Release Notes
HRPP News Forum: January 13, 2026

#	Topic	Description
1.	Update on HRPP and IRB Operations	The HRPP will release a report of approval numbers and approval turn-around-times by the end of January. Summary slides are available in the presentation.
2.	New Process: Failure to Respond	Beginning January 2026, IRES IRB submissions in '*clarifications requested*', '*deferred*', and '*modifications required*' states for more than 60 days will be withdrawn back to '*pre-submission*' state. They can be resubmitted once all outstanding issues are resolved.
3.	Updates to Existing Documents	**Consent Glossary:** • Taxable research payments: Language was revised to remove references to specific amounts as the taxable income threshold was revised to $2000 and will be adjusted annually, • Research with prisoners: Language was revised to address contacting the HRPP via mail as prisoner populations cannot use email as a form of contact with individuals not in their approved list of contacts; **Investigator Manual:** • Added exempt research guidance and when modifications are warranted, • Updated ancillary reviews guidance, • Updated the instructions for obtaining Certificate of Confidentiality, • Clarify when research staff need to be listed in IRES IRB; **Assent Documents:** • Simplified language; **Minor edits to:** • IRB Submission Form • External IRB Request Form • Permission Form to Serve as the PI • Request for Unaffiliated Investigator Agreement • Local Context Questionnaire • Quick Guides (IRES IRB/Help Center)
4.	New Documents	• New suite of documents specific to repositories: repository guidance, consent template, protocol template (11/1/2025); • Guidance on research and GDPR and associated consent template (11/10/2025); • Guidance on Use of Health Information Exchanges in Research (4/24/2025) • eConsent Guidance (3/31/2025) • Part 11 Compliance Guidance (3/31/2025) • Sharing Data for Research Purposes (2/3/2025) – in collaboration with the Privacy Office

5.	Upcoming Changes	• Continuing Review (CR) Report – expected by the end of January, a notification will be sent out; • Update to Investigator Manual and HRPP SOP Manual; • Toolkit Update: IRB Worksheets and Checklists (mostly visual)
6.	Ongoing Project: IRES IRB Upgrade	IRES IRB upgrade to the newer version is ongoing and is currently planned for summer 2026 release. Most changes affect the HRPP/IRB office. Any relevant updates will be communicated to the research community as the new features/revisions are tested and are approved for implementation.
7.	HRPP Highlight: HRPP Post-Approval Monitoring	• Post-Approval Monitoring (PAM) is the process of reviewing research studies after they have received approval by the IRB to ensure that the study is being conducted ethically and in compliance with federal regulations, state and local laws, and institutional policies and procedures. • The Yale HRPP launched its own PAM Program in 2025. All active, non-exempt human subjects research studies are eligible for PAM. • For more information on the HRPP PAM Program, visit our website HERE.
8.	Upcoming Training Schedule	Training Schedule for "IRB Essentials" • The training calendar has been released for the first 6 months of 2026. Suggestions for additional training can be sent to hrpp@yale.edu.
9.	Current Challenges	• Integration of Workday, CITI, and IRES IRB related to training completions, instructions are available; • Website: recently redesigned, work still in progress to make it more user-friendly; • Studies in active state ('approved' or 'active') in IRES IRB with no action in the last few years – we will begin a clean up process in the first quarter of the year.
10.	Frequent Information Requests	Use of short forms for enrollment of non-English speaking participants and required signatures • Short form is a way of documenting consent process with individuals who do not speak English; • Signature requirements: Short form is signed by the participant and a witness, English consent document is signed by the person obtaining consent and a witness; • Who can be a witness: anyone outside of the research team who understands both languages, including the interpreter or a family member of the participant; • At YNHHS locations - interpreters generally do not serve as witnesses. If a researcher needs a witness, two interpreters must be booked (one to serve as a witness, one as an interpreter); • Use of short form does not replace HIPAA Authorization: you either must obtain an alteration of HIPAA authorization (to obtain it verbally) OR use one of the translated HIPAA Research Authorization Forms available at Yale HIPAA Privacy Office website (5032 section).