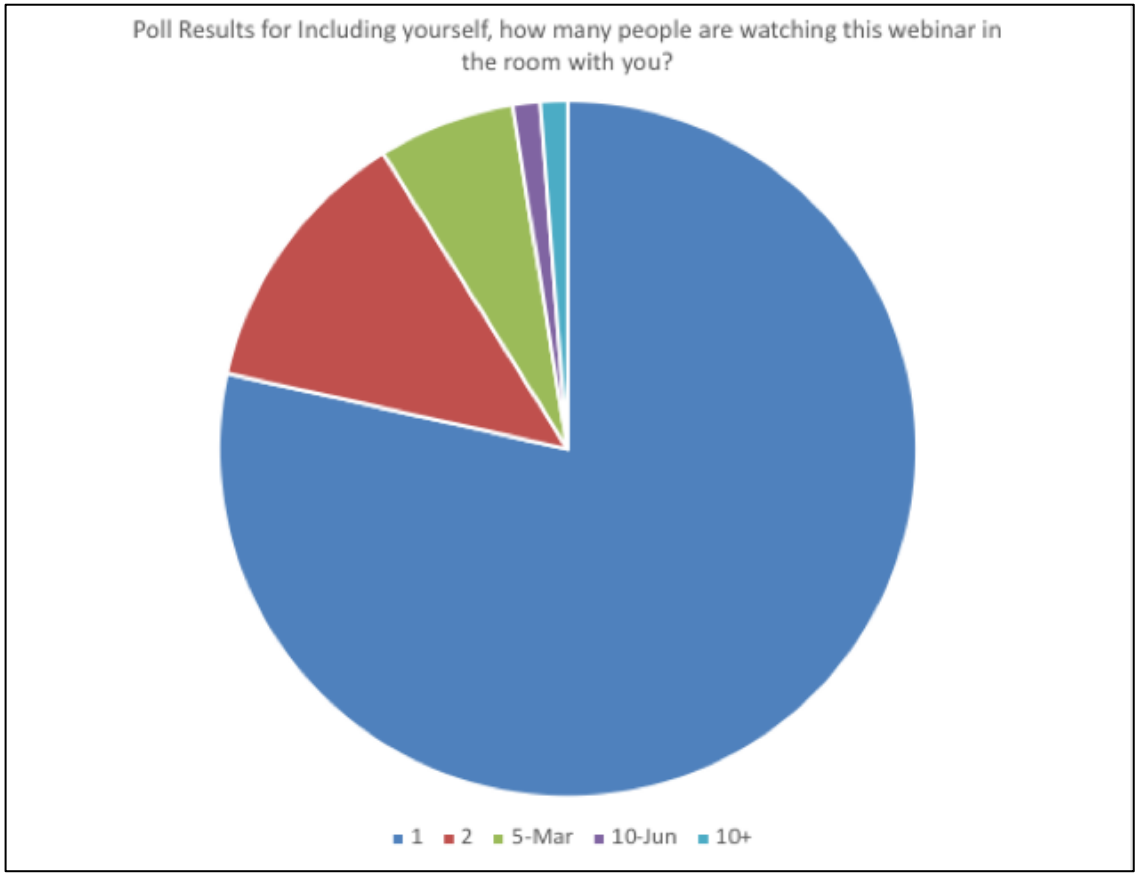
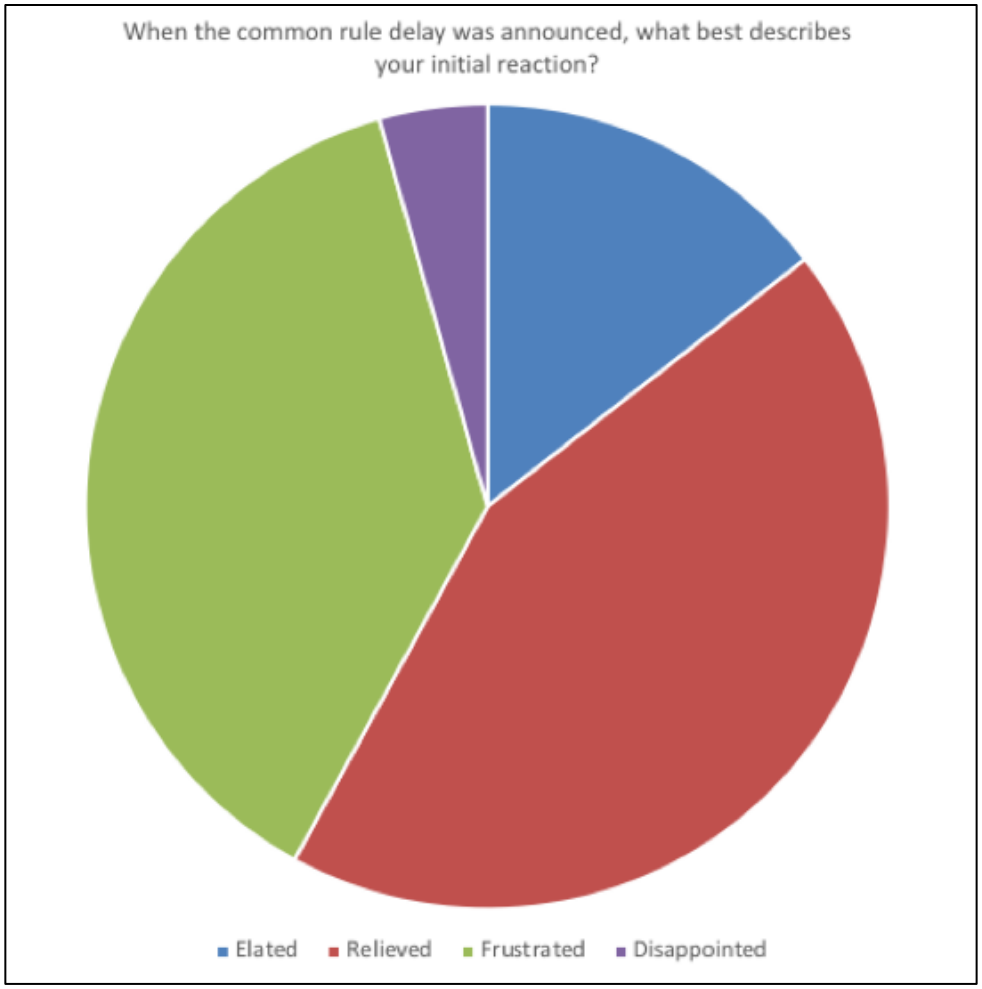



Poll Results for Including yourself, how many people are watching this webinar in the room with you?
1
2
5-Mar
10-Jun
10+


When the common rule delay was announced, what best describes your initial reaction?
Elated
Relieved
Frustrated
Disappointed

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# GENERAL NOTES

# 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 and the Interim Final Rule (IRF). 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) |
| NPRM, Revision to the New Rule | The request to delay the Final Rule, posted to the Office of Management and Budget (OMB) website on October 7, 2017 |
| Interim Final Rule | Formal rulemaking which delayed the 2018 Rule until July 19, 2018 (or possibly longer) |
| NIH Single IRB Policy | Policy requiring Single IRB Review of multi-site research, effective January 25, 2018 |

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# KEY TAKEAWAYS: PREVIOUS WEBINARS

# KEY TAKEAWAYS

## + July 19, 2017: “Prepare Your IRB Operations for Your IRB Operations for The Revised Common Rule”

- Making the switch
  - Considerations for moving studies from the Current Rule to the New Rule
- Broad Consent
- Continuing Review for expedited projects
- Planning ahead and timeline for implementation

## + September 20, 2017: “Achieve IRB Operations Success for The Revised Common Rule”

- System-related considerations
- Further discussion on Broad Consent
- Benign behavioral interventions
- Planning ahead and timeline for implementation

# KEY TAKEAWAYS

- **November 15, 2017: “The Revised Common Rule – What’s Next?”**
  - Proposed delay to the Final Rule, including potential scenarios and timelines
  - Planning ahead and timeline for implementation

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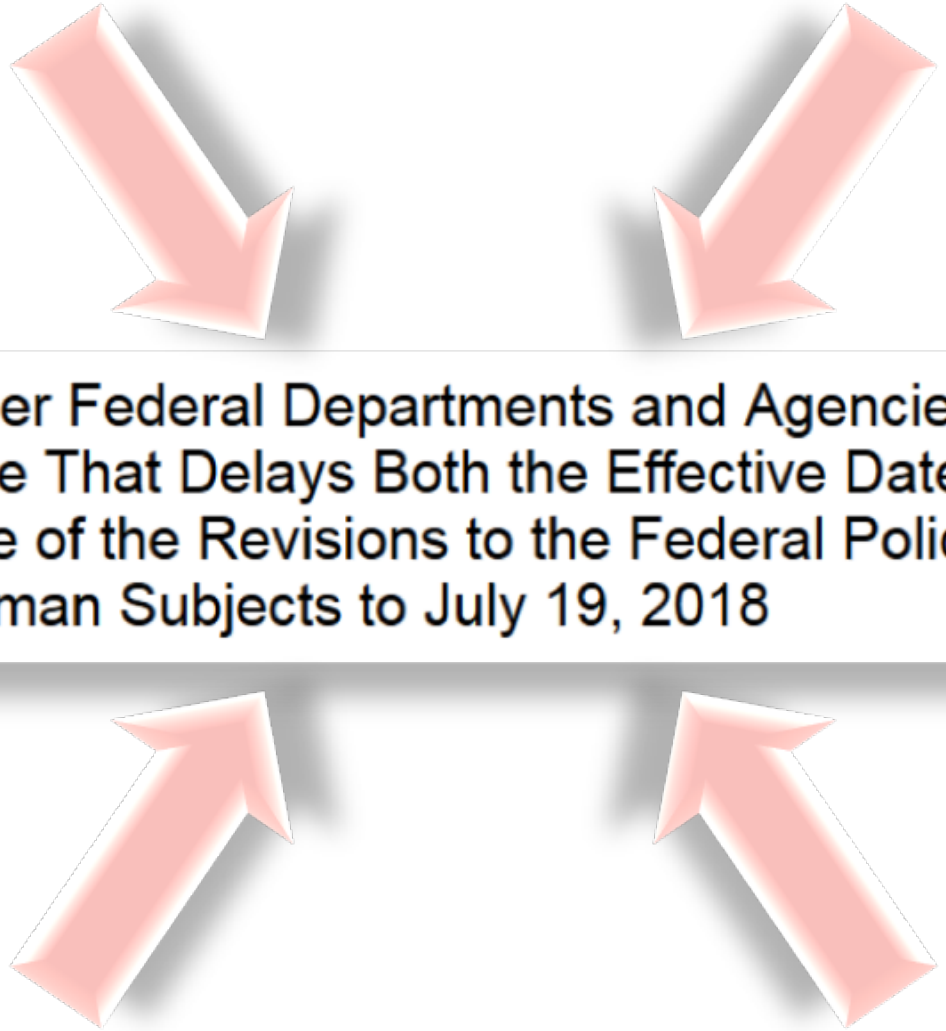
# COMMON RULE DELAY

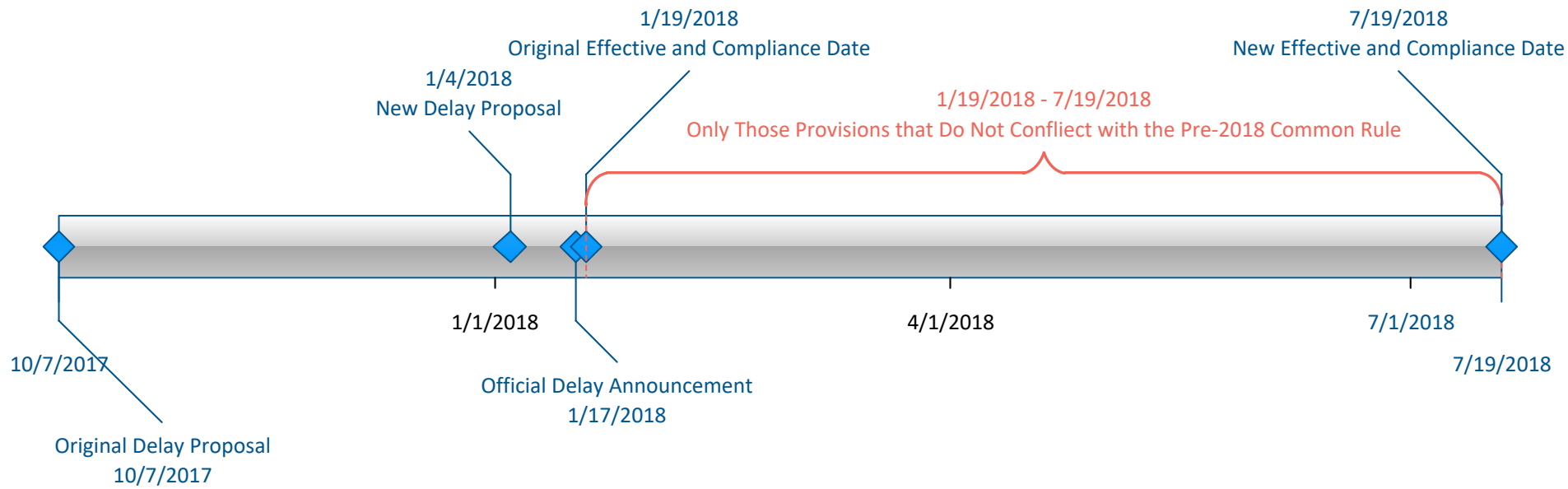
# COMMON RULE DELAY
# IT'S OFFICIAL!



HHS and 15 Other Federal Departments and Agencies Announce an Interim Final Rule That Delays Both the Effective Date and General Compliance Date of the Revisions to the Federal Policy for the Protection of Human Subjects to July 19, 2018

https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html

# COMMON RULE DELAY
# TIMELINE



# COMMON RULE DELAY
# NEXT STEPS

- Before July 19, 2018, institutions may implementing *only those provisions* of the Revised Common Rule *that do not conflict* with the Pre-2018 Common Rule.

- The Interim Final Rule does not delay the compliance date for the cooperative research provision of the 2018 Requirements (§ _.114(b)), which remains January 20, 2020.

- The Interim Final Rule indicates that the Common Rule agencies are developing a Notice of Proposed Rulemaking in order to fully engage regulated entities and the public regarding further delay of the 2018 Requirements until January 21, 2019.

- The Comment Period for the Interim Final Rule is open until March 31, 2018.

# REVISED COMMON RULE TIMELINE

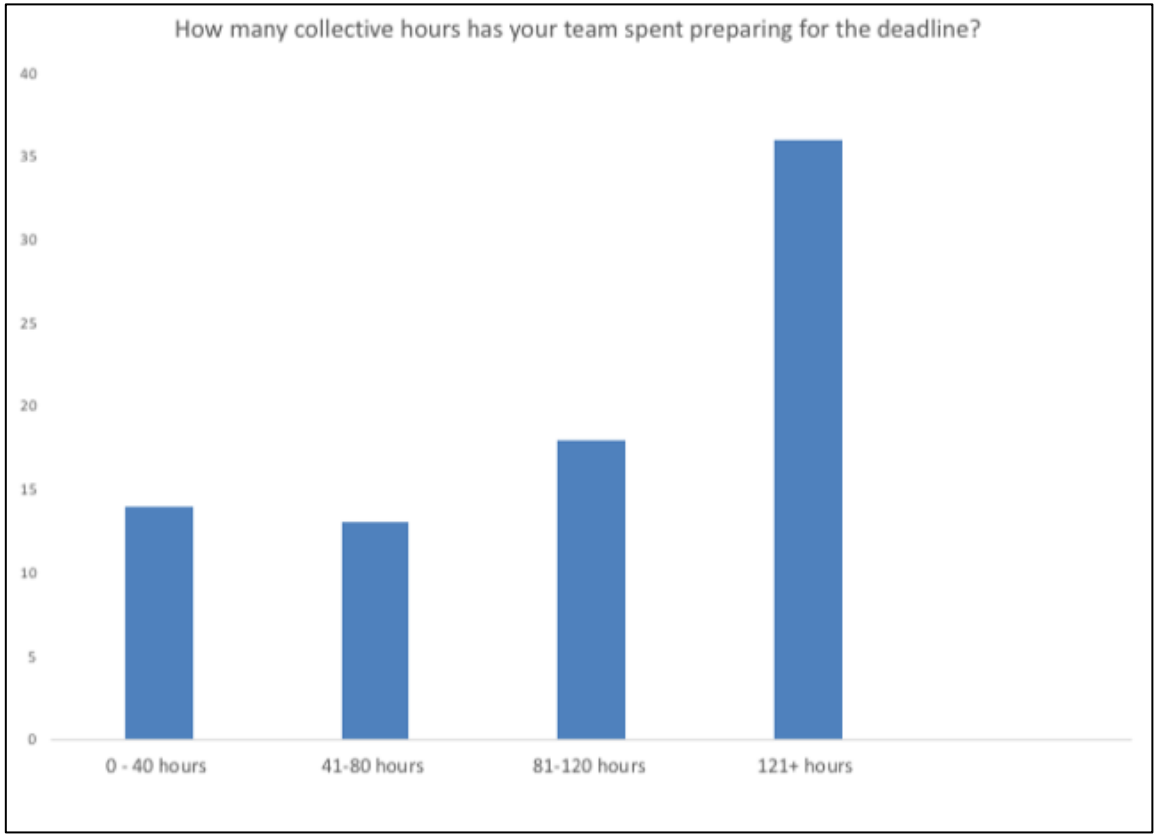
**1/19/17**
- Release of the Final Rule from OHRP
- First major update to the Common Rule since the '90s

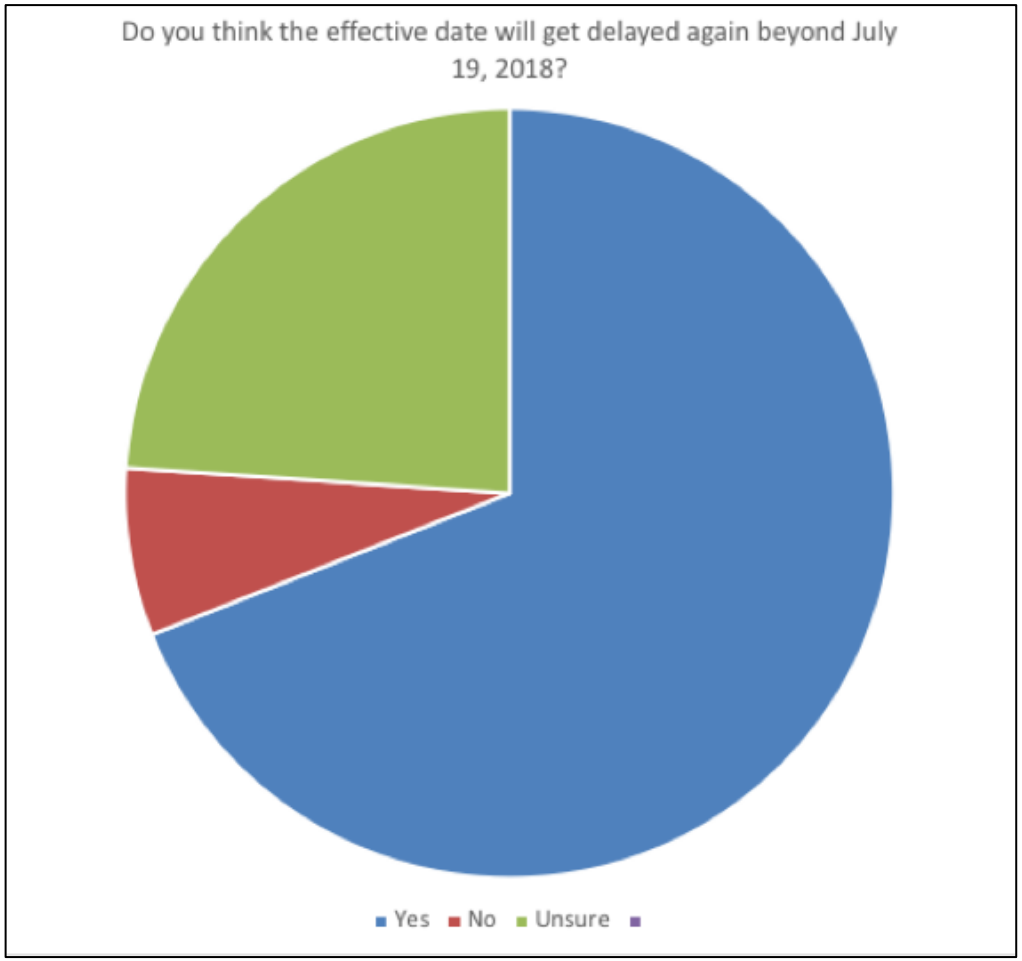
**1/19/18**
- Effective *and* Compliance date for the Final Rule
- All research *approved* on or after this date must follow the Final Rule

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

**7/19/19**
- Revised Effective and Compliance date for the Final Rule
- All research approved on or after this date must follow the Final Rule

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


How many collective hours has your team spent preparing for the deadline?
40
35
30
25
20
15
10
5
0
0 - 40 hours
41-80 hours
81-120 hours
121+ hours


Do you think the effective date will get delayed again beyond July 19, 2018?
Yes
No
Unsure

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# WHAT CAN WE DO NOW?

# WHAT CAN WE DO NOW?
# EXAMPLES

- The delay announcement from HHS states the following: *…institutions may only begin implementing provisions of the revised Common Rule that do not conflict with the pre-2018 Common Rule*. What does this mean?
- HHS provided two examples:
  - Example 1: *Permissible.* Incorporation of new elements of consent at §__.116(b)(9), (c)(7)-(9).
  - Example 2. *Not permissible.* Elimination of Continuing Review at §__.109(f).

# WHAT CAN WE DO NOW?
# ANALYSIS

- Institutions can use those examples to determine what other provisions are permissible or not permissible.
- For the incorporation of new elements of consent, consider the following:
  - The new elements of consent at §__.116(b)(9), (c)(7)-(9) do not replace previously existing elements of consent in the Pre-2018 Common Rule.
  - Institutions have always been allowed to incorporate local elements of consent that do not conflict with the Pre-2018 Common Rule, e.g., subject injury language, state-specific requirements.
- For the elimination of Continuing Review, consider the following:
  - That provision at §__46.109(f) of the Revised Common Rule conflicts with the requirement to conduct Continuing Review for non-exempt Human Research at §__46.109(e) precisely because the elimination of Continuing Review depends on an accompanying revision to §__.109(e) that is also being delayed: "An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, not less than once per year, ***except as described in §46.109(f)***" (emphasis Huron's).

# WHAT WE CANNOT DO NOW
# MAINTAIN PRE-2018 POLICIES

- Analyze the changes that you made to your policies, systems, and other tools using the HHS examples as guidance, to determine what you *cannot* do during the delay period.
- Some examples are:
  - Human Subject Definition
  - Revised Exempt Categories
  - Broad Consent
  - Limited IRB Review
  - Default “unchecking the box” for projects that do not have Common Rule oversight
  - Eliminating grant congruency review
  - Eliminating continuing review for expedited projects, or projects that have reached certain milestones

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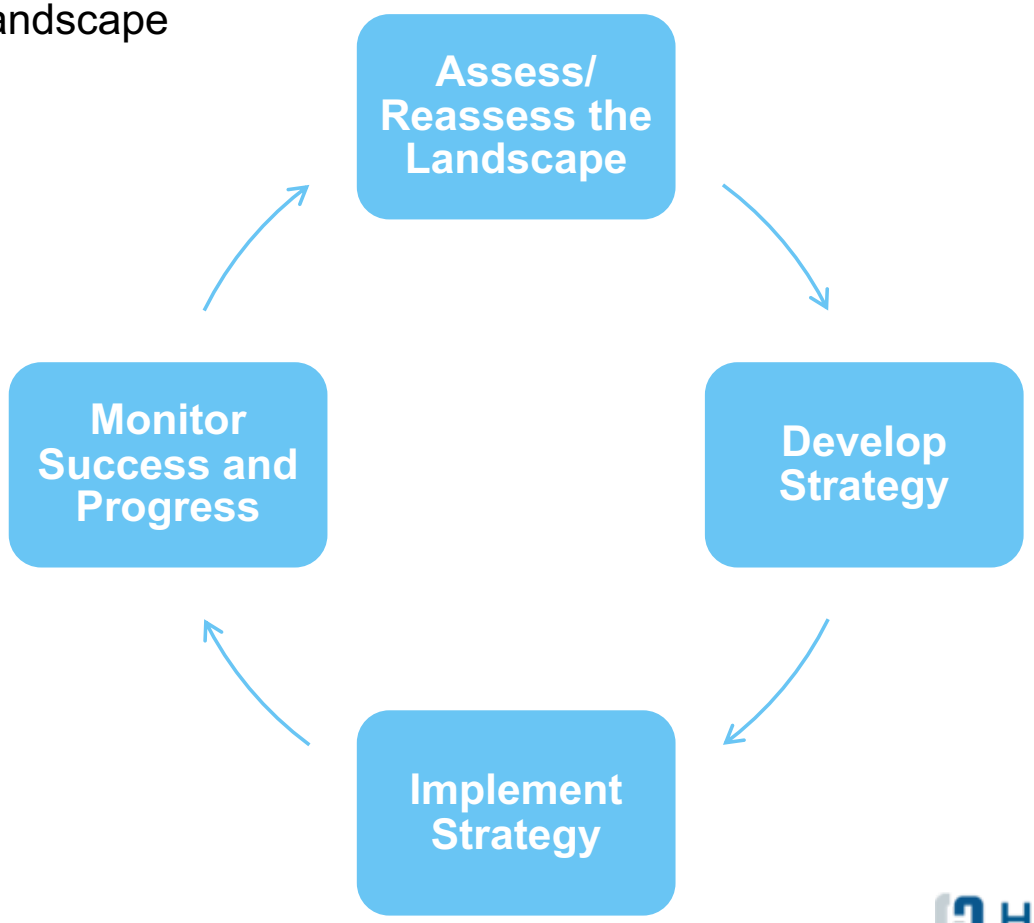
# FUTURE PROOFING IRB OPERATIONS

# FUTURE-PROOFING
# WHAT DOES IT MEAN?

- In an uncertain environment, it's critical that organizations are prepared for upcoming changes and challenges, especially in these areas:
  - Regulatory and Guidance Landscape
  - Accreditation
  - Business Process
  - Staffing
  - Technology

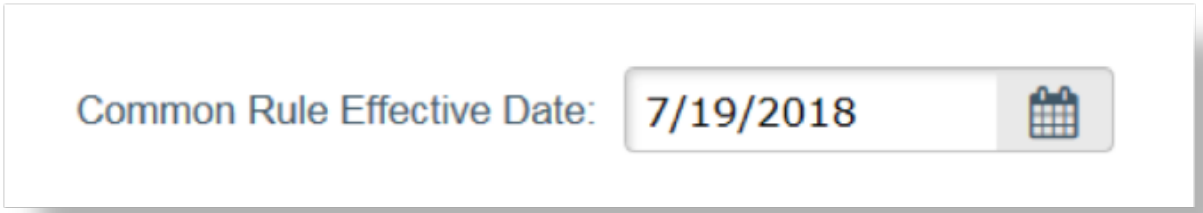


# FUTURE-PROOFING IRB OPERATIONS
# LEARNING FROM THE DELAY

- Consider how you prepared for the Revised Common Rule and what you have to unwind or roll back as a result of the delay.
- Do you have to undo any of the functionality you developed to get your IRB system ready?
  - In the first webinar, we encouraged you to create flexibility in your IRB system by removing regulatory and routing questions from your new study submission application.
  - How can you create additional IRB system flexibility moving forward?
- Are there any policies or procedures that you need to adjust for the delay?
  - In the second webinar, we recommended for you not to implement broad consent until further guidance.
  - As you make adjustments, can you utilize decision trees to stage New Rule considerations for future determinations rather than removing them altogether?

# FUTURE-PROOFING IRB OPERATIONS
# HURON'S APPROACH

- Like you, the Huron IRB team had to prepare for the Revised Common Rule.
- For example, we attempted to future-proof our IRB system by building in a delay switch.
  - All Revised Common Rule functionality is activated only once the specified date has been reached.



# FUTURE-PROOFING
# GENERAL SUGGESTIONS

Be vigilant:

- Talk to colleagues at other institutions
- Review available resources:
  - Huron Webinars
  - PRIM&R website and conferences
  - IRB Forum

Prepare to be responsive

- Update policies, procedures and review tools as guidance is released
- Plan ongoing trainings with IRB staff and reviewers to incorporate revisions

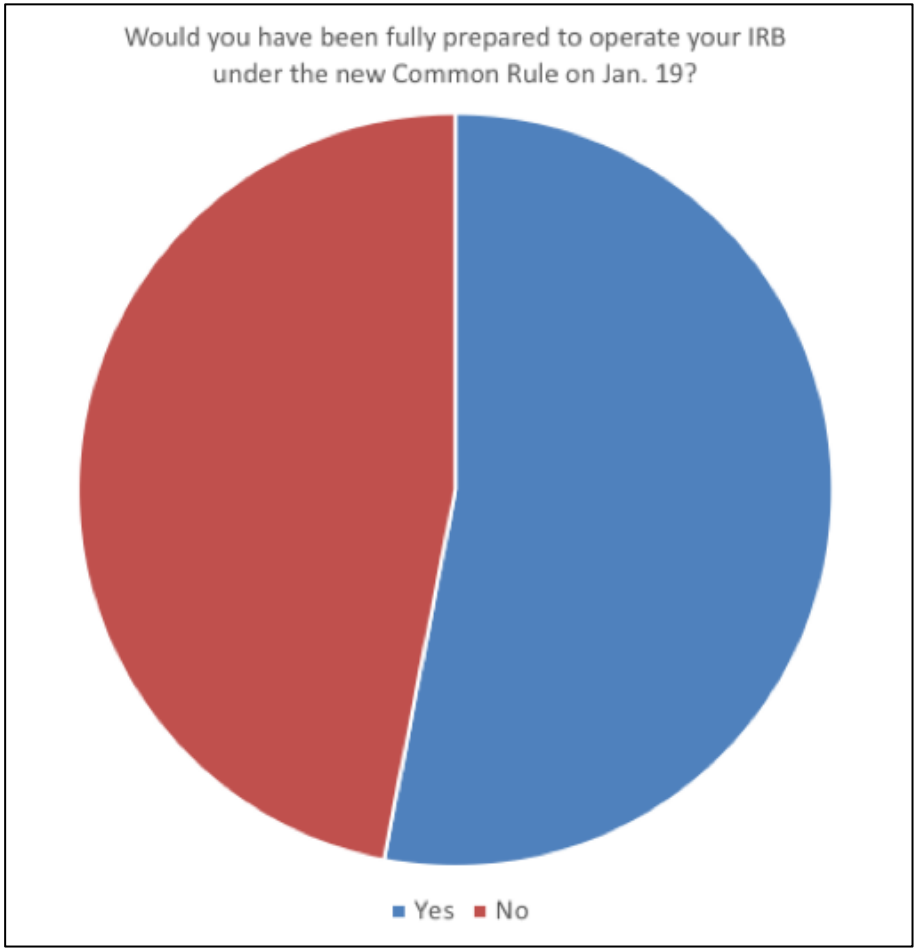
# FUTURE-PROOFING
# SPECIFIC EXAMPLES

*Process*:

- Ensure SOPs, review tools, etc. are updated and maintained in a way that they can be easily adjusted
- Have a plan in place for if there is a need to revert, or partially revert

*Technology:*

- Utilize smart technology to ensure that work done during technology design and implementation will not need to be re-done
  - Add date setting for the Compliance date, that drives when users see Final Rule options throughout the system


Would you have been fully prepared to operate your IRB under the new Common Rule on Jan. 19?
Yes
No

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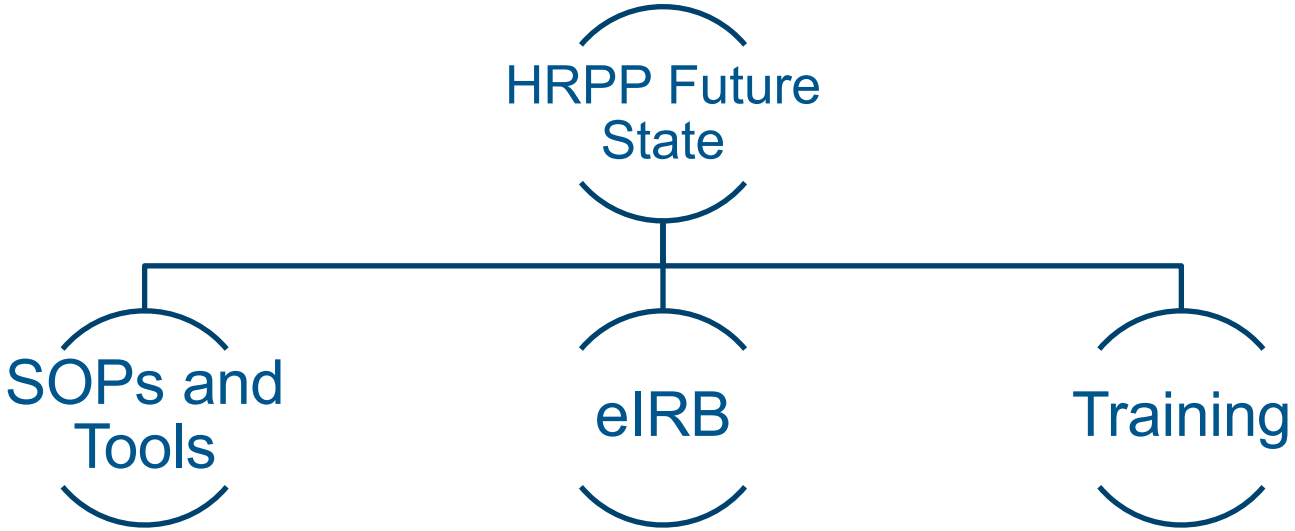
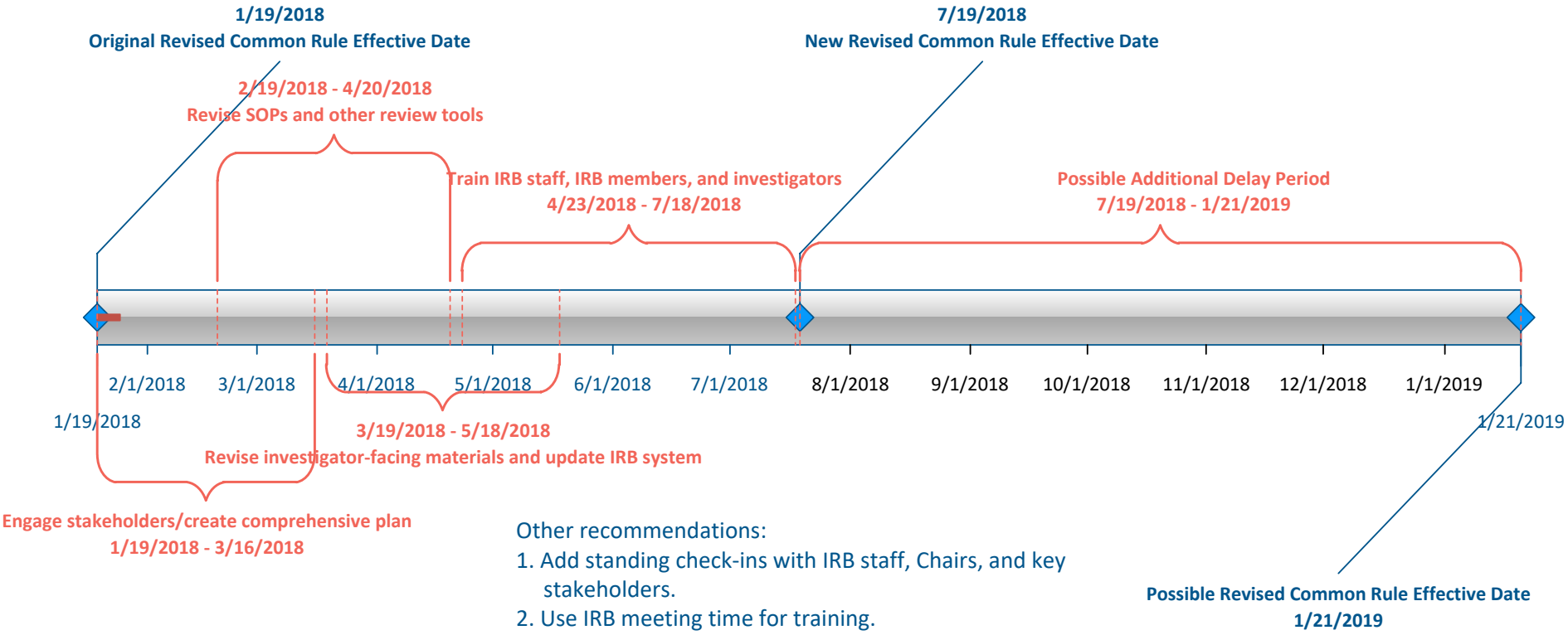
# PLANNING AHEAD

# PLANNING AHEAD
# HRPP PROCESS CHANGE



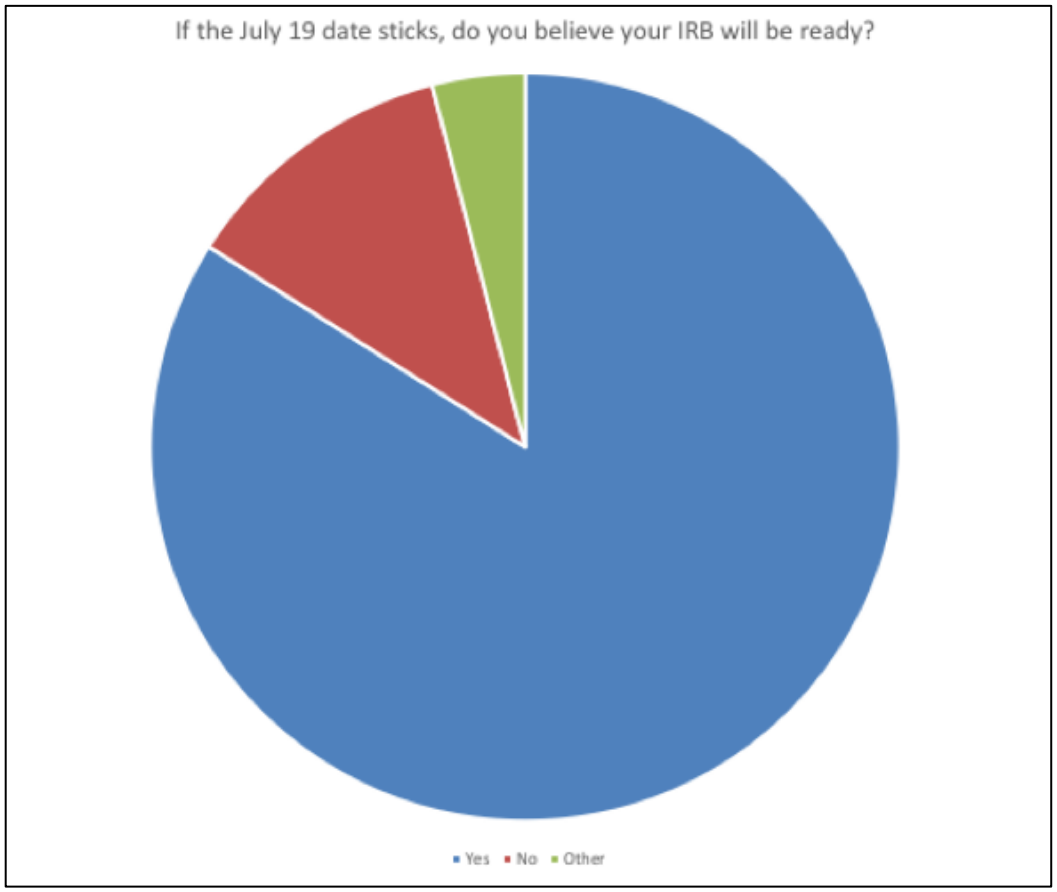

| | | |
|---|---|---|
| Develop an approach to updating your SOPs and other tools to accommodate the 2018 requirements. | Create a project plan for updating your IRB system; secure SME input and IT resources. | Determine which groups need what training, and who will develop the curriculum and lead it.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

# PLANNING AHEAD
# NEW EXAMPLE




Other recommendations:

1. Add standing check-ins with IRB staff, Chairs, and key stakeholders.
2. Use IRB meeting time for training.


If the July 19 date sticks, do you believe your IRB will be ready?
Yes
No
Other

# 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.

+ Notice of the delay to the Revised Common Rule: https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html.

+ SACHRP recommendations for broad consent, and draft template: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2017/index.html

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# CONTACT US

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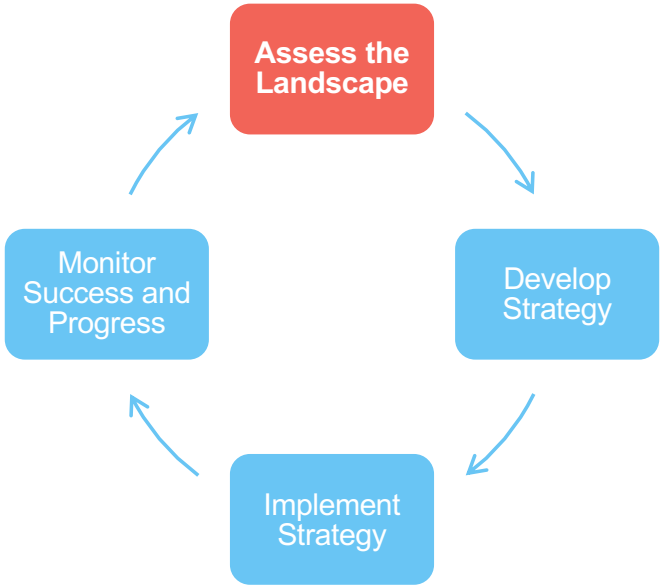
HURON
THANK YOU!

# APPENDIX

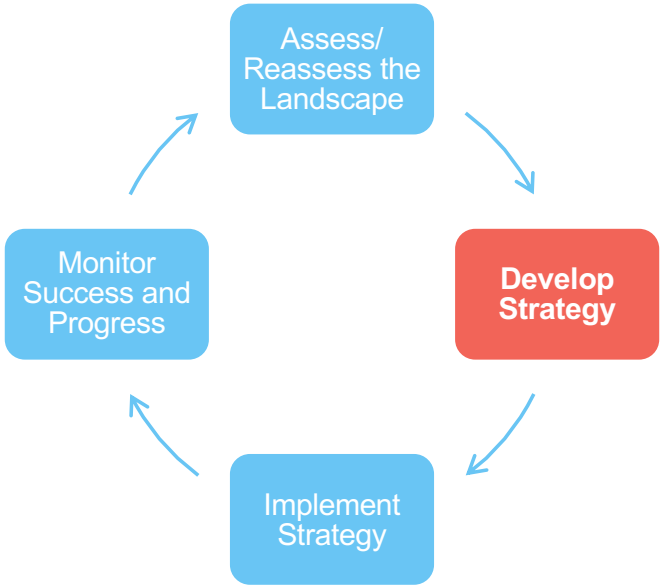
# ASSESSING THE LANDSCAPE
# USING AVAILABLE RESOURCES

- Use all the resources available to you:
  - Colleagues in the industry
  - Industry and Professional Organizations
  - Consultants
  - Message Boards and Forums



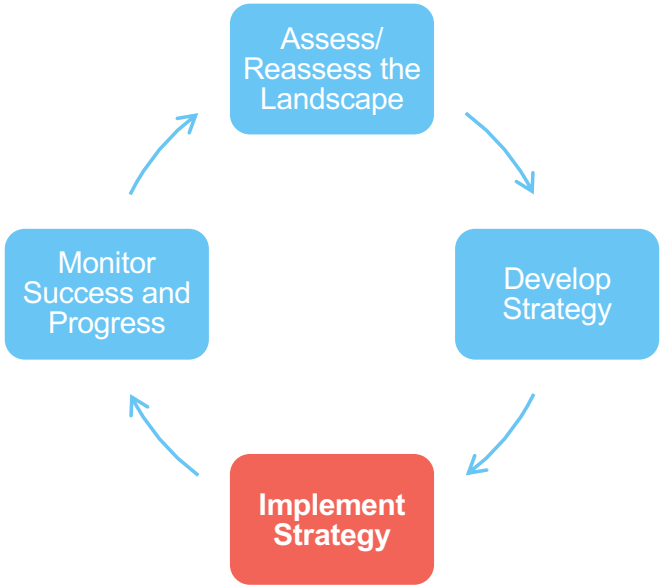
# DEVELOP A STRATEGY
# TAKE INTO ACCOUNT KEY INFORMATION

- Document a plan with the information that is known
  - Outline what follows logically from what is known
  - Identify a contingency plan
- Consider key areas of process change:
  - Policies/Procedures/Tools/Guidance
  - Training and Education
  - Technology
- Identify owners for each step of the process, and develop actionable tasks



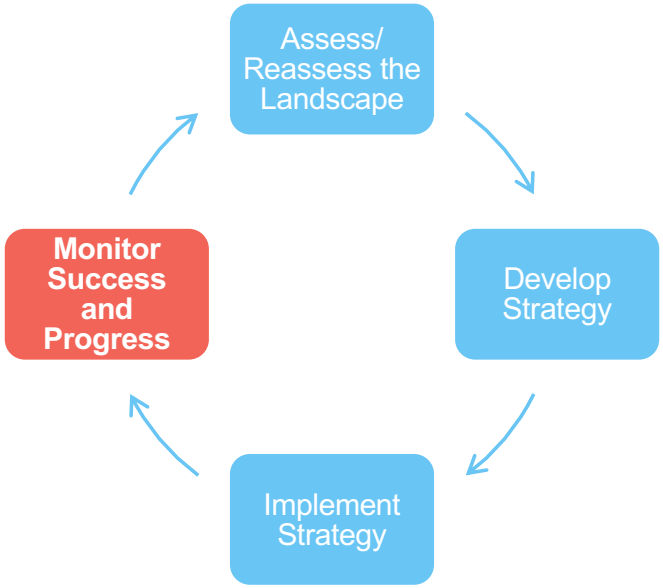
# IMPLEMENT A STRATEGY
# REVIEW INTERNAL REQUIREMENTS

- Implement a strategy that is or has:
  - Clear and concise
  - Executable by owners
  - Clear expectations, timelines and milestones



# MONITOR SUCCESS ON AN ONGOING BASIS

- Have regular check-in meetings with owners to determine progress
- Document milestones
- Communicate success and areas of development
- Consider surveying teams to understand areas of further development



# REASSESSING THE LANDSCAPE
# START THE PROCESS AGAIN!

- Continuously look for opportunities for process improvement
- Honestly review wins and areas for development
- Tweak the strategy as appropriate