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 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.*

To learn more about Alignment:

- Yale New Haven Health System and Yale School of Medicine Alignment [https://ynhhs.yale.edu/](https://ynhhs.yale.edu/)
Current State

Research conducted by Yale investigators engaging NMG investigators

Yale IRB

Bridgeport Hospital IRB

Oncology Research

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

Human Research Protection Program
*If an external IRB review is requested, a sign-off will be needed from Yale HRPP
<table>
<thead>
<tr>
<th>Topic</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FWA</strong></td>
<td>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?)</td>
</tr>
<tr>
<td><strong>Conflict of Interest</strong></td>
<td>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?</td>
</tr>
<tr>
<td><strong>Institutional Conflict of Interest</strong></td>
<td>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?</td>
</tr>
<tr>
<td><strong>Training Requirements</strong></td>
<td>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?</td>
</tr>
<tr>
<td><strong>Contracts and Grants Information</strong></td>
<td>What is the office responsible for contracts/grants? How is congruency review provided?</td>
</tr>
<tr>
<td><strong>Ancillary Review Requirements</strong></td>
<td>What are the ancillary committees at the institution? Does the IRB review need to be held until documentation of the ancillary reviews is provided?</td>
</tr>
</tbody>
</table>
| **Medicare Coverage Analysis** | What recruitment practices are NOT allowable? What is the institution’s position on:  
  * Cold calling  
  * Identification of possible participants from medical records |
| **Recruitment Policies** | Is there institutionally required language that must be included in research consent forms? Can HIPAA authorization be combined with consent form? |
| **Consent Language** | 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? |
| **Privacy Board** | 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? |
| **Monitoring and Auditing** | Is there a group within YNHHS that oversees registration of applicable trials on clinicaltrials.gov? |
| **Clinical Trial Registration** | Who can provide an institutional sign-off on initial studies to ensure local approval? |
| **Sign-Off** | What is the current fee schedule for IRB review and HRPP oversight for ceded review? |
| **Current Fee Schedule (HRP and IRB review)** | Do we need representation of the researchers, clinicians, community members as members on the IRB panels? |
| **IRB Representation** | Individual to provide additional information to local context when necessary  
  Institutional sign-off  
  COI/ICOI Information  
  Grant/Contracts Information |
| **Contacts** | 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. |
| **Additional Local Policies that may affect IRB review** | |
### Timeline

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

*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

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.
Human Research Protection Program

Team Responsibilities

HRPP/IRB OPERATIONS
- Billing
- Metrics
- Projects
- Systems (IRES IRB, etc.)
- Change Management
- Maintenance of SOPs
- Website Maintenance
- IRB Rosters
- On-Call schedules
- Assist Director with staffing and managing hiring and onboarding for all teams and positions in the office.
- Organizational Collaboration

HRPP-INSTITUTIONAL REVIEW
- Ancillary Review Management (including COI, ICOIC, RDRC, RIDC, RSC, ESCRRO, etc.)
- Review for institutional requirements for both external and internal IRB (training, COI, DUA, Recruitment, MTAs, Genomic Data Sharing, etc.)
- Management of NIHR; Exempt; QI; Personnel Changes
- Consultation on studies not yet submitted to the HRPP office for IRB review.

RELIANCE & sIRB ADMINISTRATION
- Reliance Agreements with external IRBs
- Budget Preparations for sIRB review
- Unaffiliated Investigator Agreements
- Providing local context reviews to external IRBs
- Facilitating collection of information regarding local context from institutions under Yale IRB purview
- External IRB RNI Review (if submitted)
- Tracking local context

REVIEWs
- Exempt (including limited IRB review)
- Personnel

REVIEWs
- QI
- Other

DATA PROTECTION & HIPAA PRIVACY
- Management of Data Protection and HIPAA Privacy Matters

REVIEWs
- HIPAA Privacy Board
- Data Protection

YALE IRB COMMITTEE REVIEW
- YALE LOCAL IRB
  - Full Board Review
  - Expedited
  - Including review of RNIs for Yale IRB only

HRPP ASSURANCE (REGULATORY, COMPLIANCE & QUALITY)
- Joint YCCI/HRPP HRPP Assurance Activities
- Training Plan
- Training (external to research community and internal)
- Policies/Procedures Review and Approval
- AAHRPP Accreditation
- Audit Prep
- Quality Assurance for HRPP/YCCI; Non-YCCI Investigators; IRB, RDRC, RIDC, ICOIC-limited to HRPP office responsibilities;
  - Complex regulatory/compliance issues as assigned

Matt Stafford
Assistant Director, HRPP
Operations & HRPP-Institutional Review

Monika Lau
Assistant Director, HRPP
Reliance & sIRB Administration

Alan Teller
Assistant Director, HRPP
Yale Local IRB

OPEN
Associate Director, HRPP & YCCI
Regulatory, Compliance & Quality
## Yale IRB Committee Structure

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

- 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
- Other Forms and Templates
- Protocol Builder
## Training Requirements

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

*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;*
IRES IRB is Yale University’s electronic submission and review system for human subjects research studies. You will need Yale netID and password to log into the system. Use VPN in order to access the system from off-campus locations.

IRES IRB Training Options

- Registration for live training sessions
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.

- IRB LOGIN

- 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
- Other Forms and Templates
- Protocol Builder

Documents are available on the HRPP website and in IRES IRB
### Protocol Documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research requiring IRB review</strong></td>
<td></td>
</tr>
<tr>
<td>Protocol*</td>
<td>Describes the background, rationale, objectives, design, methodology, statistical considerations, etc.</td>
</tr>
<tr>
<td>IRB Submission form</td>
<td>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.</td>
</tr>
<tr>
<td>COI Disclosure</td>
<td>Asks questions about significant interest related to the study for any of the key personnel</td>
</tr>
<tr>
<td><strong>Exempt Research</strong></td>
<td></td>
</tr>
<tr>
<td>Exemption Request</td>
<td>If research fits exemption criteria, you can replace Protocol and IRB Submission form with this request</td>
</tr>
<tr>
<td>COI Disclosure</td>
<td>Asks questions about significant interest related to the study for any of the key personnel</td>
</tr>
</tbody>
</table>

*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

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

#### Templates

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-593D EXEMPTION REQUEST FORM 1-21-2019.docx</td>
<td>Request for exemption determination.</td>
</tr>
<tr>
<td>HRP-593C - Medical Record Protocol Template</td>
<td>Protocol template for research consisting SOLELY of medical record reviews.</td>
</tr>
<tr>
<td>HRP-593H - Secondary Data Analysis Template</td>
<td>Protocol template for research consisting SOLELY of secondary data analysis, used when no sponsor protocol is available.</td>
</tr>
<tr>
<td>HRP-593 - Humanitarian Use Device Template</td>
<td>Humanitarian Use Device (HUD) template.</td>
</tr>
<tr>
<td>IRB Submission Form</td>
<td>A submission form to be completed and submitted for review to the Yale IRB along with a research protocol for 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 that the study does not meet criteria for human subjects research.</td>
</tr>
<tr>
<td>Protocol Template: Devices</td>
<td>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 devices, and companion diagnostic devices.</td>
</tr>
<tr>
<td>Protocol Template: Investigational Drug</td>
<td>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.</td>
</tr>
<tr>
<td>Protocol Template: Observational Study of Individual or Group</td>
<td>Protocol Template for Observational Study of Individual or Group for an investigator-initiated research.</td>
</tr>
<tr>
<td>Protocol Template: Repository</td>
<td>Repository Protocol Template for an investigator-initiated repository.</td>
</tr>
</tbody>
</table>

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Human Research Protection Program
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.
Submission Process

Protocol Submission Overview

The protocol submission overview guide gives a high-level overview of the submission process. Information on specific steps required for different types of actions can be found in the Help Center tab of IRES IRB.

Preparing a Protocol for Submission

When preparing your protocol for review, there are many things to consider. This document was created to give you a quick guide of helpful hints to get you going in the right direction.

General FAQs

General FAQs for all research.

General FAQs for Student Research

FAQs specific to student research.
Transfer of Existing Studies
Transfer of Studies

- 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

<table>
<thead>
<tr>
<th>Status of the Study</th>
<th>IRB Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Recruitment is open</td>
<td>IRB review of entire study, as if it was initial (can be expedited or full board depending on category)</td>
</tr>
<tr>
<td>2. Recruitment is closed, participants are undergoing interventions</td>
<td>IRB review of entire study, as if it was initial (can be expedited or full board depending on category)</td>
</tr>
<tr>
<td>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</td>
<td>IRB review of remaining activities, qualifies for Expedited Review</td>
</tr>
<tr>
<td>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,</td>
<td>IRB review of remaining activities, Full Board Review</td>
</tr>
<tr>
<td>5. Recruitment is closed, analysis of identifiable data only (no intervention or follow-up)</td>
<td>IRB review of remaining activities, Expedited</td>
</tr>
<tr>
<td>6. Recruitment is closed, data analysis only (no intervention or follow-up)</td>
<td>Study should be closed prior to transfer unless it is FDA regulated</td>
</tr>
</tbody>
</table>

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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-when-transferring-clinical-investigation-oversight-another-irb)
Transfer of IRB Approved Studies

**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.
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
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

- 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

<table>
<thead>
<tr>
<th>Name and contact</th>
<th>Types of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Linda Coleman, HRPP Director, <a href="mailto:linda.coleman@yale.edu">linda.coleman@yale.edu</a></strong></td>
<td></td>
</tr>
<tr>
<td><strong>Main Phone Number: 203-785-4688</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Email</th>
<th>Type of Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:OneIRB@yale.edu">OneIRB@yale.edu</a></td>
<td>Questions related to the transition to Yale IRBs</td>
</tr>
<tr>
<td><a href="mailto:hrpp@yale.edu">hrpp@yale.edu</a></td>
<td>General questions related to reviews, systems, etc. questions are triaged to the Regulatory Analyst on call</td>
</tr>
<tr>
<td><a href="mailto:external.reviews@yale.edu">external.reviews@yale.edu</a></td>
<td>Questions related to use of external IRBs</td>
</tr>
<tr>
<td>Gina Larsen: <a href="mailto:gina.larsen@yale.edu">gina.larsen@yale.edu</a></td>
<td>Education, OneIRB, Compliance</td>
</tr>
<tr>
<td>Dawn Pedevillano: <a href="mailto:Dawn.Pedevillano@yale.edu">Dawn.Pedevillano@yale.edu</a></td>
<td>Full Board Review, OneIRB, compliance issues subject to IRB review</td>
</tr>
<tr>
<td>Cathi Montano: <a href="mailto:Cathleen.montano@yale.edu">Cathleen.montano@yale.edu</a></td>
<td>Expedited Review, OneIRB, Regulatory, Quality Control</td>
</tr>
</tbody>
</table>
Human Research Protection Program

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