Welcome! People are still arriving in Zoom. We will get started in just a few minutes after 12:00.

IOWA

IRB Efficiency Initiative (IRB EI) – Sept 24

IRB Efficiency Initiative (EI) What's Next?

- Consent Summary
  - Recap
  - Go Live
- ICH-GCP & CITI Update
- IRB Fee update
- HawkIRB application redesign
  - Recap – what's live now?
  - What's next?
  - What will change when?
- Communication and resources

Consent Summary Recap

FDA & OHRP Draft Guidance

In 2024, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS) announced draft guidance, "Key Information and Facilitating Understanding in Informed Consent."

Agency Consistency with Key Info

When finalized, the guidance will add identical language from HHS regulation

45 CFR 46.116(a)(5)(i) to the

FDA regulation 21 CFR 50.20(e)(1).

(21st Century Cures Act Harmonization requirement)

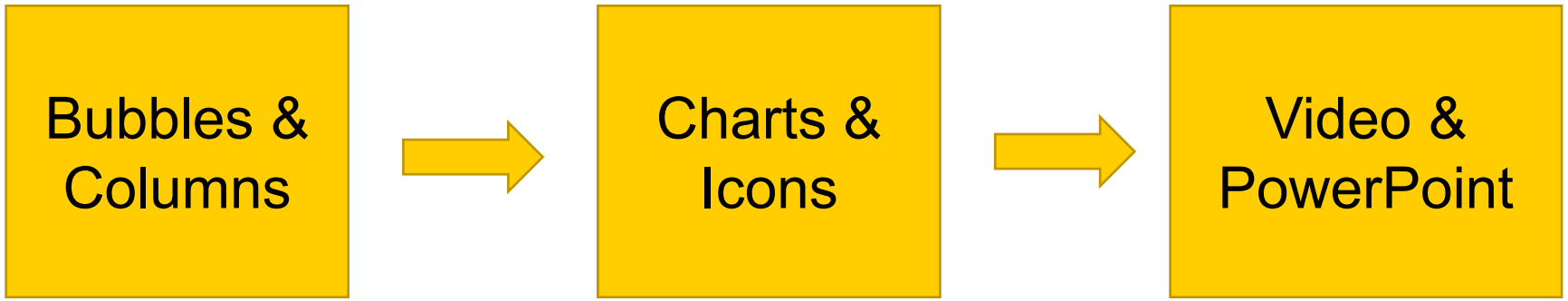
Current OHRP Guidance

45 CFR 46.116(a)(5)(i)

"Informed consent must begin with a **concise** and **focused** presentation of the **key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the **reasons** why one **might or might not want to participate** in the research. This part of the informed consent must be organized and presented in a way that **facilitates comprehension**."

Facilitating Comprehension

Innovative Ways to Present Information



Lay Language and Reading Level

Most important points first.

Break down complex information.

Use simple language.

Define technical terms.

Rollout and Application

Go Live September 29th

Only applies to NEW projects

NEW: Consent Summary-Key Information Educational Tool

CITI-GCP Training Change

CITI-GCP Training Changes

GCP ICH E6(R3) Announcement Summary

- As of July 23, 2025 CITI has updated their content.
- Newly registered users will get updated content.
- Existing users can recomplete the course to see the new content.
- Instructions on how to recomplete modules in CITI announcement.
- General CITI announcement sent to anyone enrolled in a GCP course.
- GCP FDA Basic and Refresher courses still refer to ICH E6(R2) as the U.S. Food and Drug Administration (FDA) just recently (9/8/25) adopted E6(R3) as guidance.

IRB Fees: Changes Effective 11/1/25

IRB Fee Changes Effective 11/1/25

IRB Fee Changes

- New IRB fees as of 11/1/25.
- Why: Increasing costs of doing business.
  - No changes since FY22 for sIRB fees.
  - No changes to other IRB fees since FY20.
- VAHCS IRB fees remain unchanged
- Will apply to grants or budgets submitted on or after 11/1/25
- IRB fees charged for industry sponsored research regardless of risk level.
- Unchanged:
  - F&A still applies per current UI policy.
  - Method of invoicing remains unchanged.

HawkIRB Application Redesign Recap

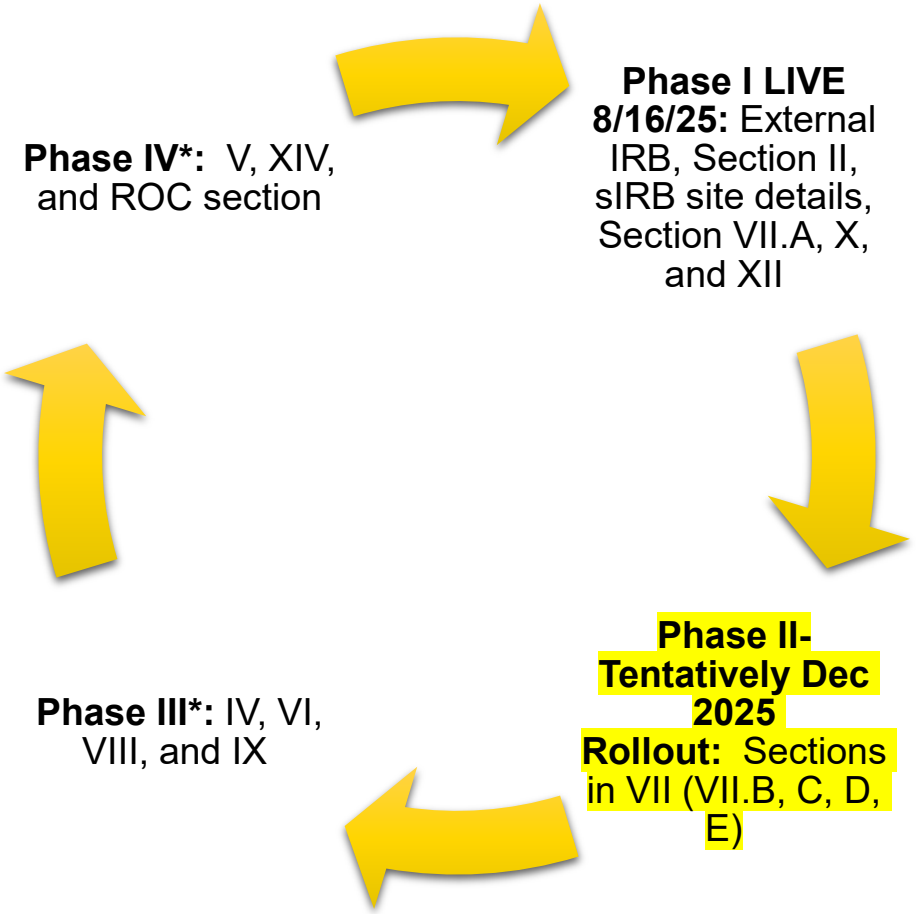
Recap – What's Live Now?

What's Next and What Will Change?

Phase I: HawkIRB Redesign Released August 16, 2025

Section II: Study Team	Section II will only be UI team members
sIRB Section: Multi Site research with Iowa as IRB of Record	Ability to capture relying institutions, organization, and individual details previously captured on PDFs.
Section III.5: COI	New question If COI = yes, a brief description is now required.
Section VII.A: sIRB details	Moving PDF information required for sIRB relationship to HawkIRB
Section X: Privacy, Confidentiality and Security	Clarify how and where research data, specimens and materials are stored
Section XII: Future Use	Add detail regarding DMSP requirements (NIH funding)

Next Set of Changes*



*Later section work is subject to change.

Phase II: HawkIRB Redesign

1

VII.D: Informed Consent & Recruitment Plans (impact all IRBs*)

2

VII.E: Study Design, Procedures & Compensation (impact all IRBs*)

3

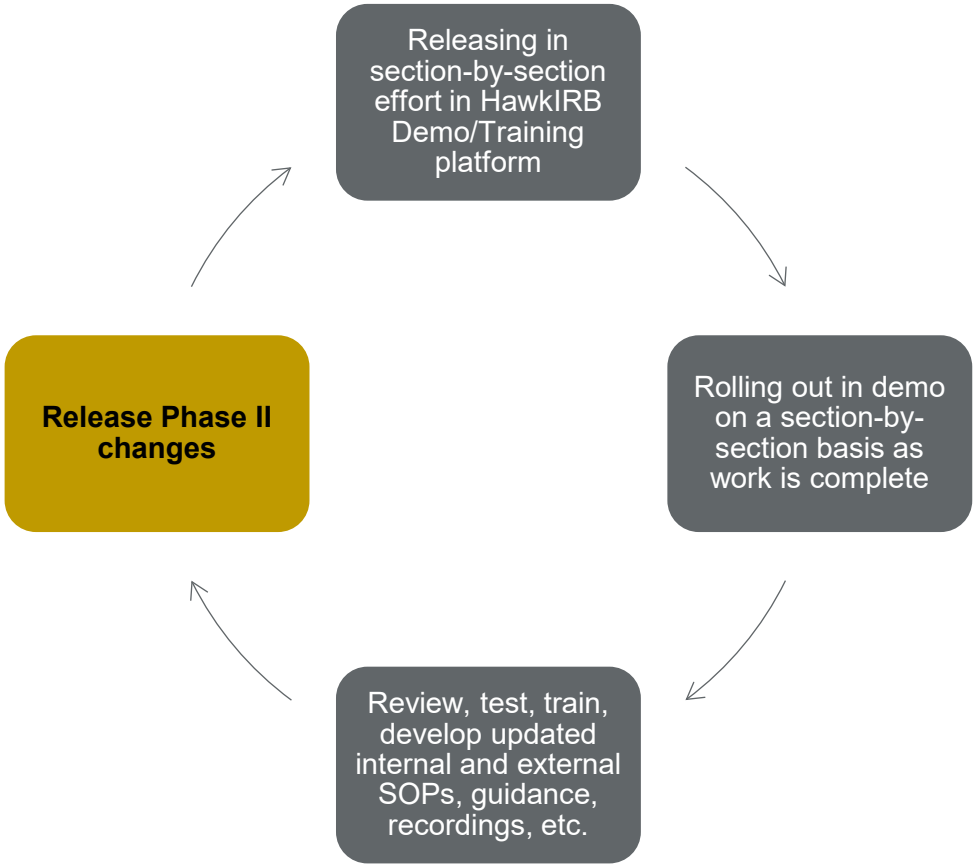
VII.C: Genetic Testing (impact IRB-01 & 03 only)

4

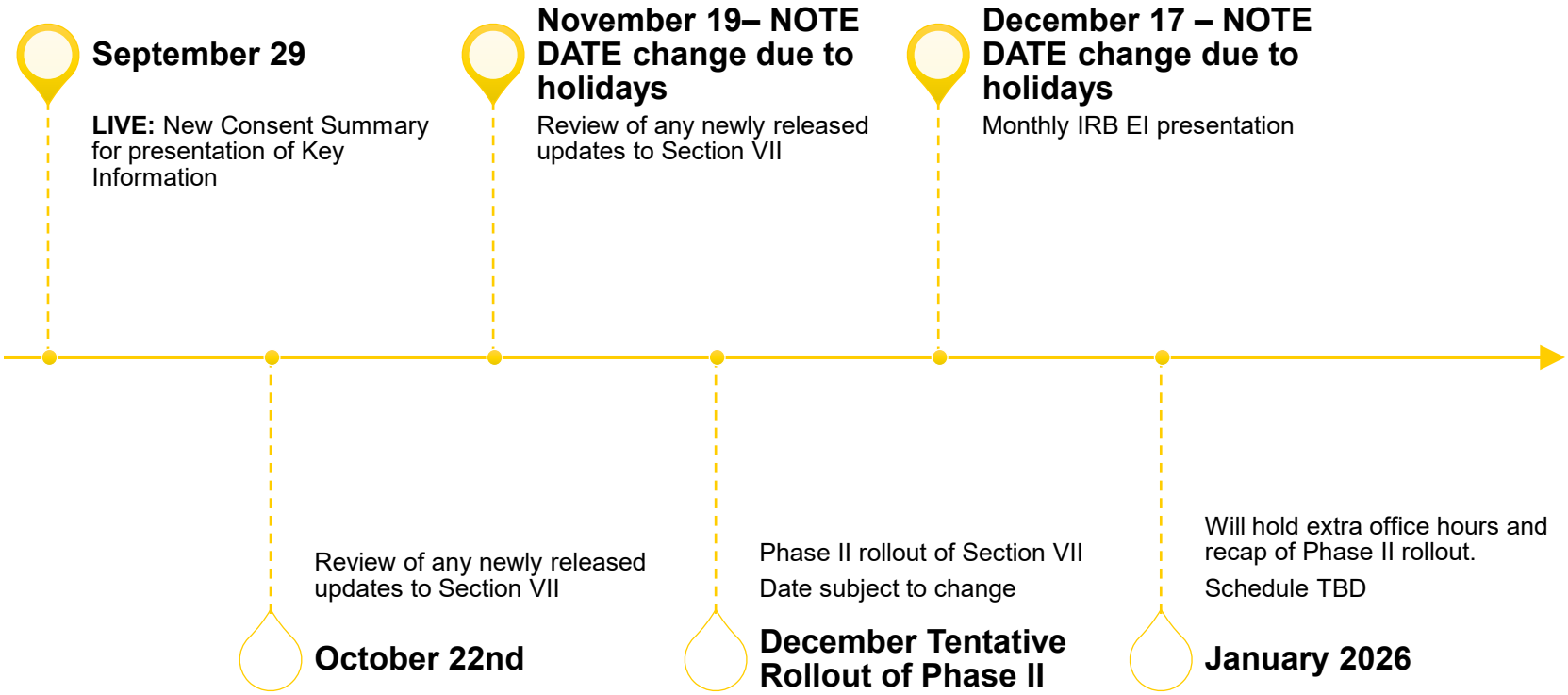
VII.B: Study Design (impact IRB-01 & 03 only)

* External IRB submission forms will have limited impact

What Happens Before Changes Go Live?



Timeline for HawkIRB Redesign: Phase II



IRB EI Communication & Resources

IRB Efficiency Initiative Communication Plan

OVPR Campus Initiatives: IRB Efficiency Initiative

HSO Website contains specific how to and policy information

Learn More>IRB Efficiency Initiative

IRB Connection Newsletter

Fourth Wednesday of every month 12-1, educational presentations*

Short How-To Videos:
Short videos covering IRB EI and HawkIRB Changes

*Note changes in schedule for holidays

Questions?

Human Subjects Office/Institutional Review Board

Thank you!

https://research.uiowa.edu/irb-efficiency-initiative

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Please scan this QR code to complete a feedback survey on today's presentation.

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