

**Submission Form to Yale IRB**

|  |  |
| --- | --- |
| Protocol Title: |  |
| Principal Investigator: |  |
| Version Date: |  |
| NCT# (if applicable): |  |

|  |
| --- |
| **INSTRUCTIONS** |
| This document must be submitted in addition to the study protocol and study materials. See the list of possible relevant materials below. **Upload it under Supporting Documents in IRES IRB. Select *IRB Submission Form* as the Category.** 1. Review the next page for sections that are required and supplemental sections that are applicable to certain types of research only.
2. If the research protocol addresses the questions with sufficient detail, reference the section of the protocol. Do not copy and paste the responses from the protocol.

Study materials may include:* Recruitment materials,
* All assessments, surveys, questionnaires, etc. (may be in a zip file or one document that includes links),
* Behavioral intervention manuals,
* Consent documents (forms, scripts, debriefings, sponsor templates),
* Any other related materials.
 |
| Version Date# 7/24/2023 |

**Table of Contents**

|  |  |  |  |
| --- | --- | --- | --- |
| **Section #**  | **Title** | **When to Complete** | **Checklist** |
| 1 | [Yale Specific Comments](#_Section_1._Yale) | Required Section. |[ ]
| 2 | [Recruitment](#_Section_3._Recruitment) | Required Section. |[ ]
| 3 | [Consent Process](#_Section_4._Consent) | Required Section. |[ ]
| 4 | [Confidentiality and Privacy](#_Section_5._Confidentiality) | Required Section. |[ ]
| 5 | [Risk/Benefits Analysis](#_Section_6._Risks/Benefits) | Required Section. |[ ]
| 6 | [Attestations](#_Section_7._Attestations) | Required Section. |[ ]
| Supplement I | [Waivers](#_Section_8._Waivers) | Complete only when requesting waivers of HIPAA (full or partial) or consent (documentation or entire consent for recruitment OR entire/portion of a study). | [ ]  N/A[ ]  |
| Supplement II | [Multicenter Management](#_Section_9._Multicenter) | Complete only when Yale serves as the coordinating center for a multi-site research study. | [ ]  N/A[ ]  |
| Supplement III | [Drugs](#_Section_10._Drugs) | Complete only when the proposed research includes drugs. | [ ]  N/A[ ]  |
| Supplement IV | [Devices](#_Section_10._Devices) | Complete only when the proposed research includes devices. | [ ]  N/A[ ]  |
| Supplement V | [Research with Tobacco Products](#_SUPPLEMENT_V) | Complete only when the proposed research includes the use of tobacco products. | [ ]  N/A[ ]  |
| Supplement VI | [Research with Radiation](#_Section_12._Research) | Complete only when the proposed research includes ionizing radiation. | [ ]  N/A[ ]  |
| Supplement VII | [Research with Cold Isotopes](#_SUPPLEMENT_VI) | Complete only when the proposed research includes use of unapproved cold isotopes. | [ ]  N/A[ ]  |
| Supplement VIII | [Special Populations](#_Section_2._Special) | Complete only if the proposed research involves vulnerable populations: minors, prisoners, pregnant women, or decisionally impaired individuals. | [ ]  N/A[ ]  |
| Supplement IX | [Research Under an IND or IDE Held by a Yale Investigator](#_SUPPLEMENT_IX) | Complete only if the proposed research involves use of a drug conducted by an IND held by Yale investigator or it is a device study conducted under an IDE held by the Yale investigator. | [ ]  N/A[ ]  |
| Supplement X | [Ancillary Committees](#_SUPPLEMENT_X) | Review prior to submission and identify any ancillary committees that may have to review your research in addition to the IRB.  | [ ]   |
| Supplement XI | [Data Sharing and Management Policy](#_SUPPLEMENT_XI) | Complete if the study is subject to [NIH Data Sharing and Management Policy](https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview).  | [ ]  N/A[ ]  |
| 7 | [Reminders](#_13._Reminders) | Review prior to submission.  | [ ]   |

|  |
| --- |
| Section 1. Yale Specific Comments |
| This section asks about the specifics of how the protocol will be implemented at Yale. any differences between the research protocol and its implementation at Yale or by Yale investigators (if the research location is outside of Yale). Answer the questions below **OR** provide the section and/or page numbers in the protocol that addresses this topic. |
| **Number of Subjects**  |
| **1.** | **If it is not included in the protocol, what is the targeted number of subjects to be enrolled at Yale sites? Specify by cohort/arm if applicable**. |
|  |
| **Note:**"*Enrolled" is defined in 42 CFR 11.10(a) as a human subject's, or their legally authorized representative's, agreement to participate in a clinical trial following completion of the informed consent process, as required in 21 CFR Part 50 and/or 45 CFR Part 46, as applicable. The regulation explains that, for the purposes of this part, potential subjects who are screened for the purpose of determining eligibility for a trial, but do not participate in the trial, are not considered enrolled, unless otherwise specified by the protocol.* *The Final Rule preamble (81 FR 65022) provides additional clarification of the "enroll or enrolled" definition in 42 CFR 11.10(a) by addressing two scenarios involving signing of the informed consent document. The first scenario involves the use of a separate informed consent document for screening. In this situation, there are two distinct informed consent documents: one for trial screening (for eligibility) and if eligible, one for trial participation. Under this first scenario, the signing of the second separate informed consent document for trial participation would mean the subject is enrolled in the clinical trial.* *In the second scenario, there is only one informed consent document for both trial screening and trial participation. In this scenario, the Final Rule preamble explains that a participant would not be considered enrolled until he or she met all the eligibility criteria assessed during screening, unless the participant is considered enrolled as outlined specifically in the protocol (81 FR 65022). The Final Rule preamble further explains that when there is only one informed consent document for both trial screening and trial participation, registration information must be submitted as described in 42 CFR 11.24 no later than 21 calendar days after the first participant signs the informed consent form and begins trial participation, in accordance with the protocol.* *Based on this clarification, when there is only one informed consent document for both trial screening and trial participation, whether a human subject "participates" in a study, and is therefore considered "enrolled" under the definition in 42 CFR 11.10(a), is determined by the protocol. This determination may vary across clinical trial protocols. For example, assignment to a study arm may be considered the beginning of trial participation based on a particular study protocol. In this example, if the study was halted prematurely before any subjects were assigned to a study arm (i.e., the Overall Recruitment Status is "Withdrawn"), none of the subjects would be considered enrolled, even though they had already signed the informed consent document. Also, if a human subject signs the informed consent document but then withdraws his or her informed consent before participation begins, the subject would not be considered "enrolled" in the clinical trial under the definition.* *We also note that the definition of "enrolled" is important for determining the Study Start Date. Study Start Date is defined in 42 CFR 11.10(b)(16) as the estimated date on which the clinical trial will be open for recruitment of human subjects, or the actual date on which the first human subject was enrolled.* ***See*** <https://clinicaltrials.gov/ct2/manage-recs/faq#fr_28>.  |
| **Differences between protocol and Yale implementation** |
| **2.****☐ N/A** | **Is there any specific site information that is either not contained in or different from the research protocol? If yes, please describe (otherwise indicate N/A):**Examples include, but are not limited to: Yale site not enrolling minors although the sponsor protocol allows for it.Yale site not enrolling individuals with diminished capacity. Yale site not participating in a particular section of the protocol (cohort), etc. |
|  |
| **Payments for Participation and/or reimbursement for expenses incurred** |
| **3.**☐ N/A | **How much will the participants be paid for participation (receive stipends) and/or be reimbursed for expenses incurred? Describe both the amounts and methods of payment/reimbursement.**  |
| Paid for participation (stipends):Reimbursed for expenses:  |
| **4.** | **What is the timing of the payment for participation and/or reimbursement for expenses incurred?** |
|  | **Payments for Participation** [ ]  There will be no payment for participation [ ]  Subjects will be paid at the end of each completed visit[ ]  Subjects will be paid at the end of their participation in the study[ ]  Subjects will be paid following each study visit or at the end of their participation in the study, per their preference[ ]  Other:  | **Reimbursement for Expenses** [ ]  There will be no reimbursement for expenses incurred [ ]  Subjects will be reimbursed at the end of each completed visit[ ]  Subjects will be reimbursed at the end of their participation in the study[ ]  Subjects will be paid following each study visit or at the end of their participation in the study, per their preference[ ]  Other:  |
| **Note:** ***Stipends*** are paid to the study subject at a flat rate by procedure or study without regard to any actual out-of-pocket costs and are taxable. Stipends can be paid using a bank card or by cash/check. ***Expense Reimbursements*** are costs reimbursed to the study subject based on their actual costs incurred and not as a flat rate payment. Generally, there are specific sponsor criteria associated with such expense reimbursements such as minimal travel distance, maximum amounts for hotel, meals, etc. There may also be specific pre-approval requirements. Receipts are normally required to be submitted to the sponsor. These costs are invoiced to the Sponsor and not paid automatically. Expense reimbursements are not taxable. If such costs are allowed by the Sponsor, expense reimbursement terms must be clearly explained in the consent form. It is important not to confuse the stipends (taxable) with reimbursements (non-taxable).  |
| **Standard of Care Vs. Research** |
| This section pertains to biomedical interventional research only. Skip to Data Safety and Monitoring section, question 10, if you are conducting noninterventional research.  |
| **5.** [ ]  **N/A** | **Identify any procedures conducted under this protocol that subjects will undergo as a direct result of participation in this study. These are procedures conducted for research purposes only, as a consequence of participation in this research, procedures occurring with greater frequency than standard of care, or randomization to different standards of care, for example.**  |
|  |
| **6.**[ ]  **N/A** | **According to national standards (or Yale practice if different from national standards), list the protocol procedures that the subjects will undergo as part of their routine clinical care (regardless of their participation in the research).**  |
|  |
| **7.**[ ]  **N/A** | **Explain who will pay for the research related procedures that are experimental. Note: this should be reconciled with the formal** [**coverage analysis**](https://medicine.yale.edu/ycci/oncore/availableservices/medicarecoverageanalysis/) **if performed by Yale Center for Clinical Investigation.**  |
|  |
| **8.** [ ]  **N/A** | **Identify whether there is use of a placebo condition.****Explain whether participation in this study will prevent or delay the standard of care.** |
|  |
| **9.**[ ]  **N/A** | **If relevant, describe the alternative procedures or courses of treatment that may be advantageous to participants.** |
|  |
| **Data Safety Monitoring** |
| **10.** | **What is the investigator’s assessment of the overall risk level for each group of subjects participating in this study (e.g., treatment arm, control arm, etc.)? Check all that apply and add detail if both are checked.**  |
| [ ]  Minimal Risk: **If minimal risk, provide rationale**:***Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*[ ]  Greater than Minimal Risk: |
| **11 A.** | **Minimal risk protocols: check the DSMP that applies to your research.** |
| [ ] **N/A** | [ ]  **See research protocol page:** **☐ As a Principal Investigator:** * I will monitor the data, assure protocol compliance, and conduct the safety reviews at least annually. I will evaluate whether the study should continue unchanged, require modifications, or close to enrollment.
* I will promptly report any Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) Unanticipated Problems Involving Risks to Subjects or Others to the IRB and any appropriate funding and regulatory agencies.
* I will immediately report any Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities (if possible), followed by a written report within 5 calendar days of my becoming aware of the event to the IRB and any appropriate funding and regulatory agencies.
* I will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project.
* I will report all UPIRSOs and adverse events that occur during the conduct of this research project to other applicable oversight bodies as required (e.g. protocol’s research monitor, industrial sponsor, Cancer Center Protocol Review Committee (PRC), Yale Cancer Center Data and Safety Monitoring Committee, DSMBs, etc.) within applicable reporting timeframes.

[ ]  **Other (add):** |
| **11 B.**[ ] **N/A** | **Greater than minimal risk protocols: Check the box that applies and identify an appropriate Data and Safety Monitoring Plan (DSMP), if applicable.** Examples of DSMPs are available here <http://your.yale.edu/policies-procedures/forms/420-fr-01-data-and-safety-monitoring-plans-templates>.  |
|  | **☐ See research protocol page:** **☐ DSMP Template for a greater than minimal risk study:**  |
| [ ] **N/A** | **Billing Instructions – only for studies with external non-federal support**Guidance on the new HRPP and IRB billing process can be found [here](https://yale.box.com/s/qlcgg8qyh47biud0u8urnjk257gr83n0). |
| **12 A** | **Have you received a waiver from the HRPP for the IRB review fees?**[ ]  **Yes** [ ]  **No**If yes, STOP filling out this section. |
| **12 B** | **Provide Chart of Accounts (COA) - either general departmental or study specific - where the IRB fees should be invoiced:**Note: Within a week of the IRB determination, the HRPP will send an invoice for the IRB review to the Department via Journal Entry in Workday. |
| **12 C** | **Provide contact information to your Business Office:** Last name:First name:Email address:Phone #:Dept: |
| Section 2. Recruitment |
| This section asks about recruitment methods at Yale. Answer the questions below **OR** provide the section and/or page numbers in the protocol that addresses this topic. |
| **1.** | **Indicate recruitment methods below:**  |
| [ ]  JDAT services, specify:

|  |
| --- |
|[ ]  Medical Record Review |
|[ ]  EPIC/My Chart Alerts |
|[ ]  Mailing |
|[ ]  Other: |

[ ]  Medical Record Review [ ]  Flyers [ ]  Internet/web postings[ ]  Radio [ ]  Telephone | [ ]  Departmental/Center newsletters [ ]  Web-based clinical trial registries[ ]  Clinicaltrials.gov[ ]  YCCI Recruitment Database[ ]  Social Media (Twitter/Facebook): [ ]  Posters[ ]  Mass email solicitation | [ ]  Departmental/Center research boards [ ]  Newspaper[ ]  Letter [ ]  Departmental/Center website[ ]  Television[ ]  Other: |
| **Note:** **‘**Cold calling’ is generally not permitted. Potential participants identified through medical records or in clinical setting should be first contacted by individuals known to them, e.g. their primary care providers. The use of JDAT services is generally required, for the review of medical records at YNHH and Yale Medical Group. Requests for medical records should be made through JDAT as described at <http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx>.YNHH and Yale University consider it a violation of patient privacy for research personnel to review medical records of patients who have opted out of research use of their records. If you are using JDAT for recruitment through My Chart, specific recruitment language is available in the IRES IRB Library. Tailor it to your study and upload it in Recruitment Materials section of IRES IRB. |
| **2.** | **Describe how potential participants will be contacted and by whom:** |
|  |
| **Note:** HIPAA waivers are necessary if you are accessing or using protected health information without authorization from the individual. Refer to [HIPAA Waivers](#_Waivers) section. |

|  |
| --- |
| Section 3. Consent Process |
| This section asks about the consent process to enroll participants into research. Answer the questions below **OR** provide the section and/or page numbers in the protocol that addresses this topic  |
| **Consent**  |
| **1.** | **Select how subjects will provide informed consent for the study.** |
| [ ]  **Consent will not be obtained (e.g; research involves data only). STOP Filling out this section and skip to Section 5. Ensure that the** [Waivers section](#_Section_8._Waivers) **includes a request for a waiver of consent.**[ ]  **Consent will be obtained (verbally or in writing). Answer the questions in this section. If consent is verbal only and will not be documented, ensure that a waiver of documentation of consent is requested in the** [Waivers section](#_Section_8._Waivers)**.** |
| **Setting** |
| **2.** | **If signed consent will be documented electronically, indicate the platform that will be used:**  |
| [ ]  REDCap (Note: the Part 11 compliant instance must be used for FDA regulated studies) [ ]  EPIC [ ]  Other: Specify **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **3.** | **Describe the settings and conditions under which consent/assent will be obtained, including the physical space where the discussions will take place.**  |
|  |
| **4.** | **Describe who will provide consent. If consent will be obtained from Legally Authorized Representatives (LARs) or surrogates for some or all subjects, describe how the status as LAR/surrogate will be confirmed.** |
|  |  |
| **4.** | **How much time will participants have to provide informed consent prior to the start of the research procedures?** |
|  |
| **Subjects Understanding** |
| **5.** | **Describe how you are going to ensure that participants understand the information about the study presented during the consent process. For example, you can ask participants to explain in their own words what the research is about, the risks and benefits of the research, ask open-ended questions about the consent information to evaluate their understanding, etc. This strategy should reflect the populations you are enrolling (considering those cognitively impaired vs. medically and psychiatrically healthy, for example).**  |
|  |  |
| **Note:** If you are using any supplemental informed consent materials, such as presentations, quizzes, or interactive media, you must submit them to the IRB for approval. |

|  |
| --- |
| Section 4. Confidentiality and Privacy |
| Confidentiality concerns data (treatment of information that an individual has disclosed) and Privacy concerns people (control over the extent, timing, and circumstances of sharing oneself, physically, behaviorally, or intellectually, with others). This section asks about confidentiality of the data kept at Yale. Answer the questions below **OR** provide the section and/or page numbers in the protocol that addresses this topic |
| **Recording of data** |
| **1.** | **How will the research data be collected and recorded?** |
|  | [ ]  Handwritten surveys entered into the computer[ ]  Audio-recordings[ ]  Video-recordings [ ]  Paper files[ ]  Electronic data collection devices such as IPads, etc.[ ]  Other: |
| **If recording was selected, address the following:** |
| **What media device is used to record?**  |
|  |
| **When are the recordings transcribed?** |
|  |
| **Are the transcriptions deidentified?** |
|  |
| **When are the recordings deleted?** |
|  |
| **2.** | **How will the identifiers be protected? For example, coding and separating identifiers from health information.**  |
|  |
| **3.** | **What are the plans for destruction of identifiers?**  |
|  |  |
| **Note:** If the research is conducted at a [HIPAA covered entity](https://hipaa.yale.edu/) and identifiable health information is collected, it is subject to HIPAA rules. Subjects need to authorize access to and use of their protected health information (PHI) either by signing a Compound Authorization Form or HIPAA RAF. The investigator can request a waiver of [HIPAA authorization](#_Section_8._Waivers) in certain situations.  |
| **Storage and Access** |
| **4.** | **How will the data be stored?** |
| **Digital:** [ ] CD/DVD [ ] Flash Drive [ ] Portable Hard Drive [ ] Yale Server [ ] Another Server[ ]  Yale BOX[ ]  Yale Sharepoint[ ]  Other cloud services: *List* | [ ] Laptop Computer[ ] Desktop Computer [ ] RedCap[ ] Oncore [ ] Other:  | **Paper Data:** [ ] Paper files in locked cabinets[ ] Scanned Documents [ ] Other:  |
| **Note:** All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url <http://its.yale.edu/egrc> or email it.compliance@yale.edu.Review the [**Data Classification Guideline**](https://cybersecurity.yale.edu/data-classification) and [**Risk Classification of Commonly Used Services at Yale**](https://cybersecurity.yale.edu/service-classification) that outlines the commonly used services at Yale and indicates the risk level (high, moderate, low) of work allowed on the service. |
| **5.** | **Describe how long the following type of data will be kept at Yale.** |
| **Identifiable data:** |
| **Deidentified data:** |
| **6.** | **Who will have access to the data and how will it be managed?** |
|  |
| **7.**  | **Will you be sharing specimens or provide research materials to another institution?** |
|  | [ ]  YES [ ]  NO**If YES, what is the status of the Material Transfer Agreement(s)?**[ ]  Pending with the Office of Sponsored Projects[ ]  Not yet submitted to the Office of Sponsored Projects[ ]  Not needed as the terms of the sharing are included in the contract[ ]  Other:Read more about Material Transfer Agreements:<https://your.yale.edu/research-support/office-sponsored-projects/contracts/material-transfer-agreements-mtas>  |
| **8.** | **Will you be sharing data with another institution during the research or after the research is completed?** |
|  | [ ]  YES [ ]  NO**If YES, what is the status of the Data Use Agreement(s)?**[ ]  Pending with the Office of Sponsored Projects[ ]  Not yet submitted to the Office of Sponsored Projects[ ]  Not needed as the terms of data sharing are included in the contract[ ]  Other:Read more about Data Use Agreements:<https://your.yale.edu/research-support/office-sponsored-projects/contracts/data-use-agreements-duas> |
| **Note:** If individuals/vendors external to Yale performs or assists Yale in performing activities that require receiving, creating, transmitting, accessing, using or disclosing PHI (protected health information), a **Business Associate Agreement** may be needed. See [Yale HIPAA Privacy Office](https://hipaa.yale.edu/policies-procedures/tracking-management-business-associates) for additional information regarding Business Associates. |
| **9.** | **For non-NIH funded research, are you planning on obtaining Certificate of Confidentiality/Privacy Certificate for this research?**  |
| [ ] **YES** [ ] **NO If YES, What agency?** |
|  |
| **Note:** The majority of NIH funded research is automatically covered by Certificate of Confidentiality. Refer to the Consent Glossary document for language to be included in the consent forms. To learn about Certificates of Confidentiality for non-NIH funded research that is NOT subject to FDA, [visit the NIH website](https://grants.nih.gov/policy/humansubjects/coc.htm). For information on FDA-issued Certificates of Confidentiality, visit <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality>.  |
| **Privacy of research participants** |
| This section asks about privacy of the research participants. Answer the questions below OR provide the section and/or page numbers in the protocol that addresses this topic. |
| **10.** | **If the research involves interaction with or observation of subjects, describe the provisions to protect the privacy interests of subjects.** [ ]  NA – No interaction or observation **Describe:** |
| **The settings where subjects will be interviewed, examined, or observed for the purposes of the research:** |
|  |
| **The settings where interventional components of the research and research procedures will take place:** |
|  |
| **Any provisions being taken to maximize privacy (for example, when reaching out to participants by phone, how will you avoid disclosing their research participation to others):** |
|  |

|  |
| --- |
| Section 5. Risks/Benefits Analysis |
| This section asks about the anticipated risks and benefits of the proposed research. Answer the questions below **OR** provide the section and/or page numbers in the protocol that addresses this topic  |
| **Benefits**  |
| **1.**  | **1. Are there direct benefits to subjects?** |
| [ ]  **YES** [ ]  **NO** |
| **If YES, what are the direct benefits?** |
|  |
| **2.** | **What are the benefits of the study in general?** |
|  |
| **Risks** |
| **3.** | **What are the anticipated risks? Note that studies that randomize subjects to an experimental condition vs a standard treatment or placebo must include the risks of the standard treatment or no treatment so that subjects can weigh all risks, including the risks of randomization (removing the decision from the treatment provider and subject).**  |
|  |

|  |
| --- |
| Section 6. Attestations |
| By submitting this form to the IRB, the Principal Investigator attests to the following. Please, check off the attestations to document your agreement. |
|[ ]  The information provided in this application is complete and accurate. |
|[ ]  I assume full responsibility for the protection of human subjects and the proper conduct of the research. |
|[ ]  Subject safety will be of paramount concern, and every effort will be made to protect subjects’ rights and welfare. |
|[ ]  The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects. |
|[ ]  All members of the research team will be kept apprised of research goals. |
|[ ]  I will obtain approval for this research study and any subsequent revisions prior to my initiating the study or any change and I will obtain continuing approval of this study prior to the expiration date of any approval period (if applicable). |
|[ ]  I agree to promptly inform the IRB of the change to the information provided on this form via a modification submitted in IRES IRB. |
|[ ]  I will report to the IRB any potential unanticipated problems involving risk to participants or others as well as reports of noncompliance that could be serious or continuing according to Yale IRB reporting policy. |
|[ ]  I have the necessary departmental support and sufficient resources to conduct this research appropriately.  |
|[ ]  I will identify a qualified successor should I cease my role as principal investigator and facilitate asmooth transfer of investigator responsibilities. |
|[ ]  I will inform the IRB about any significant financial interest related to this research (my own or any member of the study team) should one arise during the study. |

|  |
| --- |
| SUPPLEMENT I |
| **Waivers** |
| This section applies to situations when waivers of consent and HIPAA are necessary. This would apply when you will be performing research activities without informed consent or obtaining signature on a consent document. There are two sections: ***Consent Waivers***, and ***HIPAA Waivers*** for all studies subject to HIPAA. |
| **Consent** **Waivers** |
| **Note:** Obtaining information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects does not require informed consent if you are obtaining information through oral or written communication with the prospective subject or legally authorized representative (ie: by Screening by phone), or obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. If you are conducting these activities, ensure that procedures for identifying and screening subjects are described the protocol or this submission form and **DO NOT fill out the section below.** |
| **1.** | **What is the reason for the consent waiver? Identify the activities conducted under the waiver and populations to which they apply, e.g., requesting a waiver for the entire study, requesting a waiver of documentation for an online survey, etc.** |
|  |
| **2.** | [ ] **Waiver of Documentation of Consent**Answer the questions below if you do not plan to obtain a written signature from the participant, e.g., verbal consent, online consent, etc.  | [ ] **Waiver/Alteration of Consent**Answer the questions below if you do not plan (i) to obtain any consent from the participant, e.g. medical record review without asking for participant’s consent, or (ii) to include all of the required informed consent elements e.g. your research involves deception. |
| **Select ONE of the conditions under which the waiver of documentation is selected.**[ ]  Scenario 1: The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR[ ]  Scenario 2 for non-FDA regulated research only: The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR[ ]  Scenario 3 for non-FDA regulated research only: The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.  | **Select ONE of the conditions under which the waiver is selected. Provide the answers to the following:**[ ]  Scenario 1: (i) The research involves no more than minimal risk to the subjects; [ ] YES [ ]  NO(ii) The research could not practicably be carried out without the requested waiver or alteration; [ ] YES [ ]  NO(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;[ ] YES [ ]  NO**Provide justification:**(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and[ ] YES [ ]  NO(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. [ ] YES [ ]  NO[ ]  Scenario 2 for non-FDA Regulated Research Only:Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Officials, OR[ ]  Scenario 3 for FDA Regulated Research Only:Planned Emergency Research |
| **Alteration vs. Waiver of Consent:**  An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent. Refer to the Consent Glossary in IRES IRB or HRP-314 Worksheet, Criteria for Approval for the general requirements (cannot be altered), basic elements, and additional elements of consent.  |
| **HIPAA Waivers/Alterations** |
| **This section must be completed if you wish to obtain and use identifiable "protected health information" (PHI) for a study without obtaining written approval ("authorization") from the research participant for the use of the data. Questions pertain to the protected health information collected/accessed under a waiver.**  |
| **1.** | **What type of waiver are you requesting?** |
| [ ]  **Full Waiver**The investigator will access, use, or disclose research participants’ PHI for the research study ***without obtaining authorization*** for that use or disclosure. | [ ]  **Alteration**The investigator will access, use, or disclose research participants’ PHI for the research study ***with verbal authorization*** for that use or disclosure or with a written authorization that does not include all of the required HIPAA statements. | [ ]  **Partial Waiver**The investigator will access, use, or disclose research participants’ PHI for ***a portion of the research*** e.g. for recruitment or identification of potential participants without obtaining authorization for that use or disclosure. |
| **Note:** For HIPAA Required Statements, refer to HRPP Worksheet, HRP-330, HIPAA Authorization available in the IRES IRB Library. |
| **2.** | **What is the purpose for which you are requesting the HIPAA waiver/alteration?** |
|  |
| **3.** | **Describe Protected Health Information collected under the waiver/alteration that is needed for this study** *[Include the anticipated data locations as well as the type of information that will be required]:* |
|  |
| **4.** | **Who Will Have Access to the Protected Health Information** *[Describe each person and organization by name or category. Examples include the research sponsor, the investigator, the research staff, and all research monitors.]:* |
|  |
| **5.** [ ]  YES  [ ]  NO | **Does the use or disclosure of protected health information involve no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**1. **An adequate plan to protect the identifiers from improper use and disclosure;**
2. **An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and**
3. **Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted.**
 |
| **6.** | **Plan for Protecting Identifiers collected under the waiver/alteration:** *[Describe how access to study data is controlled; who will monitor access to study data; where will identified information be stored]* |
|  |
| **7.** | **Plan for Destroying Identifiers collected under the waiver/alteration:** *[Describe how, by whom and when identifiers will be destroyed; or provide justification for retaining the identifiers]* |
|  |
| **8.** | **Explain why the research activity could NOT practicably be conducted without the waiver/alteration:** |
|  |
| **9.** | **Explain why the research activity could NOT practicably be conducted without access to and use of the protected health information:** |
|  |

|  |
| --- |
| SUPPLEMENT II |
| Multi-Site Study Management |
| **Complete this section if this is a multi-site study and where the Yale Principal Investigator (PI) will serve as the** **[lead PI](#Bk1" \o "The individual with primary responsibility for oversight and management of the conduct of the study at all participating research sites.) of the overall study,** **or Yale will serve as the** [**coordinating center**](#Bk2)**, and/or data management center.** * Please ensure that your IRES IRB application reflects involvement in a multi-site study (Study Scope section, Question #11).
* If any of the requested information is stated in the sponsor protocol, you may reference the protocol and provide the corresponding page and section number.
 |
| **1.** | **Select all that apply:**  |
| [ ]  Yale is an enrolling site[ ]  Yale PI serves as the lead PI[ ]  Yale will serve as the coordinating center☐ Yale serves as the data coordinating center |
|  **2.** | **If applicable, who will serve in the coordinating center capacity? Select all that apply below.**  |
| [ ]  Designated Study Team Members[ ]  Project Manager[ ]  Yale Center for Clinical Investigation Multicenter Unit (MCU)[ ]  Other: |
| **Site Management and Oversight**  |
| **3.** | **Describe the process for ensuring collaborating sites obtain IRB approval documents (such as protocol, informed consent documents, approved study amendments) in a timely manner.** ***Note:*** *IRB approval must be secured prior to distribution of study documents to study sites.* |
|  |
| **Data Management**  |
| **4.** | **Describe the data management systems in place that assure fidelity of the data and maintain the privacy and confidentiality of the private information.**  |
|  |
| **5.**  | **Describe the process for secure data transmission and storage to the coordinating center.** |
|  |
| **6.** ☐ Yes ☐ No | **Will the data transmitted to the coordinating center contain any private identifiable information from sites?** If “Yes”, describe the procedures to minimize risk of disclosure of private identifiable information and to protect the confidentiality of subjects. |
|  |
| **7.** ☐ Yes ☐ No | **Will private identifiable information be provided to any central laboratory or investigator for central review?**If “Yes”, provide justification and confirm that the consent document informs the participant of this disclosure.  |
|  |
| **8.** | **What provisions are in place for management of interim results?** Describe how often the data will be analyzed and how frequently these results will be reported to the Yale IRB and/or IRB of record. Describe the process for ensuring adherence to stopping rules (including participant-specific rules) that have a major impact on the rights or welfare of research participants. |
|  |
| **Adverse Events and Unanticipated Problems**  |
| **9.** | **How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed?** Please include details on procedures for the timely review of reports, who is responsible for reporting to regulatory authorities and procedures for distribution to study sites. |
|  |

|  |
| --- |
| SUPPLEMENT III |
| Drugs |
| This section is required if the research involves administering a drug for research purposes.  |
| **STATUS OF THE DRUG** |
| **1.**[ ] YES [ ] NO  | **Is there an IND issued for the drug used in this research?** |
| If yes, STOP filling out this section and move to the Drug Information. Ensure the numbers are listed in IRES IRB.  |
| **2.**[ ] YES [ ] NO | **Is the study with the FDA for review of the IND application?** **What is the receipt date of the FDA IND application?**  |
| If yes, STOP filling out this section and move to the Drug Information. Ensure any correspondence from the FDA is uploaded in the Drugs section of the IRES IRB. |
| **3.**[ ] YES [ ] NO | **Are you planning to submit this study to FDA for IND application?** |
| If Yes, STOP filling out this section and move to the Drug Information. Ensure any correspondence from the FDA is uploaded in the Drugs section of the IRES IRB. Resources are available at Yale to help with IND support. Please, visit <https://medicine.yale.edu/ycci/researchers/ors/indide/> for more information. |
| **4.**[ ] YES [ ] NO | **Has the FDA issued a determination that this study is exempt from IND requirements?** |
| If yes, STOP filling out this section and move to the Drug Information. Ensure the FDA Letter is uploaded in the Drug page in IRES IRB. |
| **5.** [ ] YES  | **Do you believe the drug used in this research is exempt from IND requirements? Select the applicable exemption category below.** Please annotate the criteria below to provide justification, as needed, where it is not otherwise clear that ‘the investigation does NOT involve a route of administration or dosage level or use in populations or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product,’ for example. |
| **Exempt Category 1** | **The clinical investigation of a drug product that is lawfully marketed in the United States can be exempt from IND regulations if all of the following are true (please check):** [ ] The intention of the investigation is NOT to report to the FDA as a well-controlled study in support of a new indication for use or to be used to support any other significant change in the labeling for the drug. [ ] The drug that is undergoing investigation is lawfully marketed as a prescription drug product, and the intention of the investigation is NOT to support a significant change in the advertising for the product. [ ] The investigation does NOT involve a route of administration or dosage level or use in populations or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.[ ] The investigation will be conducted in compliance with the requirements for institutional (HIC) review and with the requirements for informed consent of the FDA regulations (21 CFR Part 50 and 21 CFR Part 56).[ ] The investigation will be conducted in compliance with the requirements regarding promotion and charging for investigational drugs.  |
| **Exempt Category 2** | [ ]  The clinical investigation is for an *in vitro* diagnostic biological product that involves one ormore of the following (check all that apply):[ ]  Blood grouping serum[ ]  Reagent red blood cells [ ]  Anti-human globulin[ ]  The diagnostic test is intended to be used in a diagnostic procedure that confirms thediagnosis made by another, medically established, diagnostic product or procedure; and[ ] The diagnostic test is shipped in compliance with 21 CFR §312.160. |
| **Exempt Category 3** | [ ]  A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND. |
| **Storage, Preparation, and Use** |
| **6.** | **If not sufficiently detailed in the sponsor protocol, describe the method of storage, preparation, stability information, and for parenteral products, method of sterilization and method of testing sterility and pyrogenicity.**  |
|  |
| **7.** | **Check applicable Investigational Drug Service utilized:** |
| [ ] YNHH IDS [ ] CMHC Pharmacy [ ] West Haven VA[ ] Other (list or describe): |

|  |
| --- |
| SUPPLEMENT IV |
| Devices |
| Complete this section if your research involves use of one or more subjects **to determine the safety and/or effectiveness of a device or combination product for human use**. Note that devices include invitro diagnostics. Devices used as intended to provide data, for example, not under investigation for new indications would not require a device determination. Note that ‘Devices’ include things like invitro diagnostics and diagnostic algorithms. *Devices used as intended to provide data, for example, not under investigation for a new indication would not require a device determination or this section completed.* Note that by FDA definition ‘devices’ include things like invitro diagnostics, lab tests, and diagnostic algorithms. Consult the FDA website for additional guidance.Ensure that the information reported here and in IRES IRB is completed for each applicable device in the research. The sections below will walk you through the regulatory framework presented in the diagram below.Device InvestigationsExempt from the IDE RegulationsSubject to IDE RegulationsSignificant Risk Devices (full requirements, IDE )Nonsignificant Risk Devices (abbreviated requirements) |
| **1.**[ ]  YES [ ]  NO | **Full name of the Device:****Maker/Manufacturer:** **Has the FDA assessed this device as exempt from IDE requirements?** **If YES** – Check off ‘*Exempt from IDE Requirements’* in IRES IRB, upload the FDA correspondence that indicates IDE requirements do not apply to this research activity and STOP completing this section. |
| **2.**[ ]  YES [ ]  NO | **Do you or the sponsor believe that the device under investigation in this research is is** **exempt from IDE regulations under 21 CFR 812.2(c)?****If YES** - The IRB will review for the IDE exemption determination. Select the exemption category below. Check off ‘*Exempt from IDE Requirements’* in IRES IRB.**If NO –** Skip to section **3.** |
|  | **Identify the exemption category below.** |
|[ ]  The device was not regulated as a drug before enactment of the Medical Device Amendments (Transitional device), it is FDA approved/cleared, and it is being used or investigator in accordance with the indications in the FDA approved/cleared labeling. |
|[ ]  A diagnostic device, if the sponsor complies with applicable requirements in section 809.10(c) of the regulations and the testing meets all the following requirements:i. Is noninvasive;ii. Does not require an invasive sampling procedure that presents significant risk;iii. Does not by design or intention introduce energy into a subject; andiv. Is not used as a as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. |
|[ ]  A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk. |
|[ ]  A custom device as defined in 812.3(b) of the regulations, unless the device is being used to determine safety or effectiveness for commercial distribution. |
| If the research is not exempt from the IDE regulations, then either **full IDE regulations apply and IDE is required** from FDA **OR** **abbreviated IDE regulations** apply if the device is considered nonsignificant risk device. |
| **4.**[ ] NO[ ]  YES  | **Has the FDA made a risk determination related to the investigational device?**IF **YES,** select determination below.If no, skip to question 5 below. |
|  | [ ]  Significant Risk [ ] Nonsignificant Risk**If Significant Risk** – select *IDE number* in IRES IRB, provide the number and a holder of an IDE. STOP completing this section. **If Nonsignificant Risk** – select *Claim of abbreviated IDE* in IRES IRB and upload the FDA documentation. STOP completing this section. |
| **5.**[ ]  NO [ ]  YES | **Do you or the sponsor believe the device is considered nonsignificant risk device?****If YES** – Provide explanation below.**If NO** – Skip to question 6 below.  |
|  | **Explain why the device does not meet the definition of a** [**significant risk device**](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/significant-risk-and-nonsignificant-risk-medical-device-studies) **(21 CFR 812.3(m)).** |
|  |  |
| **6.**[ ]  NO [ ]  YES | **Is the device part of a combination product and is being regulated by the FDA under an IND application?****If YES:** Fill out a section for Drugs in IRES IRB and provide IND # and the holder of an IND.**IF NO:** Full IDE requirements apply. The sponsor must obtain IDE # from the FDA. Select IDE number in IRES IRB, enter Pending for the IDE number, and provide a name of the planned holder of an IDE.  |

|  |
| --- |
| **SUPPLEMENT V** |
| Tobacco Products used in the investigation |
| This section is required if the research involves Tobacco Products intended for investigational use.  |
| **STATUS OF THE TOBACCO PRODUCT** |
| **1.**Complete for each product in the study  | **Full name of tobacco product:** *Include for ENDS/e-cigarettes, liquids, pods, etc****.*****Maker/Manufacturer:** \*\***Is the product commercially available?** [ ]  NO [ ]  YES **If yes, date commercialized:**  \***Will the product(s) be modified for this research?**[ ]  NO [ ]  YES*If yes, please described the modification(s) to the Tobacco Product:***Is/Are the product(s) being created in the lab?** |
| *\*\*Tobacco products intended for investigational use would be considered ’new tobacco products' requiring ITP if they meet the definition in section 910(a)(1) (21 U.S.C. 387j(a)(1)).**Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of the “Deeming Compliance Period” of August 8, 2016 or has been since modified is considered a new tobacco product requiring review.*  |
| (rows may be added and the section can be copied and pasted) | **[for additional tobacco products if more than one used in the study]** |
| **2.**[ ] YES [ ] NO [ ]  Pending[ ]  UI number assigned[ ]  not sure | **Will an investigational tobacco product (ITP) from FDA Center for Tobacco products (CTP) be sought for any or all products?**  *An ITP must be sought from FDA Center for Tobacco products for new tobacco products intended for investigational use.***Include UI number(s) (if applicable and available):** |
| *Include corresponding information in IRES-IRB, for example the CTP acknowledgment and letter of no concerns assigning the ITP (UI#), confirmation of commercialization dates on products not requiring ITP (via company letter or something from the web, device IFU, etc.).*  |
| **3.**☐YES ☐NO | **Do the product(s) require other FDA review – for example as an FDA investigational drug or medical device** (21 CFR part 312; 21 CFR part 812)**?** |
| If yes, please describe here:  |
|  |

|  |
| --- |
| SUPPLEMENT VI |
| Research with Radiation  |
| This section asks about research with radioactive drugs. If the research is taking place at Yale PET Center, the protocol will be sent to Yale Radioactive Investigational Drug Committee (RIDC) or Yale Radioactive Drug Research Committee (RDRC), and Yale Radiation Safety Committee (Yale RSC). Complete *Application to Involve Human Subjects in Biomedical Research with Ionizing Radiation* and *Yale RSC Cover Sheet* and upload them as Supporting Documents in IRES IRB. |
| **1.**  | **Name of the radiotracer:**  |
|  |
| **2.** | **Select as applicable:** |
| [ ]  The radioactive drug is used under an IND # [ ]  The study will be conducted under RDRC oversight[ ]  The radiotracer/radioactive drug is FDA approved and used as indicated |
| **3.** | **Background Information:** Provide a description of previous human use, known risks, and data addressing dosage(s), interval(s), route(s) of administration, and any other factors that might influence risks. If this is the first time this radiotracer is being administered to humans, include relevant data on animal models. |
|  |
| **4.** | **Source:** Identify the source of the radiotracer to be used. |
|  |

|  |
| --- |
| SUPPLEMENT VII |
| Research with Unapproved Cold Isotopes  |
| This section asks about research with cold isotopes conducted without an IND. FDA does not intend to object to clinical investigations using cold isotopes of unapproved drugs being conducted without an IND, provided the conditions described in question # 2 below are met (based on the criteria for studies using radiolabeled drugs (see 21 CFR 361.1)).  |
| **1.**  | **Name of the isotope:**  |
|  |  |
| **2.** | **Background Information:** Provide a description of previous human use, known risks, and data addressing dosage(s), interval(s), route(s) of administration, and any other factors that might influence risks. If this is the first time this isotope is being administered to humans, include relevant data on animal models. |
|  |  |
| **2.** | **Review and attest to the following:** |
|[ ]  The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry. |
|[ ]  The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject. |
|[ ]  The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies. |
|[ ]  The quality of the cold isotope meets relevant quality standards. |

|  |
| --- |
| SUPPLEMENT VIII |
| Special Populations |
| This section asks about enrollment of participants who may require additional protections.  |
| **1. Select the participants that will be enrolled into your research.**  |
| [ ] YES [ ] NO  | **Minors**  |
| **If YES, answer the questions below and describe assent/parental permission process in the** [**Consent Process**](#_Section_4._Consent) **section.** |
| **What is the age range? Note: the age of majority in CT is 18.** Click or tap here to enter text.**What is your assessment of risk for each group of subjects participating in this study (treatment arm, control arm, etc.)? Check all that apply.** [ ] Not greater than minimal:[ ] Greater than minimal:[ ] Minor increase over minimal risk:**Is there a prospect of direct benefit to minor participants? Check all that apply and specify per group if applicable.** [ ] YES:[ ] NO:**Parental Permission:**[ ]  Parental Permission will be obtained and documented[ ]  Parental Permission will be obtained but a waiver of documentation is requested (***complete*** [***Supplement I Waivers***](#_SUPPLEMENT_I) ***section to indicate a request for a waiver of documentation of consent***)[ ]  A waiver of parental permission is requested (***select the category below***):

|  |  |
| --- | --- |
| [ ] Protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects | [ ] The protocol meets the requirements for a waiver of consent. [***Supplement I Waivers***](#_SUPPLEMENT_I) ***must be completed.*** |

**Assent (check all that apply):**[ ]  Assent will be obtained and documented, describe:[ ]  Assent will be obtained but NOT documented, justify:[ ]  Assent will not be obtained, justify: |
| [ ] YES [ ] NO | **Wards of the state****Note:** Research with wards of the state in CT requires approval from the Department of Children and Families (DCF). |
| [ ] YES [ ] NO | **Cognitively Impaired (including subjects with temporary impairment)** |
| **If YES, answer the questions below.** |
| **Which of the below describes the study? Check all that apply.**[ ] Participants are temporarily or progressively impaired; e.g., intubated participants who are expected to regain capacity to provide informed consent.[ ] Participants are cognitively impaired throughout the duration of their participation in the study.[ ]  There is an anticipated benefit to the cognitively impaired subjects.[ ]  There is NO anticipated direct benefit to the cognitively impaired subjects but the following criteria are met: [ ]  Subjects have a disease or condition for which the procedures involved in the research are intended [ ] The foreseeable risk to cognitively impaired individuals is minimal**Assent will be obtained from:** [ ] All subjects, describe:[ ]  Some subjects, specify:[ ]  None of the subjects, justify: **Consent will be obtained from:**[ ]  Participant’s Legally Authorized Representative[ ]  Participant’s Next-of-Kin[ ]  Participant’s Study Partner [ ]  Other:**Describe the process of obtaining ongoing assent:** |
| [ ] YES [ ] NO | **Students/Employees**  |
|  | **Does the investigator have supervisory/power relationship to the targeted participants?**[ ]  **YES** [ ]  **NO** |
| **Note**: Refer to Policy on Participation of Yale Students, Fellows, Trainees, or Employees for guidance regarding recruitment and enrollment of participant with direct professional relationship. |
| [ ] YES [ ] NO | **Non-English Speaking** |
| **If YES, answer the questions below and describe the consent process in the** [**Consent Process**](#_Section_4._Consent) **section.** |
| **How will you document consent?**[ ]  Translated consent document[ ]  Short form |
|  | **Describe how the consent process will be provided in the language understood by the potential subject e.g., through the use of interpreters, by study personnel fluent in the language of the potential participant, etc.** |
|  |
| **Note:** Translated short forms are posted in the IRES IRB Library for investigator’s use. Consent forms should be translated into the language of the participant upon enrollment of the 3rd participant speaking the same language.**Note for FDA regulated studies:** If a participant was enrolled in a study with a use of a short form, the FDA expects the investigator to promptly obtain a translated copy of the IRB-approved English version of the long form, obtain the IRB approval of the translated version, and provide the IRB approved translated version to the participant as soon as possible. For more information, see [the FDA Informed Consent Guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#nonenglish). |
| [ ] YES [ ] NO | **Prisoners or Parolees (under jurisdiction of CT DOC)** |
| [ ] YES [ ] NO | **Pregnant Women** |

|  |
| --- |
| SUPPLEMENT IX |
| Research Under an IND or IDE Held by a Yale Investigator |
| This section is required if the study is conducted under an IND or IDE that is held by a Yale School of Medicine Investigator or when exemption from IND is requested by the Investigator. A Yale University policy related to investigator-sponsored INDs and IDEs was published in May 2021. Please visit <https://medicine.yale.edu/ycci/researchservices/supportservices/general/indide/> for more information. |
| **1.**[ ] N/A (complete #2) | **Name of individual who is the IND Sponsor:**  |
| Is this study the initial IND study or a study being submitted to an existing open IND? [ ]  Initial [ ]  Existing |
| **2.**[ ] N/A(complete #1) | **Name of individual who is the IDE Sponsor:** |
| Is this study the initial IDE study or a study being submitted to an existing open IDE? [ ]  Initial [ ]  Existing |
| **3.** | **Who is managing the submissions to FDA?** |
| [ ] YCCI IND/IDE Office[ ] External CRO, specify: [ ] Other, specify:  |
| **4.** | **Who is performing study monitoring for the study?** |
| [ ]  YCCI Monitoring Office[ ]  External Data Coordination Center, specify: [ ]  External CRO, specify: [ ]  Other, please describe:  |
| **5.** | **Who is performing project management activities for the study?** |
| [ ]  YCCI Project Management Office [ ]  External Coordination Center, specify: [ ]  Other, please describe:  |
| **6.**  | **What system will be used for electronic data capture?****Note: 21 CFR Part 11 compliant system is required for FDA regulated research.**[ ] OnCore[ ] RedCap[ ] Advarra EDC[ ] Other: |

|  |
| --- |
| SUPPLEMENT X |
| Review by Ancillary Committees |
| Review by additional oversight committees may apply to certain research studies. Review the research scenarios below and select the applicable ancillary review. See Investigator Manual for information on types of modifications that may require review by the ancillary committee. |
| **#** |  | **Research Scenario** | **Applicable Ancillary Review** | **Quick instructions for obtaining approval** |
| 1. |[ ]  Involves interactions with participants (including online) | **HRPP**  | Complete ‘Safety protocol during pandemic’ form available in IRES IRB, and upload it in the Local Site documents; HRPP will document review and document approval in IRES IRB prior to sending the submission to IRB for review;  |
| 2. |[ ]  Includes minors as research participants  | **Pediatric Protocol Review Committee** | No additional documents needed, when appropriate, the HRPP will request Ancillary Review upon submission of your research (at Pre-Review); the HRPP will hold submission until the PPRC has provided approval (submission will not proceed to the IRB for review without approval); Additional information about exceptions from the PPRC review is available here: <https://medicine.yale.edu/ycci/researchservices/qa/committees/pedsprotocols/>  |
|  3. |[ ]  Yale investigator serves as the IND/IDE holder for the drug/device used in this study | **IND-IDE Management Office** | Complete a Supplement IX titled ‘Research Under an IND or IDE Held by a Yale Investigator’ in this IRB Submission Form; HRPP will request Ancillary Review at Pre-review and hold the submission until IND-IDE Management Office has provided its approval (submission will not proceed to the IRB for review without approval); Additional information about the IND/IDE support services is available here: <https://medicine.yale.edu/ycci/researchservices/supportservices/general/indide/>  |
| 4. |[ ]  Industry sponsored clinical trial or registry | **Office of Sponsored Projects** | HRPP will request Ancillary Review at Pre-review; no additional documents needed; IRB review and OSP sign-off can be concurrent; approval will have to be obtained prior to final IRB approval;  |
| 5. |[ ]  Includes oncology patients at Smilow Hospital or area of research is related to oncology | **Protocol Review Committee** | You must obtain approval by submitting the research documents via ePRMS.**Timing:** * For PI initiated research: prior to submitting the study in IRES IRB; upload the approval in the Local Site Documents
* For industry sponsored research: at the same time as the study is submitted in IRES IRB, reviews can be concurrent

Additional information is available here:* [PRC amendments](https://www.yalecancercenter.org/research/resources/crs/prc/amendement/)
* [PRC](https://www.yalecancercenter.org/research/resources/crs/prc/prc/)
 |
| 6. |[ ]  Will include MRI scans at Magnetic Resonance Research Center (The Anlyan Center) | **MRRC Protocol Review Committee** | Complete the [Proposal to use the MRRC Resources](https://ires-irb.yale.edu/IRB-PROD/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b75456C05488ED043B88308FA6D00E090%5d%5d&Tab2=com.webridge.entity.Entity%5bOID%5bD152606A24E4814B9C23CC730C71CF9A%5d%5d) form and upload it in the Local Site Documents; indicate MRRC in the Research Locations page in IRES IRB; HRPP will request review by MRRC at Pre-Review and hold the submission until the MRRC has provided its approval (submission will not proceed to the IRB for review without approval); |
| 7. |[ ]  Will include MRI scans at FAS Brain Imagining Center | **Central Campus Scanner Governance Committee** | Complete the [Request for Scanner Access Faculty of Arts and Sciences (FAS) Brain Imaging Center (BIC)](https://ires-irb.yale.edu/IRB-PROD/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b75456C05488ED043B88308FA6D00E090%5d%5d&Tab2=com.webridge.entity.Entity%5bOID%5bD152606A24E4814B9C23CC730C71CF9A%5d%5d) and upload it in Local Site Documents; indicate Brain Imagining Center in Research Locations page in IRES IRB; HRPP will verify consent language and request the ancillary review at Pre-Review and hold the submission until the approval by the ancillary committee has been provided (submission will not proceed to the IRB for review without approval); |
| 8. |[ ]  Will include research procedures at HRU, CSRU, or WCRU | **YCCI Clinical Trial Services** | Obtain approval prior to IRES IRB submission - via submission [YCCI HRU/CSRU/West Campus Clinic Reservation Form](https://ycci.co1.qualtrics.com/jfe/form/SV_4V0v73gDpLmoa0d) online, upload the approval letter in the Local Site documents; HRU/CSRU must be indicated in Research Locations page; |
| 9. |[ ]  Includes use of radioactive drugs at PET Center that are FDA approved or exempt from IND requirements | **Radioactive Investigational Drug Committee**AND **Yale Radiation Safety Committee** | Complete three documents available in IRES IRB Library: * RIDC/RDRC application
* Dosimetry calculator
* Yale RSC cover page;

Upload the documents in the Local Site Documents; indicate the PET Center in the Research Locations page; HRPP will request ancillary reviews from RIDC and YRSC at Pre-Review and will notify PET Center, reviews can be concurrent so the submission will proceed to IRB for review; if approval has not been provided by the ancillary committees prior to the final IRB approval, approved consent forms will not be released; |
| 10. |[ ]  Includes use of radioactive drugs at PET Center under RDRC purview | **Radioactive Drug Research Committee**AND **Yale Radiation Safety Committee** | Complete the following three documents available in IRES IRB Library: * RIDC/RDRC application
* Dosimetry calculator
* Yale RSC cover page;

Upload the documents in the Local Site Documents; indicate the PET Center in the Research Locations page; HRPP will request ancillary reviews from RIDC and YRSC at Pre-Review and will notify PET Center, reviews can be concurrent so the submission will proceed to IRB for review; if approval has not been provided by the ancillary committees prior to the final IRB approval, approved consent forms will not be released; |
| 11. |[ ]  Includes research only scans with radiation at YNHH | **Yale New Haven Radiation Safety Committee** | Complete two documents: * YNHH RSC application
* Dosimetry calculator

Upload the documents in the Local Site Documents; indicate the YNHH in the Research Locations page; HRPP will request ancillary reviews from YNHH RSC at Pre-Review, reviews can be concurrent so the submission will proceed to IRB for review; if approval has not been provided by the YNHH RSC prior to the final IRB approval, approved consent forms will not be released; |
| 12. |[ ]  Targets Yale medical students as study participants | **Committee on research on Yale medical students** | Obtain sign-off from Associate Dean of Student Affairs and upload it in Local Site Documents; approval must be obtained prior to submission in IRES IRB; For contact information see <https://medicine.yale.edu/md-program/student-affairs/meet-student-affairs/>  |
| 13. |[ ]  Uses psychology pool for recruitment of psychology students as participants | **Intro to Psych Pool Committee**  | Obtain approval and upload it in Local Site Documents; HRPP will verify language in consent forms; approval must be obtained prior to submission in IRES IRB; For instructions see [Yale Psych Website Documents](https://www.dropbox.com/sh/7r2vjt5m2q0ssja/AABZxjOjT3vt6s5ToYi7DtAta?dl=0) |
| 14. |[ ]  It is NIH funded clinical trial or applicable trials under FDA purview and Yale is responsible for registering the protocol at clinicaltrials.gov | **YCAS**  | HRPP will initiate sign-off from YCAS and notify PI if registration is required or recommended; no additional documents are required; For more information see <https://ysph.yale.edu/ycas/clinical-trials-gov/>  |
| 15. |[ ]  The study will be conducted at embargoed countries | **Export Controls - OSP** | Contact exports@yale.edu to obtain approval; reviews can be concurrent; |
| 16. |[ ]  Is conducted by nurses at YNHH | **Nursing Research Committee** | Contact Nursing Research Committee at NursingScientificReviewComm@ynhh.org and upload approval in Local Site Documents; approval must be obtained prior to submission in IRES IRB; |
| 17. |[ ]  Enrolls at Emergency Department (adult) | **Sign-off from Departmental Chair** | PI must complete [Emergency Department Approval form](https://ires-irb.yale.edu/IRB-PROD/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5B75456C05488ED043B88308FA6D00E090%5D%5D&tab2=D152606A24E4814B9C23CC730C71CF9A) and obtain appropriate signature; upload it in Local Site Documents; Emergency Department must be indicated in Local Research Locations page; approval must be obtained prior to submission in IRES IRB  |
| 18. |[ ]  Enrolls at Maternal Fetal Medicine at 1 Long Wharf (pregnant women) | **Approval from Maternal Fetal Medicine**, contact: Lauren.perley@yale.edu  | Complete ‘*Request to Conduct Research Activities, Including Recruitment, at**Maternal Fetal Medicine: Outpatient Clinic at 1 Long Wharf’* and upload it in the Local Site Documents page, indicate the location in the Local Research Locations page, HRPP will request Ancillary Review in IRES IRB; approval must be obtained prior to the IRB review  |
| 19. |[ ]  Involves use of CMHC locations | **Notification to CMHC** | HRPP will notify CMHC to allow for verification of training; be aware that additional state requirements apply; indicate CMHC units (e.g., Clinical Neuroscience Research Unit) in the Local Research Locations |
| 20. |[ ]  Requires waivers of HIPAA authorization or stand-alone HIPAA RAF  | **HIPAA Privacy Board** | For request for HIPAA waiver, complete the Supplement I ‘Waivers’ in this IRB Submission Form, The Yale IRB serves as the Privacy Board and requests for waivers and authorizations are reviewed at the same time as the IRB review; if Yale IRB serves as a Privacy Board for a study under an external IRB purview, a separate Request Form for HIPAA waiver must be completed and submitted in IRES IRB;  |
| 21. |[ ]  Includes use of any of the following: * Infectious agents (bacteria, fungi, viruses, parasites),
* Recombinant DNA,
* Insects,
* Biological toxins
 | **Biosafety Committee** | Obtain approval from IBC (email protocol documents to ehs@yale.edu; contact phone: 203- 785‐3550); for additional information see: <https://ehs.yale.edu/biosafety-committee>, approval must be uploaded in the Local Site Document page; reviews can be concurrent but the approval must be obtained prior to final IRB approval |
| 22. |[ ]  Is considered Dual Use Research of Concern as it uses one of the following:* Avian influenza virus (highly pathogenic)
* Bacillus
* Botulinum neurotoxin
* Burkholderia mallei
* Burkholderia pesudomallei
* Ebola virus
* Foot-and-mouth disease virus
* Francisella tularensis
* Marburg virus
* Reconstructed 1918 Influenza virus
* Rinderpest virus
* Toxin-producing strains of Clostridium botulinum
* Variola major virus
* Variola minor virus
* Yersinia pestis
 | **Biosafety Committee (Subcommittee for Dual Use Research of Concern)** | Obtain approval from IBC (email protocol documents to ehs@yale.edu; contact phone: 203- 785‐3550); for additional information see: <https://ehs.yale.edu/biosafety-committee>, approval must be uploaded in the Local Site Documents page, reviews can be concurrent but the approval must be obtained prior to final IRB approval |

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

|  |
| --- |
| Section 7. Reminders |
| Research with billable services. | A billable service is defined as any service rendered to a study subject that, if he/she was not on a study, would normally generate a bill from either Yale-New Haven Hospital or Yale Medical Group to the patient or the patient’s insurer. The service may or may not be performed by the research staff on your study, but may be provided by professionals within either Yale-New Haven Hospital or Yale Medical Group (examples include x-rays, MRIs, CT scans, specimens sent to central labs, or specimens sent to pathology). Notes: 1. There is no distinction made whether the service is paid for by the subject or their insurance (Standard of Care) or by the study’s funding mechanism (Research Sponsored). 2. This generally includes new services or orders placed in EPIC for research subjects. If answered, “yes”, this study will need to be set up in OnCore, Yale’s clinical research management system, for Epic to appropriately route research related charges. Please contact oncore.support@yale.edu |
| Research at Yale New Haven Hospital | Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the HRU, the Principal Investigator and any co-investigators who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. By submitting this protocol as a PI, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH. |
| Research at Embargoed Countries | If your research is proposed in an embargoed country, there might be additional requirements that you need to meet, including approval from Yale Export Control. Contact Office of Export Controls at exports@yale.edu to obtain the approval to proceed with research after the IRB approval.  |
| Research with Prisoners | You cannot enroll a prisoner or continue research with individuals who become incarcerated while enrolled in the study without specific IRB approval for enrollment of prisoners. |
| Research with Minors | You cannot enroll minors in research without specific IRB approval for enrollment of minors. |
| International Research  | Confirm whether any local/country specific approvals are required, e.g., IRB/ Ethics Committee. Complete an International Research Checklist available in IRES IRB. Upload it as a Supporting Document. |