Yale

Yale Research Community Training

New Yale HRPP/IRB Manuals & Related Documents

Yale University
Human Research Protection Program
January 2023

TRAINING OVERVIEW

Training Overview

Yale

- The Yale Human Research Protection Program (HRPP) is excited to announce the upcoming launch of the new **Yale HRPP Policy and Standard Operating Procedure Manual**, **updated Investigator Manual**, and **updated submission forms and related documents**.

- The effective date for these documents is **January 30, 2023**.

- This session will provide a high-level overview of these documents, including a discussion regarding significant new or updated information found in the documents that the Yale research community should be aware of.

Learning Objectives

Yale

- Understand the purpose, structure, and general content of all new and/or updated HRPP documents.

- Obtain a foundational understanding of new and/or updated regulatory information and Yale HRPP/IRB processes that may impact study teams and the research community broadly.

- Understand where to access all relevant documents.

Training Agenda

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Agenda Item	Slide Numbers
Introduction	1-5
New Yale HRPP Policy and Standard Operating Procedure Manual	6-17
Updated Investigator Manual	18-21
Updated Checklists, Worksheets, and Other Forms	22-36
Summary	37-39

Yale Research Community Training

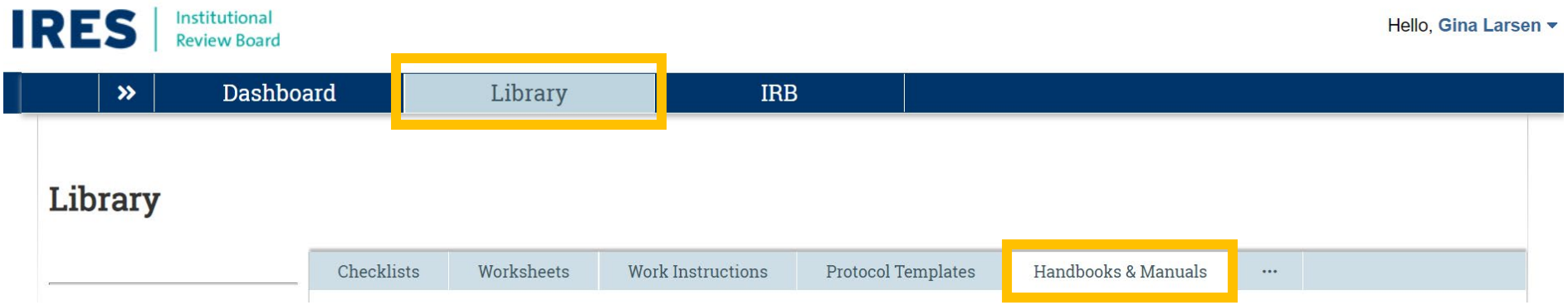
YALE HRPP POLICY AND STANDARD OPERATING PROCEDURE MANUAL

Yale HRPP Policy and Standard Operating Procedure Manual – Overview

- This purpose of the manual is to consolidate existing standalone Yale HRPP policies, procedures, and select guidance documents into one streamlined manual.

- The manual also includes new topics related to human subjects research conduct and oversight, reflecting the most up-to-date regulatory information.

- Located in the IRES IRB Library (Handbooks and Manuals tab).



Yale HRPP Policies & Procedures – Old Format

Yale

It's Your Yale

YCARDS · WORKDAY · NEWS · DIRECTORIES · MEDIA · LOGIN · SEARCH

Work at Yale | Technology at Yale | Policies & Procedures | Research Support | Community

HOME > RESEARCH SUPPORT > HUMAN RESEARCH PROTECTION PROGRAM > POLICIES, PROCEDURES, GUIDANCE, AND CHECKLISTS

HUMAN RESEARCH PROTECTION PROGRAM

- Policies, Procedures, Guidance, and Checklists
- Forms & Templates
- Protocol Builder
- Career Opportunities

Policies, Procedures, Guidance, and Checklists

Policies

- 100) IRB Review
- 110) IRB Fees
- 120) Investigator Initiated and Multicenter Research
- 200) Informed Consent in Research
- 310) Participation of Children in Research
- 320) Prisoners in Research
- 330) Pregnant Women, Women of Childbearing Potential, Fetuses and Neonates
- 340) Individuals with Impaired Consent Capacity

Example: Informed Consent in Research

Policy

- 200) IRB Policy 200 Informed Consent for Human Research

Procedures

- 200 PR.1 - Informed Consent for Research Participation: Competent Adult Participants
- 200 PR.2 - Exception From Informed Consent (EFIC) Research

Guidelines

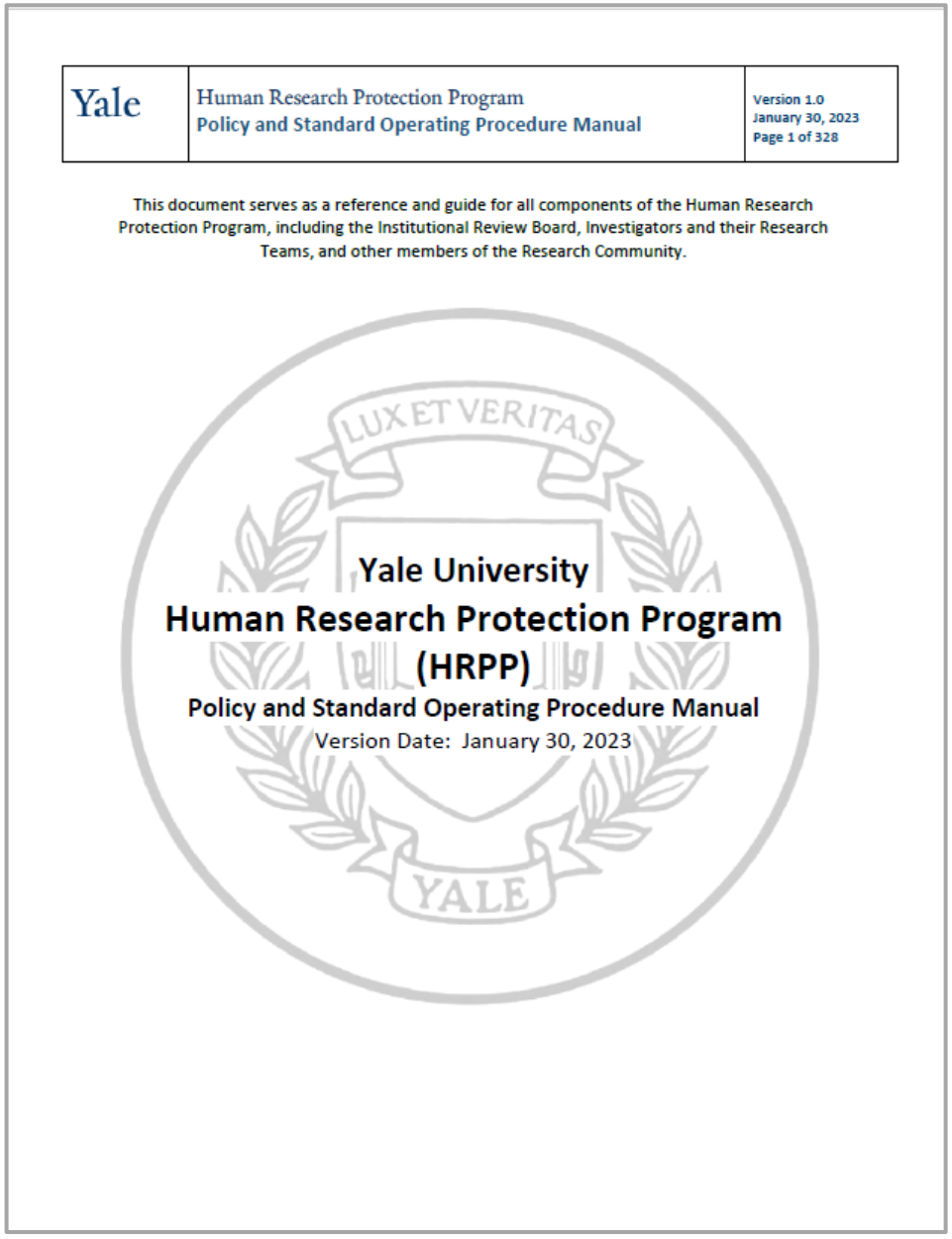
- 200 GD.1 - Deception in Human Research
- 200 GD.2 - Guidance on Inclusion of Non-English Speaking Participants in Human Research
- 200 GD.3 - Re-Consent and/or Notification of Significant New Findings That Develop During the Course of Research

Yale HRPP Policy and Standard Operating Procedure Manual – New Format

Yale

- Most Yale HRPP policies, procedures, and guidance documents have been consolidated into the new **Yale HRPP Policy and Standard Operating Procedure Manual**.

- **The manual is divided into two (2) parts:**
  - ***Part I*** outlines Yale HRPP policies and procedures.
  - ***Part II*** encompasses standalone policies, procedures, and guidelines that could not be consolidated into Part I for a variety of reasons.



Yale HRPP Policy and Standard Operating Procedure Manual – Layout

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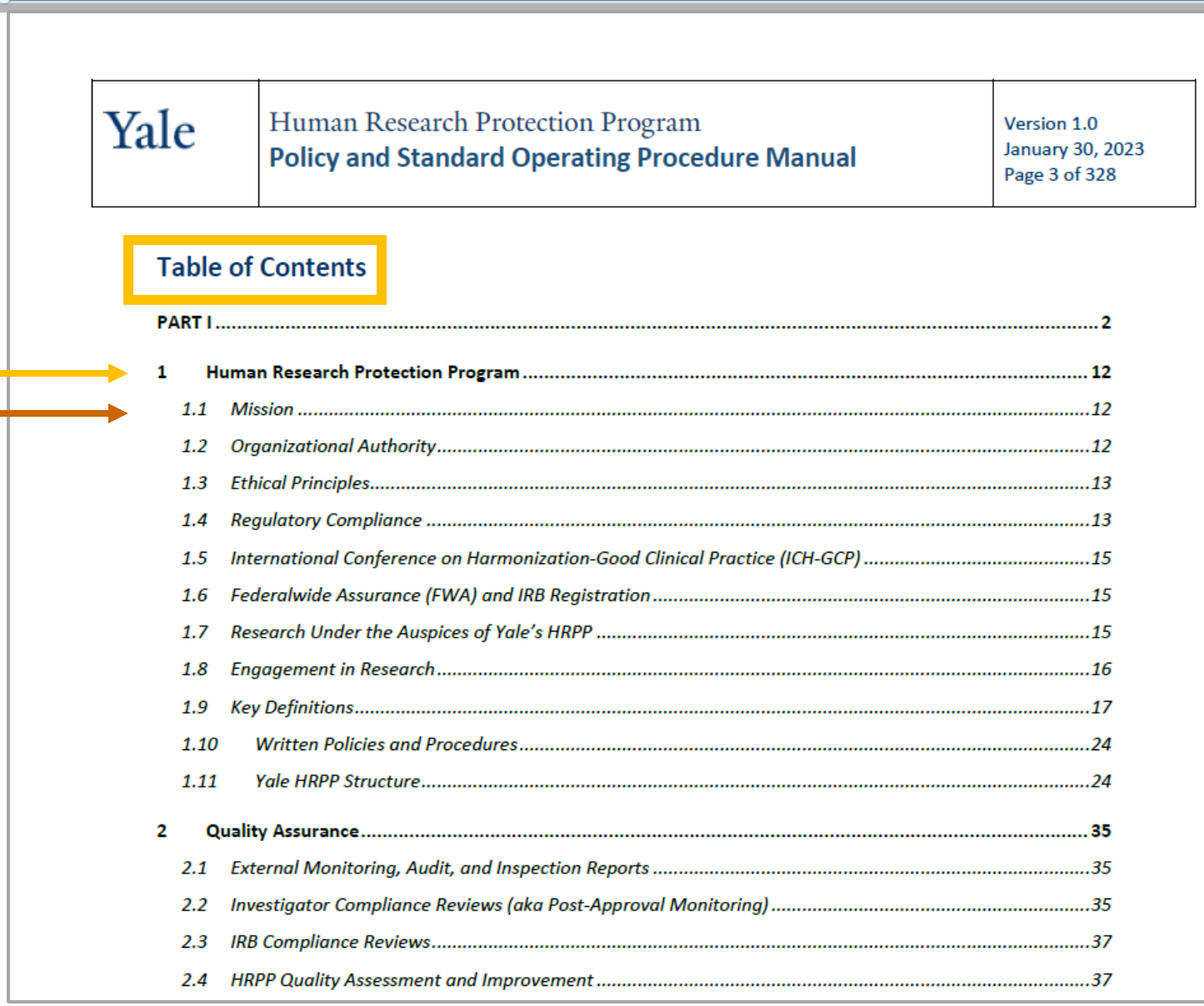
Sections

Sub- Sections

*Each section and sub-section is **hyperlinked** to the appropriate page of the PDF for easy navigation.*



Yale | Human Research Protection Program
Policy and Standard Operating Procedure Manual | Version 1.0 January 30, 2023 Page 3 of 328

Table of Contents

Yale HRPP Policy and Standard Operating Procedure Manual – Search Function

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*You can also use the **"Ctrl" + "F" function** to search for specifics topics/words/phrases*

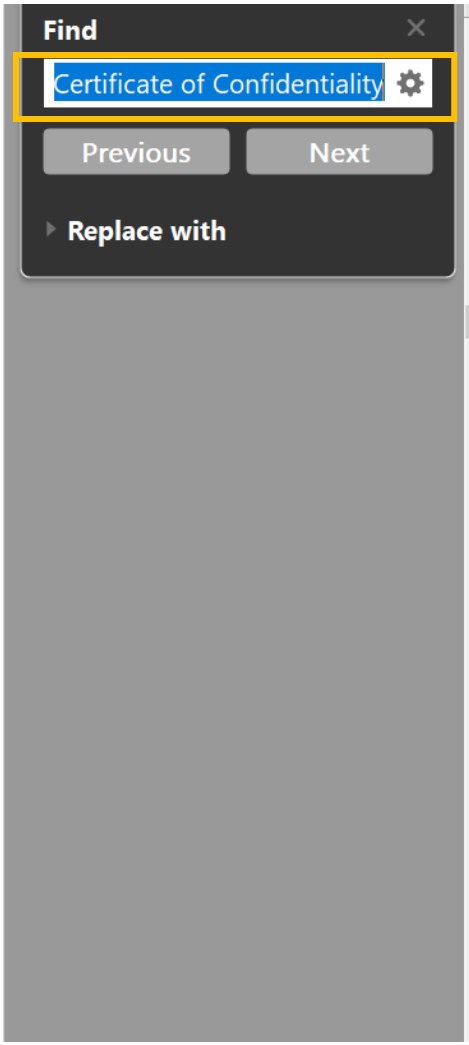
- Methods used to obtain information about participants, and the nature of the requested information, including whether the data is the minimum necessary to achieve the aims of the research
- Information that is obtained about individuals other than the "target subjects", (e.g., a subject provides information about a family member for a survey) and whether such individuals meet the regulatory definition of "human subject"

11.3.5.3 Confidentiality

The IRB must determine if appropriate protections are in place to minimize the likelihood that information about subjects or their participation in research will be inappropriately accessed or divulged. Safeguards designed to protect confidentiality should be commensurate with the potential of harm from unauthorized, inappropriate or unintentional disclosure.

The IRB assesses whether there are adequate provisions to protect data confidentiality by evaluating the methods used to obtain, record, share, and store information about individuals who may be recruited to participate in studies and about subjects. The investigator will provide the IRB with a plan regarding the procedures to be taken to protect the confidentiality of research data and sensitive information. The investigator will provide information regarding information security procedures and plans to address the protection of paper documents, other physical media (e.g., audio or videotapes), and electronic data, and information regarding the use, maintenance, storage, and transmission of information. The IRB will review the information received from the investigator and determine whether the confidentiality of research data is sufficiently protected. In some cases, the IRB may also require that a Certificate of Confidentiality is obtained to protect data from compelled disclosure (See Section 35).

In reviewing confidentiality protections, the IRB shall consider whether or not the data or other information accessed or gathered for research purposes is sensitive, and the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. The IRB will evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, methods of transmission, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections. In reviewing confidentiality protections, the IRB will also consider regulations and organizational requirements and policies regarding the use of information and information security.

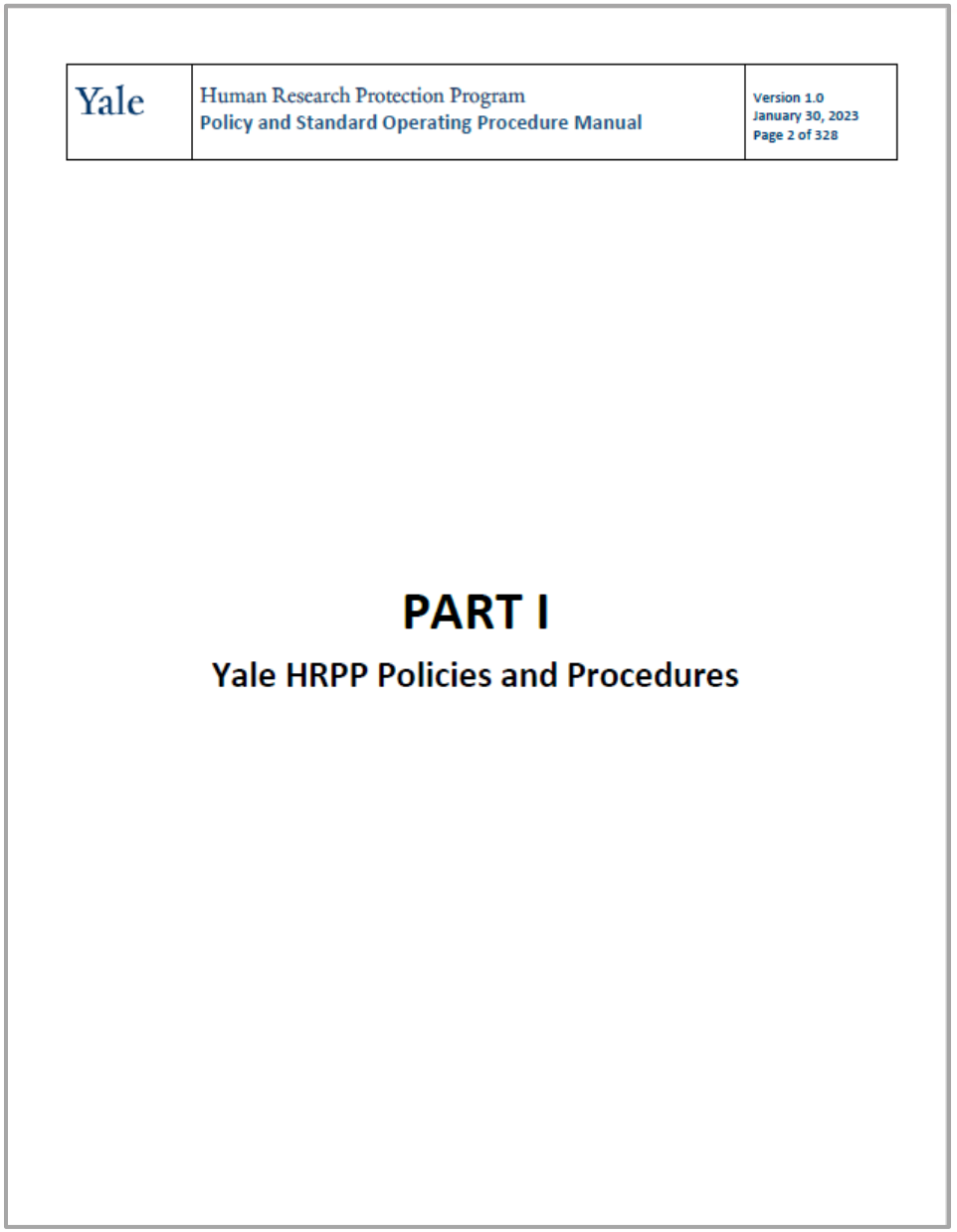


Yale HRPP Policy and Standard Operating Procedure Manual – Part I

Yale

- **Part I** of the Yale HRPP Policy and Standard Operating Procedure Manual covers everything from the mission of the Yale HRPP, IRB functions, investigator responsibilities, informed consent requirements, reporting requirements, considerations for enrolling vulnerable populations, requirements for federally funded research studies, and many other related research topics.

- This manual is the "go to" document for referencing federal, state, and Yale HRPP policies, procedures, and guidance information related to human research protections and research requirements.



Yale HRPP Policy and Standard Operating Procedure Manual – Part I

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Yale HRPP Policy & Standard Operating Procedure Manual Sections (Part I)			
1	Human Research Protection Program	25	Conflict of Interest in Research
2	Quality Assurance	26	Participant Outreach
3	Education & Training	27	Health Insurance Portability and Accountability Act (HIPAA)
4	"Human Subjects" and "Research" Determinations	28	IRB and HRPP Billing
5	Exempt Determinations	29	Select State Statues Related to Human Subjects Research
6	IRB Reliance	30	ICH-GCP E6
7	Research Previously Approved by Another IRB	31	Databases, Registries, & Repositories
8	HRPP Business Continuity	32	Research Involving or Generating Genetic Information
9	Yale Institutional Review Board	33	Incidental Findings with Possible Health and Safety Significance for Research Participants
10	IRB Actions, Failure to Respond, Appeals	34	NIH Data Management and Sharing
11	IRB Review Process	35	Genomic Data Sharing (GDS)
12	Suspensions, Terminations, and Investigator Holds	36	Certificates of Confidentiality
13	Documentation and Records	37	Self-Experimentation
14	Obtaining Informed Consent from Research Subjects	38	Student Research
15	Vulnerable Subjects in Research	39	Community Based Research
16	FDA-Regulated Research	40	Transnational Research
17	Unanticipated Problems Involving Risks to Subjects or Others	41	Lead Investigator/Coordinating Center
18	Noncompliance	42	Research Involving the VA Connecticut Healthcare System
19	Complaints	43	Department of Defense
20	Other Reportable Information	44	Department of Justice
21	Reporting to Federal Agencies, Departments, and Organizational Officials	45	Department of Energy
22	Reporting to AAHRPP	46	Environmental Protection Agency
23	Investigator Responsibilities	47	Department of Education
24	Sponsored Research		

Yale HRPP Policy and Standard Operating Procedure Manual – Part I: NEW or REVISED Content

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New Content or Areas of Heavily Revised Content/Layout

- **Section 6** – IRB Reliance
- **Section 8** – HRPP Business Continuity
- **Section 10** – IRB Actions, Failure to Respond, Appeals
- **Section 37** – Self-Experimentation
- **Section 39** – Community Based Research

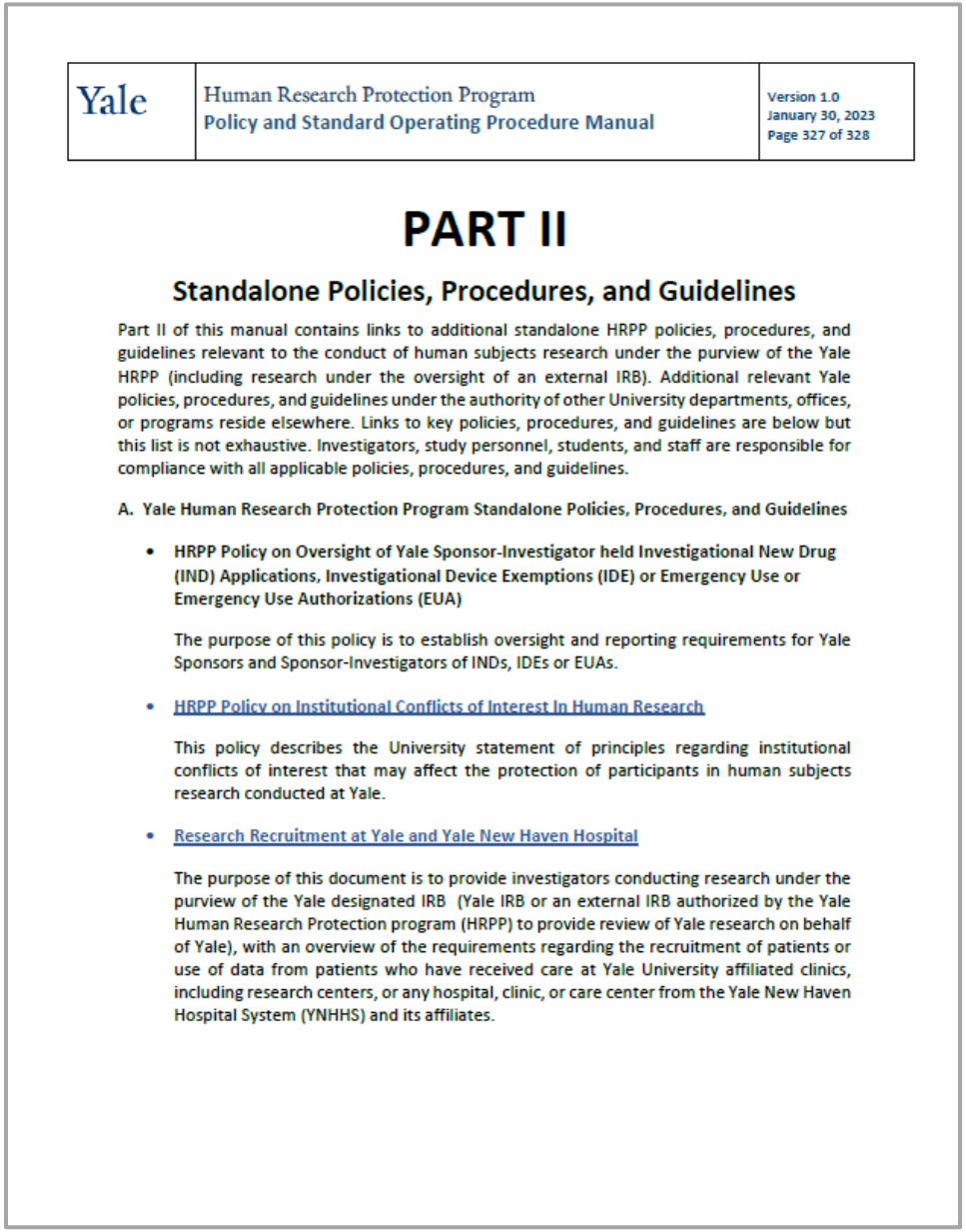
Streamlined Navigation for Study Team Regarding Reporting Requirements/Guidance *(content has not changed)*

- **Section 12** – Suspensions, Terminations, and Investigator Holds
- **Section 17** – Unanticipated Problems Involving Risks to Subjects or Others
- **Section 18** – Noncompliance
- **Section 19** – Complaints
- **Section 20** – Other Reportable Information

Yale HRPP Policy and Standard Operating Procedure Manual – Part II

- **Part II** of the of the Yale HRPP Policy and Standard Operating Procedure Manual contains links to additional standalone HRPP policies, procedures, and guidelines relevant to the conduct of human subjects research under the purview of the Yale HRPP **(Section A)**.

- Additional relevant Yale policies, procedures, and guidelines under the authority of other University departments, offices, or programs reside elsewhere. **However, links to key policies, procedures, and guidelines are included in Part II (Section B)**



PART II

Standalone Policies, Procedures, and Guidelines

Part II of this manual contains links to additional standalone HRPP policies, procedures, and guidelines relevant to the conduct of human subjects research under the purview of the Yale HRPP (including research under the oversight of an external IRB). Additional relevant Yale policies, procedures, and guidelines under the authority of other University departments, offices, or programs reside elsewhere. Links to key policies, procedures, and guidelines are below but this list is not exhaustive. Investigators, study personnel, students, and staff are responsible for compliance with all applicable policies, procedures, and guidelines.

A. Yale Human Research Protection Program Standalone Policies, Procedures, and Guidelines

- **HRPP Policy on Oversight of Yale Sponsor-Investigator held Investigational New Drug (IND) Applications, Investigational Device Exemptions (IDE) or Emergency Use or Emergency Use Authorizations (EUA)**

  The purpose of this policy is to establish oversight and reporting requirements for Yale Sponsors and Sponsor-Investigators of INDs, IDEs or EUAs.

- HRPP Policy on Institutional Conflicts of Interest In Human Research

  This policy describes the University statement of principles regarding institutional conflicts of interest that may affect the protection of participants in human subjects research conducted at Yale.

- Research Recruitment at Yale and Yale New Haven Hospital

  The purpose of this document is to provide investigators conducting research under the purview of the Yale designated IRB (Yale IRB or an external IRB authorized by the Yale Human Research Protection program (HRPP) to provide review of Yale research on behalf of Yale), with an overview of the requirements regarding the recruitment of patients or use of data from patients who have received care at Yale University affiliated clinics, including research centers, or any hospital, clinic, or care center from the Yale New Haven Hospital System (YNHHS) and its affiliates.

Yale HRPP Policy and Standard Operating Procedure Manual – Part II

Yale

Yale HRPP Policy & Procedure Manual Sections (Part II)
Section A: Yale Human Research Protection Program Standalone Policies, Procedures, and Guidelines
HRPP Policy on Oversight of Yale Sponsor-Investigator held Investigational New Drug (IND) Applications, Investigational Device Exemptions (IDE) or Emergency Use or Emergency Use Authorizations (EUA)
HRPP Policy on Institutional Conflicts of Interest In Human Research
Research Recruitment at Yale and Yale New Haven Hospital
Guidance on Committee Reviews Required for Human Subjects Research Protocols Using Radiation
Clinical Trial Registration and Reporting Requirements
Guideline - Quality Improvement Projects (Clinical Setting)
Yale Human Research Protection Program Business Continuity Plan
Section B: Yale University and Other University Schools, Departments, Offices, or Programs Standalone Policies, Procedures, and Guidelines
University Policy 1360, Human Research Protection
University Policies & Procedures
Researchers: Policy guidelines for Yale Faculty, Students, and Staff governing Research at Yale
Research Administration University-Wide Policy Documents
Yale Research Support
Yale Faculty Handbook
Yale University Policy on Conflict of Interest

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UPDATED INVESTIGATOR MANUAL

Investigator Manual – Overview of Changes

Yale

- **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; and
  - Description of ancillary committees.

- **Revised format** – sections were streamlined (topics grouped accordingly) and the question-and-answer format was removed.

- Updated the information regarding regulatory requirements for research subject to federal agencies' oversight.

- Added instructions that previously lived as standalone documents (e.g., obtaining Certificates of Confidentiality, adding Unaffiliated Investigators, submitting RNI vs. MODs, etc.).

Investigator Manual – Format

Yale

Yale University Institutional Review Boards

Investigator Manual		
NUMBER	DATE	PAGE
HRP-103	7/12/2016, 3/9/2018, 12/11/2020	2 of 4

Table of Contents

Old format

Yale	Human Research Protection Program Investigator Manual	Version 2.0 01/30/2023

Revised format

Investigator Manual – How to Use this Resource

Yale

- Think about the Investigator Manual as the "how-to" manual for investigators and research staff. The information contained in the document may need to be supplemented with additional regulations and agency guidance.

- If a question arises during the conduct of research, look for guidance in the Investigator Manual first. You may also review the HRPP Policy and Standard Operating Procedure Manual to understand any relevant regulatory frameworks.
  - For example, the HRPP Policy and Standard Operating Procedure Manual will include information about Certificates of Confidentiality with instructions for the IRB regarding when one should be required, while the Investigator Manual will include instructions for the investigator on how to obtain one.

- Located in the IRES IRB Library (Handbooks and Manuals tab) - Same location as the HRPP Policy and Standard Operating Procedure Manual.

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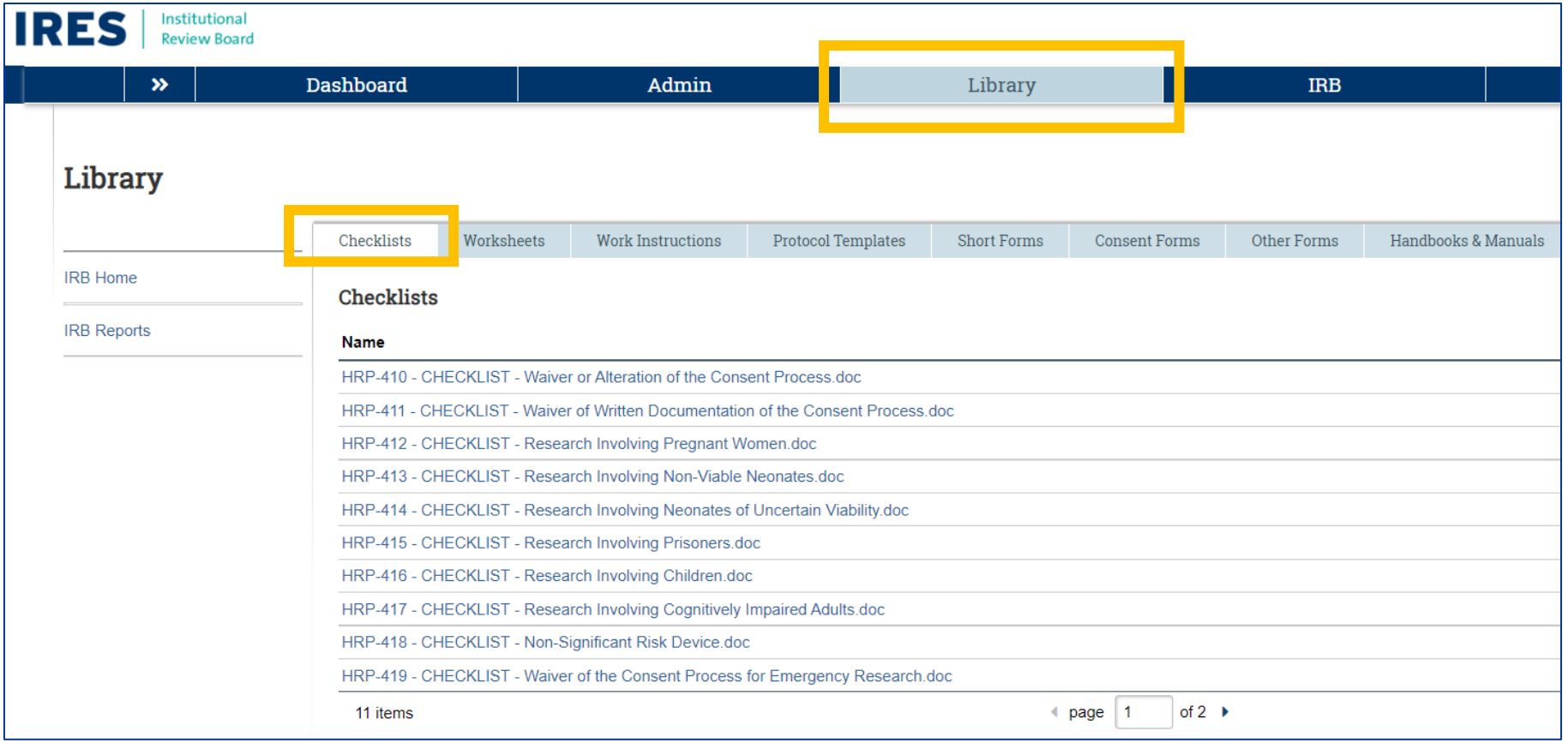
UPDATED CHECKLISTS, WORKSHEETS, AND OTHER FORMS

Yale HRPP/IRB Checklists – Summary and Location

Yale

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 – however Investigators are not required to complete the checklists. They will continue to be posted in the Checklists tab of the IRES IRB Library.



Yale HRPP/IRB Checklists – Changes to Documents

Yale

The following checklists were recently revised for clarity or new regulatory requirements. **The effective date for these checklists is January 30, 2023**:

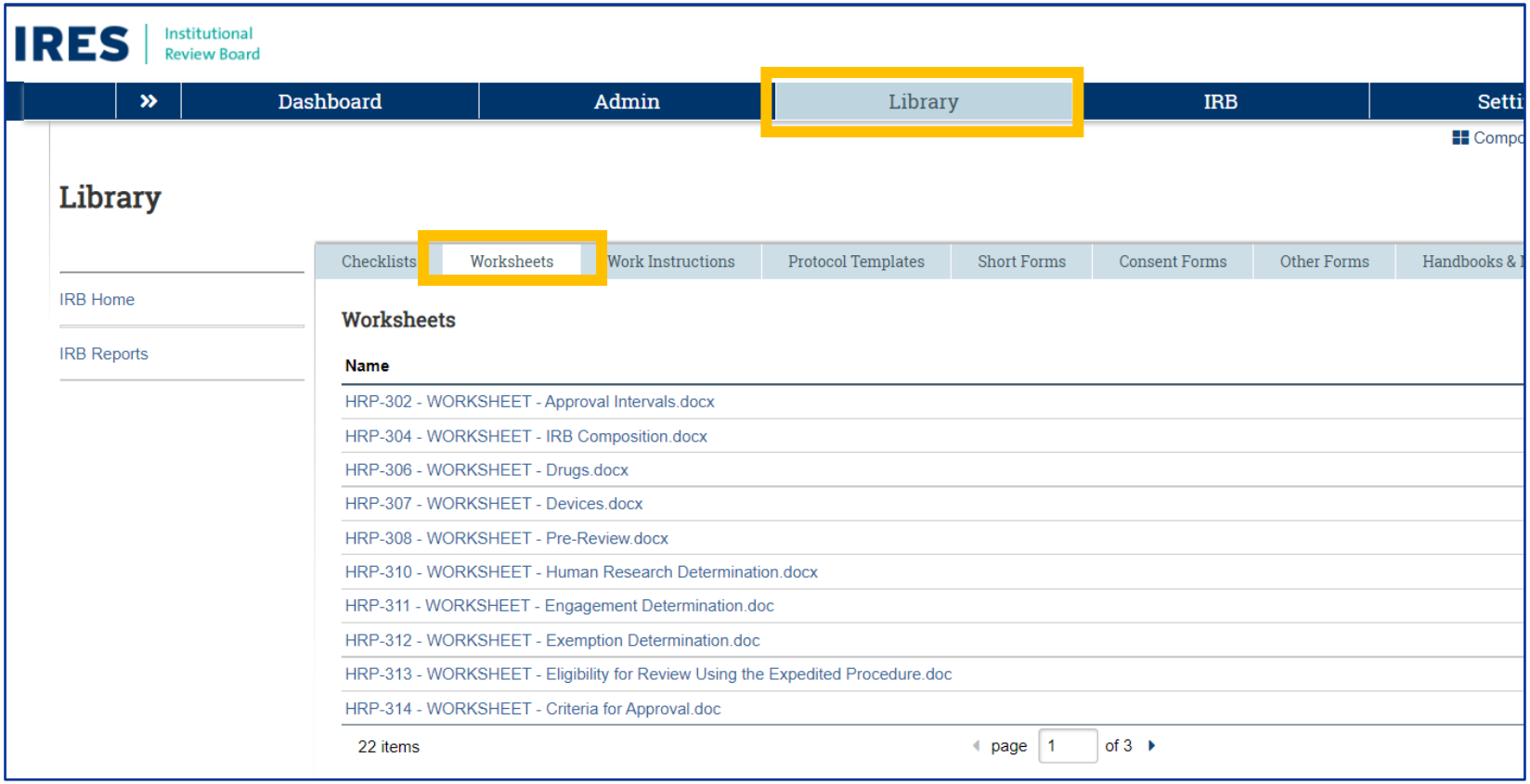
- HRP-414 – CHECKLIST – Neonates of Uncertain Viability
- HRP-412 – CHECKLIST – Pregnant Women
- HRP-411 – CHECKLIST – Waiver of Written Documentation of Consent
- HRP-417 – CHECKLIST – Cognitively Impaired Adults

➢ **PLEASE NOTE:** The revisions made to the checklists are not substantial and will not impact study teams or the conduct of research. The changes have been made to better assist Yale IRB staff with reviewing research applications involving the above topics.

Yale HRPP/IRB Worksheets – Summary and Location

Yale

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 - however Investigators are not required to complete the worksheets. They will continue to be posted in the Worksheets tab of the IRES IRB Library.



Yale HRPP/IRB Worksheets – Changes to Documents

Yale

The following worksheets were revised for clarity or new regulatory requirements. **The effective date for these worksheets is January 30, 2023**:

- 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

➢ **PLEASE NOTE:** Most revisions made to the worksheets are not substantial and will not impact study teams or the conduct of research. **The biggest change was the revision of HRP-312 (Exemption Determination), which was updated to reflect the updated 2018 Common Rule exemption categories.**

Yale IRB Submission Form – Overview of Changes

Yale

Two types of changes:

- Addition of new sections (required only for certain types of studies).
- Addition of new questions/reminders to existing sections.

What the changes mean for the research community:

- Use of the revised submission form is only applicable to new submissions of initial studies.
- Initial submissions of protocols using older version of the form will be rejected as of **March 1, 2023.**
- The IRB may request that the investigator add any of the applicable new sections/questions to the existing IRB Submission Form at the time of a specific modification (e.g., submission of modification to add a new federal grant that includes a data sharing plan may mean that the new supplement on data sharing be added to the existing IRB Submission Form*)

**This is consistent with the current practice (e.g., Supplement on Multicenter Management must be completed at the time of a modification to add new sites to the protocol and where the Yale site becomes the coordinating center).*

Yale IRB Submission Form – New Sections

Yale

Section	Description
Supplement V: Research with Tobacco Products	Complete only when the research includes the use of tobacco products.
Supplement IX: Research Under an IND or IDE Held by a Yale Investigator	Complete only if the research involves use of a drug conducted under an IND held by a Yale investigator or a device study conducted under an IDE held by the Yale investigator; currently this supplement exists as a stand-alone document; the information is used by the YCCI IND/IDE Management Office.
Supplement X: Ancillary Committees	Investigators should review this section to identify any ancillary committees applicable to the research.
Supplement XI: Data Sharing and Management Policy	Complete if the study is subject to the NIH Data Sharing and Management Policy.

Yale IRB Submission Form – Supplement V – Tobacco Products

Yale

The supplement is only for studies that involve tobacco products as the Drugs page in IRES IRB does not include specific questions relevant to tobacco products

SUPPLEMENT V	
Tobacco Products used in the investigation	
This section is required if the research involves Tobacco Products intended for investigational use.	
STATUS OF THE TOBACCO PRODUCT	
1. Complete for each product in the study	**Full name of tobacco product:** *Include for ENDS/e-cigarettes, liquids, pods, etc.* **Maker/Manufacturer:** ****Is the product commercially available?** ☐ NO ☐ YES **If yes, date commercialized:** ***Will the product(s) be modified for this research?** ☐ NO ☐ YES *If yes, please described the modification(s) to the Tobacco Product:* **Is/Are the product(s) being created in the lab?**
	*****Tobacco products intended for investigational use would be considered 'new tobacco products' requiring ITP if they meet the definition in section 910(a)(1) (21 U.S.C. 387j(a)(1)).* *Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of the "Deeming Compliance Period" of August 8, 2016 or has been since modified is considered a new tobacco product requiring review.*

Yale IRB Submission Form – Supplement X - Ancillary Committees

Yale

Description of when the ancillary review applies; if the scenario applies to your research, check off the box in the second column

SUPPLEMENT X

Review by Ancillary Committees

Review by additional oversight committees may apply to certain research studies. Review the research scenarios below and select the applicable ancillary review. See Investigator Manual for information on types of modifications that may require review by the ancillary committee.

#		Research Scenario	Applicable Ancillary Review	Quick instructions for obtaining approval
1.	☐	Involves interactions with participants (including online)	**HRPP**	Complete 'Safety protocol during pandemic' form available in IRES IRB, and upload it in the Local Site documents; HRPP will document review and document approval in IRES IRB prior to sending the submission to IRB for review;
2.	☐	Includes minors as research participants	**Pediatric Protocol Review Committee**	No additional documents needed, when appropriate, the HRPP will request Ancillary Review upon submission of your research (at Pre-Review); the HRPP will hold submission until the PPRC has provided approval (submission will not proceed to the IRB for review without approval); Additional information about exceptions from the PPRC review is available here: https://medicine.yale.edu/ycci/researchservices/qa/committees/pedsprotocols/
3.	☐	Yale investigator serves as the IND/IDE holder for the drug/device used in this study	**IND-IDE Management Office**	Complete a Supplement IX titled 'Research Under an IND or IDE Held by a Yale Investigator' in this IRB Submission Form; HRPP will request Ancillary Review at Pre-review and hold the submission until IND-IDE Management Office has provided its approval (submission will not proceed to the IRB for review without approval); Additional information about the IND/IDE support services is available here:

Name of the ancillary committee

Instructions on how and when to obtain approval from the committee

Yale IRB Submission Form – Supplement XI – Data Management and Sharing

Yale

Applies to federally funded studies with the grant application dated January 25, 2023 or later; additional information is available in the Investigator Manual and on the OSP website: https://tst.your.yale.edu/research-support/office-sponsored-projects/data-management-and-sharing-dms

SUPPLEMENT XI	
Data Management and Sharing Policy	
This section is required if the study is subject to NIH Data Management and Sharing Policy and Yale is the direct recipient of the federal grant subject to the policy. You can attach Data Management and Sharing Plan in lieu of this supplement if it covers all of the items described below. Consent Glossary in the IRES IRB Library includes sample language for sharing data and biospecimen for future research. Ensure that the consent form adequately describe the data sharing. Review Investigator Manual for data sharing considerations.	
1.	**Describe the data that will be shared.**
2.	**Describe the deidentification methods used. Describe the level of the identifiability of the information including risk of individual subject identification.**
3.	**What is the name of the repositories where data will be donated? Include url if available.**
4.	**Describe how protections for privacy, rights, and confidentiality of human research participants will be protected.**
5.	**Describe how access to the data will be controlled.**

Yale IRB Submission Form – Revised Sections

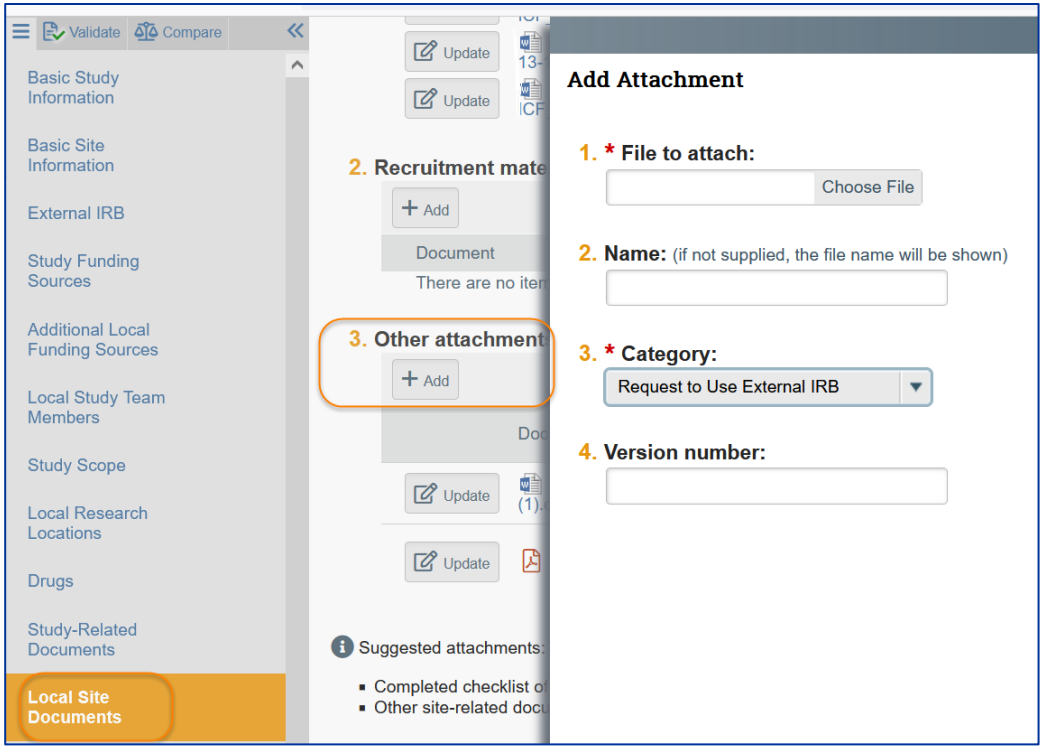
Yale

Section	Description
Section 4. Confidentiality and Privacy	**Questions added regarding:** • Cloud data storage • Data Use Agreements • Material Transfer Agreements • Privacy of research participants **Guidance added regarding:** • Business Associate Agreements • Data classification
SUPPLEMENT VIII: Special Populations	**Question added regarding:** • The consent process for non-English speaking individuals to ensure the process is conducted in the language understood by the potential participant **Guidance added regarding:** • FDA expectations regarding translation of the consent document if a short form is used for enrollment

Request to Use External IRB Form – Overview of Changes

Yale

- Form that must be completed at the time of the initial request to use an external IRB (with the exception of NCI CIRB studies).
- Will be required for submissions on **January 30, 2023.**
- Must be uploaded as the category '*Request to Use External IRB*' in the Local Site Documents page (Other attachments [Item #3]).



Request to Use External IRB Form – Summary

Yale

- **The Request to Use External IRB form asks questions relevant to the institutional review of local context:**
  - Recruitment of participants
  - Storage of data
  - HRPP billing instructions
  - Data Use Agreements and Material Transfer Agreements
  - Review by Ancillary Committees
  - Research under an IND or IDE held by a Yale Investigator
  - Data Management and Sharing for NIH funded studies

- Most of the questions and guidance are identical to the IRB Submission Form (used for initial submission to Yale IRB).

COA Form for Billable Protocol Charge Information – Overview

Yale

- 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.*

- **The COA form must be uploaded in IRES IRB as follows:**
  - For CRs and MOD/CRs, upload in the "*Attach supporting documents*" section of the "Continuing Review/ Study Closure Information" page of the application.
  - For MODs, upload in the "*Other attachments*" section of the "Local Site Documents" page of the application.

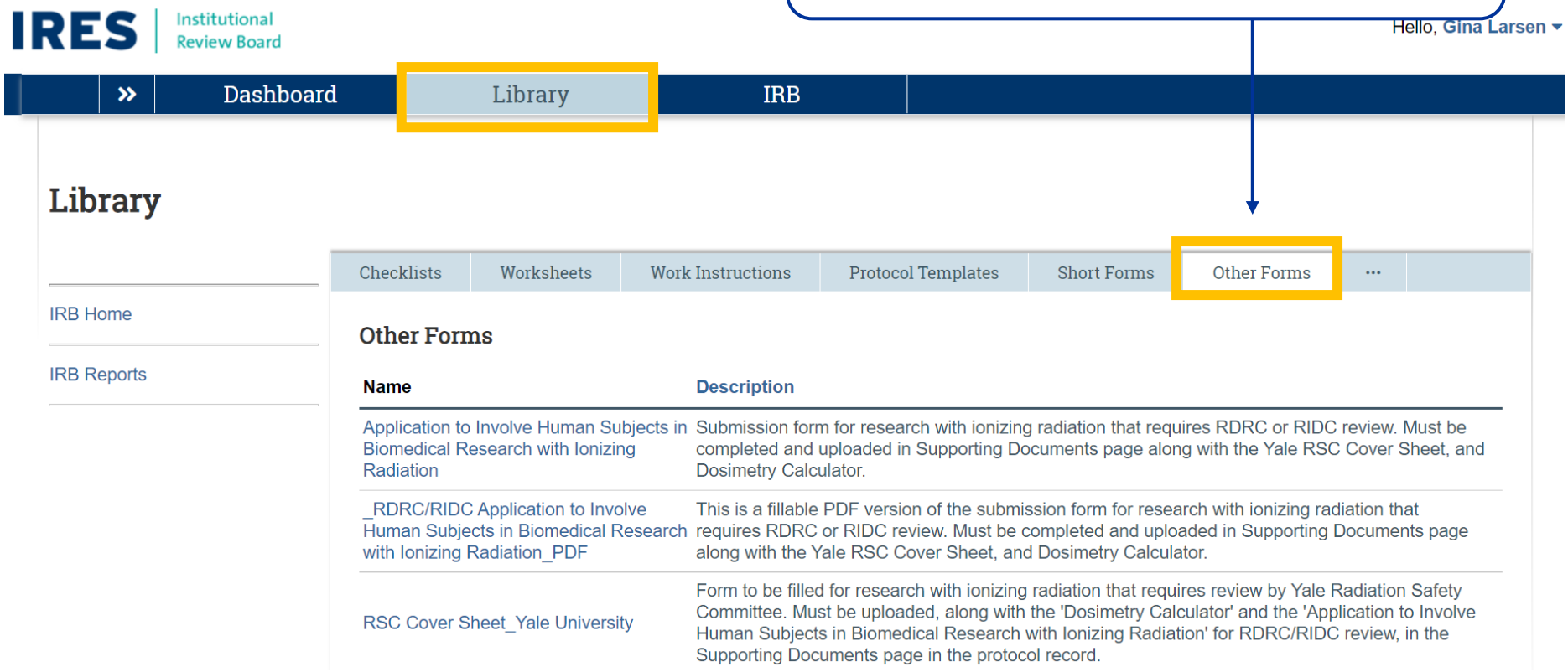
- For information about the billing process, see the HRPP announcement dated July 12, 2022, on the HRPP website.

**IRB Submission Form includes charging instructions for invoicing the IRB review fees, however, when the study specific COA is not available at the time of the initial review, the investigator must provide a general departmental account.*

Location of New/Revised Forms

Yale

Location of IRB Submission Form, Request to Use External IRB Form, and COA Form



Training Summary

Yale

- The Yale HRPP has streamlined our policies, procedures, guidance documents, worksheets, checklists, and other related documents and we have reimagined some of the ways in which we educate our research community and HRPP team.

- The majority of Yale HRPP/IRB policies and processes are not changing. The manuals are simply new ways of providing information to our research community, with some minor regulatory changes included.

- The effective date for all new/revised documents is **January 30, 2023**.

- All new/revised documents will be posted in the IRES IRB Library.

- The Yale HRPP is committed to a partnership with the research community in the promotion of safe and ethical research. Yale HRPP/IRB staff are available to the research community for consultation, education, and guidance.

Reference: HRPP and IRB Leadership

Yale

HRPP Main Office Number and Helpline Access:	25 Science Park, 150 Munson St., 3rd Floor	203-785-4688 or hrpp@yale.edu
HRPP Leadership	**Linda Coleman**, Director, HRPP	linda.coleman@yale.edu
	Jessica Rowe, Associate Director, HRPP/YCCI	jessica.rowe@yale.edu
	Monika Lau, Assistant Director, HRPP & Deputy HIPAA Privacy Office, HIPAA Data Privacy Office	monika.lau@yale.edu
	Cathi Montano, Assistant Director, HRPP	cathleen.montano@yale.edu
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Questions?

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Thank you for your dedication to protecting research participants and for conducting ethical research at Yale!