**Yale University Human Research Protection Program**

Request to Use External IRB

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| Version date: | | January 30, 2023 | | |
| This form is required for requests of use of external IRBs, except NCI CIRB and requests for Yale to serve as a sponsor of a multi-site research. Request for acknowledgement of NCI CIRB approval and request to use external IRB for Yale as a sponsor can be submitted directly in IRES IRB without this form.  Complete all sections and upload it in the Local Site Documents page. Ensure that all materials received from the proposed IRB are uploaded in IRES IRB e.g., Local Context Questionnaire. Please, review the Investigator Manual for your ongoing obligations related to reporting to the HRPP. | | | | |
| **1.** | **IRES IRB#:** | | | |
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| **2.** | **Select the most fitting description of this request:** | | | |
| Industry sponsor requested use of a central IRB  Investigator prefers to use the selected IRB, it does not serve as a central IRB for all sites  It is a federally funded study with a requirement to use sIRB – Yale is a participating site only  Yale serves as the sponsor of this multi-site research (regardless of funding)\* and is also an enrolling site  If this option is selected, provide the following:   * IRES IRB# for the sponsor level authorization: Write here * Name of the overall PI: Write here   There is an institutional conflict of interest related to this study and use of an external IRB is part of the management plan  Collaborator’s site requested use of this IRB  Other:  **IMPORTANT REMINDER:**  \*If Yale serves as the sponsor of the research and is also an enrolling site, two submissions are required in IRES IRB: sponsor level and a site level. Only site level submission will require this form. | | | | |
| **3.** | **Contact for IRB billing (where IRB of record will send invoices for IRB review):** | | | |
| N/A (not externally supported)  Not billable  Unsure about the billing contact  Billing contact for IRB fees:  **IMPORTANT REMINDER:**  \*The sponsor is expected to pay the external IRB directly for the sIRB fees. | | | | |
| **4.** | **Contact for HRPP billing:** | | | |
| Not billable (fee was waived, federally funded, no external support, etc.)  Billable:   * Chart of Accounts (COA) where the HRPP fees should be invoiced: * Provide contact information to your Business Office:   + Last name:   + First name:   + Email address:   + Phone #:   + Dept:   **Note:** If you initially provide a general departmental Chart of Accounts, please, contact the HRPP to update the COA once the study specific account is set up. Guidance on the new HRPP and IRB billing process can be found [here](https://yale.box.com/s/qlcgg8qyh47biud0u8urnjk257gr83n0). | | | | |
| **4.** | **Research activities taking place at Yale:** | | | |
| Recruitment and/or enrollment of participants  Review of medical records without subject authorization (under HIPAA waiver)  Data Analysis  None – Yale received federal money with a subaward to another site  None – Yale investigator acts as agents of both institutions (Yale and the non-Yale affiliated institution where research will be conducted)  Other: | | | | |
| **5.** | **If recruiting subjects at Yale, which of the following will be used for research at Yale sites:** | | | |
| N/A (no recruitment at Yale)  Review of medical records of Yale investigator’s patients followed by direct contact  JDAT Services:  Review of medical records at YNHS with direct contact by the primary provider OR by the investigator with documented permission of the primary provider  My Chart Recruitment  Mailing letters to potential participants  YCCI's Study Recruitment and Marketing unit  Use of existing registries at Yale (list them):  Referrals from centralized recruitment or referring physician  Use of recruitment flyers  Other:  **IMPORTANT REMINDERS:**   * Contact with patients without direct provider relationship is not allowed at Yale sites unless permission from a provider is obtained. * Information from medical records can only be provided by JDAT. * Contacting potential participants through My Chart and medical record reviews for recruitment purposes require a HIPAA waiver. **Remember to request a waiver of HIPAA authorization from the IRB.** * Notifications sent to potential participants via My Chart messaging must be approved by the IRB.   Read more about JDAT services:  <https://medicine.yale.edu/ycci/researchservices/systems/epic/datarequests/> | | | | |
| **6.** | **Number of subjects to be enrolled at Yale sites:** | | | |
| N/A (no enrollment at Yale)  Estimated number: | | | | |
| **7.** | **Will you send data to another institution?** | | | |
| 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. | | | | |
| **8.** | **Will you be sending 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> | | | | |
| **9.** | **How will the data be stored at Yale?** | | | |
| CD/DVD  Flash Drive  Portable Hard Drive  Yale Server  Another Server | | | Yale BOX  Yale Sharepoint  Other cloud services: Write here  RedCap  Oncore | Laptop Computer  Desktop Computer  Other: Write here |
| **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](mailto: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. | | | | |

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| SUPPLEMENT I | | | | |
| 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 authorizing use of external IRB; |
| 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 receive authorization to proceed to the IRB 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 II titled ‘Research Under an IND or IDE Held by a Yale Investigator’ in this Request 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 receive authorization to proceed to the IRB 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; submission will not receive authorization to proceed to the IRB without OSP sign-off |
| 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 receive authorization to proceed to the IRB 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 receive authorization to proceed to the IRB without approval |
| 8. |  | Will include research procedures at HRU or CSRU | **YCCI Clinical Trial Services** | Obtain approval prior to IRES IRB submission - via submission [YCCI HRU/CSRU/COVID Out-Patient 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, submission will not receive authorization to proceed to the IRB without approvals |
| 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, submission will not receive authorization to proceed to the IRB without approvals |
| 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, submission will not receive authorization to proceed to the IRB without approval |
| 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](mailto: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](mailto: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; submission will not receive authorization to proceed to the IRB without approval |
| 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** | 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, Local Site Documents, verify with the sponsor and/or IRB whether the reviewing IRB will also serve as the HIPAA Privacy Board |
| 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](mailto: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; submission will not receive authorization to proceed to the IRB without 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](mailto: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, submission will not receive authorization to proceed to the IRB without approval |

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| **SUPPLEMENT II** | |
| 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. | |
| **IRES IRB#** | |
| **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: |

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| **SUPPLEMENT III** | |
| 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 biospecimens 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.** |
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| **2.** | **Describe the deidentification methods used. Describe the level of the identifiability of the information including risk of individual subject identification.** |
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| **3.** | **What is the name of the repositories where data will be donated? Include url if available.** |
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| **4.** | **Describe how protections for privacy, rights, and confidentiality of human research participants will be protected.** |
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| **5.** | **Describe how access to the data will be controlled.** |
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