

## Human Research Protection Program

### Frequently Asked Questions

Links to the [Investigator Manual](#) and [Human Research Protection Program Policy and Standard Operating Procedure Manual](#)

#### Table of Contents

|                                                                                                              |    |
|--------------------------------------------------------------------------------------------------------------|----|
| <b>General</b> .....                                                                                         | 3  |
| Who can serve as Principal Investigator (PI) on a study? .....                                               | 3  |
| Do I need a faculty advisor? .....                                                                           | 4  |
| What does “Investigator Initiated” study mean? .....                                                         | 4  |
| What is the difference between expedited review and full board review?.....                                  | 5  |
| <b>Types of Research</b> .....                                                                               | 6  |
| What qualifies as quality improvement, and do I need to submit my QI project?.....                           | 6  |
| Do I need to submit my oral history, case study or journalism project?.....                                  | 7  |
| What is exempt research, and do I have to submit my exemption to the IRB?.....                               | 7  |
| Collecting data on the deceased .....                                                                        | 8  |
| What is Not Human Subject Research? .....                                                                    | 8  |
| <b>Study Team and Training</b> .....                                                                         | 8  |
| What training is required?.....                                                                              | 8  |
| <b>Application Process</b> .....                                                                             | 9  |
| How do I know what protocol application to use?.....                                                         | 9  |
| How do I submit a protocol application? .....                                                                | 9  |
| What application do I use if my research is a medical record review only? .....                              | 9  |
| What application do I use if my research is secondary data analysis?.....                                    | 9  |
| What application do I use if I am collecting only de-identified, coded, or anonymous data or specimens?..... | 10 |
| My study does not fit any of these categories, now what? .....                                               | 10 |
| <b>Consent</b> .....                                                                                         | 10 |
| What is e-consent? .....                                                                                     | 10 |
| What platforms can I use for e-consent? .....                                                                | 10 |
| What’s the difference between a waiver of documentation of consent and a waiver of consent? .....            | 11 |

|                                                                                                                           |    |
|---------------------------------------------------------------------------------------------------------------------------|----|
| <b>Collaborating with Other Institutions and Agencies</b> .....                                                           | 12 |
| I am working with researchers from other universities/institutions, what do I need to do? .....                           | 12 |
| I am conducting research at Community Agencies: are there special steps I must follow? .....                              | 14 |
| I am collaborating with researchers from another institution. Can I rely on their IRB? Can they rely on Yale's IRB? ..... | 16 |
| Can a reliance agreement be used for my exempt study? .....                                                               | 16 |
| <b>International Research</b> .....                                                                                       | 17 |
| Are there special considerations for international search? .....                                                          | 17 |
| <b>Approval</b> .....                                                                                                     | 18 |
| When can I expect my protocol to be approved? .....                                                                       | 18 |
| <b>Modifications</b> .....                                                                                                | 18 |
| When should a Modification (MOD) to an approved study be submitted? .....                                                 | 18 |
| Do I need to use track changes? .....                                                                                     | 18 |
| Do I need to submit a modification to an exempt study? .....                                                              | 18 |
| Do I need to submit a modification to research not involving human subjects? .....                                        | 19 |
| <b>Continuing Review</b> .....                                                                                            | 19 |
| Do I need to submit for annual approval? .....                                                                            | 19 |
| How long is my approval valid? .....                                                                                      | 19 |
| <b>Contact Information</b> .....                                                                                          | 19 |
| Who do I contact if I have technical issues with IRES IRB? .....                                                          | 19 |
| Who do I contact for general questions? .....                                                                             | 19 |

|                       |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                             |
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| <p><b>General</b></p> | <p>Who can serve as Principal Investigator (PI) on a study?</p> | <p>Faculty with the status of assistant professor, associate professor, professor, research scientist/scholar, or senior research scientist/scholar can serve as PI without other approvals. Exceptions require the approval of the Provost or, where appropriate, the Dean of the relevant professional school or of the FAS. In some cases, the Provost or Dean may delegate approval to the department chair. The form Request for Special Permission to Serve as the PI can be found in IRES IRB/library/other forms or click on the link in this document. This form must be completed and signed by your Department Chair and the Dean's Office. click Yale University Faculty Handbook (page 161) for more information. Principal Investigators must also have:</p> <ul style="list-style-type: none"> <li>a) taken the appropriate human subjects protection training;</li> <li>b) completed HIPAA training (if applicable); and</li> <li>c) completed the University required conflict of interest disclosure form.</li> </ul> | <p>See Investigator Manual Section 3.1</p> <p><a href="#">Faculty Handbook</a></p> <p><a href="#">Request for Special Permission to Serve as the PI</a></p> |
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|  | <p>Do I need a faculty advisor?</p>                   | <p>Students and trainees cannot serve as PI on a research project. Students and trainees require a Faculty Advisor.</p> <p>Advisor who meets the eligibility criteria to serve as PI and who agrees to serve in that role.</p> <p>Faculty Advisors must be faculty with the status of assistant professor, associate professor, professor, research scientist/scholar, or senior research scientist/scholar or have permission from the Dean of the student's school (via letter or email).</p> <p>Once you have identified a faculty advisor:</p> <ul style="list-style-type: none"> <li>a) Provide documentation from a faculty advisor/mentor who agrees to take the responsibility of serving in that role. The form to be used can be found in the IRES IRB library/Other Forms/Faculty Advisor Agreement.</li> <li>b) Upload this in the Other Attachments section of the Local Site Documents tab in IRES IRB.</li> <li>c) Add this individual to the 'Study Team Member' section of the IRES record indicating their role of faculty advisor.</li> </ul> | <p>See Investigator Manual Section 3.1 Faculty Advisor Agreement</p> <p><a href="#">Faculty Advisor Agreement</a></p> |
|  | <p>What does "Investigator Initiated" study mean?</p> | <p>An investigator initiated study is one in which the investigator conceives the research, develops the protocol, and serves as investigator.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                       |

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|  | <p>What is the difference between expedited review and full board review?</p> | <p>An expedited review is a method of IRB review, where the review is conducted by a single designated IRB reviewer, rather than the convened board. In order for a study to qualify for expedited review, it must meet one of the 9 categories of Expedited review. It does not mean that the review will be handled in an especially “quick” manner. How long a review takes is based on how many studies have been submitted and what the time constraints are for each of those studies. For more information, click on the associated link to the right.:</p> <p>A full board review applies to initial review of research proposals that are not exempt and that do not qualify for expedited review procedures. All new studies requiring full board review will undergo regulatory review by IRB staff and will be scheduled to the next available Yale IRB meeting based on when the agenda closes. For more information, click on the associated link to the right.</p> <p>At Yale, the determination of expedited or full board review is made by the IRB staff at time of submission. You cannot request an expedited review of your study.</p> | <p>See Investigator Manual Section 5.6</p> <p><a href="#">OHRP Expedited Review Categories 2018 Requirements</a></p> |
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| <p><b>Types of Research</b></p> | <p>What qualifies as quality improvement, and do I need to submit my QI project?</p> | <p>Quality Improvement (QI) and Quality Assurance (QA) projects involve systematic, data-guided initiatives or processes designed to improve clinical care, patient safety, health care operations, services and programs or for developing new programs or services (e.g. teaching evaluations, patient/employee service surveys). QI/QA is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the immediate impact or effect of the implemented changes.</p> <p>IRB approval is <b>usually</b> not needed to perform quality improvement/quality assurance (QI/QA) activities or to present or publish QI results internally or externally, because QI/QA does not <b>usually</b> meet the regulatory definition of "research".</p> <p>The QI checklists published on the HRPP website will help investigators determine whether their proposed activity would fall into the category of quality improvement.</p> | <p>See Investigator Manual Section 2.</p> |
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|  | <p>Do I need to submit my oral history, case study or journalism project?</p>    | <p>Most oral history projects would not be considered research and would not need IRB review as they are simply a collection of stories to be used to describe peoples' experiences of a past event. Projects that involve the collection and use of oral histories to draw generalizable conclusions may meet the federal definition of "human subjects research" and require submission to the IRB.</p> <p>Case studies that do not draw generalizable conclusions would not be considered research and would not require IRB review. Projects that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, may meet the federal definition of "human subjects research" and require review by the IRB office.</p> <p>Journalism with the aim of informing the public about current events is not considered research and does not need to be submitted to the IRB for review and approval.</p> |                                                                                                                                                                                     |
|  | <p>What is exempt research, and do I have to submit my exemption to the IRB?</p> | <p>Research can qualify for an exemption if it is no more than minimal risk and all the research procedures fit within one or more of the exemption categories defined in the federal regulations. Studies that qualify for exemption must be submitted to the IRB for review and determination before starting the research. See the OHRP decision tree for help in determining what level of review your project may need.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>See Investigator Manual Section 2.1; 2.3; 3.7</p> <p><a href="#">Exemptions Categories under 2018 Regulations</a></p> <p><a href="#">2018 Regulations OHRP decision tree</a></p> |

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|                                | Collecting data on the deceased     | IRB approval for recording of decedent data is not needed. However, HIPAA applies to medical records for 50 years post death and to request medical record data of the deceased permission from next of kin is needed. In cases where you are not in touch with or cannot connect with next of kin, you can certify to the health care facility that the request is for research purposes and that the individual is deceased.                                                                                                                         | <a href="#">Researcher's Guide to HIPAA</a><br>(page 7)                                                     |
|                                | What is Not Human Subject Research? | Research projects may be classified as "not involving human subjects" if they involve obtaining, collecting and/or using coded, non-identifiable, or anonymous confidential information or human biologic specimens or if they do not collect information <i>about</i> an identified living individual. If your study meets the criteria of Non-Human Research and you would like an IRB concurrence of this determination, submit the Not Human Subjects Research Form.                                                                               | <a href="#">HRP 503G - Not Human Subjects Research Template</a>                                             |
| <b>Study Team and Training</b> | What training is required?          | <p><b>Human Subject Protection Training</b><br/>You and every person listed on your protocol who will be interacting with research participants, or their identifiable data or samples, must complete the human subject protection training before IRB approval can be granted.</p> <p><b>HIPAA Training</b><br/>HIPAA training is also required for studies involving personnel or facilities of YSM, YSN, the Psychology clinics, Yale Health Services, or agencies or institutions external to Yale that are subject to the HIPAA Privacy Rule.</p> | <a href="#">HSP Training</a><br><br><a href="#">HIPAA Training</a><br><br><a href="#">CITI GCP training</a> |

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| <b>Application Process</b> | How do I know what protocol application to use?                           | <p>Protocol applications are found in the IRES IRB Library under the Protocol Templates tab, and IRB, are available for researchers to use without any additional software. To use these applications, you will need to determine what kind of protocol application fits your study.</p> <p>If unsure, please contact the HRPP office at <a href="mailto:HRPP@yale.edu">HRPP@yale.edu</a> and ask for the analyst on call to contact you.</p> | <a href="#">Protocol Templates</a>                          |
|                            | How do I submit a protocol application?                                   | Submissions to the IRB must be made using the IRES IRB system. Information and login are available on the IRES IRB page. IRES IRB training links can also be found on this page.                                                                                                                                                                                                                                                              | <a href="#">IRES IRB Log-in</a>                             |
|                            | What application do I use if my research is a medical record review only? | <p>If your study solely involves the review of medical records, submit the Medical Record Review form or Exemption Request form (choose category 4).</p> <p>NOTE: Exempt category 4 only applies to investigators under the HIPAA covered departments.</p>                                                                                                                                                                                    | <a href="#">HRP-503C – Medical Record Protocol Template</a> |
|                            | What application do I use if my research is secondary data analysis?      | Most secondary data analysis research can be considered exempt or Research Not Involving Human Subjects. However, research studies that include secondary analysis of previously collected data for which Determinations of Research Not Involving Human Subjects or Exemption are not allowed by the Data Holder/Sponsor should be submitted on the Secondary Data Analysis template to the IRB.                                             | <a href="#">HRP-503H – Secondary Data Analysis Template</a> |

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|                | What application do I use if I am collecting only de-identified, coded, or anonymous data or specimens? | For research that collects and analyzes anonymous, coded (with no access to link) or de-identified (with no access to identifiers) data or specimens a formal protocol is not required to be submitted. However, the Request for Not Human Subjects Research template is available to be submitted when a formal letter of determination from the IRB is warranted or wanted.                                                                                                                                                                          | <a href="#">Protocol Templates</a>  |
|                | My study does not fit any of these categories, now what?                                                | If your study does not meet any of the criteria above (Exempt, medical record review, secondary data analysis, not human subject research), it may require a full IRB application be completed. There are several templates to choose from depending on the nature of your study. In addition to the protocol application, the IRB submission form must be filled out. This form is also found in the Protocol Templates tab.                                                                                                                          | <a href="#">Protocol Templates</a>  |
| <b>Consent</b> | What is e-consent?                                                                                      | Electronic consent (eConsent) is when an electronic platform is used to obtain consent. eConsent can include the entire consent form being administered electronically, or just collecting the subject's electronic signature. Please note that checking a yes or no box for a survey on a survey platform such as MTurk or Prolific is not considered obtaining signed e-consent, as there is no signature involved.                                                                                                                                  | See Investigator Manual Section 6.2 |
|                | What platforms can I use for e-consent?                                                                 | Yale allows REDCap, Oncore and Hugo platforms to obtain e-consent. Qualtrics is NOT currently approved to obtain e-consent. If your study is FDA regulated, any electronic platform used for eConsent must be compliant with 21 CFR 11.<br><br>At Yale, any platform that is proposed to be used for eConsent must be validated by Yale ITS before it can be utilized. Additionally, any Part 11 compliance declaration must also be validated by Yale ITS before it is confirmed to meet the University's requirements for Part 11 compliant systems. | See Investigator Manual Section 6.2 |

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|  | <p>What's the difference between a waiver of documentation of consent and a waiver of consent?</p> | <p>"Waiver of documentation of consent" means a participant may consent by oral consent and simply state that "", they are willing to participate, which could consist of checking a box online that they are agreeing to participate and then completing the research task. An information sheet or consent script would be required when a waiver of written documentation of consent is approved.</p> <p>A "waiver of informed consent" (1) alters some or all of the required elements of informed consent, or (2) completely waives the requirement to obtain informed consent (with or without a signature).</p> | <p><a href="#">2018 regulations 45 CFR 46.117 Documentation of informed consent</a></p> <p><a href="#">2018 regulations 45 CFR 46.116(f) – General waiver or alteration of consent</a></p> |
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| <p><b>Collaborating with Other Institutions and Agencies</b></p> | <p>I am working with researchers from other universities/institutions, what do I need to do?</p> | <p>For non-exempt research approval by the collaborating researcher's IRB may be required, or an IRB Authorization Agreement can be established. Generally, documentation of IRB approval must be provided when employees or agents of that university or institution, as part of the research, obtain (1) data about the research subjects through intervention or interaction with them or (2) identifiable private information about the subjects. Such documentation must be received by the IRB prior to such colleagues taking part in the research.</p> <p><b>Required Documentation</b><br/>Researchers from other institutions must submit a copy of their institution's IRB approval or other determination to the Yale principal investigator, who is responsible for ensuring that it is submitted to the Yale IRB.</p> <p><b>Institution that does not have an IRB</b><br/>In situations where an external investigator does not come from an assured institution, meaning an institution with a Federal Wide Assurance (FWA), an unaffiliated investigator agreement may be signed. The unaffiliated investigator agreements are used to extend the terms of Yale FWA (Federal-wide Assurance) over individuals engaged in human subject research who are NOT affiliated with an assured institution (institution that has its own FWA and IRB).</p> <p>Fill out the request for unaffiliated investigator agreement, available in the IRES IRB Library/Other Forms/Request for Unaffiliated Investigator Agreement and upload to the Other Attachments section of the Local Site Documents tab in IRES IRB.</p> | <p><a href="#">Reliance Agreements</a></p> <p>See Investigator Manual Section 13</p> <p>See HRPP Policy and Standard Operating Procedure Manual Section 6</p> <p>You may also email us at <a href="mailto:external.reviews@yale.edu">external.reviews@yale.edu</a> to ask for a consultation.</p> <p><a href="#">FWA look up</a></p> <p><a href="#">Request for Unaffiliated Investigator Agreement</a></p> |
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|  | <p>I am conducting research at Community Agencies: are there special steps I must follow?</p> | <p>Research conducted within a community agency requires a letter of support from the agency. The letter must indicate that 1) there is an understanding by the agency of what the purpose of the study is and the procedures it involves, 2) that the study is supported by the agency and 3) permission is granted to the investigator to conduct the research at the site and/or with their clients. This letter should be submitted to the IRB before the research at that agency can begin.</p> <p>The agency may also require that other conditions be met before the research can begin. These conditions should be considered when planning the research, as time is required to obtain the necessary permissions.</p> <p><b>Using Community Agency Staff in Your Research Project</b></p> <p>If you plan to engage the community agency in your research by having its staff, as part of the research team, obtain (1) data about the research participants through intervention or interaction with them or (2) identifiable confidential information about the research subjects, arrangements must be made in one of the following ways:</p> <p>If the community agency has its own IRB, or is affiliated with an IRB, that IRB must review the research for the agency's participation. A copy of the IRB approval must be provided to the Yale IRB.</p> <p>Alternatively, the agency's IRB may request that a Yale IRB review the research on its behalf; 1) or if the community agency plans to routinely engage in other research and does not have an IRB, it may be necessary for that institution/organization to designate an IRB (or a Yale IRB) to review its research. This may require the agency to file a formal agreement with a federal agency and the organization</p> |  |
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|  |  | <p>funding the IRB. If the collaborating institution/organization wishes to designate a Yale IRB and become a Research Affiliate, the review of the research by an IRB representing the external institution/organization must take place prior to the institutional/organizational representatives taking part in the research; 2) or If the community agency a) does not plan to regularly take part in other research projects and b) is only interested in taking part in the research being proposed by a Yale faculty member, the agency staff working on the research can enter into an agreement with Yale whereby the Yale IRB review covers their participation. This agreement is known as a Collaborating Institutional Investigator Agreement.</p> |  |
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|  | <p>I am collaborating with researchers from another institution.<br/>Can I rely on their IRB?<br/>Can they rely on Yale's IRB?</p> | <p>When Yale investigators are engaged in the conduct of <b>non-exempt human subjects research</b> in collaboration with investigators from another institution, an IRB Authorization Agreement can be established allowing one institution to rely on the IRB review conducted by the other institution. The agreement will delineate responsibilities of each institution in regard to review of the study, reporting requirements, and research oversight.</p> <p>Requests to enter into an IAA with another IRB may be initiated (a) by a Principal Investigator whose research includes the engagement of staff, resources or personnel of an institution with a Federal-wide Assurance (FWA) under the purview of a non-Yale IRB, (b) by the IRB of an FWA institution whose staff, resources or personnel will be engaged in Yale research or (c) by the Yale IRB when Yale staff, resources or personnel will be engaged in research of or at another institution. Investigators are encouraged to discuss the best review options with the IRB representatives and colleagues from collaborating institutions.</p> | <p><a href="#">Reliance Agreements</a></p> <p>See Investigator Manual Section 13</p> <p>See HRPP Policy and Standard Operating Procedure Manual Section 6</p> <p>You may also email us at <a href="mailto:external.reviews@yale.edu">external.reviews@yale.edu</a> to ask for a consultation.</p> |
|  | <p>Can a reliance agreement be used for my exempt study?</p>                                                                       | <p>Yale HRPP does not allow for reliance agreements on Exempt Status studies, as the determination itself states that the study is outside the purview of IRB review. However, in the rare case that a study is determined Exempt Status with Limited Review, the IRB may decide to create a reliance based on that determination.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                   |

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| <b>International Research</b> | <p>Are there special considerations for international search?</p> | <p>All human research conducted outside the United States must receive approval from the Yale Institutional Review Board (IRB) and the IRB used by the international site (or justification for why the international IRB approval cannot be obtained) before researchers initiate work under the protocol. Researchers should anticipate the time that obtaining local review and approval will require. This varies from country to country and can take several months. To ensure review and approval by Yale IRBs, protocols should be submitted two months prior to leaving the country. The Yale IRB is responsible for ensuring that human research conducted outside the United States conforms to the same ethical and regulatory standards to which research conducted in the United States is held. International human research must be conducted in accordance with applicable Yale policies for the conduct and review of human research, including informed consent and use of vulnerable populations.</p> <p>Human research conducted outside the United States must comply with the relevant laws of the host country. If an international institution or site is considered engaged in research, and if the research is supported by federal funding, specific requirements must be met.</p> | <p>See HRPP Policy and Standard Operating Procedure Manual Section 40</p> <p><a href="#">International Checklist</a></p> |
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| <b>Approval</b>      | When can I expect my protocol to be approved?                       | It is difficult to predict a general length of time for protocol development and approval. Protocol development time is unique to each study and varies depending on the complexity of the research and the number of pre-reviews that must be obtained by investigators or the HRPP Pre-Review team, (e.g., YCCI, MRRC, etc.) You can help speed up the process by ensuring that all staff have completed training and all documents are properly filled out and uploaded. | <a href="#">Yale IRB Submission Deadlines</a>                     |
| <b>Modifications</b> | When should a Modification (MOD) to an approved study be submitted? | Any changes to a study that has received IRB approval must be reviewed and approved by the IRB before the changes are implemented. Be sure to describe the proposed changes and their rationale in the modification summary and attach any documents that have been changed. Changes/revisions must be made using the Track Changes feature.                                                                                                                                | <a href="#">Researcher Guide – Modification Submission</a>        |
|                      | Do I need to use track changes?                                     | Yes, all changes must be tracked when submitting revised documents. The most current documents should be downloaded from IRES IRB, any approved track changes and comments associated with previous IRB reviews should be accepted, and the new changes should then be tracked. Only the track changes associated with the specific modification being submitted should be included.                                                                                        |                                                                   |
|                      | Do I need to submit a modification to an exempt study?              | Changes to exempt studies are not required to be submitted unless they change the exemption determination of the study. However, the HRPP reminds PIs to maintain good records of any changes (when, why and what was changed). For example, changes can still be kept track of in IRES IRB via the Add Comment function. The comment box can include the modification summary and rationale and the revised documents can be uploaded.                                     | See HRPP Policy and Standard Operating Procedure Manual Section 5 |

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|                            | Do I need to submit a modification to research not involving human subjects? | Modifications are not required for projects determined to be not human subjects research. The revised document with the changes tracked can be uploaded into IRES IRB as a comment to <b>keep track</b> of the document history. Should the modification be to add the collection of identifiers the project is no longer considered Not Human Subjects Research and a new protocol would need to be completed and submitted for review and approval.                                                                                                                                                                                                                                                                                                                                         |                                     |
| <b>Continuing Review</b>   | Do I need to submit for annual approval?<br>How long is my approval valid?   | <p>If IRES IRB main study record shows an approval end date, the study requires "continuing review" and re-approval at regular intervals. The approval end date can also be found on your initial approval letter or subsequent continuing review approval letters along with the date you are to submit documentation for continuing review.</p> <p>The approval period is usually one year. Approval can only be extended by IRB approval of a "continuing review" submission.</p> <p>Some ongoing studies no longer require annual Continuing Review (CR) per the 2018 Revised Common Rule (effective January 21, 2019). The IRES IRB main study record will not show an expiration date and the initial approval letter will state "The protocol does not require annual IRB Review".</p> | See Investigator Manual Section 5.4 |
| <b>Contact Information</b> | Who do I contact if I have technical issues with IRES IRB?                   | <p>For technical issues regarding IRES IRB, contact IRB Team Support at <a href="mailto:irb.support@yale.edu">irb.support@yale.edu</a>.</p> <p>You can also find Help Guides and videos in the IRES IRB Help Center</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <a href="#">Help Center</a>         |
|                            | Who do I contact for general questions?                                      | For general questions or to request to speak with the analyst on call, contact our office at 203-785-4688 or email <a href="mailto:HRPP@Yale.edu">HRPP@Yale.edu</a> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                     |

## Revision History

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| v.1 | 5/16/2022 |
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# Yale

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| v.2 | 6/8/2023  |
| v.3 | 8/26/2026 |