|  |
| --- |
| **ORDERS FOR NEEDED EQUIPMENT, ANIMALS, DRUGS, SUPPLIES**  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Order: (Expected Delivery \_\_ weeks) |  |  |  |  |  |
| Please include, in detail, any problems that have been encountered which have affected either the supply or receipt of any of the above supplies:  |
| **MATERIAL TRANSFER AGREEMENTS** [**Material transfer agreements**](https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/) (MTAs) are binding legal agreements between the provider of research material and the recipient, which outline the rights and obligations (i.e. rights of publication, inventorship, liability, etc.) of parties exchanging tangible and intangible research material.  All transfers of research material in and out of Johns Hopkins University need to be memorialized by a MTA. To initiate MTAs that are associated with **any of the following three categories, the appropriate research administration office (listing follows below) is contacted:*** A sponsor-controlled research study
* A funded or unfunded collaborative study between Johns Hopkins School of Medicine and the provider of the materials
* **Research involving patients or protected health information (PHI), clinical testing or procedures or drug/device testing in humans or any planning/lab/clinical service in support of such clinical research**

**Depending on your primary affiliation, the Johns Hopkins University Research Administration Office that should be contacted is:*** [**School of Medicine (ORA)**](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/)
* [**Krieger School of Arts and Sciences (BARA)**](https://sites.krieger.jhu.edu/kasper/sponsored-projects/)
* [**All Other Schools (JHURA)**](https://research.jhu.edu/jhura/)

**MTAs that are connected to any other situation besides the ones listed above are reviewed by** [**JH Technology Ventures**](https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/) **.****[ NOTE: MTAs can take 4-8+ weeks to obtain]** |
| MATERIAL TRANSFER AGREEMENT  |  |  |  |  |  |
| **BIOSPECIMEN TRANSFER INFORMATION SHEET**If the material around which an MTA is focused on human biospecimen(s) collected at Johns Hopkins, including associated data, autopsy specimens or immortalized cell lines derived from human tissue samples, a formal transfer request must be submitted in Section 23, Item 4 of a JHM eIRB application (under “Other”). **This request consists of the following: a completed** [**Biospecimen Transfer Information Sheet**](https://www.hopkinsmedicine.org/institutional_review_board/forms/biospecimen_transfer_information_form.docx)**, a Data Use Agreement, consent form(s) with the language associated with the transfer highlighted, the name of the ORA specialist who is working on completing the contract/MTA, applicable approval document(s) from the recipient site, and the COEUS PD.** Questions about transferring human biospecimens outside of Hopkins may be directed to **Suzanne Damaré**, the JHM Biospecimen Program Administrator at **sdamare1@jhmi.edu**. |
| BIOSPECIMEN TRANSFER INFORMATION SHEET |  |  |  |  |  |
| **DATA USE AGREEMENTS**A “limited data set” is a limited set of identifiable patient information as defined in the Privacy Regulations issued under HIPAA. A [**“limited data set**](https://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html)” of information may be disclosed to an outside party without a patient’s authorization if certain conditions are met. First, the purpose of the disclosure may only be for research, public health or health care operations. Second, the person receiving the information must sign a data use agreement **(DUA)** with Hopkins. This agreement has specific requirements which are discussed [**here**](https://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html)**.** **If you have questions about whether or not a Data Use Agreement (DUA) is required for your project or to initiate a DUA for your project, please contact** [**ORA**](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/index.html) **or JHURA** **jhura@jhu.edu****.**  |
| DATA USE AGREEMENT |  |  |  |  |  |
| **INSTITUTIONAL REGULATORY APPROVALS AND REGISTRATIONS\*** Regulatory approvals are not required to be in place at the time of ATIP application submission. However, for applicable awarded projects requiring submission of a prior approval request to NCATS (***See Appendix 12 of the RFA for additional information)***, that process cannot be initiated until **IRB and/or ACUC approvals have been obtained. Projects requiring NCATS review and approval include those involving** [**human subjects research**](https://ctsa.ncats.nih.gov/wp-content/uploads/2022/01/NCATS-New-Projects-with-Human-Subjects-Research-Addendum-and-Instructions-for-PIs-and-SOs-v3-Updated-01.07.2022.docx) **and/or** [**vertebrate animals**](https://ctsa.ncats.nih.gov/wp-content/uploads/2020/10/NCATS-CTSA-Program-Instructions-for-Submitting-Prior-Approval-Requests-of-Planned-Research-Involving-Live-Vertebrate-Animals-10.05.2020.docx). In light of the accelerated nature of this program, investigators are **strongly encouraged** to initiate necessary approvals prior to grant submission.  |
| **INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE APPROVAL:** |
| [**REVISION OF AN EXISTING ACU PROTOCOL**](https://web.jhu.edu/animalcare/policies/Significant%20Changes%20to%20Previously%20Approved%20Animal%20Activity.docx)**\*** *(\*Please review ACUC Office information linked here)* |  |  |  |  |  |
| NEW ACU PROTOCOL  |  |  |  |  |  |
| **INSTITUTIONAL REVIEW BOARD APPROVAL OF HUMAN SUBJECTS RESEARCH** |
| REVISION AN EXISTING IRB APPLICATION  |  |  |  |  |  |
| NEW IRB APPLICATION |  |  |  |  |  |
| **SINGLE IRB FOR MULTI-SITE RESEARCH**As the source of ATIP pilot awards is the NIH-NCATS, funded projects that involve [non-exempt human subjects research](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/exempt_research.html) which is being conducted using the same protocol at multiple U.S. sites, are subject to the NIH single IRB (sIRB) requirement. This requirement applies even if the study is partially funded by the NIH, but is waived if the source of the NIH funding is a career development, research training or fellowship award, or where prohibited by a federal, tribal, or state law, regulation, or policy. If an ATIP proposal meets the requirements for sIRB review, the first step would be to determine whether or not the JHM IRB is being asked to serve as the sIRB of record, or to rely on an external IRB by delegating institutional review board review responsibilities to the IRB of another institution. A Reliance Agreement is a formal, written document that provides the mechanism for sIRB review arrangements between institutions. The terms of the Reliance Agreement must be agreed to by the participating institutions before research can begin. **If this ATIP proposal meets the definition of a multisite study, a Reliance Agreement must be initiated in advance of IRB approval.****For questions about whether your proposal may require a reliance agreement and/or to initiate an agreement,** please contact the **JHM IRB Reliance Office** at**jhmirbreliance@jhmi.edu**for assistance.**NOTE:** [**sIRB REVIEW FEES APPLY**](https://www.hopkinsmedicine.org/institutional_review_board/about/fees.html) **WHEN THE JHM IRB WILL BE THE IRB OF RECORD**. sIRB review fees may be included in the ATIP budget. |
| sIRB Reliance Agreement Required (JHU IRB of Record) |  |  |  |  |  |
| sIRB Reliance Agreement Required (JHU Relying on Outside IRB) |  |  |  |  |  |
| **CRMS SYSTEM REGISTRATION**Studies requiring a[**Prospective Reimbursement Analysis (PRA)**](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/ora2.html)(i.e. that have the potential to generate a patient care charge) MUST comply with all of the terms and conditions in the Vice Dean for Clinical Investigation’s letter entitled ***“***[***Expectations for Registering Research Participants in CRMS and Research Consent Form Availability***](https://www.hopkinsmedicine.org/institutional_review_board/news/letters_dean/archive/crms_research_consent_form_availability.html)(August 31, 2020)*”*. |
| NEW CRMS REGISTRATION  |  |  |  |  |  |
| **CLINICAL ENGINEERING CLEARANCES**The Johns Hopkins Hospital (JHH) and the Johns Hopkins Bayview Medical Center (JHBMC) follow JCAHO requirements for environment of care and safety of equipment used at the facilities. In addition, the Hospitals are required to conduct acceptance testing of all equipment that comes into contact with patients. In order to meet the JHH and JHBMC policy requirements, JHM established Clinical Engineering Services (CES) at JHH and JHBMC to assure that the appropriate review, safety inspection, testing, reporting, and documentation required for equipment has been met before equipment is used or installed at JHM. The requirement for equipment testing applies to both clinical **care and to research related procedures.** [**All applicable equipment, software, and devices**](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/clinical_engineeringservices.html) **provided to an investigator by a sponsor or vendor require CES review before the IRB may issue final approval of a protocol that involves either a marketed or investigational device or equipment.** The eIRB application contains questions to assist investigators in submitting information regarding equipment/devices that will require CES review and subsequent IRB approval. |
| CLINICAL ENGINEERING CLEARANCE |  |  |  |  |  |
| **“FOREIGN COMPONENTS”**As the source of ATIP pilot awards is the NIH-NCATS, projects involving a “*foreign component*”, defined as “the performance of any significant element or segment of the project outside the United States, either by the recipient or by a researcher employed by a foreign organization, **whether or not grant funds are expended”, must undergo review and secure approval from the Fogarty Center and/or the US State Department before they are allowed to begin.** As per Section 16 of the [**NIH Grants Policy Statement**](https://grants.nih.gov/policy/nihgps/index.htm), activities that meet this definition include, but are not limited to, **the involvement of human subjects or vertebrate animals at a foreign site; extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling and similar activities; and any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may meet this definition include 1) collaborations with investigators at a foreign site that are anticipated to result in co-authorship, 2) use of facilities or instrumentation at a foreign site; and/or 3) receipt of financial support or resources from a foreign entity.****If your ATIP proposal will involve a foreign component (e.g. secondary analysis of data or blood samples obtained from a cooperative group clinical trial that has sites outside of the United States, regardless of whether or not the sites outside of the US are participating in the study or enrolling subjects), please contact the Navigators at** **ICTR\_Navigators@jhmi.edu** **prior to submission of the ATIP application.** |
| Foreign Component Review is **REQUIRED** |  |  |  |  |  |
| Foreign Component Review is **COMPLETED** and State Department / Fogarty Center foreign component clearance # has been issued by the NIH Institution or Center (IC) Program Officer |  |  |  |  |  |
| [**INSTITUTIONAL BIOSAFETY COMMITTEE**](https://www.hopkinsmedicine.org/hse/ibc/regtype2.html)Investigators at JHU who use or possess Recombinant or Synthetic Nucleic Acid Materials, Potential Infectious Agents/Pathogens, Biological Toxins, and/or Human-derived tissues and/or body fluids are responsible for registering these [research materials](http://www.hopkinsmedicine.org/hse/ibc/regtype2.html) with the Biosafety Office and describing the research programs and procedures in which they will be used. **This rule applies to all independent investigators**. [**Collaborators may not "piggy-back" on each other's registrations**](https://www.hopkinsmedicine.org/hse/ibc/index.html)**.** Postdoctoral or Clinical fellows, graduate or undergraduate students, and research associates are covered by the registrations of their Principal Investigator. **Please contact the Institutional Biosafety Office at** **ibc@jhmi.edu** **or call (410) 955-5918 for questions or assistance.**For applicable human studies, this review will be conducted concurrently with IRB review and will be needed before IRB approval is issued.  |
| INSTITUTIONAL BIOSAFETY REGISTRATION |  |  |  |  |  |
| **INSTITUTIONAL STEM CELL RESEARCH OVERSIGHT**It is the policy of the Johns Hopkins University School of Medicine that some types of research involving human pluripotent stem cells (hPSCs) being conducted by JHU faculty, staff or students or involving the use of JHU facilities or resources shall be subject to oversight by the **JHU Institutional Stem Cell Research Oversight (ISCRO) Committee**.  More information regarding covered research can be found [**here.**](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_4.html) |
| ISCRO APPROVAL  |  |  |  |  |  |
| **COVID-19 RELATED RESEARCH PROPOSALS** For studies that involve **secondary use of data,** the process for accessing and working with the [**JH-CROWN Registry**](https://ictr.johnshopkins.edu/covid-research-center/registry-dashboard/jh-crown/) should be first be reviewed, using the information linked [**here**](https://ictr.johnshopkins.edu/covid-research-center/review-committees/cadre/)**.**All studies requiring **any manner of contact** (e.g. therapeutic studies, surveys, etc.) with COVID+ patients (including JH HCW, JH employees, JH students, etc.) **OR use of data OR use of biospecimens** from **COVID+ patients:*** Review the [**COVID Research Checklist for Inpatient and Outpatient Studies**](https://ictr.johnshopkins.edu/wp-content/uploads/COVIDResearchChecklist-v2-03082022.pdf). This checklist was developed by the COVID-19 Research Center Implementation Committee to provide study teams will a list of, and links to, many of the required elements needed for COVID study start-up. The links guide users to documents and resources needed for IRB submission, Contracts & Budgeting, order set creation, and other resources for study implementation.
* **Institutional review is required even where an external IRB is the reviewing IRB for the study**. An external IRB application must be submitted to the responsible JHU IRB in these cases.
* There are many ancillary reviews required for COVID research before studies may be approved. [See linked checklist.](https://ictr.johnshopkins.edu/wp-content/uploads/COVIDResearchChecklist-v2-03082022.pdf)
* Studies that will include patient data requests (such as from JH-CROWN) **may require review from the CADRE Review Committee.**
* Studies that involve the use of stored specimens **may require review by the Biospecimen Oversight Committee**.
* Study teams should be working on the IRB application concurrently while receiving approval from committees–most of the ancillary review processes require an IRB number and can be initiated simultaneously with IRB review.

**NOTE:** Studies involving COVID-19 Infected and/or PUI Study Participants, must first contact COVID19ResearchCtr@jhmi.edu before submitting a proposal. **Please contact the ICTR Research Navigators at** **ICTR\_Navigators@jhmi.edu** **with any questions.** |
| [**COVID-19 Biospecimen Committee**](https://ictr.johnshopkins.edu/coronavirus/biospecimencommittee/) **Review** |  |  |  |  |  |
| [**COVID-19 & Data Research Evaluation (CADRE) Committee**](https://ictr.johnshopkins.edu/coronavirus/cadre/) **Review**  |  |  |  |  |  |
| **CLINICAL RESEARCH UNITS**All investigators must submit an application to a Johns Hopkins Institutional Review Board (IRB) before beginning their ICTR [**Clinical Research Units**](https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/) (CRUs) application. **NOTE**: COVID+ individuals and persons under investigation for COVID-19 infection, who are still subject to COVID-19 isolation precautions per the daily updated information on the [**HEIC Intranet**](https://intranet.insidehopkinsmedicine.org/heic/novel_coronavirus/index.html), may ONLY be seen in the designated outpatient [COVID CRU space at Bayview](https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/locations/). If your project will require use of the COVID CRU space, you must contact **Covid19ResearchCtr@jhmi.edu** **BEFORE** submitting your proposal to the IRB and CRU.**NOTE:** Obtaining CRU review and approval can add several weeks to your clinical research timeline. |
| [**CRU SUBMISSION**](https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/apply/)*(COVID-19 negative/NON-PUI Study Participants* ***only****)* |  |  |  |  |  |
| [**COVID CRU SUBMISSION**](https://ictr.johnshopkins.edu/service/study-conduct/clinical-research-units/apply/)*(COVID-19 Infected* and*/*or *PUI Outpatient Study Participant*s **only***)* |  |  |  |  |  |
| **RADIATION SAFETY AND USE OF RADIOACTIVE MATERIALS**The use of radioactive materials by personnel at JHMI is authorized by a radioactive materials license issued by the Maryland Department of the Environment. **The Radiation Control Committee (RCU) is the review body which certifies the responsible investigator and facilities to be used for each radioactive nuclide**. Application for an authorization to use radioactive material is made through the RCU, Ext. 5-3710. **See the** [**JHU Health Safety and Environment Manual: Authorization to Use Radioactive Materials (HSE Policy 903)**](https://hpo.johnshopkins.edu/hse/policies/156/11013/policy_11013.pdf?_=0.938517763683) **linked here.** *(Intranet hyperlink, which can be accessed via the “Policies” button at the bottom of the* [*Health/Safety and Environment/Radiation Safety page*](https://www.hopkinsmedicine.org/hse/radiation_safety/) *)* **Forms for projects that involve radiation exposure to human subjects are available at:**[**https://www.hopkinsmedicine.org/institutional\_review\_board/forms/**](https://www.hopkinsmedicine.org/institutional_review_board/forms/)All applications for such use shall be submitted to the [**Radiation Control Committee through the Radiation Safety Officer**](https://www.hopkinsmedicine.org/hse/radiation_safety/)**.** Radioactive materials, including what are sometimes called exempt quantities, shall not be used within the JHMI without prior approval of the Committee. **Please contact the Radiation Safety Office at (410) 955-3710 for questions or assistance**. For applicable human studies, this review will be conducted concurrently with IRB review and will be needed before IRB approval is issued. |
| [**RADIATION CONTROL COMMITTEE**](https://www.hopkinsmedicine.org/hse/radiation_safety/index.html)[**AUTHORIZATION**](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/handbook/handbook_IVa.html) |  |  |  |  |  |
| [**CRRC/RDRC**](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/103_21.html) APPROVAL |  |  |  |  |  |
| **STATE AND FEDERAL REGULATORY APPROVALS, CLEARANCES, AND REGISTRATIONS**Regulatory approvals are not required for ATIP application submission, however, in light of the accelerated nature of this program, investigators are strongly encouraged to initiate any necessary approvals prior to grant submission***.***  |
| **FDA OVERSIGHT OF INVESTIGATIONAL DRUG AND DEVICE RESEARCH** The FDA Centers for Drug Evaluation and Research (CDER), Biologics Evaluation and Research (CBER) and Devices and Radiological Health (CDRH) collectively oversee both development of new investigational drugs, biologics and devices as well as ‘off label use’ of approved drugs, biologics and devices in clinical research. |
| NEW IND/IDE APPLICATION  |  |  |  |  |  |
| IND/IDE AMENDMENT TO EXISTING IND/IDE |  |  |  |  |  |
| IND EXEMPTION REQUEST |  |  |  |  |  |
| NSR/SR DETERMINATION REQUEST |  |  |  |  |  |
| Please include any pertinent details regarding the status of any FDA submissions below (e.g. Pre-IND meeting already scheduled, etc.) |
| **CLINICALTRIALS.GOV REGISTRATION****Awarded PIs with human subjects research projects** meeting the definition of an [**“applicable clinical trial”**](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered) under FDAAA 801, as well as those meeting the **NIH** [**definition of a clinical trial**](https://grants.nih.gov/policy/clinical-trials/definition.htm), **are expected to register their trial at** [**www.ClinicalTrials.gov**](http://www.ClinicalTrials.gov) **prior to enrollment of the first study participant and to submit updates and results as per federal requirements.** For guidance as to whether or not your project must be registered and assistance with questions about the registration process, **contact the** [**ICTR ClinicalTrials.gov program**](https://ictr.johnshopkins.edu/service/regulatory/ct-gov/) **at** **registerclinictrials@jhmi.edu****.**  |
| NEW CLINICALTRIALS.GOV REGISTRATION  |  |  |  |  |  |
| UPDATE TO EXISTING CLINICALTRIALS.GOV REGISTRATION |  |  |  |  |  |
| If applicable, please include any pertinent details regarding the status of registration below: |
| **PURCHASE ORDERS**Activities such as purchase of equipment, supplies, and even services from entities outside of JHU (where the contributions of the supplier of those goods and services does not meet the definition of a subcontractor) may be paid for via Purchase orders (PO). POs are set up through JH Purchasing Department. Please note that purchase orders with aggregate totals of $5000 or more are subject to the [**JH SOM Competitive Bidding Policy.**](https://www.hopkinsmedicine.org/supply-chain/policies-and-procedures/jhhs-competitive-bidding-policy.html) Please contact the Research Navigators at**ICTR\_Navigators@jhmi.edu** for any questions.  |
| DETAILED QUOTE  |  |  |  |  |  |
| DETAILED SCOPE OF WORK FOR SERVICE TO BE PERFORMED |  |  |  |  |  |
| ENSURE THAT VENDOR IS APPROVED IN JH SAP SYSTEM |  |  |  |  |  |
| **SUBCONTRACTS** * + - If an entity external to JHU will be performing **substantive program work**, have responsibility for making programmatic decisions, have a key role in the ATIP proposal, will have responsibility for compliance with federal program requirements, or other significant contributions, a subcontract may be required for compensation for work performed.
		- **NOTE:** Applicants with questions about the need for a subcontract or with projects they know will require a subcontract should contact the ICTR Financial Office at**ICTRSponsored@jhmi.edu** or the Research Navigators at**ICTR\_Navigators@jhmi.edu** as soon as possible **PRIOR** to submission of their ATIP application in order to obtain **authorization and instruction for preparation of their subcontract budget**.
* If authorized, the subcontract may be subject to certain restrictions (e.g. inclusion of IDC from subcontracted institution, subcontract budget is no more than 50% of total requested ATIP funds, etc.).
* If authorized, the total requested funds (**including subsite indirects, if applicable**) for the subcontract must be listed in the overall project budget. **A separate budget specific to the subsite must ALSO be submitted with the overall ATIP budget along with a separate justification, and scope of work for the subsite. Subcontracts are set up through ORA.**
 |
| SUBSITE JUSTIFICATION  |  |  |  |  |  |
| SUBSITE DETAILED SCOPE OF WORK TO BE PERFORMED |  |  |  |  |  |
| SEPARATE SUBSITE BUDGET WITH INDIRECTS  |  |  |  |  |  |
| **HIRING/TRAINING OF STUDY TEAM** |
| DRAFT JOB/FELLOW DESCRIPTION AND OBTAIN DEPARTMENTAL APPROVAL (AS APPROPRIATE) |  |  |  |  |  |
| POST, INTERVIEW, AND HIRE |  |  |  |  |  |
| REQUIRED TRAINING AND CERTIFICATIONS |  |  |  |  |  |
| **OTHER**Please add any other approvals or clearances needed for your specific project which were not included in this list in the space below (e.g. pre-written order sets, permissions for importation of human samples from international sites, etc.) |
|  |  |  |  |  |  |
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