Yale

Use of Yale Human Research Protection Program (HRPP) & Institutional Review Board (IRB) for Yale New Haven Health System Research

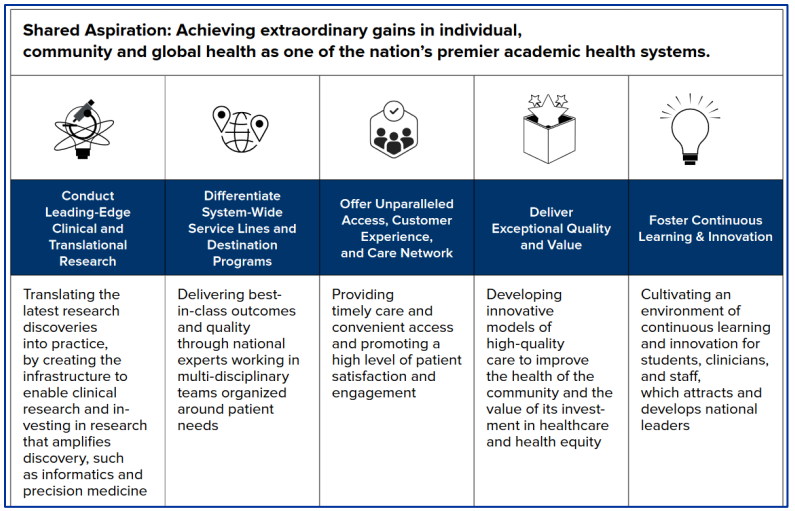
Yale University
Human Research Protection Program

Version# 2

Yale New Haven Health System and Yale School of Medicine Alignment

Yale School of Medicine (YSM) and Yale New Haven Health System (YNHHS) developed a joint strategic plan, which includes five strategic pillars.

OneIRB Project is one of the goals within one of those pillars: *Conduct Leading-Edge Clinical & Translational Research*.



Shared Aspiration: Achieving extraordinary gains in individual, community and global health as one of the nation's premier academic health systems.

Conduct Leading-Edge Clinical and Translational Research	Differentiate System-Wide Service Lines and Destination Programs	Offer Unparalleled Access, Customer Experience, and Care Network	Deliver Exceptional Quality and Value	Foster Continuous Learning & Innovation
Translating the latest research discoveries into practice, by creating the infrastructure to enable clinical research and investing in research that amplifies discovery, such as informatics and precision medicine	Delivering best-in-class outcomes and quality through national experts working in multi-disciplinary teams organized around patient needs	Providing timely care and convenient access and promoting a high level of patient satisfaction and engagement	Developing innovative models of high-quality care to improve the health of the community and the value of its investment in healthcare and health equity	Cultivating an environment of continuous learning and innovation for students, clinicians, and staff, which attracts and develops national leaders

To learn more about Alignment:

Yale New Haven Health System and Yale School of Medicine Alignment

- https://ynhhs.yale.edu/

02-05-2024 - YSM and YNHHS Alignment Town Hall

- https://ynhhs.yale.edu/media-player/02-05-2024-ysm-and-ynhhs-alignment/

Current State

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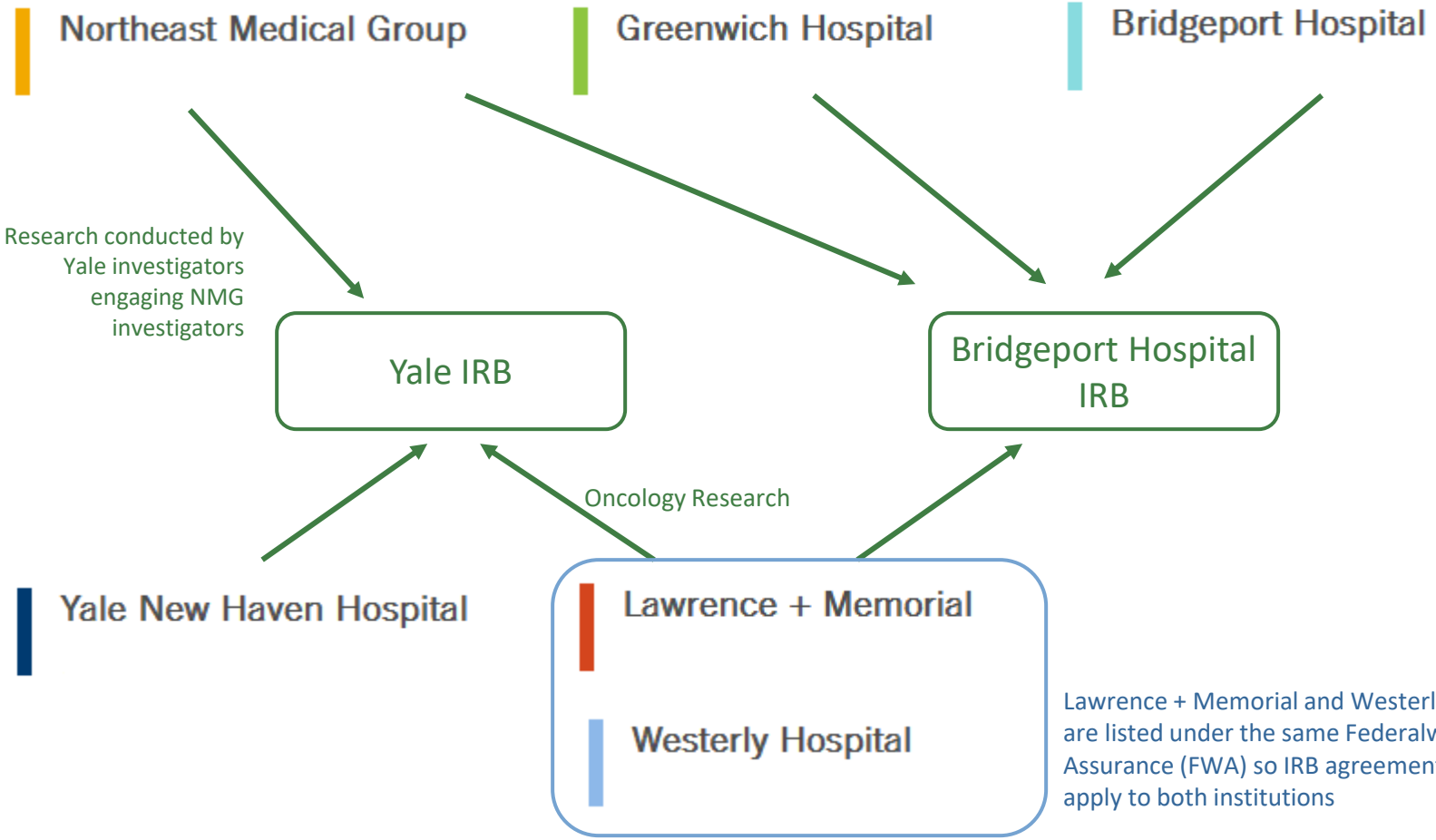

Lawrence + Memorial and Westerly Hospital are listed under the same Federalwide Assurance (FWA) so IRB agreements in place apply to both institutions

**All of the YNHHS entities also conduct studies under purview of external IRBs (non-Yale, non-BH), however, the submissions to those IRBs require a sign-off from Yale HRPP for Yale New Haven Hospital research, or BH IRB for all other groups*

Goal State

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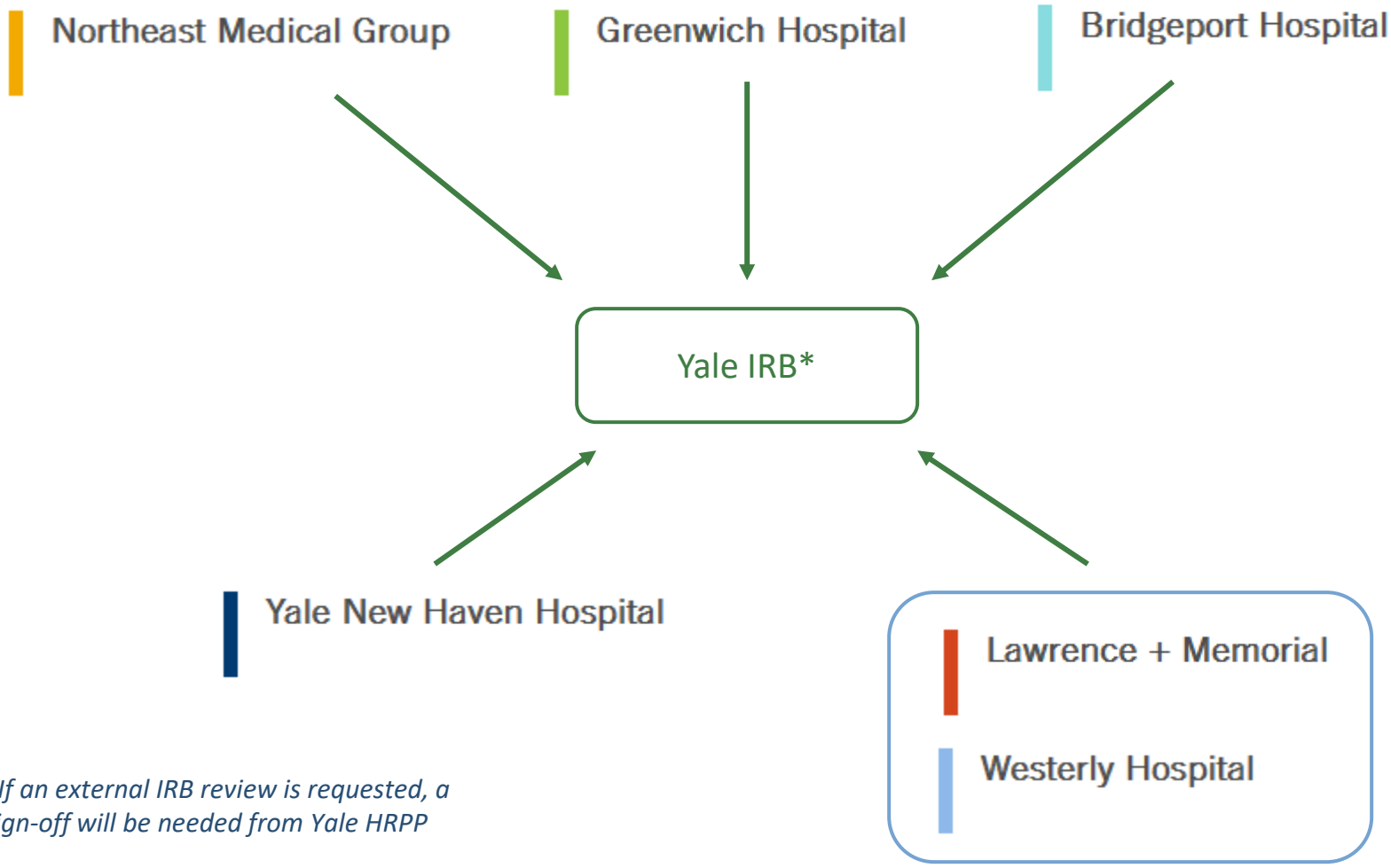

**If an external IRB review is requested, a sign-off will be needed from Yale HRPP*

Local Context Considerations

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Topic	Considerations
FWA	Does the institution's current FWA require OHRP regulations to all research regardless of funding or applicable oversight agencies? (Did the institution check the box?)
Conflict of Interest	How is the COI evaluated by the institution (including definitions of the SFI)? Is there a COI Office? How will the information be conveyed to the IRB?
Institutional Conflict of Interest	Is there a mechanism for evaluating ICOI at the institution? How will the information be conveyed to the Yale University HRPP and IRB-of-record?
Training Requirements	What are the training requirements for individuals engaged in human subjects research? Will the institution verify training prior to submission to Yale University HRPP for IRB review?
Contracts and Grants Information	What is the office responsible for contracts/grants? How is congruency review provided?
Ancillary Review Requirements	What are the ancillary committees at the institution? Does the IRB review need to be held until documentation of the ancillary reviews is provided?
Medicare Coverage Analysis	Is there an institutional process for coverage analysis? How will the information about what is considered routine care at the institution be communicated to the IRB?
Recruitment Policies	What recruitment practices are NOT allowable? What is the institution's position on: • Cold calling • Identification of possible participants from medical records
Consent Language	Is there institutionally required language that must be included in research consent forms? Can HIPAA authorization be combined with consent form?
Privacy Board	Is there a separate Privacy Board conducting reviews of HIPAA waivers and alterations? Is there a specific locally required language for HIPAA authorization that cannot be altered?
Monitoring and Auditing	Is there a separate group that audits studies and monitors compliance? If so, how will the information be provided to the Yale University HRPP and IRB-of-record?
Clinical Trial Registration	Is there a group within YNHHS that oversees registration of applicable trials on clinicaltrials.gov?
Sign-Off	Who can provide an institutional sign-off on initial studies to ensure local approval?
Current Fee Schedule (HRP and IRB review)	What is the current fee schedule for IRB review and HRPP oversight for ceded review?
IRB Representation	Do we need representation of the researchers, clinicians, community members as members on the IRB panels?
Contacts	• Individual to provide additional information to local context when necessary • Institutional sign-off • COI/ICOI Information • Grant/Contracts Information
Additional Local Policies that	Are there any additional institutional policies that are relevant to review of research at this institution? Are there any additional policies that provide stringent regulations above those required by regulations? For example, requiring that certain categories of minimal risk studies always require CR, requiring continuing review for exempt research, etc.

Timeline

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Actions	Time
Investigators can obtain Yale NetID, email, and access to Yale systems	NOW
Submission of initial studies for IRB review	May 8th, 2024
Transfer of existing studies	Will be announced – expected to commence by Fall 2024
Yale and Yale New Haven Hospital researchers adding YNHHS sites to research*	NOW but a study specific reliance will be needed

**If the only activity at another YNHHS site is medical record review, the site is not considered engaged in human subjects research (no reliance will be required); Yale HRPP has a process in place to ensure BH IRB is aware of the chart reviews*

Overview of Yale HRPP and Yale IRB Panels

Protocol Review

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Responsibilities of the Human Research Protection Program

Institutional Review

Review of compliance with local requirements

- Training of investigators and staff
- Locally required language in consent forms
- Identification of Conflicts of Interest
- Compliance with local recruitment policies
- Ancillary reviews
- Consistency with contracts/agreements

IRB Review

Review for approval criteria and other regulatory requirements

- IRB findings and determinations related to approval criteria
- Compliance with state laws
- Review of identified conflicts of interests
- HIPAA related determinations (if IRB serves as the Privacy Board)

Post-Approval Activities

- Institutions conducting research establish monitoring procedures to ensure compliance with regulations and IRB determinations

The IRB review can be ceded to another IRB. A Reliance Agreement establishes overall responsibilities of the reviewing IRB and institution that ceded review.

Office of Research Administration

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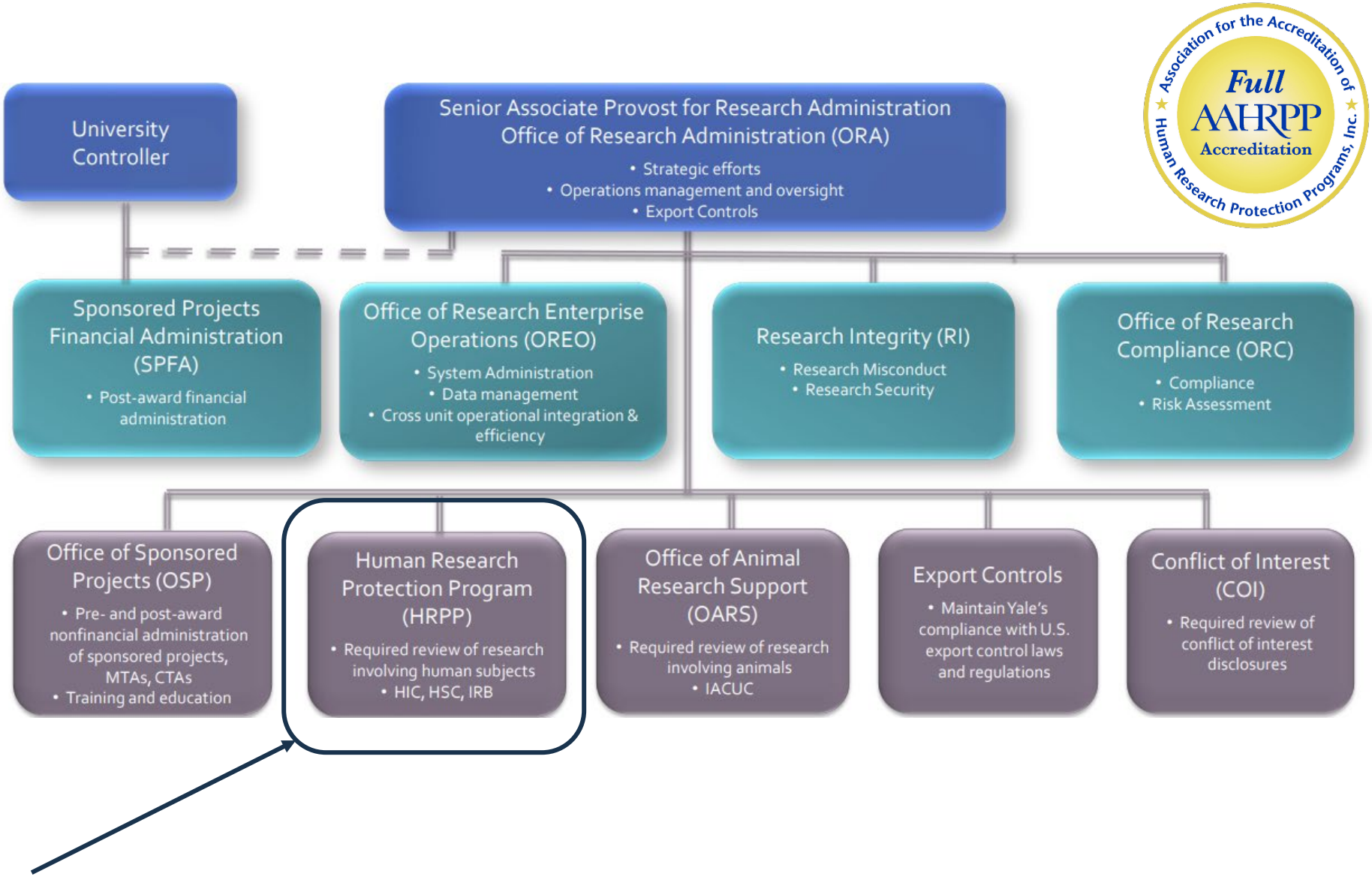
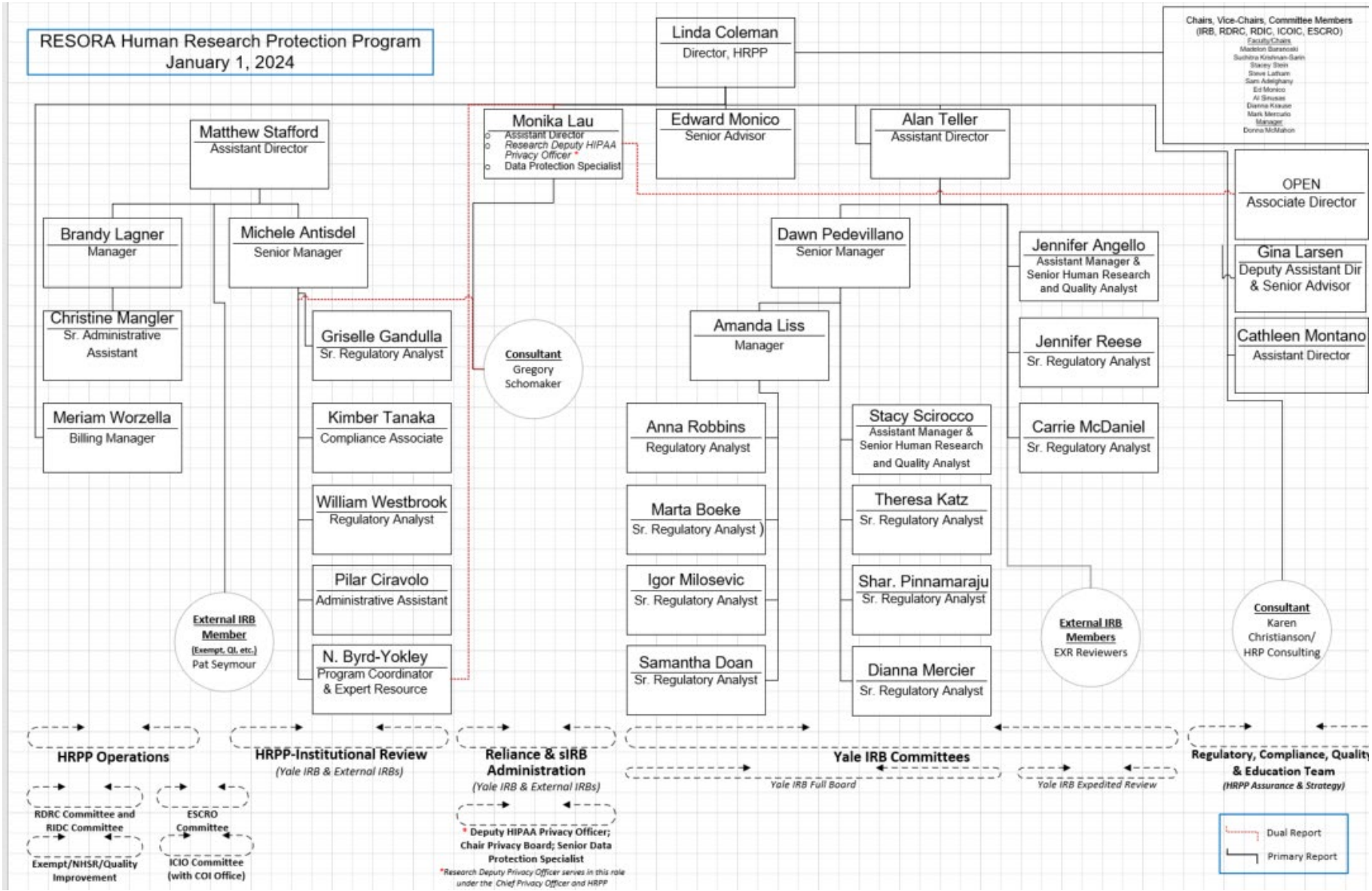


Human Research Protection Program

Yale University HRPP Structure



Team Responsibilities

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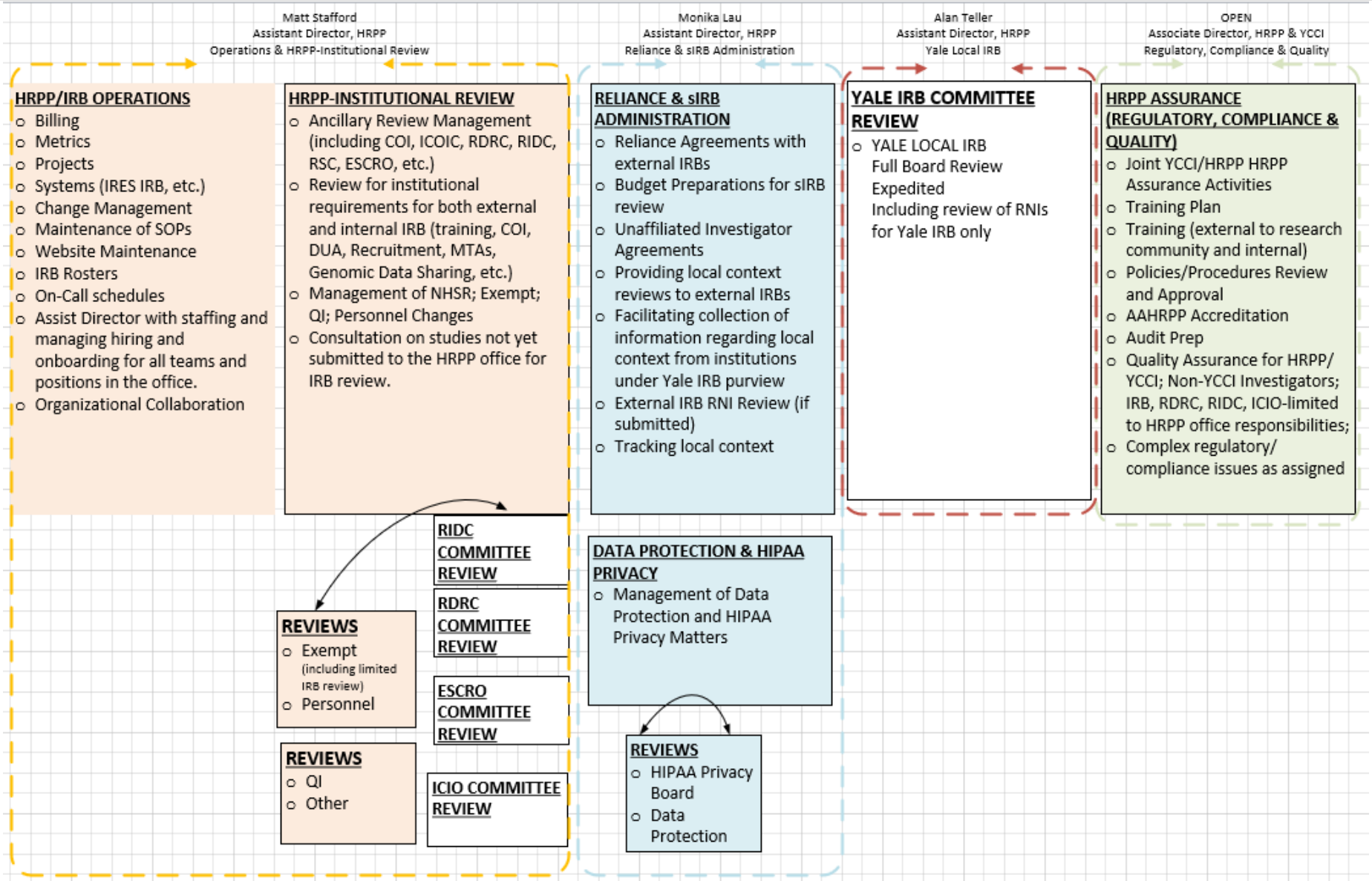

Yale IRB Committee Structure

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IRB Panel	Registration Number	Description	Submission Type Focus	Frequency	Chair
0	IRB00011725	All study types, including COVID-19	All	On Demand	Monico
1A	IRB00011455	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 1st W/3:00 PM	Baranoski
1B	IRB00013243	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 1st W/10:00 AM	Monico
2A	IRB00000730	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 2nd W/5:00 PM	Krishnan-Sarin
2B	IRB00013244	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 2nd W/9:00 AM	Monico
3A	IRB00006865	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 3rd W/3:00 PM	Baranoski
3B	IRB00013245	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 3rd W/4:00 PM	Monico
4A	IRB00000596	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 4th W/4:30 PM	Baranoski
4B	IRB00013246	Biomedical	Initial; MOD; Complicated MOD/CR	1x/month 4th W/4:00 PM	Krishnan-Sarin
5	IRB00013247	Biomedical	CR; Less Complicated MOD/CR	Weekly/Wednesday	Baranoski
A	IRB00000594	Social, Behavioral, Education	Initial; MOD; Complicated MOD/CR	1/x per month/ On Demand	Latham
B-1	IRB00000595	Oncology	Initial; MOD; MOD/CR; CR	1x/month 1st Th/7:30 AM	Abdelgany
B-2	IRB00013240	Oncology	Initial; MOD; MOD/CR; CR	1x/month 2nd Th/2:00 PM	Abdelghany
B-3	IRB00011728	Oncology	Initial; MOD; MOD/CR; CR	1x/month 3rd Th/2:00 PM	Abdelghany
B-4	IRB00013241	Oncology	Initial; MOD; MOD/CR; CR	1x/month 4th F/7:30 AM	Baranoski
C	IRB00011726	Compliance	Compliance	On Demand	Baranoski
D	IRB00011727	Cutting edge, AI and emerging research	All	On Demand	Baranoski
E	IRB00013242	sIRB	All	2x/month and On Demand	Monico
F	IRB00013248	VA Research	VA studies	On Demand	Baranoski

Deadlines for IRB Reviews

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The **IRB meeting Agenda closes every Tuesday at 05:00 pm** and studies are reviewed either 1 business week or 2 business weeks later (on a TU, WE, TH, or for one Oncology meeting per month on a FR morning) based on the following, unless the IRB chair determines that there are substantive issues with the approvability of the study that would require deferral:

- **1 business week later** for Industry and other externally funded/authored research for initial submissions of research; modifications to approved research; continuing reviews of previously approved research
- **1 business week later** for Investigator-initiated initial submissions of oncology research
- **2 business weeks later** for Investigator-initiated initial submissions of non-oncology research

The Yale IRB panels below convene monthly and/or as needed depending on the panel:

- IRB 0: Ad-hoc panel for emergency submissions, including COVID-19 studies
- IRB A: Commonly known as Human Subjects Committee for social, behavioral and educational research)
- IRB C: Compliance panel
- IRB D: Cutting Edge, and Emerging Research
- IRB E: sIRB
- IRB F: VA Studies

Complete submissions of studies qualifying for expedited reviews and exemption determinations are assigned to reviewers within 2 business days.

Policies and Procedures

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- Policies, Procedures, Guidance, and Related Documents
  - HRPP Policy and Standard Operating Procedure Manual
  - HRPP Investigator Manual
  - IRB Members and Chairs Manual
  - HRPP Supplemental Guidance Manual
  - IRB Submission Documents (Protocol Templates, Submission Forms, Consent Templates)
  - IRB Checklists and Worksheets
  - Forms & Templates
  - Protocol Builder

Policies, Procedures, Guidance, and Related Documents

This section includes Yale HRPP policies, procedures, guidance, and related documents that aid members of the Yale research community in fulfilling their obligations to ensure that human subjects research is designed, conducted, and approved consistently and in compliance with applicable laws, regulations, and Yale's commitment to the protection of research participants. Copies of these documents are located in the HRPP's electronic IRB submission system.

IRES IRB LOGIN ▸

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Training Requirements

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	Training	When Required	How often to repeat it	Accepted training
1.	Human Subject Protection Training	Every Human Subject Research	Initial Full Training, Refresher every 3 years (unless research is exempt)	CITI, OHRP, Other institutions
2.	Good Clinical Practice	Human Subjects Research that meets a definition of a clinical trial	Initial Full Training, Refresher every 3 years	CITI, in-person Yale training, any TransCelerate recognized training
3.	HIPAA Training	Research with PHI	Initial + Annual attestation	Yale activated training

** Investigators and research staff will be given 6 months grace period to update training if they currently do not meet these requirements for accepted training;*

IRB System

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IRES | Institutional Review Board

Documents for Submission

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Policies, Procedures, Guidance, and Related Documents

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Documents are available on the HRPP website and in IRES IRB

Protocol Documents

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Document	Purpose
Research requiring IRB review	
Protocol*	Describes the background, rationale, objectives, design, methodology, statistical considerations, etc.
IRB Submission form	Describes how research is conducted at a specific site, e.g., how consent process is conducted, provides information for requests for consent waivers, details about confidentiality, etc.
COI Disclosure	Asks questions about significant interest related to the study for any of the key personnel
Exempt Research	
Exemption Request	If research fits exemption criteria, you can replace Protocol and IRB Submission form with this request
COI Disclosure	Asks questions about significant interest related to the study for any of the key personnel

**If study received external funding e.g., contract with industry sponsor, a foundation, or NIH grant, the HRPP will ask for the copies of the grant/contracts, even if it's a draft only*

Templates for Investigator Initiated Research

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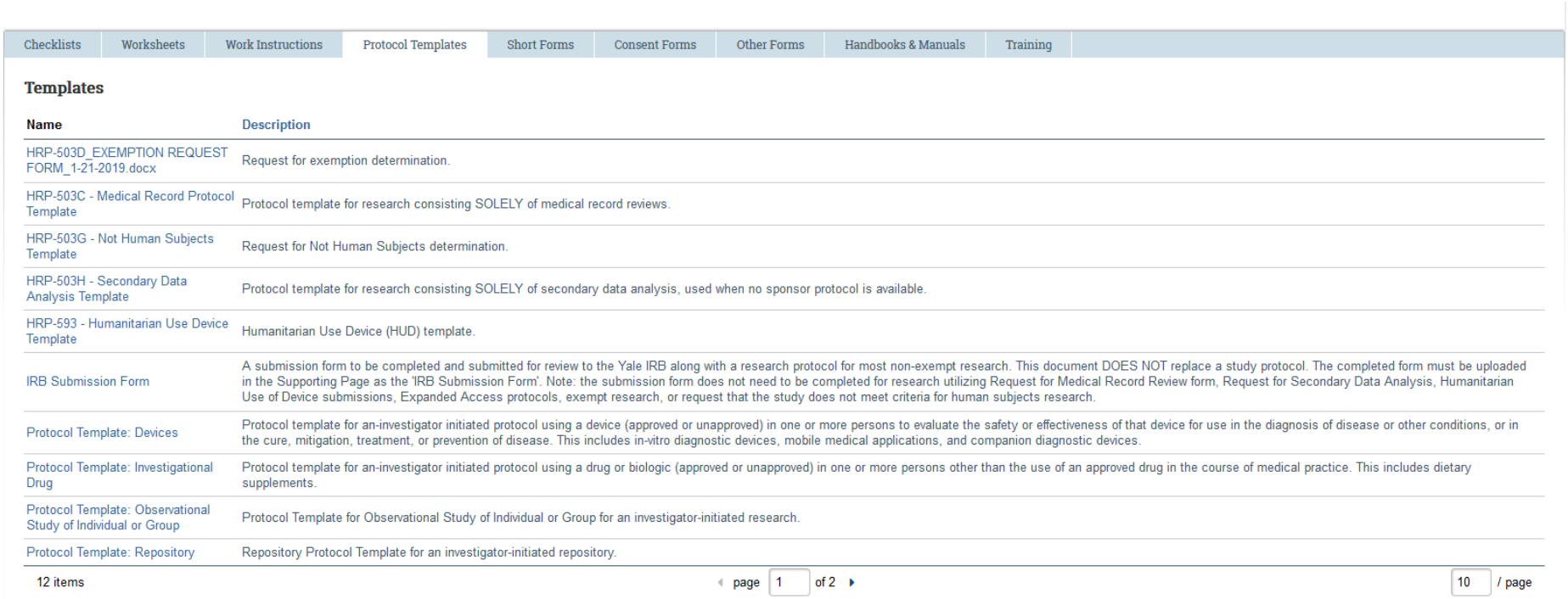
- Protocol Builder
- Templates from IRES IRB
- Other templates (TransCelerate, NIH e-protocol writing tool)



Checklists | Worksheets | Work Instructions | Protocol Templates | Short Forms | Consent Forms | Other Forms | Handbooks & Manuals | Training

Templates

Name	Description
HRP-503D_EXEMPTION REQUEST FORM_1-21-2019.docx	Request for exemption determination.
HRP-503C - Medical Record Protocol Template	Protocol template for research consisting SOLELY of medical record reviews.
HRP-503G - Not Human Subjects Template	Request for Not Human Subjects determination.
HRP-503H - Secondary Data Analysis Template	Protocol template for research consisting SOLELY of secondary data analysis, used when no sponsor protocol is available.
HRP-593 - Humanitarian Use Device Template	Humanitarian Use Device (HUD) template.
IRB Submission Form	A submission form to be completed and submitted for review to the Yale IRB along with a research protocol for most non-exempt research. This document DOES NOT replace a study protocol. The completed form must be uploaded in the Supporting Page as the 'IRB Submission Form'. Note: the submission form does not need to be completed for research utilizing Request for Medical Record Review form, Request for Secondary Data Analysis, Humanitarian Use of Device submissions, Expanded Access protocols, exempt research, or request that the study does not meet criteria for human subjects research.
Protocol Template: Devices	Protocol template for an-investigator initiated protocol using a device (approved or unapproved) in one or more persons to evaluate the safety or effectiveness of that device for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. This includes in-vitro diagnostic devices, mobile medical applications, and companion diagnostic devices.
Protocol Template: Investigational Drug	Protocol template for an-investigator initiated protocol using a drug or biologic (approved or unapproved) in one or more persons other than the use of an approved drug in the course of medical practice. This includes dietary supplements.
Protocol Template: Observational Study of Individual or Group	Protocol Template for Observational Study of Individual or Group for an investigator-initiated research.
Protocol Template: Repository	Repository Protocol Template for an investigator-initiated repository.

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Consent Forms

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Listed below are several templates to assist Investigators in creating informed consent document(s):

- Consent Glossary of preferred and required terms for consent forms
- Adolescent Assent
- Child Assent
- Compound Authorization and Consent Template Biomedical Research
- Compound Authorization and Consent Template Social Behavioral and Educational Research
- Consent Addendum
- Consent Template Social Behavioral and Educational Research
- Emergency Expanded Use Consent
- Information Sheet
- Parental Permission Form
- Video-Audio Consent

Consent templates are also available in the IRES IRB Library.

Consent templates include helpful instructional language.

Consent Glossary document includes additional consent language.

Helpful Information

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Submission Process: *https://your.yale.edu/research-support/human-research-protection-program/yale-irb-yale-university-institutional-review-0*

Transfer of Existing Studies

Transfer of Studies

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- Communication will be sent out to current investigators with instructions and when the submissions with transfer can begin
- Anticipated date to begin transfer submissions: Fall 2024
- Only Active Studies with IRB Approval will be transferred

Projects that will not be transferred to Yale IRB:

- Not Research Determinations e.g., Quality Improvement
- Not Human Subjects Research Projects
- Projects that received Exemption Determinations

If a researcher needs to submit a modification to existing studies in these categories, a request for a new determination will be needed.

Projects that will not be transferred to Yale IRB BUT will have a record in IRES IRB System:

- Research under external IRB purview (e.g., reviewed by a commercial IRB)

The HRPP will work with the reviewing IRBs to notify them of the transfer of HRPP oversight. PIs will be asked to create a record in IRES IRB system.

Approach to review of transferred studies

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	Status of the Study	IRB Review
1.	Recruitment is open	IRB review of entire study, as if it was initial (can be expedited or full board depending on category)
2.	Recruitment is closed, participants are undergoing interventions	IRB review of entire study, as if it was initial (can be expedited or full board depending on category)
3.	Recruitment is closed, participants completed research interventions and are in long term follow-up only; follow-up consists of minimal risk procedures such as medical record review or a phone survey	IRB review of remaining activities, qualifies for Expedited Review
4.	Recruitment is closed, participants completed interventions and are in long term follow-up that requires greater than minimal risk procedures or procedures that would not qualify for expedited review e.g., research scans with radiation,	IRB review of remaining activities, Full Board Review
5.	Recruitment is closed, analysis of identifiable data only (no intervention or follow-up)	IRB review of remaining activities, Expedited
6.	Recruitment is closed, data analysis only (no intervention or follow-up)	Study should be closed prior to transfer unless it is FDA regulated

For FDA guidance on transfer of IRB oversight, see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-when-transferring-clinical-investigation-oversight-another-irb

Transfer of IRB Approved Studies

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Steps:

- Close the study with Bridgeport IRB if you are no longer conducting human subjects research activities e.g., analysis of deidentified data not subject to FDA regulations

- For ongoing studies, obtain Yale IRB approval first before closing out record in Bridgeport Hospital IRB

- Prioritize transfer of studies that have an expiration date prior to September 1, 2024

- If your study expires prior to July 1, 2024 – plan on submitting request for continuing review to BH IRB prior to the transfer

Transfer of IRB Approved Studies

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What will be needed:

- Current record:
  - Study Protocol
  - WORD version of consent forms (if still enrolling)
  - Most recent approval letter of the study (initial approval or most recent continuing review)
  - IB, device manuals, FDA letters
  - Current recruitment materials, study questionnaires, surveys, etc.
- Transfer Request Form (will be posted on the HRPP website and emailed to investigator)

- If still enrolling, revisions may be needed to the consent form to add Yale HRPP as one of the entities that may have access to the identifiable data (HIPAA Authorization section)

Next Steps

Next Steps: Yale NetID, email, IRES IRB System

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The Principal Investigator and study staff that require access to Yale IRB system must have Yale NetID, password, and email

- Request Yale NetID and password by completing this Qualtrics form:

» OR Complete **a Request Form**

- You will receive an email with instructions to activate the NetID within 4 business days from submitting the request

Next Steps: IRES IRB

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- Log into IRES IRB to familiarize yourself with the system – training is available
- Download any forms for initial submission from IRES IRB Library or Yale HRPP website
- Sign up for a newsletter (link on last page)
- Contact the HRPP staff with any additional questions

Contact Information

Contact Information

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Name and contact	Types of questions
Linda Coleman, HRPP Director, linda.coleman@yale.edu Main Phone Number: 203-785-4688	
OneIRB@yale.edu	Questions related to the transition to Yale IRBs
hrpp@yale.edu	General questions related to reviews, systems, etc. questions are triaged to the Regulatory Analyst on call
external.reviews@yale.edu	Questions related to use of external IRBs
Gina Larsen: gina.larsen@yale.edu	Education, OneIRB, Compliance
Dawn Pedevillano: Dawn.Pedevillano@yale.edu	Full Board Review, OneIRB, compliance issues subject to IRB review
Cathi Montano: Cathleen.montano@yale.edu	Expedited Review, OneIRB, Regulatory, Quality Control

Pages

Yale

Human Research Protection Program

- https://your.yale.edu/research-support/human-research-protection-program

HIPAA Training

- https://hipaa.yale.edu/training/training-modules

Links to Training Information

- https://your.yale.edu/research-support/human-research-protection-program/education-and-training/human-research-training

Email Subscription

- https://subscribe.yale.edu/

**HRPP Newsletter is available in Research Administration category*