

**Yale University**

**Human Research Protection Program (HRPP)**

**IRB Member and Chair Manual**

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## 1. IRB Members Roles and Responsibilities

As a member of the Yale Institutional Review Board (IRB), you are serving an important federal mandate that allows research to be conducted at Yale. Yale has established multiple IRBs to ensure the protection of human subjects in research it engages in. The structure and composition of the Yale IRB is based upon regulatory requirements set forth at [45 CFR 46.107](#) (Department of Health and Human Services) and [21 CFR 56.107](#) (Food and Drug Administration). IRB composition is also based on the characteristics of the research reviewed at Yale. The role of the IRB is to safeguard the rights and welfare of human participants that take part in research that comes before the Yale IRB. IRB members must possess the professional and ethical competence necessary to review specific research activities.

### 1.1 Terms of Membership

When the need for a new IRB member or alternate member is identified, the Human Research Protection Program (HRPP) Director and/or other members of HRPP leadership seek out qualified candidates. Once a qualified candidate has been identified, the HRPP Director will elevate the appointment recommendation to the Institutional Official (IO). Any member of the Yale community may recommend candidates for IRB membership. Recommendations may also be made by persons external to Yale (e.g., an unaffiliated IRB member).

Appointments for all IRB members (including IRB Chairs, Vice Chairs, full members, and alternate members) are made for an annual term. Any change in appointment, including reappointment or removal before the end of a member's term, requires written notification. Members may resign by verbal or written notification to the HRPP Director, IRB Chair, and/or other designated HRPP staff.

### 1.2 Member Roles

Much of the HRPP's work is focused on supporting you in your role as a Yale IRB member. The role of an IRB member involves careful review of research protocols with emphasis on human subject protections issues and in accordance with applicable regulations, policies and procedures, and ethical standards. Yale IRBs review research conducted by Yale affiliated investigators as well as investigators from Yale New Haven Hospital and other hospitals in the Yale New Haven Health System. On occasion, Yale IRBs will review research conducted by investigators from other institutions. The Yale IRB rosters include members from diverse backgrounds and with varied areas of expertise to provide an array of perspectives and knowledge.

#### **The Yale IRBs are responsible for the following:**

- Approvals (initial studies), reapprovals (continuing reviews), deferrals, and disapprovals for non-Exempt or non-Expedited human subjects research.
- Review and approval of Modification applications for studies already approved.
- Reviewing and issuing determinations on Reportable New Information (RNI) reports, Adverse Events, and Unanticipated Problems, and addressing issues of non-compliance.
- Suspending research when appropriate.

- Guiding and educating research staff in research design and revision of protocol and consent forms.
- Providing other guidance, as required.

**The general skills and qualifications required for all IRB members include:**

- A commitment to the promotion of an ethical research climate at the University and the advancement of research through the ethical treatment of human research participants.
- The ability to collaborate effectively with IRB members and HRPP staff.
- The ability to interact effectively with a broad spectrum of individuals including faculty, research participants, investigators, research staff, administrators, students, and agency representatives.

Please read about the specific roles and responsibilities related to your specific IRB appointment below. Please note, you may fit into more than one IRB membership category (e.g., you may be a scientific member AND an unaffiliated member).

**Appointment Specific IRB Roles and Responsibilities:**

- [Chairs/Vice Chairs](#)
- [Scientific Member](#)
- [Nonscientific Member](#)
- [Nonaffiliated Member](#)
- [Prisoner Representative](#)
- [IRB Consultant](#)

**Chair/Vice Chair**

The IRB Chair/Vice Chair is a highly respected individual and must manage the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the research community falls primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by administration, the investigators whose research plans are brought before it, and other committees and departments.

In addition to member responsibilities listed above, the Chairs review all studies presented to the IRB committee and communicate with other reviewers as needed so that important IRB issues or concerns are resolved or identified prior to the convened IRB meeting. Chairs are empowered to administer convened IRB decisions. Chairs also direct the proceedings and discussion of convened IRB meetings and serve as a reviewer for research eligible for Expedited review, Exemption, and determinations of whether projects involve research with human subjects, as necessary.

**Responsibilities:**

- Chair the meetings to which they are assigned.
- Substitute as chair on other IRB committees.
- Serve as an alternate IRB member, as needed.
- Serve as Designated Expedited Reviewer.
- Serve as a Consultant to the HRPP on matters related to human subjects research and the IRBs.

- Facilitate and/or participate in IRB educational activities.
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research.
- Adhere to and administer determinations by the IRB.
- Represent the IRBs throughout the University and broader research community as necessary to promote the mission of the HRPP.

### Scientific Member

Scientific members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects. The IRB Scientific Member must hold a scientific degree. Scientific members must have professional training and experience in an occupation that would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline. Registered nurses, nurse practitioners, pharmacists, therapists, radiologists and other biomedical health professionals would be regarded to have primary concerns in the scientific area. Social Scientists and professionals with advanced degrees in non-biomedical disciplines are considered as a Scientific member only for research projects whose primary aim focuses on social science disciplines.

#### Responsibilities:

- Participate as a reviewer on studies to which the individual is assigned.
- Review and participate in a discussion of all studies and agenda items for each convened IRB meeting.
- When acting as primary IRB reviewer, attempt to resolve questions or concerns prior to the meeting.
- Serve as an alternate IRB member as needed.
- Provide a written review summary to the Committee Chair prior to the meeting, if assigned as a primary reviewer and unable to attend the meeting due to an Emergency.
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research.
- Participate in IRB educational activities.

### Nonscientific Member

Nonscientific members are expected to provide input on matters relevant to their individual knowledge, expertise, and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if a research project adequately protects the rights and welfare of subjects. The IRB Nonscientific Member must have experience with complex information processing and interpersonal communication. Examples of nonscientific or nonmedical occupations may include, but not be limited to, lawyers, clergy, ethicists, teachers, accountants, musicians, or business majors.

#### Responsibilities:

- Participate as a reviewer on studies to which the individual is assigned.
- Review and participate in a discussion of all applications and agenda items for each meeting.

- Serve as an alternate IRB member as needed.
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research.
- Participate in IRB educational activities.
- Contribute expertise with regulations, policies and the conduct of human subjects research.
- Represent nonscientific interests such as: how well is the research explained in order to comprehend the risk, benefit, and distributable justice (Belmont Principles).

### Nonaffiliated Member

Nonaffiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. A nonaffiliated member is also a scientific or nonscientific member and would be expected to provide input on areas relevant to his/her knowledge, expertise, and experience, professional and otherwise. The Nonaffiliated Committee Member is experienced with complex information processing, interpersonal communication, and is sensitive to unique community populations and cultures. The Nonaffiliated Member is not a current employee or student of Yale and does not have a close family member (spouse, child, parent) who is employed at Yale.

#### **Responsibilities:**

- Participate as a reviewer on studies to which the individual is assigned.
- Review and participate in a discussion of all applications and agenda items for each meeting.
- Serve as an alternate IRB member as needed.
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research.
- Participate in IRB educational activities.

### Prisoner Representative

A Prisoner Representative is an IRB member who is currently or formerly a prisoner or who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner. When research with prisoners is reviewed by the convened IRB, the prisoner representative must participate as a voting member at the IRB meeting. The prisoner representative may only count toward quorum when he or she is in attendance and reviewing studies covered by [45 CFR 46, subpart C](#).

#### **Responsibilities:**

- Review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
- Present the review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
- Review applicable research qualifying for expedited review (initial review, continuing review, or minor modifications) as a sole designated reviewer or as a secondary reviewer to concur that the research involves no greater than minimal risk or does not change the risk level.
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research.



- Participate in IRB educational activities.

### IRB Consultant

An IRB Consultant is expected to provide input on areas relevant to his/her knowledge, expertise, and experience, professional and otherwise. An IRB consultant will generally provide written feedback regarding a study within a specified timeframe prior to a convened IRB meeting, but also could be asked to assist an IRB member with the presentation of an agenda item if necessary. An IRB Consultant can be a non-IRB member or an IRB member.

### 1.3 Meeting Attendance Expectations

As an IRB member, you should attend all meetings for which you are scheduled, and you are expected to attend at least 80% of meetings annually. If you are unable to attend a scheduled meeting, you should inform a designated HRPP staff member (i.e., your full board IRB Regulatory Analyst or IRB Manager) and the IRB Chair. If your availability changes and you are no longer able to regularly attend IRB meetings or will be absent for an extended period of time, you should inform the designated HRPP staff member and IRB Chair, who will inform the IRB Manager. The Manager will assess the situation, including the availability of an alternate member when applicable, and make recommendations to the HRPP Director and IRB Chair to ensure the IRB is able to meet quorum requirements and has the necessary expertise to review the research which regularly comes before it. The performance of IRB members will be reviewed on an annual basis by the HRPP Director, the IRB Chair, and may include other designated HRPP staff. Details on member evaluations are detailed in section 1.5 below.

### 1.4 COI Disclosures

No IRB member or alternate member may participate in the review of any research project in which the member has a Conflict of Interest (COI), except to provide information as requested. It is the responsibility of each IRB member to disclose any COI related to a study submitted for review and recuse himself or herself from the deliberations and vote by leaving the room or virtual meeting space.

All members and alternate members of the IRB must complete a [conflict disclosure](#) when first appointed and annually thereafter or sooner when their circumstances change. Once completed, these forms are routed electronically to the HRPP designee, who reviews the disclosure and determines if a COI exists. To protect the privacy of members, the specific details of the conflict will only be provided to management and will not be given to staff or other members; however, the type of research where a COI exists will be provided (e.g., studies from X sponsor; studies using X device/drug; studies involving X investigator).

The IRB staff, in turn, ensures that IRB members and alternates are not assigned to conduct reviews of studies for which the member has a conflict and reminds members of conflicts at convened meetings as needed to ensure recusal. **IRB members, alternates, or consultants may be considered to have a conflicting interest requiring recusal when they, or an immediate member of their family, have any of the following:**

1. Involvement in the design, conduct, and reporting of the research.
2. Significant financial interests (See [Yale University Policy on Conflict of Interest](#) for a definition of significant financial interests) related to the research being reviewed.
3. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a study.

The IRB Chair will ask IRB members at the beginning of each convened meeting if any members have a COI regarding any of the items to be reviewed and reminds members that they must recuse themselves by leaving the room or virtual meeting space during the discussion and vote of the specific research study. If a conflicted member is participating by conference call, video conference or web meeting, the member is placed in the virtual waiting room for discussion and voting.

## 1.5 Member Evaluations

### **Chair/Vice Chair Evaluations**

The performance of the IRB Chairs and Vice Chairs will be reviewed on an annual basis by the HRPP Director and designated staff members. As part of the annual review process, the IRB Chairs/Vice Chairs may also be asked to complete a self-evaluation. The results of the annual review will be shared with the IO along with any related recommendations. Feedback will also be provided to each individual IRB Chair/Vice Chair. If the Chair/Vice Chair is not acting in accordance with the IRB's mission, following policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair/Vice Chair, they may be removed from the Yale IRB. The IO may also take other appropriate action (e.g., requiring additional training).

### **IRB Member Evaluations**

The performance of IRB members will also be reviewed on an annual basis by the HRPP Director, the IRB Chair, and may include other designated HRPP staff. As part of the annual review process, IRB members may also be asked to complete a self-evaluation. The results of the annual review will be shared with the IO along with any related recommendations. Feedback will also be provided to each IRB member, both via email and via individual "check-in" meetings with the IRB Chair(s). The purpose of the scheduled check-ins is to provide feedback and support to members and an opportunity for members to check-in with IRB Chairs. Members who are not acting in accordance with the IRB's mission, not following policies and procedures, have an undue number of absences, or are otherwise not fulfilling the responsibilities of membership, may be removed by the IO or his/her designee.

## 2. Required Training for IRB Members and Chairs/Vice Chairs

Recognizing that a vital component of a comprehensive human research protection program is an education program, Yale is committed to providing training and on-going education for IRB members related to ethical concerns and regulatory and organizational requirements for the protection of human subjects. In addition to CITI and HIPAA Privacy training, all new IRB members must complete an orientation regarding their roles and responsibilities in the review of research prior to their participation as a voting member on any of the Yale IRBs.

### 2.1 CITI & HIPAA Training Requirements for IRB Members and Chairs/Vice Chairs

#### **CITI Training Requirements:**

All IRB members must complete the online Human Research Protection (CITI) training. Instructions are provided [HERE](#). Once completed, the CITI certification is valid for three (3) years and must be maintained. Prior to CITI expiration, IRB members must complete the CITI refresher training. IRB Chairs are also asked to complete the CITI IRB Chair Course.

#### **HIPAA Training:**

All IRB members must complete Health Insurance Portability and Accountability Act (HIPAA) training, to understand the nuances and risks associated with the collection of and/or interaction with Protected Health Information (PHI). Additional information and access to training modules can be found [HERE](#).

### 2.2 New Member Orientation

#### **New IRB Member Orientation:**

As part of the onboarding process, new Yale IRB members must attend a new IRB Member Orientation. This orientation is conducted by an IRB Chair or designee and may be scheduled individually or in groups, as necessary. The training covers IRB history, IRB member responsibilities, federal regulations, etc. An IRB Chair or designee will contact IRB members to schedule the orientation session. HRPP/IRB staff will also provide a PowerPoint presentation and/or demonstration of how to navigate as a board member in the IRB electronic system, [IRES IRB](#). This presentation may be scheduled separately from the new IRB Member orientation. Members may be provided with written supplemental materials to support the learning/orientation objectives (See Appendix 7.2 below).

### 2.3 Additional Training/Education Opportunities for IRB Members

To ensure that oversight of human research is ethically grounded, and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. In addition to CITI training, HIPAA training, and orientation, the Yale HRPP also uses the following activities as a means for offering continuing education to IRB members:

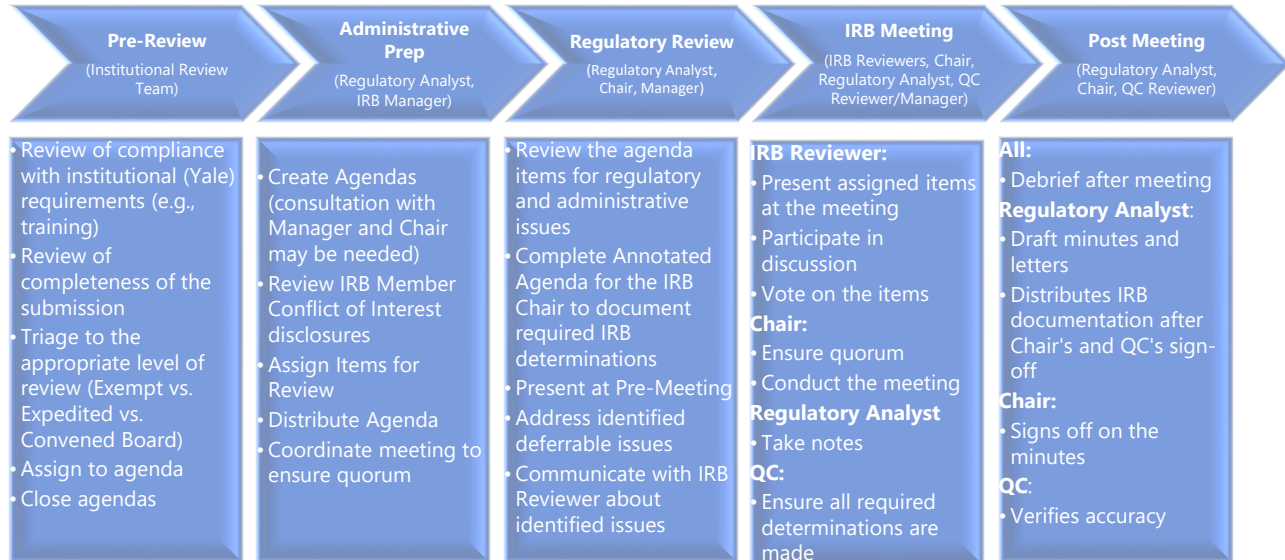
- In-service training at IRB meetings
- Training workshops

- Webinars
- Email distribution of articles, announcements, presentations, etc. relevant to human subject protections

The Director or designee determines minimum attendance requirements for continuing education and tracks participation. Fulfillment of training requirements is included as part of the evaluation of the performance of IRB members and alternate members. Ongoing failure to complete training may result in a member's service being discontinued or not renewed.

### 3. Submission review cycle

Protocol related submissions that are reviewed at a convened IRB meeting go through several review and administrative steps before they can receive final IRB determination. Different groups/reviewers are involved in each step.



All these functions follow specific schedules, which are included in [Appendix](#). The section below focuses on the tasks relevant to your role as the IRB member and Chair. Further details related to Chair's role are described in [Chapter 6](#).

#### 3.1. Agenda

You will receive an email to your Yale email address with a link to the agenda a week prior to the meeting. See [Section 4.1](#) for instructions on how to locate the items for your review. Each item on the agenda will have a **Primary Reviewer** assigned to it. As an IRB member, you are asked to review all agenda items so that you can participate in discussion on approvability of the submission. If you are assigned as a **Primary Reviewer**, you will also present that item at the meeting. See [Section 4.2](#) on how to locate the worksheets that will help guide your review and presentation.

#### 3.2. Member review

The goal of your review is to help determine whether the submission meets approval criteria or whether there are any conditions or modifications that can be made for the submission to meet the approval criteria.

Your review should include:

- Review of IRES IRB application – information provided by the investigator in the electronic pages of the system;
- Review of documents that are uploaded in the system;

- Review of the information provided by the IRB/HRPP Office – either in the History tab of the submission or in the Reviews tab of the system.

[Section 4](#) provides screenshots and instructions on how to access documents and information contained in the electronic system for different types of submissions. The section below describes documents that you may see uploaded in the submission.

### 3.2.1. Documents

The documents tab in the study submission workspace will list different types of documents:

- Protocol Related Documents: Documents that are related to the overall protocol and Yale’s role in the research;
- Site Related Documents When Yale serves as the IRB for that site: Documents that are related to the role of external sites in the research if Yale IRB serves as the IRB of record for those sites;
- Non-IRB related documents: Documents used by ancillary committees or institutional review to request review or document compliance with institutional requirements, e.g., *Request for Scanner Time at FAS Brain Imaging Center (BIC)* must be uploaded for review by the ancillary committee that reviews and approves proposals of brain MRI scans at Brain Imaging Center, which uses IRB electronic to document its approvals.

Protocol related documents and site related documents must be reviewed by the IRB. The Non-IRB related documents may provide additional information, however, they do not get approved by the IRB. The following table lists documents that will contain information relevant to the IRB review. They must be reviewed in preparation for the meeting:

Name of the Document	Page where it could be uploaded in IRES IRB	Purpose
<b>Overall protocol documents and documents related to Yale’s site</b>		
Protocol	Basic Information Page	Describes the purpose of the research, rationale of why it is important to conduct the research, describes research procedures, statistical analysis, it can be written by the investigator or provided by the sponsor of the research;
IRB Submission Form	Local Site Documents	Describes how the research will be conducted at Yale e.g., differences between the protocol and what will happen at Yale, specifies recruitment at Yale, includes requests for waivers of consent and HIPAA Authorization;
Consent Template	Study Documents	Provided by the sponsor for multi-site studies; if Yale investigator serves as the overall PI for multi-site research, consent template may be prepared as a basis for consent documents to be used at other sites; consent templates must meet regulatory requirements

		for consent but they will not include Yale specific information;
Consent Documents	Local Site Documents	Consent document prepared for use at Yale site or by Yale investigators; they must meet regulatory requirements for consent and will include Yale specific information and locally required language;
Drug Attachments	Drugs	Studies that involve administration of drugs will either include an Investigator's Brochure or FDA Package Insert with prescribing information and patient labeling (for FDA approved drugs); FDA correspondence related to the status of the drug (e.g., letter showing IND #) or the trial (Clinical Hold letters) may also be included;
Device Attachments	Device	Studies investigating safety or effectiveness of a medical device should include device manuals; FDA correspondence related to the status of the device (e.g., FDA letter if exemption from IDE requirements) or the trial (Clinical Hold letters) may also be included;
Recruitment Materials	Local Site Documents	Materials proposed for recruiting participants, may include posters, flyers, phone scripts, script for audio or video recordings, screenshots of website;
<b>Additional documents for studies where Yale serves as the IRB of record for other sites</b>		
Local Context Questionnaire	Local Site Documents, <b>Site</b> workspace	Describes how the research will be conducted at the site under purview of investigator from another institution for which Yale IRB serves as the IRB, includes information about the local (state or institutional) requirements related to the research, includes requests for waivers of consent and HIPAA Authorization;
Consent Documents	Local Site Documents, <b>Site</b> workspace	Consent documents developed for the site, should be based on the IRB approved template;
Recruitment Materials	Local Site Documents, <b>Site</b> workspace	Recruitment materials that were specifically designed to be used by the site in addition to the recruitment materials developed for the protocol;
HIPAA RAF	Local Site Documents, <b>Site</b> workspace	If a site's institution does not allow use of the HIPAA Authorization in the consent form (compound authorization) but the research collects or uses PHI, then there will be a stand-alone HIPAA Research Authorization Form developed by the site;

### 3.2.2. Questions to ask during review

The table below provides summary of the questions you need to ask during your review.

The resources column includes worksheets and checklists that are available to help you with your review. **IRB Member Review Worksheets** will help you prepare for your presentation. You may complete these

along with your comments and upload them with your comments in IRES IRB. The determination specific worksheets and checklists provide regulatory framework for certain determinations, e.g., criteria that need to be met for waivers of consent. They also provide guidance on how to approach a topic, e.g., considerations related to payments to research participants. There is no need to complete these. Regulatory analysts and the Chair may display these during the meeting to help guide discussion. For example, during the discussion on allowable research with minors, the Chair may ask that the regulatory criteria are visible on the screen.

Submission Type	Overall Goal	Questions to Ask	Resources to Guide Review
Initial Submission	To determine whether the study meets approval criteria and any additional regulatory requirements.	<ul style="list-style-type: none"> <li>• What regulatory requirements does the study need to meet: Common Rule, FDA, Subpart B (pregnant women), C (Prisoners), or D (minors), other?</li> <li>• Does the study meet the approval criteria (includes the elements of consent) and additional requirements from the Subparts or other sets of regulations?</li> <li>• Are there any ethical issues that you identified that would preclude this research from being approvable?</li> </ul>	<ul style="list-style-type: none"> <li>• IRB Member Review Worksheet_Initial</li> <li>• HRP-314 - WORKSHEET - Criteria for Approval.doc</li> <li>• Determination specific worksheets (see appendix)</li> <li>• Determination specific checklists (see appendix)</li> </ul>
Modification	To determine whether the proposed changes affect any of the approval criteria or other regulatory requirements.	<ul style="list-style-type: none"> <li>• What regulatory standards does the study need to meet?</li> <li>• The IRB previously determined that the approval criteria are met. Do any of the proposed changes specifically affect any of the approval criteria?</li> <li>• Are there any ethical issues that the proposed change introduces?</li> </ul>	<ul style="list-style-type: none"> <li>• IRB Member Review Worksheet_Modification</li> <li>• Determination specific worksheets (see appendix)</li> <li>• Determination specific checklists (see appendix)</li> </ul>
Continuing Review	To determine whether the study continues to meet the regulatory approval criteria.	<ul style="list-style-type: none"> <li>• What regulatory standards does the study need to meet?</li> <li>• The IRB previously determined that the approval criteria are met.</li> <li>• Has anything happened in the last year based on the report about the study, published literature, etc. that would affect the approval criteria?</li> </ul>	<ul style="list-style-type: none"> <li>• IRB Member Review Worksheet_Continuing Review</li> <li>• Determination specific worksheets (see appendix)</li> <li>• Determination specific checklists (see appendix)</li> </ul>
Report of New Information	To determine whether the RNI represents serious or continuing noncompliance or UPIRSO (unanticipated problem to subjects or others) and	<ul style="list-style-type: none"> <li>• Is the incident reported in the RNI noncompliance? If yes, is it serious? Is it continuing? The IRB will review specific definitions of serious/continuing noncompliance to determine whether the RNI meets them.</li> <li>• Can the incident reported in the RNI be considered an Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO)? The IRB will review the specific</li> </ul>	See definitions of UPIRSO, serious noncompliance, and continuing noncompliance in <a href="#">Appendix</a> .



	whether proposed CAPA is acceptable.	definition of a UPRISO to determine whether the incident meets the definition. <ul style="list-style-type: none"> <li>• Are there any additional requirements for the proposed Corrective and Preventative Action Plan that should be considered?</li> <li>• Does the study need to be suspended?</li> <li>• Does the consent form or protocol need to be modified with the new information?</li> </ul>	
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### 3.3. Additional Steps for Primary Reviewers

In addition to reviewing the items listed in the agenda, if you are assigned as a **Primary Reviewer**, you are asked to:

- Share your comments regarding any potential issues with the IRB Regulatory Analyst and the Chair prior to the IRB meeting (a Friday before the meeting),
- Present the review of the agenda item at the meeting ([see Presenting Agenda Items](#)).

There are two ways you can share your review notes with the Chair and the IRB staff. You can submit your review comments in IRES IRB system (see [Uploading Review Comments](#) for instructions) or email them to the IRB Regulatory Analyst listed as the IRB coordinator for the agenda item. You can also provide a completed review worksheet instead of your notes.

Your review should include proposed determinations about applicable items and the submission overall. The Chair and the analyst will discuss any deferrable issues related to the agenda items at the pre-meeting typically held two days before the meeting. Having your comments and any questions for the research team by that time is essential in ensuring any issues that can be resolved prior to the meeting are addressed.

### 3.4. IRB determinations

You will propose and later vote on two types of determinations:

- Determinations related to specific elements of the study, and
- Overall approval of the study.

Your IRB reviewer worksheet will guide you about the elements of the study that require additional considerations. They may include determinations related to:

- Research with minors (meeting approval criteria under Subpart D, parental permission and documentation of parental permission, assent from children),
- Research with prisoners (meeting approval criteria under Subpart C),
- Research with pregnant women (meeting approval criteria under Subpart B),
- Waivers of consent for all or certain aspects of the study,
- Waivers of documentation of consent for all or certain aspects of the study,
- Significant vs. non-significant device.

Refer to your worksheets and available checklists for guidance on any of the determinations. If at any point of your review, you would like help thinking through any of the determination, contact the Chair and the IRB Analyst assigned to the agenda item. They will be available to provide assistance.

A study can be approved if it meets approval criteria (see links in [Appendix](#)). If the IRB can determine what specific revisions must be made for the study to meet the approval criteria, a conditional approval can be issued. That determination is called Modifications Required to Secure Approval. That determination can also be made if the investigator confirms the IRB’s understanding or assumptions when reviewing a study, or to supply a missing document. If the approval criteria cannot be met, the study should be deferred. See the table below for the description of the determinations:

<b>Does the study meet approval criteria?</b>		
<b>Yes.</b> All criteria are met in the protocol as submitted.	<b>Yes,</b> the study <b>will</b> meet the approval criteria <b>if</b> the investigator confirms some of the IRB’s assumptions or makes specific changes to the protocol.	<b>No,</b> the IRB does not have sufficient information to determine if approval criteria are met OR the protocol clearly does not meet the criteria and there is no specific direction that the IRB can give the investigator to make it approvable.
<b>Approval</b>	<b>Modifications Required to Secure Approval</b>	<b>Deferral</b>
Regulatory Analyst prepares the approval documents.	Regulatory Analyst sends the documents and reviews the response from the PI.	The response from the PI is reviewed by the board.

## 4. Review of agenda items for the meeting in IRES IRB

### 4.1 Locating the agenda items

You can locate the agenda document in the email sent to your Yale email address a week prior to the meeting. Alternatively, you can log into [IRES IRB system](#) and navigate to the meeting space:

- Click on **IRB** tab (see #1 in the screenshot below),
- Click on **Meetings** (#2),
- Select the next IRB meeting in the **Upcoming Meetings** tab (#3). If you are a member of multiple IRB panels, you will be able to access meetings for all of the panels in this space.

Meeting details from the screenshot:

Name	State	Location	Time	Committee	Agenda Items
IRB 3A - 10/19/2022	Scheduled	https://yale.zoom.us/j/98991874662	10/19/2022 3:00 PM	Human Investigation Committee 3A	5
IRB 3A - 11/16/2022	Scheduled	https://yale.zoom.us/j/98991874662	11/16/2022 3:00 PM	Human Investigation Committee 3A	
IRB 3A - 12/21/2022	Scheduled	https://yale.zoom.us/j/98991874662	12/21/2022 3:00 PM	Human Investigation Committee 3A	

The WORD version of the agenda is available in the top space (#1). For the list of all the agenda items, look under the **Agenda Items** tab. The number in the top right corner (#2) indicates the total number of the items for review at the meeting. Only 10 items are displayed at a time. You can navigate to the remaining items in the next page by clicking a forward arrow at the bottom of the Agenda Items tab (#3). The Primary and Secondary Reviewer (if assigned) are listed in the **Reviewers/Presenters** column (#4). Click on the Name of the submission to open up the submission workspace and begin your review.

Legend:

- I - Initial submission
- M - Modification
- C - Continuing Review
- CM - Continuing Review with Modification
- R- RN1
- S - Site submission

Meeting details from the screenshot:

Meeting Date & Time: 10/19/2022 3:00 PM  
 Location: https://yale.zoom.us/j/98991874662  
 Items on Agenda: 5

Agenda Item #	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	RES Sponsor	Funding Sponsor - Manual
I01	2000032623	Repeated Psilocybin Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kelmend	Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
M01	MOD00051226	Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marla Boeke		Ethaskar	Roy	Test 19 Informed (Primary Reviewer)		
C01	CR00011356	Continuing Review for Study PreVent 2	Committee Review	Marla Boeke		Miriam	Treggiani	Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NINDS/DHHS Duke University Medical Center	
R01	RNI00002578	Cannabidiol Pharmacotherapy for Comorbid Addiction: Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	Test 19 Informed (Primary Reviewer)		
S01	SITE00000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	Monika Lau (Primary Reviewer)		

## 4.2 Accessing worksheets and checklists to guide review

Worksheets that will help guide your review and presentation are available in the **Member Worksheets** tab in the IRES IRB Library. They are focused on type of submission: Initial, Continuing Review, or Modification.

The screenshot shows the IRES IRB Library interface. At the top, there are navigation tabs: Dashboard, Library (selected), and IRB. Below the navigation, there is a sidebar with 'Library' and 'IRB Home'. The main content area is titled 'Library' and contains a sub-section 'Worksheets'. This section has a list of worksheets with columns for 'Name' and 'Description'. A green arrow points to the 'Library' tab, and another green arrow points to the 'Member Worksheets' section, which is highlighted with a green box. The 'Member Worksheets' section lists three items: 'IRB Member Review Worksheet\_Continuing Review\_1-21-2019.docx', 'IRB Member Review Worksheet\_Initial\_1-21-2019.docx', and 'IRB Member Review Worksheet\_Modification\_1-21-19.docx'. The page shows 22 items in the main 'Worksheets' section and 3 items in the 'Member Worksheets' section.

Worksheets and checklists that can help guide your study specific determinations and provide regulatory framework and guidance of how to think about different aspects of the study are available in the top part of the **Checklists and Worksheets** tabs.

Checklists are used by IRB reviewers conducting expedited review. They document the IRB required determinations. Determinations made at convened meeting are documented in the minutes. While checklists are not completed for convened board, they can help guide you.

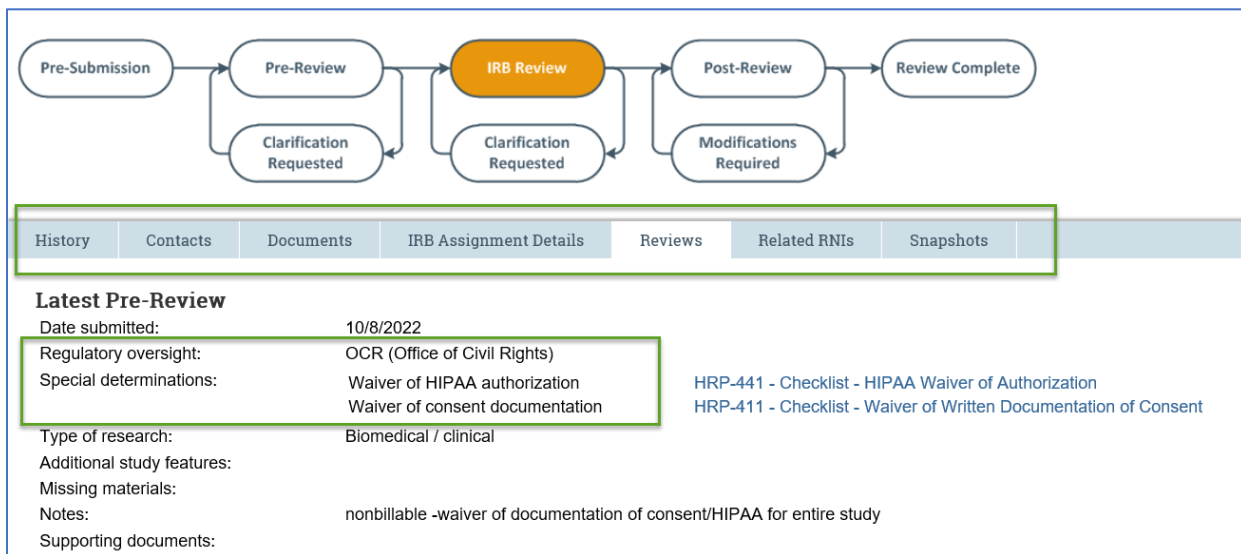
The screenshot shows the IRES IRB Library interface with the 'Checklists' section selected. The navigation tabs at the top are Dashboard, Library, and IRB. The 'Checklists' tab is highlighted with a green box and a green arrow. Below the navigation, there is a sidebar with 'Library' and 'IRB Home'. The main content area is titled 'Checklists' and contains a list of checklists with columns for 'Name' and 'Description'. The list includes items such as 'HRP-410 - CHECKLIST - Waiver or Alteration of the Consent Process.doc', 'HRP-411 - CHECKLIST - Waiver of Written Documentation of the Consent Process.doc', and 'HRP-419 - CHECKLIST - Waiver of the Consent Process for Emergency Research.doc'. The page shows 11 items in the 'Checklists' section.

### 4.3 Accessing Documents for Review of Initial Submissions

Initial Reviews are indicated by letter **I** in the submission ID. Click on the name of the submission to open the study workspace.

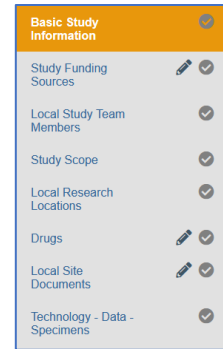
Agenda Item #	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	IRES Sponsor	Funding Sponsor - Manual
I01	2000032623	Repeated Psilocybin Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kelmendi	• Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
M01	MOD00051226	Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marta Boeke		Bhaskar	Roy	• Test 19 Infoed (Primary Reviewer)		
C01	CR00011356	Continuing Review for Study PreVent 2	Committee Review	Marta Boeke		Miriam	Treggiani	• Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NIH/DHHS Duke University Medical Center	
R01	RNI00002578	Cannabidiol Pharmacotherapy for Comorbid Addiction: Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	• Test 19 Infoed (Primary Reviewer)		
S01	SITE00000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	• Monika Lau (Primary Reviewer)		











You can review the tab underneath diagram with the study submission cycle for some quick, read-only, information about the study e.g., list of the study team members. The **History** tab will show all actions on that submission, including any comments added by the investigators or research staff. At times, the investigator may attach an additional document to the comment for the IRB review (e.g., a missing letter of support from the recruitment site). The **Reviews** tab will provide you with important information about the regulatory oversight (e.g., whether the study is regulated by FDA) and special determinations that made need to be made for the research (e.g., waiver of consent).



To access the information entered by the investigator in the electronic pages, click on **Review Study** or **Printer Version** button under Next Steps. The **Printer Version** mode allows you to view the study information on one screen. You will need to scroll down through the page. The **Review Study** option

will include a menu of all of the pages in the study electronic record. If any changes were made to any of the screens during the administrative review phase (conducted by the HRPP and IRB staff) or if the submission was deferred and is now returning for additional review, the menu will indicate which pages were modified since the last review. See the pencil icon next to the page.



Basic Study Information	
Study Funding Sources	 
Local Study Team Members	
Study Scope	
Local Research Locations	
Drugs	 
Local Site Documents	 
Technology - Data - Specimens	

## **Basic Study Information**

This page will include the following information:

- **Title:** The official title of the protocol, which will appear in the correspondence from the IRB; it should match the protocol document;
- **Short title:** Investigators can assign a shorter title to the record (e.g., the sponsor protocol #, an acronym, etc.), the title will appear in the system but not in the correspondence from the IRB;
- **Brief Description:** Investigators will type a brief description of what the protocol is about;
- **Type of a study:** Investigators can select from single site or multi-site/cooperative research; if the study involves more than one site, Yale's role will be indicated (e.g., coordinating center);
- **For multi-site research, whether Yale will serve as the IRB of record for other sites:** If the investigator indicates that Yale will also serve as the IRB for other sites, IRB will review the protocol and consent templates along with Yale's role first, and review site specific information during a subsequent submission;
- **Name of the PI:** Only one Yale investigator can be named as the Principal Investigator, for multi-site studies, names of the overall PIs may also be provided but it will not be a required field;
- **Indication of financial interest:** Investigators are asked to self-identify if they have any financial interests related to the research; that information is verified by the HRPP staff and if there is a significant financial interest identified, you will be provided with that information by the Regulatory Analyst and the Chair;
- **Information on whether the study meets definition of a clinical trial:** If the study prospectively assigns research participants to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes, the study is likely to meet the NIH definition of a clinical trial; if so, Yale HRPP will work with investigator to ensure they are aware of their registration and reporting requirements and all members of the research team will need to complete GCP training;
- **Protocol:** A study protocol (either authored by Yale investigator or external sponsor) will be uploaded;

## **Study Funding Sources**

This page will include the following information:

- **External Funding:** If the study receives external support (e.g., grant or contract), the name of the grant/contract and the name of the sponsor will be provided, most of the time the funding details

are pulled directly from the Office of Sponsored Projects database using IRES #, which is the number of the funding record;

- **Internal Funding:** If there is no external funding directly supporting the study, investigators may indicate funding from sources internal to Yale e.g., Departmental funding or departmental fellowships or awards;

### **Study Team Members**

This page will include list of investigators and staff engaged in the conduct of the study. Investigators are asked to assign roles to study team members and indicate whether they have any financial interest related to the study and whether they can obtain consent from participants.

**Note:** It is possible that not all members of the research team will be listed in the page. The required staff include investigators, research team members with financial interests, and research team members that require unaffiliated investigator agreements. Study coordinators and other members of the research team do not need to be listed. The IRB can require addition of other staff members to be added e.g., if it is decided that the research team is lacking an expert in a specific field, etc.

### **Study Scope**

This page will include the following information:

- **Indication whether the study is a clinical investigation of a drug or biologic:** Any time a drug or a biologic is administered as part of the research protocol, the FDA regulatory requirements will apply; additional page will be added that will include information on the name of the drug, drug related attachments, and indication of the applicability of the IND regulations (study conducted under IND vs. exemption from IND requirements);
- **Indication whether the study is a device investigation:** If the study investigates safety or effectiveness of a medical device, the FDA regulatory requirements will apply; additional page will be added that will include information on the name of the device, device related attachments, and indication of the applicability of the IDE regulations (study conducted under IDE, abbreviated IDE for nonsignificant devices, or exemption from IDE requirements);
- **Type of research:** The study will be classified as biomedical or social-behavioral; for biomedical research, additional questions are added related to use of controlled substances and human embryonic stem-cells;
- **Study Type:** Investigator will identify study as interventional, observational, or expanded access;
- **Indication whether the study is considered investigator initiated:** Investigators will self-identify whether the study was authored by them or whether an external sponsor authored the protocol;
- **Phase of the Study:** Investigators will select from a list of phases consistent with the clinicaltrials.gov registration;
- **Indication whether the study involves genetic or genomic testing**

- **Indication on use/creation of a data or specimen repository:** Investigators will indicate whether the study uses or donates specimen or data from/to repositories, if so, the repository will be identified;

### **Local Research Locations**

This page will include list of locations where research activities will occur under the purview of the Yale Principal Investigator. If the research involves multiple sites with local investigators overseeing research activities there, they will NOT be listed in the Local Research Locations page. Sites under purview of local investigators will live in their own space, listed under SITES tab (see section on review of [Site information](#)).

### **Local Site Documents**

Consent forms, local recruitment materials, and other Yale specific forms will be listed here. All of the templates created by an external sponsor or templates created by Yale investigator for multi-site research will live in Study Documents.

### **Technology - Data - Specimens**

This page will include the following information:

- **Identification of where the study will be conducted:** Investigators will indicate whether the research will be conducted at Yale or outside locations, and further, what countries and/or US states the participants are specifically recruited from;
- **Identification of what technology will be used for collection or storage of research data:** Investigators select the types of technologies that will be used in research e.g., electronic medical records, Wearable devices;
- **Classification of data risk:** Investigators identify the risk classification for data that will be collected for the research; [Yale policy classifies data risk into three levels](#) and dictates minimum security standards for systems used to handle the data and available services for data storage or collection;
- **Identification of countries, states, and organizations where data or biospecimen will be transferred from or to:** Investigators indicate names of organizations and geographic locations where the research data or specimens will be sent from or to as part of the research protocol.

Use the [Member Worksheet: Initial](#) to help you organize your review. Once you complete your review, you can [add your review comments](#) and upload any supporting documents for the IRB review.



#### 4.4 Accessing Documents for Review of Addition of Sites

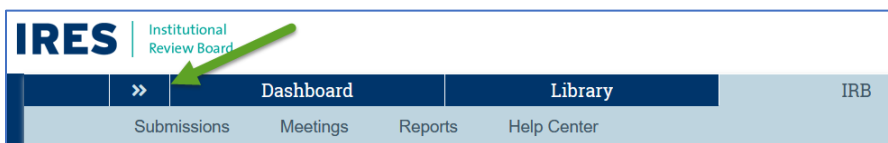
For multi-site research where Yale serves as the IRB of Record for other sites, in addition to Yale, the site-specific information is not reviewed until after the main study is approved. Site-specific information requires a subsequent submission. Protocol and Yale documents live in the main study workspace, while site documents (e.g., consent forms used by that site) live in the Site workspace.

Initial Site Reviews are indicated by letter **S** in the submission ID. Click on the name of the submission to open the study workspace.

Agenda Item #	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	IRES Sponsor	Funding Sponsor - Manual
I01	2000032623	Repeated Psilocybin Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kelmendi	Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
M01	MOD00051226	Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marta Boeke		Bhaskar	Roy	• Test 19 Infoed (Primary Reviewer)		
C01	CR00011356	Continuing Review for Study PreVent 2	Committee Review	Marta Boeke		Miriam	Treggiari	Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NIH/DHHS Duke University Medical Center	
R01	RNI00002578	Cannabidiol Pharmacotherapy for Comorbid Addiction: Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	• Test 19 Infoed (Primary Reviewer)		
S01	SITE00000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	• Monika Lau (Primary Reviewer)		

You can review the tab underneath diagram with the study submission cycle for some quick, read-only, information about the study, e.g., study-related and site-specific documents. The **History** tab will show all actions on that submission, including any comments added by the investigators or research staff. At times, the Yale investigator may attach, on behalf of the local site investigator, an additional document to the comment for the IRB review (e.g., a missing letter of support from the recruitment site).

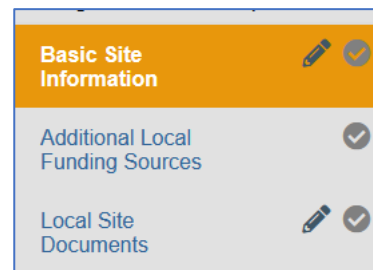
If you wish to view the regulatory oversight (e.g., whether the study is regulated by FDA) and special determinations that were made on the protocol during the initial review of the research (e.g., waiver of consent), go back to the main study workspace by clicking on the double arrow icon on top of the screen. A link will appear that will take you back to the study workspace.



To return to the site space, you can go back to the Meeting space and select the submission OR you can click on Sites tab in the protocol space and select the name of the site that is under review.

History	Funding	Contacts	Documents	Sites	Follow-on Submissions	Reviews	Snapshots
Filter by <span>⊕</span> ID <span>▼</span> <input type="text" value="Enter text to search for"/> <span>🔍</span> <span>+ Add Filter</span> <span>✕ Clear All</span>							
ID	Name	SmartForm	Institution	Principal Investigator	State	FWA Number	
SITE00000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository		Phoenix Children's Hospital	Michael Krueer	Committee Review	FWA00003458	

To access the information entered by the investigator in the electronic pages, click on **Review Site** or **Printer Version** button under Next Steps. The **Printer Version** mode allows you to view the study information on one screen. You will need to scroll down through the page. The **Review Study** option will include a menu of all of the pages in the study electronic record. If any changes were made to any of the screens during the administrative review phase (conducted by the HRPP and IRB staff) or if the submission was deferred and is now returning for additional review, the menu will indicate which pages were modified since the last review. See the pencil icon next to the page.



### **Basic Site Information**

This page will include the following information:

- **Short Title:** The main study title also applies to the study, however, investigator may assign an abbreviated name for the study at the site; it will only appear in the system and will NOT appear in any IRB correspondences;
- **Local Principal Investigator:** Name of the local/site PI will appear; most often the local PI will not have access to the system and all communications are coordinated by the Yale study team;
- Indication of the investigator’s financial interest: Investigators are asked to self-identify if they have any financial interests related to the research; that information is verified by the HRPP staff and if there is a significant financial interest identified, you will be provided with that information by the Regulatory Analyst and the Chair;
- **Brief description of the activities performed by the site:** If the research is implemented by the site as written in the IRB approved protocol, the investigator may simply indicate ‘ALL’ in this field; if the site’s engagement is limited to only certain activities described in the protocol (e.g., data analysis only), then this field would include the description of these activities;

### **Additional Local Funding Sources**

This page will include information about additional funding sources that the site may use to support the research e.g., internal grants.

### **Local Site Documents**

Consent forms, local recruitment materials, and other site-specific forms will be attached here. Consent templates should be based on the templates approved by the Yale IRB. Local Context Questionnaire will

also be uploaded here. Refer to the local context to understand how the approved study is operationalized at the site and what additional state or local requirements apply to the research.

The overall study has already been approved by the IRB so you do not need to repeat determinations or findings that were made by the IRB for the study. If you wish to see the minutes documenting these findings, let the Regulatory Analyst know. Once you complete your review, you can [add your review comments](#) and upload any supporting documents for the IRB review.

## 4.5 Accessing Documents for Review of Modifications

Modifications are indicated by **MOD** letters in the submission **ID**. Click on the name of the submission to open the modification workspace.

**Human Investigation Committee 3A**  
 Meeting Date & Time: 10/19/2022 3:00 PM  
 Location: https://yale.zoom.us/j/68991874662  
 Items on Agenda: 5

**Agenda Items**

Agenda Item	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	IREs Sponsor	Funding Sponsor - Manual
	I01	2005001523 Repeated Paliperidone Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kalmendi	• Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
	M01	MOD0051226 Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marta Boeke		Bhaskar	Roy	• Test 19 Infoed (Primary Reviewer)		
	C01	CR00011356 Continuing Review for Study PreVent 2	Committee Review	Marta Boeke		Miriam	Treggiari	• Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NHLBI/NIH/NIHES Duke University Medical Center	
	R01	RNI00002578 Cannabidiol Pharmacotherapy for Comorbid Addiction: Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	• Test 19 Infoed (Primary Reviewer)		
	S01	SITE00000003 Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	• Monika Lau (Primary Reviewer)		

You can review the tab underneath diagram with the study submission cycle for some quick, read-only, information about the study e.g., list of the study team members. The **Reviews** tab will provide you with important information about the regulatory oversight (e.g., whether the study is regulated by FDA) and what special determinations apply to the research (e.g., waiver of consent).

**Study Submission Cycle:**

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[IRB Review]
      C --> D[Post-Review]
      D --> E[Review Complete]
      B --> B1[Clarification Requested]
      B1 --> B
      C --> C1[Clarification Requested]
      C1 --> C
      D --> D1[Modifications Required]
      D1 --> D
  
```

**Navigation Tabs:** History | Contacts | Documents | IRB Assignment Details | **Reviews** | Related RNIs | Snapshots

**Latest Pre-Review**

Date submitted: 10/8/2022

Regulatory oversight: OCR (Office of Civil Rights)

Special determinations: Waiver of HIPAA authorization  
 Waiver of consent documentation

Type of research: Biomedical / clinical

Additional study features:

Missing materials:

Notes: nonbillable -waiver of documentation of consent/HIPAA for entire study

Supporting documents:

[HRP-441 - Checklist - HIPAA Waiver of Authorization](#)  
[HRP-411 - Checklist - Waiver of Written Documentation of Consent](#)

To quickly identify documents that were revised for the purposes of the modification, click on **Documents** tab. You will see a column **'Updated in Modification'**. Documents with word NO have not been changed. Documents with word YES have been modified. To review the proposed document, open the version listed in **Draft** column. To review previously approved version of that document, open the version listed in **Final** column.

Study ID: 2000027420

Document submitted for purposes of this submission

Previously approved version

Study Related Documents		Updated in Modification	Category	Final	Last Finalized	Document History
Draft	Updated protocol	Yes	IRB Protocol	Updated protocol	9/2/2021 8:36 AM	History

Site Related Documents		Updated in Modification	Category	Final	Last Finalized	Document History
Muscle Biopsy	Repository_SubmissionForm_23May2022.docx	Yes	IRB Submission Form	Muscle Biopsy Repository_SubmissionForm_5May2021 (3) (2).docx	9/2/2021 8:36 AM	History
Muscle Biopsy ICF_research only.docx		Yes	Consent Form			History
Recruitment material for JDAT		No	Recruitment Materials	Recruitment material for JDAT	9/2/2021 8:36 AM	History

Under **Next Steps**, click **Review Modification/CR** or **Printer Version** button. The **Printer Version** mode allows you to view the study information on one screen. You will need to scroll down through the page. The **Review Modification/CR** option will include a menu of all of the pages in the study electronic record and will indicate which pages were modified for the modification. This guide includes screenshots in **Review Modification/CR** mode.

You can scroll through all screens or click directly on the screen with a pencil next to it to view the page where changes were made.

**Modification Summary**

Modification Details

- IRB00109147
- Basic Study Information
- Study Funding Sources
- Study Scope
- Local Research Locations
- Local Site Documents

**Modification Summary** screen includes information entered by the member of the research team regarding the requested changes. **Notification of subjects** question provides investigator's assessment whether requested changes require notification of participants. If so, the investigator would be expected to describe a plan in question #3. The IRB can approve the plan, require changes, or require that a plan be put in place if the requested changes constitute a significant new finding that needs to be communicated to the participants.

**Question # 3** will include a summary of the changes along with the rationale for the change and investigator's assessment of the impact on subject safety.

## Modification Information

### 1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

### 2. \* Notification of subjects: (check all that apply)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes
- No re-consent/notification needed

 Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

### 3. \* Summarize the modifications, provide rationale for the changes, address impact on subject safety, and explain where in the study record the changes have occurred (including sections of the documents that are modified).

**Note: insufficient information may lead to rejection of the modification request.**

We have revised the protocol to reflect that we will also recruit subjects to undergo a muscle biopsy for research purposes only. The protocol has been revised with tracked changes to reflect this, and also to further offer rationale and explanation of the purpose of the study.


We have added a new ICF for those subjects who agree to undergo a muscle biopsy for research purposes only.

We have updated the HIC Submission Form to indicate that some subjects will undergo a muscle biopsy for research purposes only.


We have added Greenwich Hospital as a location for recruitment.

Pages with a pencil icon in the menu indicate screens where changes were made. You will see an explanation of what was revised under the specific question on that screen. If revised documents were uploaded, you can view the old version of the document (beware that previously made changes may show as track changes), the revised version, or you can create a version that compares and indicates changes between the previously approved document and the revised one.

9. \* Attach the protocol:

Document	Category	Date Modified	Document History
<a href="#">View</a>  Updated protocol(4.01)	IRB Protocol	5/18/2022	<a href="#">History</a>

▼ Differences

 **Joan Nye** • modified 5 months ago • version 3.1 (MOD00051246: Modification submitted to IRB)

▼ Changed: Updated protocol


Property: Updated protocol.Draft.targetURL

New Value: [View](#)

Old Value: [View](#)

[Compare](#)

Property: Updated protocol.Draft.version

New Value: 4 

Old Value: 4

Use the [Member Worksheet: Modification](#) to help you organize your review. Once you complete your review, you can [add your review comments](#) and upload any supporting documents for the IRB review.

## 4.6 Review of Continuing Reviews and MODCRs

Continuing Reviews are indicated by **CR** letters in the submission **ID**, Continuing Reviews with Modifications show as **MODCR**. Click on the name of the submission to open the modification workspace.

### Human Investigation Committee 3A

Meeting Date & Time: 10/19/2022 3:00 PM Location: <https://yale.zoom.us/j/90991874662>

Agenda: [Agenda for IRB 3A - 10\\_19\\_2022.doc\(0.01\)](#) ... Items on Agenda: 5

Draft Minutes:

Agenda Items | Expedited Submissions | Attendees | History


**Agenda Items**

Filter by Agenda Item #  + Add Filter X Clear All

Agenda Item #	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	IRES Sponsor	Funding Sponsor - Manual
I01	2000032623	Repeated Psilocybin Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kelmendi	• Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
M01	MOD00051226	Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marla Boeke		Bhaskar	Roy	• Test 19 Infoed (Primary Reviewer)		
C01	CR00011356	Continuing Review for Study PreVent 2	Committee Review	Marla Boeke		Miriam	Treggiari	• Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NIH/DHHS Duke University Medical Center	
R01	RNI00002578	Cannabidiol Pharmacotherapy for Comorbid Addiction: Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	• Test 19 Infoed (Primary Reviewer)		
S01	SITE000000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	• Monika Lau (Primary Reviewer)		

5 items page 1 of 1

You can review the tab underneath diagram with the study submission cycle for some quick, read-only, information about the study e.g., list of the study team members. The **Reviews** tab will provide you with important information about the regulatory oversight (e.g., whether the study is regulated by FDA) and what special determinations apply to the research (e.g., waiver of consent). Look at **History** tab to see any documents that the investigator might have uploaded as a comment to the IRB after the request for review has been submitted.



History | Contacts | Documents | IRB Assignment Details | Reviews | Related RNIs | Snapshots

**Latest Pre-Review**

Date submitted:	10/8/2022	
Regulatory oversight:	OCR (Office of Civil Rights)	
Special determinations:	Waiver of HIPAA authorization Waiver of consent documentation	<a href="#">HRP-441 - Checklist - HIPAA Waiver of Authorization</a> <a href="#">HRP-411 - Checklist - Waiver of Written Documentation of Consent</a>
Type of research:	Biomedical / clinical	
Additional study features:		
Missing materials:		
Notes:	nonbillable -waiver of documentation of consent/HIPAA for entire study	
Supporting documents:		

Under **Next Steps**, click **Review Modification/CR** or **Printer Version** button. The **Printer Version** mode allows you to view the continuing review information on one screen. You will need to scroll down through

the page. The **Review Modification/CR** option will include a menu of all of the pages. If modification is part of the CR submission, the menu will indicate which pages were modified as part of the modification. This guide includes screenshots in **Review Modification/CR** mode.

Review the Continuing Review page for number of subjects enrolled, the overall status of the study, and if applicable, a summary of the events that occurred since the last review.

**Continuing Review / Study Closure Information**

- \* Specify enrollment totals at this investigator's sites:** 20
- \* Specify enrollment totals at this investigator's sites since last approval:** 5
- \* Specify enrollment totals study-wide:** 40
- Research milestones: (select all that apply)**
  - Study is permanently closed to enrollment OR was never open for enrollment
  - All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
  - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
  - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
  - Remaining study activities are limited to data analysis
  - Study remains active only for long-term follow-up of subjects

**Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
- \* Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

Yes  No
- Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)
  - NO subjects experienced unexpected harm
  - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
  - NO subjects withdrew from the study
  - NO unanticipated problems involving risks to subjects or others
  - NO complaints about the study
  - NO publications in the literature relevant to risks or potential benefits
  - NO interim findings
  - NO multi-center trial reports
  - NO data safety monitoring reports
  - NO regulatory actions that could affect safety and risk assessments
  - NO other relevant information regarding this study, especially information about risks
  - In the opinion of the PI, the risks and potential benefits are unchanged
  - All modifications to the protocol have been submitted to the IRB
  - All problems that require prompt reporting to the IRB have been submitted
- Attach supporting documents:** (include an explanation of each item left unchecked above)

Name  
There are no items to display

**Callout 1:** If none of the items are checked off, you can assume the study is active and open to enrollment.

**Callout 2:** If items remain unchecked, the HRPP will request an explanation from the investigator. Attachments should be uploaded in question # 7.

Continuing Review with Modifications will allow you to see all of the pages of the research. If you wish to access the record of the approved research, click on the double arrow in the top left corner. From there you will be able to click on the name of the study to move to the approved study page. To return to the CR workspace, click on Follow-on Submission tab and select the name of the submission you were reviewing. See the second screenshot below.



**IRE** Institutional Review Board

Dashboard Library IRB

IRB > PreVent 2 > Continuing Review for Study PreVent 2

**Committee Review** CR00011356: Continuing Review for Study PreVent 2

Entered IRB: 10/8/2022 10:45 AM  
Last updated: 10/8/2022 10:55 AM

Principal investigator: Miriam Treggiari  
Submission type: Continuing Review/Closure  
Primary contact: Michael Kampp

IRB office: Yale IRB  
IRB coordinator: Marta Boeke  
Regulatory authority: Pre-2018 Requirements

**Next Steps**

Review Modification/CR  
Printer Version

Request Clarification by Committee Member

Study ID: 2000027877

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[IRB Review]
      C --> D[Post-Review]
      D --> E[Review Complete]
      B --> B1[Clarification Requested]
      C --> C1[Clarification Requested]
      D --> D1[Modifications Required]
  
```

**Lapsed** 2000027877: PreVent 2

Entered IRB: 4/13/2020 3:43 PM  
Initial approval: 8/31/2020  
Initial effective: 8/31/2020  
Effective: 5/27/2022  
Approval end: 6/29/2022  
Last updated: 6/30/2022 1:00 AM

Principal investigator: Miriam Treggiari  
Submission type: Initial Study  
Primary contact: Michael Kampp  
PI proxies: Michael Kampp, Laura Bankowski

Clinical Trials Registration Number: NCT03705286  
IRB office: Yale IRB  
IRB coordinator: Theresa Katz  
Letter: Correspondence\_for\_2000027877.docx(0.06) ...  
Regulatory authority: Pre-2018 Requirements

**Next Steps**

View Study  
Printer Version  
Report New Information

Add Comment  
Add Private Comment

History Pending Contacts Documents **Follow-on Submissions** Reviews Snapshots

Filter by ID Enter text to search for Add Filter X Clear All

ID	Name	Date Modified	Owner	State	IRB Coordinator
CR00011356	Continuing Review for Study PreVent 2	10/8/2022 10:55 AM	Boeke, Marta	Committee Review	Marta Boeke
MOD00051307	Modification / Update #11 for Study PreVent 2	5/27/2022 11:44 AM	Reese, Jennifer	Approved	Jennifer Reese
MOD00050650	Modification / Update #10 for Study PreVent 2	4/27/2022 8:53 AM	Ciravolo, Pilar M	Approved	Pilar Ciravolo
MOD00049812	Modification / Update #9 for Study PreVent 2	4/26/2022 3:08 PM	Ciravolo, Pilar M	Approved	Pilar Ciravolo

#### 4.7 Review of CRs and MODCRs for Multi-Site Research where Yale serves as the sIRB

This is supplemental information to what is included in the section above. Continuing Review (CR) is approved for the entire study, inclusive of all participating sites. There will be only one IRB approval letter for the study.

There are two steps to review of the continuing review report:

- Verification of the site continuing review report; and
- Review the overall study continuing review report.

#### Verification of CR site information

In the CR workspace for the study, click on Sites tab. Verify that all sites reported the information. Yale PI is expected to review that information and discuss any inconsistencies with the site investigators. If the **Report Completed** column does not show checkboxes, ask for clarifications from the Yale PI. Make sure to open any uploaded documents and review any listed Potential Concerns.

Execute Activity	Institution	Report Date	Total Enrollment	Enrollment Since Last Approval	Potential Concerns	Documents	Report Completed?
	UCONN Health Center	9/12/2022	15	15	None	None	<input checked="" type="checkbox"/> yes

1 items      page 1 of 1      10 / page

## Reviewing continuing review report for the study

The study continuing review report page should include information about the study inclusive of all sites.

- **Questions #1 and #2** apply only to Yale sites,

3. \* Specify enrollment totals study-wide:

(Confirmed sites: 0 of 1. Total enrollment for pSites with completed reports: 0)

4. Research milestones: (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

**Important!** If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

- **Questions #3 and #4** apply to the overall study e.g., do not report that the study is closed to enrollment if there are sites that are still enrolling participants,

5. \* Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?

Yes  No [Clear](#)

6. Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

- **Questions #5, #6, and #7** apply to all sites, e.g., if a statement is untrue for any of the sites under Yale IRB purview, the statement must remain unchecked.

1. \* Specify enrollment totals at this investigator's sites:

2. \* Specify enrollment totals at this investigator's sites since last approval:

## 4.8 Review of RNIs

Reports of New Information are indicated by letter **R** in the submission **ID**. The person whose name appears in the columns **PI First Name** and **PI Last Name** is not the PI of the study but the submitter of the report.

Click on the name of the submission to open the submission workspace.

Agenda Item #	ID	Name	State	Coordinator	Record Decision	PI First Name	PI Last Name	Reviewers/Presenters	IRES Sponsor	Funding Sponsor - Manual
I01	2000032623	Repeated Psilocybin Dosing in OCD	Committee Review	William Westbrook		Benjamin	Kelmendi	• Madelon Baranoski (Primary Reviewer)	The Steven & Alexandra Cohen Foundation, Inc.	
M01	MOD00051226	Modification / Update #5 for Study Muscle biopsy repository	Committee Review	Marta Boeke		Bhaskar	Roy	• Test 19 Infoed (Primary Reviewer)		
C01	CR00011356	Continuing Review for Study PreVent 2	Committee Review	Marta Boeke		Miriam	Treggiani	• Madelon Baranoski (Primary Reviewer)	National Heart, Lung, and Blood Institute/NIH/DHHS Duke University Medical Center	
R01	RNI00002578	Cannabidiol Pharmacotherapy for Comorbid Addiction. Subject stopped due to leg pain	Committee Review	Alan Teller		Stacy	Minnix	• Test 19 Infoed (Primary Reviewer)		
S01	SITE00000003	Phoenix Children's Hospital Participating Site for The Yale School of Medicine Pediatric Critical Illness Patient Registry and Biorepository	Committee Review	Monika Lau		Michael	Kruer	• Monika Lau (Primary Reviewer)		

You can review the tab underneath diagram with the submission cycle for some quick, read-only, information about the study e.g., documents uploaded with this RNI. The **History** tab will show all actions on that submission, including any comments added by the investigators or research staff. At times, the submitter may attach an additional document to the comment for the IRB review (e.g., a revised CAPA plan). **Related Submissions** tab will list all of the studies that this RNI applies to. For example, if the report is about an FDA black box warning related to a specific drug, multiple studies using that drug may be listed in **Related Submissions** tab.

To access the information entered by the investigator in the electronic pages, click on **Review RNI** or **Printer Version** button under Next Steps. All of the RNI information entered by the submitter will appear in one screen. It will include the following information:

- **RNI short title:** Investigator can assign a short title for the event being reported to the IRB;
- **Date of when the investigator became aware of the event**
- **Category of the event:** Investigator will select a category of the event e.g., Breach of Confidentiality, Participant Complaint; it is possible that the event fits into more than one categories; if there none of the categories seem to fit, an investigator may select 'Other';
- **Brief description of the information:** Investigator will type a description of the event being reported;
- **Indication whether the information requires changes to the study:** Investigator will identify whether the protocol or the consent form should be modified (if so, look for the pending modification submission, they may often be submitted together along with the RNI), and whether the event indicates a new or increased risk or a safety issue; this is only investigator's opinion, the IRB can disagree and require changes;

- **List of related studies and any pending submissions:** Any pending submissions of modifications or the studies affected by this report will be listed here; the RNI will appear in the history of submissions for all of the relevant studies;
- **List of documents:** Investigator may attach documents such as CAPA plan, a report from the monitor or a sponsor, etc.

Once you complete your review, you can [add your review comments](#) and upload any supporting documents for the IRB review.

## 4.9 Uploading review comments

Any IRB member can add review comments in IRES IRB for the Committee discussion. It is an expectation that the Primary Reviewer's comments will be submitted by Friday prior to the IRB meeting. Review comments are not visible to the study team, only to the IRB members and IRB staff.

- From the submission workspace (click on the name of the Submission in the Meeting space to open the submission workspace), click on **Add Review Comments** (#1 in the screenshot below).
- You can type any notes in the **Notes** field (#2 below).
- If you completed any worksheets as part of your review, you may upload them in **question # 2** (#3 below).
- If there are any supporting documents you wish the Committee to consider such as articles or guidance, you can upload them in **question # 3 – Other supporting documents** (#4 below).
- Click **OK** to close the window (# 5 below).

Committee Review

Entered IRB: 5/24/2022 12:30 PM  
Last updated: 10/8/2022 10:54 AM

**Next Steps**

Review Modification/CR

Printer Version

Request Clarification by Committee Member

**1** Add Review Comments

Add Comment

Add Private Comment

(IRB - ModCR - In Review)

Execute "Add Review Comments" on MOD00051226 - Internet Explorer

https://mpclkyalestage6.huronclick.com/IRB/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity%5B5B0ID%5B6BD4C

**Add Review Comments**

?  
All committee members and IRB staff can view your comments in the Reviews tab.  
All comments and attached files will be removed from the system upon the submission's approval.

**1. Notes:** **2**

**2. Checklists:** (attach relevant checklists from the IRB Library) ? **3**

+ Add  
Name  
There are no items to display

**3. Other supporting documents:** **4**

+ Add  
Name  
There are no items to display

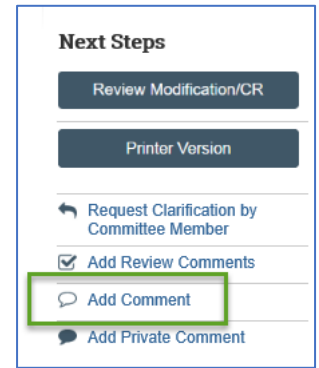
**5**

OK Cancel

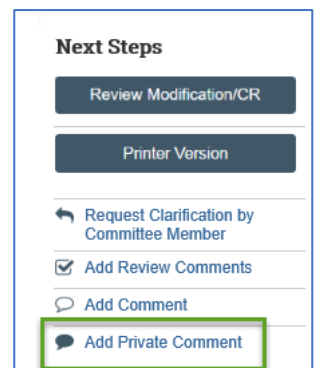
#### 4.10 Other functions: Leaving Comments for Investigator and/or IRB Staff and Requesting Clarifications by Committee Member

Under Next Steps, you will find two additional functions available to you that can be used to communicate with the study team and/or IRB staff.

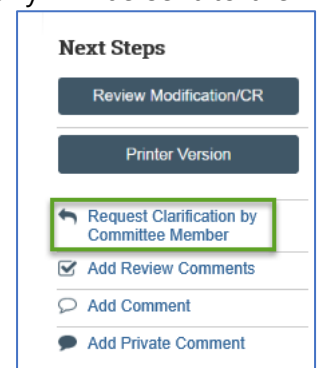
You can add a comment in the study workspace by clicking **Add Comment**. It will be visible to every person who has access to the study (e.g., researcher, IRB staff, auditors) in the History tab of the submission workspace. The IRB staff may leave comments to the investigator that do not require a response, e.g., instructions regarding registration requirement on [clinicaltrials.gov](http://clinicaltrials.gov). You should contact the IRB Regulatory Analyst before leaving a comment in the submission workspace.



You can add a private comment in the study workspace by clicking **Add Private Comment**. It will be visible only to the IRB members and staff in the History tab of the submission workspace. The IRB staff may leave private comments to explain rationale for actions taken on the submission e.g., documentation of Chair's approval of investigator's responses. You should contact the IRB Regulatory Analyst before leaving a private comment in the submission workspace.



You can communicate with the investigator and the study team by clicking **Request Clarifications by Committee Member**. While the submission will remain on the agenda, the inquiry will be sent to the investigator. Your question and the investigator's responses will be visible to every person who has access to the study (e.g., researcher, IRB staff, auditors) in the History tab of the submission workspace. Because you can only submit one clarification request at a time, you should let the IRB Regulatory Analyst and Chair know that you have questions requiring a response from the research team prior to the meeting. They can combine your inquiries with theirs into one comprehensive communication to the investigator.



## 5. Meeting Procedures

### 5.1. Meeting Invitations

Most IRB meetings are scheduled annually for the term September 1 – August 31. You should have received an email sent to your Yale email address with a calendar invitation for the entire year. The meeting invitation includes a link to Zoom and the name of the IRB Manager that may help answer any questions. If you are a member of an IRB panel that meets ad-hoc, you will receive an email invitation a week prior to the meeting.

### 5.2. Logging into a meeting

You should log into the meeting a few minutes prior to the start time. You can find the link to Zoom in your meeting invitation or in the IRES IRB system – go to the IRB Meetings space and copy the link from the **Location** tab for the meeting. Members are encouraged to attend the meetings with their cameras turned-on. All IRB meetings will be recorded. While the recording will not be part of the official record, it will be used by IRB regulatory analysts and managers to help with drafting minutes after the meeting. The recording will be saved in a secure cloud location until the end of the retention period established by Zoom.

### 5.3. Opening reminders

The Chair will open the meeting by reminding the members of the following requirements:

- Quorum is established by confirming the presence of a nonscientist, a scientist, and the presence of a majority of voting panel members;
- A member with a personal conflict of interest related to any agenda item must recuse from discussion and vote;
- The Report of Expedited Submissions approved within the past 45 days is in the electronic meeting space for review and comment; and
- Minutes from the prior meeting of the IRB are posted in the meeting space of the prior meeting for review and comment.

### 5.4. Verification of Quorum Requirements

Before the discussion of the items can begin, the Chair will confirm with the help of the IRB Manager that a majority of voting members are present and that there is a nonscientist and a scientist present. There might be additional people present at the meeting such as guests, supervising manager, IRB and HRPP staff in training, etc. They will not count toward quorum and the Chair will identify them before the meeting.

### 5.5. Member Recusals

A member who must recuse from discussion and vote due to a personal conflict of interest will be placed in the virtual waiting room for the duration of discussion and vote. The recused member will not count toward quorum. Quorum is confirmed before proceeding to discussion of the item. Please, identify yourself before the discussion of the agenda item if you believe you should be recused from the discussion and vote on that item.

## 5.6. Presenting Agenda Items

Each item on the meeting agenda is introduced by the Chair and presented by the assigned primary reviewer.

### 5.6.1. Presenting the Submission: Initial Review

- Start with a description of the purpose of the study.
- Provide a description of procedures that the protocol involves.
- Walk through approval criteria and explain how the study meets/does not meet them.
- If additional determinations need to be made, explain them.
- Identify any ethical issues that need to be addressed by the Committee.
- Propose a vote (see description of [determinations in section 3.4](#)):
  - **Approve** (a standard duration is 12 months but it can be shorter if there are concerns)
  - **Approve with Conditions/Modifications Required** (provide specific changes for the investigator to make or confirm assumptions)
  - **Defer**

### 5.6.2. Presenting the Submission: Initial Site Review

- Start with a description of the of the approved study along with the determinations that were made by the IRB.
- Provide a description of procedures that the site will be engaged in.
- Provide a description of any relevant information that affects the site e.g., local or state requirements.
- Walk through approval criteria and explain how the study as proposed at the site meets/does not meet them. Since the study is already approved, you do not need to propose all of the original determinations.
- If any additional determinations need to be made, explain them.
- Identify any ethical issues that need to be addressed by the Committee.
- Propose a vote (see description of [determinations in section 3.4](#)):
  - **Approve** (the study at a site will be approved for the same duration as the main study)
  - **Approve with Conditions/Modifications Required** (provide specific changes for the investigator to make or confirm assumptions)
  - **Defer**

### 5.6.3. Presenting the Submission: Modification

- Start with a description of the purpose of the study.
- Provide a description of the proposed changes.
- Explain whether any of the approval criteria are affected by the changes that makes the protocol no longer approvable.
- Explain if any of the changes could affect the participants' willingness to continue to be in the study. If so, they should be reconsented. How? Which groups of participants?



- Propose a vote (see description of [determinations in section 3.4](#)):
  - **Approve**
  - **Approve with Conditions/Modifications Required** (provide specific changes for the investigator to make or confirm assumptions)
  - **Defer**

#### 5.6.4. Presenting the Submission: Continuing Review

- Start with a description of the purpose of the study.
- Provide a description of the progress of the study to date, any new information that was provided by the investigator that could potentially affect the study approvability criteria.
- Propose a vote (see description of [determinations in section 3.4](#)):
  - **Approve** (a standard duration is 12 months but it can be shorter if there are concerns)
  - **Approve with Conditions/Modifications Required** (provide specific changes for the investigator to make or confirm assumptions)
  - **Defer**

#### 5.6.5. Presenting the Submission: Report of New Information

- Start with a description of the event.
- Provide a description of the studies that are affected by the event.
- Explain whether the event meets the criteria for any of the following determinations:
  - **Unanticipated Problem**
  - **Serious Noncompliance**
  - **Continuing Noncompliance**
- Provide a description of the proposed CAPA plan.
- Explain whether there are any additional actions that may be required, e.g.:
  - Modification to the protocol and or consent,
  - Suspension of the protocol,
  - Additional elements of the CAPA, etc.

### 5.7. Discussion

Once the Primary Reviewer presents the submission, the Chair will invite other members to contribute to the discussion. The discussion should include the proposed specific determinations (e.g., whether the proposed waiver of consent meet the criteria for a waiver) and overall determination related to the approvability of the research. If the discussion results in any controverted issues and members cannot agree on a solution, the individual issue may be put to a vote.

### 5.8. Voting

Once the discussion has ended, the Chair will summarize the issues raised. The Chair will repeat the proposed regulatory determinations that must be made and announce the relevant motion:

- A vote in favor of **Modifications Required to Secure Approval** means that the protocol meets the approval criteria and that IRB final approval can be granted when conditions described to the PI are adequately addressed and the response is found satisfactory by the Chair or his/her designee.
- A vote to **Defer Approval** means that the protocol does not meet the approval criteria and must return to the convened board for review of required modifications described to the PI.
- A vote to **Disapprove** means that the protocol does not meet the approval criteria and the IRB does not see any possible revisions to the protocol that could be proposed that would ensure that approval criteria are met. This motion is rarely proposed during the first review of the submission. The investigator should be given an opportunity to respond to deferral first to propose revisions before the submission is irrevocably disapproved.

You will be asked to vote **in favor of the motion, against the motion, or to abstain** from the vote. Majority of the members present for the vote must in favor of the motion for the motion to pass. The vote count will be announced and recorded.

## 6. Chairs' Manual

### 6.1. Convened Board Meetings

Most of the time, the Chair is also a voting IRB member of the panel. Sometimes, however, it will be possible that you are asked to chair a meeting on a panel where you cannot participate as a voting core or alternate member. In that case, you will preside over the meeting and while you can provide input into a discussion, you will not vote on the agenda items.

Throughout the review cycle, IRB Regulatory Analysts and the IRB Managers will provide you with support and will work closely with you on ensuring that all relevant determinations are made in compliance with regulatory requirements and Yale policies.

#### 6.1.1. Pre-Meeting Procedures

Your role as a Chair will involve activities prior to your IRB meeting as you are an integral part of the review cycle.

##### 6.1.1.1. Agenda finalization and distribution

You may be notified when investigator-initiated studies are assigned to your meeting two weeks prior to the final deadline for agenda closures. Investigator initiated studies usually require more work. As such, IRB Regulatory Analyst starts working on administrative review of such studies as soon as they are assigned to a meeting and will keep you updated on whether the study should remain on the agenda. You may also be consulted in the following situations:

- If the analyst identifies an issue that would preclude the submission from being reviewed at the meeting;
- If the analyst has questions about assignment of the agenda items prior to finalization of the agenda;
- If the analyst believes a consultation may be needed;
- If there are anticipated issues with quorum and alternate members may need to be asked to attend.

##### 6.1.1.2. Annotated agenda

As soon as the agenda is created and sent out, the regulatory analyst will create an annotated agenda, which will include important pre-meeting notes. It will later be used for the minute taking during the meeting. You will be provided with the version of the annotated agenda prior to the meeting to help you run the meeting. You will also use the annotated agenda after the meeting to review drafts of the language for minutes and IRB correspondence to the investigator.

The annotated agenda will include the following sections:

#### **Agenda Summary Sheet**

The first page of the document includes a table with a quick summary of the items that will be reviewed and a reminder of members that must be recused from the meeting.

## AGENDA SUMMARY SHEET

Agenda#	Submission ID	IRB#	PI	Funding	Primary	Expiration Date	RA	Recusals and Notes
I01	2000032593	2000032593	Michele Spencer-Manzon	Homology Medicines, Inc.	Madelon Baranoski		Sam Doan	
I02	2000032623	2000032623	Benjamin Kelmendi	The Steven & Alexandra Cohen Foundation, Inc.	Edward Monico		Sam Doan	

### **Overall Meeting Information**

This section will be used by the regulatory analyst to record start and end times of the meeting, any additional business that was discussed (e.g., training provided to the members) and names of guests that attended the meeting.

<b>START TIME</b>	10:00 AM
<b>END TIME</b>	12:02 PM
<b>GUESTS</b>	
<b>OTHER BUSINESS</b>	
<b>Minutes Approved?</b>	YES <input checked="" type="checkbox"/> N/A <input type="checkbox"/> NO <input type="checkbox"/> - Revisions Required:

### **Item Review Sheet**

Each item on the agenda will have its own review sheet. The top part will identify the information about the submission. The information is static and will not be modified during the meeting.

#### **I01. Review of 2000032593:**

Type of Review:	Initial Study
Submission:	
Title of Study:	
Investigator:	
IRB Reviewer	
RA:	
Common Rule Standard:	2018 Requirements + FDA

The section below, **IRB Actions**, will be used by the Regulatory Analyst to record the vote on the submission during the meeting.

## IRB ACTIONS

<b>Motion:</b>	<input type="checkbox"/> Approve	<input type="checkbox"/> Minor Revisions Required	<input type="checkbox"/> Defer	<input type="checkbox"/> Disapprove
<b>Votes:</b>	For:	Against: 0	Abstain: 0	Recused: 0
				Absent from Vote: 0

The next section, titled **Chair’s Section**, is what you will use during the meeting and after the meeting to review drafts of the minutes and correspondence. It contains the following sections:

**Recommended Board Motions:** Regulatory Analyst will list the language for the motions that will need to be made by the board along with recommendations based on the review of the item prior to the meeting.

**Minutes Language:** This section will be used by the regulatory analyst during the meeting to write down notes during the discussion. The language will be further refined after the meeting and will include description of any controverted issues and their resolutions and any minutes that must be recorded (e.g., specific determinations and determination-specific votes).

**Letter Language:** This section will include language that will become part of the IRB correspondence to the investigator in both Modifications Required and subsequent Approval or Deferral letters.

Following **Chair’s Section**, you will find **Staff Notes** section. This is used by the Regulatory Analysts as part of their preparation for the meeting. It will include questions that they need to follow up on with investigator after the pre-IRB meeting and notes of any issues that were identified prior to the meeting. That section does not require your review or edits as it will not serve as a basis for official minutes or IRB correspondence.

### 6.1.1.3. Pre-IRB Meeting

You will be asked to attend a pre-IRB meeting on Monday or Tuesday of the IRB meeting week. Regulatory Analyst and the IRB Manager will attend the meeting. The purpose of this meeting is to go over the agenda items and discuss any relevant issues, e.g., issues that may be resolved prior to the meeting, any notes from reviewers about potential deferrable issues, or any known recusals. You will be provided with annotated agenda prepared by the Regulatory Analyst.

### 6.1.2. Meeting Procedures

The Regulatory Analyst and/or IRB Manager will log into the meeting a few minutes prior to the start time to monitor attendance. You can find the link to Zoom in your meeting invitation or in the IRES IRB system – go to the IRB Meetings space and copy the link from the **Location** tab for the meeting. Members and staff are encouraged to attend the meetings with their cameras turned-on. The Regulatory Analyst will begin recording of the IRB meeting right when the meeting starts. The attendees will receive a message on their screen that the meeting is recorded.

#### 6.1.2.1. Running meeting tips

As Chair, your leadership of the meeting requires keeping the IRB on task and focused during discussion of a particular issue. Moving discussion forward, assessing areas of consensus, and confirming that the

same argument is not being repeated are crucial skills that make for a successful Chair and an effective meeting.

Be mindful to ensure that everyone who wants to contribute to a particular discussion is able to do so. Once an item has been presented, ask all IRB members to share their opinions and contribute to the discussion. Pay particular attention to ensuring that non-scientists and non-affiliated members are encouraged to speak and have their questions answered.

You will encourage members to raise questions and concerns relevant to the submission under review, but will also need to balance and re-direct discussion to matters that relate to the approvability – or not – of the research. Sometimes, a presenter will need support in focusing on the issues that require the board’s determination. Do so by politely interjecting with additional issues for their and other members’ consideration, while thanking them for their review.

At times during a discussion, opinions start to take on an emotionally charged tenor, or some of the stronger personalities on the IRB become too dominant. Be sensitive to this possibility and defuse the situation, by either recommending that the debated issue be handled outside the meeting (if it does not impact the ability to make a motion on the proposal), or table the study until proof for or against the “debated” issue may be obtained. It is critical that all members feel free to speak up and voice opinions, but not to the detriment of the meeting proceedings.

#### 6.1.2.2. Opening reminders

Identify any guests or new attendees. In addition, instruct the members about the following:

- Quorum is established by confirming the presence of a nonscientist, a scientist, and the presence of a majority of voting panel members;
- A member with a personal conflict of interest related to any agenda item must recuse from discussion and vote;
- The Report of Expedited Submissions reviewed within the past 45 days is in the electronic meeting space for review and comment; and
- Minutes from the prior meeting of the IRB are posted in the meeting space of the prior meeting for review and comment.

#### 6.1.2.3. Verification of Quorum Requirements

The Regulatory Analyst and IRB Manager will inform you when the Quorum is attained. Verify that there is a majority of members present, and that a non-scientist and a scientist are in attendance. Identify any alternate voting members and members they alternate for.

#### 6.1.2.4. Presentation of the Items and Member Recusal

Identify the agenda item that will be discussed. Before the Primary Reviewer presents the item, ensure that all members that must recuse from the discussion and vote on the item are moved to a virtual waiting room. Ask the board if there are any members who must recuse from the discussion.

Allow the Primary Reviewer to present the study. After the presentation, ask additional questions if needed. For example, if the reviewer presenting a modification to an approved protocol does not indicate

whether the modification is significant and could affect subjects’ willingness to participate in research, ask and elicit the presenter’s opinion whether the research participants should be informed about the new information, and if no, how.

Refer to the annotated agenda for the list of required determinations. If the presenter did not include them in the presentation, ask for them. If the presenter or other members of the board ask clarifying questions about regulatory requirements needed for the determination, refer to the Regulatory Analyst and Manager to display the relevant regulation or guidance on the screen.

Once the Primary Reviewer presents the study, open the discussion to others. If any controverted issues cannot be resolved by discussion, put the issue to a vote.

Once the discussion is over, summarize the issues raised and the determinations that were proposed by the Primary Reviewer. If necessary, explain the difference between the Deferral and Modifications Required to Secure Approval determinations. Ensure that any modifications or conditions of approval are clear and prescriptive. Should the board ask open-ended questions as part of the Modifications Required determination, ensure that it is clear what responses will be accepted by the board.

**6.1.2.5.Voting**

Put the proposed motions with all determinations to a vote. For a motion to pass, majority of the voting members present for the vote must vote in favor of the motion. Quorum must be maintained at all times (members who had to recuse do not count toward the quorum for that vote). See the following examples:

<b>Number needed for Quorum</b>	<b>Number of members attending the meeting</b>	<b>Number of members that need to recuse</b>	<b>Number of members voting in favor of motion of approval</b>	<b>Number of members voting against motion of approval</b>	<b>Number of members abstaining from the vote</b>	<b>Outcome</b>
5	7	2	4	0	1	Motion passes – to achieve majority of the votes, a minimum of 3 members would have to vote (majority of 5 members present for the vote) in favor of the motion.
3	5	0	2	1	2	Motion does not pass – to achieve majority of the votes, a minimum of 3 members would have to vote in favor of the motion.
4	6	1	3	0	2	Motion passes – to achieve majority of the votes, a minimum of 3 members would have to vote (majority of 5 members present for the vote) in favor of the motion.
6	8	0	4	4	0	Motion does not pass – to achieve majority of the votes, a

						minimum of 5 members would have to vote in favor of the motion.
--	--	--	--	--	--	---

Voting can become complicated when in order to maintain quorum alternate members stand in for those who have to recuse from the discussion and vote. For more information, watch OHRP educational video on [Alternates and Quorum](#).

### 6.1.3. Post-IRB meeting procedures

After the meeting ends, stay behind for a debriefing session with Regulatory Analyst and IRB Manager. The Analyst will quickly review the determinations made by the board for each agenda item to ensure all are in agreement about the substance of the minutes and directives to the investigator.

#### 6.1.3.1. Review of Draft Minutes and IRB Correspondence

The Regulatory Analyst will use the annotated agenda to complete the draft of the minutes for all items and correspondences to investigators. You will be notified via email when they are ready for your review. The revised annotated agenda will be sent to you via email, or you will receive a link to where the document lives. Use track changes function to indicate any edits you have for the minutes and/or correspondences in the Chair’s Section of the annotated agenda. Once you sign off on the language, let the Regulatory Analyst know. The annotated agenda with your edits will be saved in an official spot and will be used as a basis for minutes and letter generated in IRES IRB system.

Before the correspondence is sent to the investigator, the minutes and the letter will undergo a Quality Control check. Any typos or minor fixes will be made directly in the IRES IRB system. Any revisions identified by the individual conducting QC review that change the determination or substantially change the content of the minutes or letter to the investigator will be sent to you for your sign-off.

#### 6.1.3.2. Approving Minutes

After all of the IRB outcome letters are sent to investigators, the Regulatory Analyst will generate minutes from the meeting. You will be notified via email when they are ready for your final review and approval in IRES IRB system. Let the Regulatory Analyst know when you approve the minutes.

## 6.2. Chair’s Role Outside of the Convened Board Meetings

Chairs play an integral part of the IRB Office and their role spans outside of the convened board meeting.

### 6.2.1. Requests for Emergency Use of Humanitarian Use Devices

If time permits, a clinician-provider who determines an emergent need to treat a patient with an unapproved HUD should consult with you as IRB Chair in advance of the use to ensure that patient protection measures are in place and to obtain IRB approval. If prior IRB approval cannot be obtained, then within 5 business days after the emergency use of the device, the clinician must provide to you, via email, written notification of the use, including the identification of the patient involved, the date of the use, and the reason for the use. You will need to inform the IRB Manager of the emergency use so that all required documentation is obtained and securely electronically maintained within IRB records.



### 6.2.2. Requests for Emergency Use of Drugs

If time permits, a clinician-provider who determines an emergent need to utilize an investigational drug for a therapeutic or diagnostic reason should notify you as IRB Chair in writing of his/her intent and obtain your written concurrence at least 24 hours prior to the planned date of the first administration of the drug. Your review is specific and limited to the individual patient. If your approval cannot be obtained due to the emergency, you must be notified within 5 business days after such use, and provided with required documentation for review. As IRB Chair, you will review the report to verify that circumstances of the emergency use conformed to FDA regulations. This must not be construed as IRB approval, as an exemption from the requirement for prospective IRB approval has been invoked. When appropriate, in the event a manufacturer requires documentation from the IRB prior to the emergency use, you will review the proposed use, and, if appropriate, provide a written statement that the IRB is aware of the proposed use and considers the use to meet the requirements of 21 CFR 56.104(c). You will need to inform the IRB Manager of the emergency use so that all required documentation is obtained and securely electronically maintained within IRB records. The HRPP will coordinate with other groups at Yale that play an institutional role in the process: IND/IDE Office and Office of Sponsored Projects. You will be informed if any issues arise.

### 6.2.3. Study Suspensions

The IRB Chair is authorized to take immediate action to suspend a study or studies if subjects may be at risk of harm, when serious noncompliance may have occurred, or for any other reason where such action would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.

### 6.2.4. Delegation of Authority

Only Chair or the designee (who must be an experienced IRB member) can review and approve research via expedited review procedure. The HRPP and IRB Office established processes to ensure that IRB members receive adequate training and supervision before they receive delegation of your authority. The HRPP and IRB leaders will work with you on delegating your authority to experienced members.

### 6.2.5. Training of IRB Members

New members undergo an onboarding process, which includes training on history of human subjects research, ethics, regulations, Yale policies and procedures, and IRES IRB system. You may be asked to participate in training of new members and present a section of the training program.

### 6.2.6. Consultations during Expedited Reviews

IRB reviewers conducting reviews of research-related submissions using an expedited review procedure may turn to you for advice. The reviewers may raise concerns related to the nature of the research and seek your advice whether the submission would be more appropriate for review by a convened board.

### 6.2.7. Authorizing Research Activities During Lapse Period of the Protocol

While enrollment of new subjects cannot occur after the expiration of IRB approval, it may be in the best interest of the already enrolled participants to continue with research activities, especially when the

research interventions hold out the prospect of direct benefit to the subjects, or when withholding those interventions or safety monitoring procedures would place subjects at increased risk. In these instances, the investigators must contact the IRB office and submit a request to continue those research activities that are in the best interests of subjects. The IRB or HRPP staff will send the request to you for your review and determination regarding what activities, if any, may continue during the lapse.

#### 6.2.8. Consultations with the Investigators

Investigators often reach out to the IRB and HRPP Office requesting consultation prior to submitting research protocols for review. You may be asked to attend a meeting with an investigator to provide your expertise on IRB related concerns. You may ask the IRB and HRPP staff to provide you with support with researching the topic or any regulatory requirements related to the proposed research.

#### 6.2.9. Consultations with Other Groups with Oversight Responsibilities

There are other groups at Yale that are responsible for overseeing research activities conducted by Yale investigators. If an issue arises, they will often reach out to the HRPP Office for guidance related to regulatory requirements concerning human subjects research. You may be asked to attend a meeting with an investigator to provide your expertise on IRB related concerns.

#### 6.2.10. Attendance at HRPP Leadership Meetings

IRB Chairs are asked to attend periodic HRPP Leadership meetings that also include the Institutional Official, HRPP Directors and Management. The purposes of these meetings is to provide the attendees with pertinent updates to Yale and HRPP policies and procedures and agency regulations and guidance. Often, the meetings are used to discuss Yale IRB position and approach to current and emerging issues in the human subject research. You may be asked to share interesting research scenarios reviewed by your panel with others with the goal to achieve consistency among the IRB panels positions.

## 7. Appendix

### 7.1. Approval Criteria

- [Belmont Report](#)
- [45 CFR 46.111 \(OHRP/Common Rule\)](#)
- [21 CFR 56.111 \(FDA\)](#)

**Important!** Other agencies have their own regulatory citations. Use Worksheet 318-Additional Federal Criteria to guide you with review of research under regulatory oversight of the other agencies.

## 7.2. Calendar of Convened Board Review Cycle

### Wednesday Meeting: Initial and Mods

MON	TUE	WED	THU	FRI	SAT	SUN
			1	2	3	4
5	6	7	8	9	10	11
	<b>5PM, Agenda Assignments</b> <b>Deadline 1:</b> PI Initiated Initials  <b>EOD:</b> Email notification from HRPP to staff when agenda closes	<b>Morning, no later than noon:</b> Notify the Chair via email				
12	13	14	15	16	17	18
	<b>5 PM Agenda Assignments</b> <b>Deadline 2:</b> Industry Authored Initials & All MODS <b>5PM:</b> Confirmation with Chair assignments for initial IIT <b>EOD:</b> Email notification from HRPP to staff when agenda closes	<b>9AM, no later than 2 PM:</b> Agenda Out for All Items		RA Reach out to the Reviewer and IRB Chair for feedback on deferrable issues		<b>Primary Reviewer</b> <b>Deadline to provide comments</b>
19	20	21	22	23	24	25
Pre-IRB Meeting	<b>5PM:</b> Decision to pull items from the agenda for PI's nonresponse, within Chair's discretion	<b>IRB Meeting</b>  Post-Meeting Debrief	<ul style="list-style-type: none"> <li>Letter drafting</li> <li>Chair Letter Sign Off</li> </ul>	<ul style="list-style-type: none"> <li>Chair Letters Sign Off</li> <li>QC</li> <li>Sending Letters Out</li> </ul>		
26	27	28	29	30	31	
<ul style="list-style-type: none"> <li>QC</li> <li>Sending Letters Out</li> </ul>	Overall Minutes for QC Review	QC of Minutes	Chair Approval of Minutes	Email Notification to IRB about minutes		

## Wednesday Meeting: CRs

MON	TUE	WED	THU	FRI	SAT	SUN
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
	<b>5 PM: Agenda Assignments Deadline</b>  <b>EOD:</b> Email notification from HRPP to staff when agenda closes	<b>9 Am, no later than 2 PM: Agenda Out</b>		RA Reach out to the Reviewer for feedback on deferrable issues		<b>Reviewer Deadline to provide comments</b>
19	20	21	22	23	24	25
Pre-IRB Meeting		<b>IRB Meeting</b> Post Meeting Debrief	Letter drafting Chair Letter Sign Off	Chair Letter Sign Off QC		
26	27	28	29	30	31	
QC Sending Letters Out	Submission of Minutes for QC review	QC of the Minutes	Chair Approval of Minutes	Email Notification to IRB about minutes		

## Oncology Meetings (Thursday or Friday)

MON	TUE	WED	THU	FRI	SAT	SUN
			1	2	3	4
5	6	7	8	9	10	11
	<b>5 PM: Agenda Assignments Deadline</b>  <b>EOD:</b> Email notification from HRPP to Chair, staff when agenda closes	<b>Morning, no later than 2 PM: Agenda Out</b>		RA Reach out to the Reviewer for feedback on deferrable issues		<b>Reviewer Deadline to provide comments</b>
12	13	14	15	16	17	18
Pre-IRB Meeting	<b>5PM:</b> Decision to pull items from the agenda for PI's nonresponse, within Chair's discretion		<b>IRB Meeting</b> Post Meeting Debrief	<b>IRB Meeting</b> Post Meeting Debrief		
19	20	21	22	23	24	25
Letter drafting Chair Letter Sign Off	Chair Letter Sign off QC	QC Sending Letters Out	Minutes submission for QC review	QC of the Minutes		
26	27	28	29	30	31	
Chair Approval of Minutes	Email Notification to IRB about minutes					

<b>Deadlines for All Activities in the IRB Review Cycle</b>					
<b>Activity</b>	<b>Person Responsible for Meeting the Deadline</b>	<b>Description</b>	<b>Initial&amp; Mods Wednesday Meeting Deadlines</b>	<b>CR Meeting Deadlines</b>	<b>Oncology Meeting Deadlines</b>
Agenda Assignments	HRPP Reviewer conducting Pre-Review	The latest time the HRPP can assign items to the agenda before it closes for the meeting, after conducting a pre-review	5PM Tuesday, two weeks prior to the meeting for industry authored initial submissions 5PM Tuesday, a week prior to the meeting for all other submissions	5PM Tuesday, a week prior to the meeting	5PM Tuesday, a week prior to the meeting
Email Notifications about agenda closed	HRPP Pre-Review	Weekly email notification sent by the HRPP Pre-Review to HRP/IRB Staff when agenda deadlines close for the meetings. Signals to the RA to assign reviewers and generate agenda or, in case of PI initiated studies, to start reviewing for deferrable issues	The end of the day Tuesday	The end of the day Tuesday	The end of the day Tuesday
Email Notification to the Chair about IPI Initiated studies	Regulatory Analyst	RA to notify the Chair about the initial PI initiated studies	Wednesday morning, two weeks prior to the meeting	N/A	N/A
Confirmation with Chair assignments for initial IIT	Regulatory Analyst Chair	Time when the RA checks in with the Chair about withdrawal of any PI initial new studies and the assignments of the reviewers	5 PM Tuesday	N/A	N/A
Assignment of Reviewers	Regulatory Analyst	Assigning Reviewers to the agenda items	Wednesday morning, prior to sending the Agenda Out	Wednesday morning, prior to sending the Agenda Out	Wednesday morning, prior to sending the Agenda Out
Agenda Out	Regulatory Analyst Manager	Agenda to be sent to the assigned reviewers for the meeting; includes reviewing for	Morning, no later than 2 PM Wednesday, a	Morning, no later than 2 PM Wednesday, a	Morning, no later than 2 PM Wednesday, a

		COI for members, scanning for obvious issues (full board not needed, no documentation needed, etc.)	week prior to the meeting	week prior to the meeting	week prior to the meeting
RA Reach out to the Reviewer for feedback on deferrable issues	Regulatory Analyst	The latest time the RA reaches out to the Primary Reviewer to inform them about the issues that were identified, asks for feedback by the end of the day Sunday	Friday, a week prior to the meeting	Friday, a week prior to the meeting	Friday, a week prior to the meeting
Reviewer Deadline to provide comments	IRB Committee Member assigned as the Primary Reviewer	The latest time the Primary Reviewer provides comments on deferrable issues	Sunday night, the week prior to the meeting	Sunday night, the week prior to the meeting	Sunday night, the week prior to the meeting
Pre-IRB Meeting	Regulatory Analyst Chair Manager	Time to meet with the Chair to discuss any deferrable issues, feedback from the members, motions to be made at the meeting; decision by the Chair if item must be withdrawn from the agenda	Monday, the week of the meeting	Monday, the week of the meeting	Monday or Tuesday, the week of the meeting
Decision to pull items from the agenda for PI's nonresponse, within Chair's discretion	Chair Regulatory Analyst	Within the Chair's discretion, the PI may be given deadline for a response. If the deadline is not met, the item can be withdrawn from the agenda and the submission sent to the PI for revisions.	5PM Tuesday	5PM Tuesday	5PM Tuesday
Post-Meeting Debrief	Regulatory Analyst Chair Manager	Time after the meeting to review the final determinations	Immediately following the meeting	Immediately following the meeting	Immediately following the meeting
Drafting Letters	Regulatory Analyst	Completing the drafts of the minutes and correspondence in the annotated agenda tool	Thursday after the IRB meeting	Thursday after the IRB meeting	Friday after the IRB meeting on Thursday; Monday after the IRB meeting on Friday



Chair Letter Sign off	Chair	Chair's review of the minutes and letter drafts (either all at once in one annotated agenda document, or sent individually)	Thursday and Friday, following the IRB meeting	Thursday and Friday, following the IRB meeting	Friday and Monday following the Thursday IRB meeting, Monday and Tuesday following the Friday IRB Meeting
QC	QC Reviewer	Quality Control review of the minutes and correspondence in the IRES IRB, includes providing feedback via Ancillary Review, completing the checklists, updating the error tracking sheet	Friday and Monday after the meeting	Friday and Monday after the meeting	Monday and Tuesday following the Thursday meeting, Tuesday and Wednesday following the Friday meeting
Minutes for QC Review	Regulatory Analyst	Generating and completing the minutes document for the meeting and notifying the QC about the minutes being ready for review	Tuesday, week following the IRB meeting	Tuesday, week following the IRB meeting	Thursday, week after the IRB meeting
QC of Minutes	QC Reviewer	Reviewing the overall minutes document, completing the checklist and error tracking sheet, providing feedback to the Regulatory Analyst	Wednesday, week after the IRB meeting	Wednesday, week after the IRB meeting	Friday, week after the IRB meeting
Chair approval of minutes	Chair Regulatory Analyst	Reviewing and approving minutes in the IRES IRB system following the email notification from the Regulatory Analyst	Thursday, week after the IRB meeting	Thursday, week after the IRB meeting	Monday, two weeks after the meeting
Notifying the IRB Members via email about the availability of the minutes	Regulatory Analyst Manager	Sending an email notification to the members of the board with a link to the approved minutes	Friday, week after the IRB meeting	Friday, week after the IRB meeting	Tuesday, two weeks after the meeting

<b>Important Deadlines for IRB Members</b>				
<b>Activity</b>	<b>Description</b>	<b>Initial&amp; Mods Wednesday Meeting Deadlines</b>	<b>IRB 5 Deadlines</b>	<b>Oncology Panels (B-1, B-2, B-3, B-4) Deadlines</b>
Meeting Agenda	You will receive a link to the Agenda and the meeting space via email.	By 2 PM Wednesday, a week prior to the meeting	By 2 PM Wednesday, a week prior to the meeting	By 2 PM Wednesday, a week prior to the meeting
RA Reach out to the Primary Reviewer for feedback on deferrable issues	The Regulatory Analyst will reach out to you if you are the Primary Reviewer to let you know about any issues that were identified.	Friday, two weeks prior to the meeting for industry authored initial studies, Friday, a week prior to the meeting on all other submissions	Friday, a week prior to the meeting	Friday, a week prior to the meeting
Deadline to provide comments for Primary Reviewers	If you are a Primary Reviewer, you should provide comments on deferrable issues and submit your review sheet in IRES IRB.	Sunday night, the week prior to the meeting	Sunday night, the week prior to the meeting	Sunday night, the week prior to the meeting
Minutes Review	You will receive an email notification with a link to the minutes approved by the Chair. If you have comments or edits, you can share them via email OR raise them to the next IRB meeting	Friday, week after the IRB meeting	Friday, week after the IRB meeting	Tuesday, two weeks after the meeting

## 7.3. Definitions

### 7.3.1. Unanticipated problems involving risk to participants or others

Unanticipated problems involving risks to subjects or others (UAPs) refer to any incident, experience, outcome, or new information that:

1. Is unexpected; and
2. Is at least possibly related to participation in the research; and
3. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized.

**Unexpected.** The incident, experience or outcome is not expected (in terms of nature, severity, or frequency) given the research procedures that are described in the study-related documents, such as the IRB-approved research protocol/research plan and informed consent documents; and the characteristics of the subject population being studied.

**Related.** There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

**Adverse Event.** An adverse event (AE) is any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

### 7.3.2. Noncompliance

**Noncompliance** is defined as any failure to follow:

- Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
- The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

### 7.3.3. Serious Noncompliance

**Serious Noncompliance** is defined as noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data or the research.

### 7.3.4. Continuing Noncompliance

**Continuing Noncompliance** is defined as a pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.