

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

IRB Efficiency Initiative (IRB EI) – July

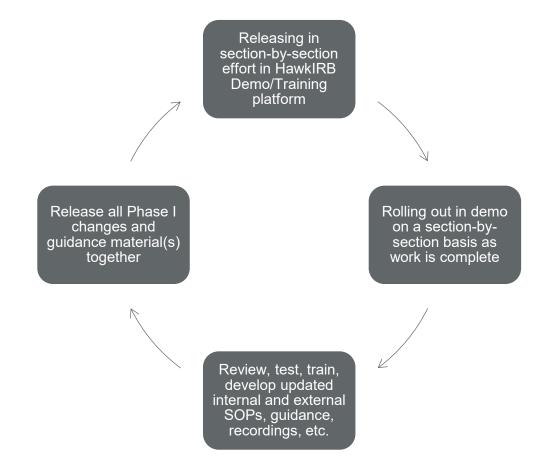
# IRB Efficiency Initiative (EI) HawkIRB Application Redesign

- ➤ HawkIRB application redesign release schedule
- ➤What's next and what will change?
- ➤ Demo of changes
- ➤ Communication and resources





## What Happens Before Changes Go Live?





### Section I Multi Site Research Triggers

### I.17 will appear for any option in I.5 except for Concept approval

- This is a change as it currently only appears when regular review is selected in 1.5
- Will be able to reflect collaborative research relationship for Exempt and review with waiver under I.5

#### I.17 and I.18 will appear for external IRB submissions

 Allow an external IRB selected in I.1 to reflect collaborative research relationship

#### I.18.a will not appear when I.5 is exempt

- lowa does not enter into a formal reliance relationship for multi site studies that meet exempt category of review.
- We will however track collaborative research for other HRPP reasons



## 2025 Phase I: HawkIRB Redesign Releasing August 16<sup>th</sup>!

•	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.
<b>O</b>	Section III.5: COI	<b>NEW</b> Question If COI = yes, a brief description is now required.
	Section VII.A: sIRB details	Moving PDF information required for sIRB relationship to HawkIRB
<b>/</b>	Section X: Privacy, Confidentiality and Security	Clarify how and where research data, specimens and materials are stored
9	Section XII: Future Use	Add detail regarding DMSP requirements (NIH funding)



# HAWKIRB Section II - Single IRB (sIRB) of Record Expansion





Key institutional contacts

Local context details to apply when extending oversight

State laws

Institutional policy(ies)



#### **Enhancing Non-UI team Member detail**

Expand on changes to I.1

Team member role, contact info (delegation log detail)

Continue integration with Oncore, eReg and eDC

Enhanced detail when individual investigator



### HAWKIRB Section VII.A - sIRB enhancement

Transition from PDF (local context) forms to direct HawkIRB input

sIRB Communication Plan when serving as the lead site and IRB

One of the only sections that will remain primarily as free text field required responses



## HAWKIRB Section X: Privacy, Confidentiality, and Data Storage

Removal of most required free text field responses

Focus on data and specimen storage options

Storage source specificity

Sharing of data outside the UI



## HAWKIRB Section XII-Future Use and Specimen collection



Identify future research\use implications



Future use external sharing detail



Incorporate long term data management and storage requirements

Research with federally funding or broad sharing requirements



### How Will I be Impacted by the HawkIRB Changes?

All projects regardless of status are required to answer updated questions in Section(s) III, VII.A, X, and XII.

**Existing** IRB approved sIRB projects will not be required to update to the sIRB section.

New sIRB section only required on **new** project forms only.



### What Else Will Change?

#### **HSO** Website

 Changes to HSO website pages and Educational Tools to update Section/Question references

#### Guides/SOPs

- Changes to Section reference updates in IRB SOP and Researcher Guide
- Other Guidance documents

#### **ICON Recordings**

Section by section recordings (Will be available at a later date)



### **HawkIRB DEMO**

# IRB El Communication & Resources

#### **Training Timeline for Phase I Rollout**



30 July 12-1

Today is a review of HawkIRB sections sIRB, VII.A, X, and XII



13 Aug 12-2

Drop in Office Hours. No presentation, stop by with your questions over the changes



20 Aug 12-1

**NEWLY ADDED** Drop In Office Hours. No presentation, stop by with your questions over the changes

Repeat of 7/30 presentation



6 Aug 12-1

Rollout of HawkIRB Phase I changes



16 Aug Evening



## IRB Efficiency Initiative Communication Plan



OVPR Campus Initiatives: <u>IRB</u> <u>Efficiency Initiative</u>



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



### **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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