Yale HRPP documents that are new or revised

Document	How it affects you	Description of the changes

Investigator Manual **(revised)**	The Investigator Manual will continue to be posted in the IRES IRB Library; the document provides information on the investigator's responsibilities related to human subjects research; it accompanies the Yale HRPP Policy and Procedure Manual that describes regulatory requirements, federal guidance, responsibilities of the HRPP and IRB, as well as university requirements related to the conduct of human subjects research.	• Added new sections:
		  ○ Working with External IRBs;
		  ○ Instructions on requesting Yale IRB to serve as the sIRB for a multi-site research project;
		  ○ Data Sharing Plans for federal grant applications;
		  ○ Description of ancillary committees.
		• Revised format – sections were grouped according to a topic, removed the question-and-answer format.
		• Updated the information regarding regulatory requirements for research subject to federal agencies' oversight.
		• Added instructions that previously lived as stand-alone documents (e.g., obtaining Certificates of Confidentiality, adding Unaffiliated Investigators, submitting RNI vs. MODs, etc).

IRB Submission Form **(revised)**	The IRB Submission Form will continue to be posted in the Protocol Templates section of the IRES IRB Library and will be required at the time of the submission of most non-exempt research protocols to the Yale IRB; **older versions of the form will not be accepted with initial submissions as of March 1, 2023**; the revisions do not affect the ongoing research.	• Added new sections:
		  ○ Ancillary Committees;
		  ○ Data Sharing;
		  ○ Research with IND/IDE held by Yale investigator;
		  ○ Research with Tobacco products.
		• Added questions to Privacy and Confidentiality section.
		• Added reminders about Data Use Agreements, Material Transfer Agreements, as well as Business Associate Agreements.
		• Revised wording for clarity.

Request to Use External IRB **(new)**	New document that will be required for submission at the time of initial request of use of an external IRB to review research (**January 30, 2023**);	This is a new document that asks specific questions about the local considerations for the research, such as ancillary reviews, storage of data, HRPP billing, etc.
Yale HRPP Policy and Procedure Manual **(new)**	Until January 30, 2023, Yale HRPP policies, procedures, and guidance are available as separate documents, with each one focusing on a specific topic. The new Yale HRPP Policy and Procedure Manual consolidates the majority of the policies, procedures, and guidance, as well as regulatory requirements, into one standalone document. In addition to the Investigator Manual, this manual should serve as the primary source of information for the research community regarding the conduct and oversight of human subject research at Yale.	This is a new document that includes all of Yale HRPP policies and procedures, regulatory requirements, and guidance in one comprehensive manual; it will be available on the HRPP website; certain joint policies that include responsibilities of multiple Yale or YNHH offices will continue to be posted separately.
COA Form for Billable Protocol Charge Information **(new)**	This is a new document that must be submitted for all CRs and MODs/MODCRs for billable protocols for which the study specific COA (chart of account) has not been provided.	This is a new document that will allow the HRPP/IRB to invoice the department for the HRPP/IRB review fees (for information about the billing process. See the announcement dated July 12, 2022, on the HRPP website).

Checklists	Checklists are used by the IRB reviewers to document required IRB determinations. Investigators may consult the checklists to understand the regulatory requirements related to research. They will continue to be posted in the Checklists tab of the IRES IRB Library.	The following checklists were revised for clarity or new regulatory requirements: • HRP-414 CHECKLIST – Neonates of Uncertain Viability • HRP-412- CHECKLIST – Pregnant Women • HRP-411 - CHECKLIST – Waiver of Written Documentation of Consent • HRP-417 – CHECKLIST – Cognitively Impaired Adults
Worksheets	Worksheets provide the IRB reviewers with additional information about regulatory requirements and guidance related to the IRB review and approval of research. Investigators may consult the worksheets to understand the regulatory landscape related to human subjects research. They will continue to be posted in the Worksheets tab of the IRES IRB Library.	The following worksheets were revised for clarity or new regulatory requirements: • HRP-332 - WORKSHEET - NIH GDS Institutional Certification • HRP-307 - WORKSHEET – Devices • HRP-311 - WORKSHEET - Engagement Determination • HRP-331 - WORKSHEET - FERPA Compliance • HRP-306 - WORKSHEET - Drugs and Biologics • HRP-312 - WORKSHEET - Exemption Determination • HRP-317 – WORKSHEET - Short Form of Consent Documentation • HRP-318 – WORKSHEET - Additional Federal Criteria • IRB Member Review Worksheet_Initial

Documents that are being retired/archived

Document	Description	Where to find the information moving forward
Guide to Obtaining IRB Approvals to Conduct Research within the Yale New Haven Health System	A guide that provides information for Yale investigators wishing to open studies or engage researchers within the Yale New Haven Health System, document was posted in the Handbooks and Manuals tab in IRES IRB.	Investigator Manual, Handbooks and Manuals, IRES IRB Library
Applying for a Certificate of Confidentiality	Instructions on obtaining the Certificate of Confidentiality, document was posted in the Help Center in IRES IRB.	Investigator Manual, Handbooks and Manuals, IRES IRB Library
Reference guide: RNI vs. MOD	Instructions on when to submit a Report of New Information vs. Modification, document was posted in the Help Center in IRES IRB.	Investigator Manual, Handbooks and Manuals, IRES IRB Library
Policies	Most of the Yale HRPP policies posted on the HRPP website will be removed; several policies that describe responsibilities of several offices outside of the HRPP will remain posted as stand-alone documents.	The Yale HRPP Policy and Procedure Manual
Procedures	Most of the Yale HRPP procedures posted on the HRPP website will be removed; procedures that describe responsibilities of several offices outside of the HRPP will remain posted as stand-alone documents.	The Yale HRPP Policy and Procedure Manual
Guidance	Most of the Yale HRPP guidance posted on the HRPP website will be removed.	The Yale HRPP Policy and Procedure Manual