|  |
| --- |
| **ORDERS FOR NEEDED EQUIPMENT, ANIMALS, DRUGS, SUPPLIES**  |
| 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 (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 your institution need to be covered under a MTA. **Non-JHU Faculty***If you are unsure as to whether your proposal will require an MTA and/or you have questions about the process for initiating an agreement, please contact your institutional Office of Research Administration for assistance. If after speaking with your institutional resources, you have additional questions, please contact the Research Navigators at* *ICTR\_Navigators@jhmi.edu* *for further assistance.* **JH Faculty***To initiate* [***Material transfer agreements***](https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/) *(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 secure]** |
| MATERIAL TRANSFER AGREEMENT  |  |  |  |  |  |
| **BIOSPECIMEN TRANSFER** If the material around which an MTA is focused includes human biospecimen(s) collected at your institution, including but not limited to associated data, autopsy specimens, or immortalized cell lines derived from human tissue samples, **a formal, institutional transfer approval may be required.** **Non-JHU Faculty***If your proposal will require sending human biospecimens collected at your institution to an outside organization/facility, and you have questions about whether or not formal approval is required prior to transfer, please contact your institutional IRB or Office of Research Administration for assistance. If after speaking with your institutional resources, you have additional questions, please contact the Research Navigators at* ***ICTR\_Navigators@jhmi.edu*** *for further assistance.* **JH Faculty***Human biospecimens obtained for clinical and/or research purposes at any Johns Hopkins Medicine (JHM) facility are the property of the applicable JHM entity under whose authority the samples were collected. (See policy:* [***ADMIN015: Transferring Human Biospecimens to Outside Organizations***](https://hpo.johnshopkins.edu/doc/fetch.cfm/XMSS7VlK)*) Formal transfer requests for materials governed under this policy must be uploaded under Section 23, Item 4 of a JHM eIRB application (Must first respond: “YES” to Sect 23, Item 1; and “YES” to Sect 23, Item 4 before selecting “Other” and “+Add” to complete the submission).* ***This request consists of the following:*** * *a completed* [***Biospecimen Transfer Information Sheet***](https://www.hopkinsmedicine.org/-/media/institutional-review-board/documents/biospecimen_transfer_information_form.docx)
* *the unsigned consent form(s) used to obtain informed consent for collection and transfer of the specimens with the language associated with the transfer highlighted*
* *the name of the ORA specialist who is working on completing the contract/MTA*
* *and applicable approval document(s) from the recipient site*

*Questions about transferring human biospecimens outside of Hopkins may be directed to* ***Jessica Williams, JHM Biospecimen Program Administrator at*** ***jh-biospecimens@jh.edu******.*** |
| BIOSPECIMEN TRANSFER INFORMATION SHEET |  |  |  |  |  |
| **DATA USE AGREEMENTS**A Data Use Agreement (DUA), also known as a Data Transfer Agreement or Data Sharing Agreement, is an agreement between two parties (academic institutions, government entities, or companies) to exchange data for furthering research. This type of agreement ensures appropriate treatment of the exchanged data under applicable laws.**Non-JHU Faculty***If you are unsure whether or not your proposal requires an executed DUA, please contact your IRB or Office of Research Administration. If after speaking with local resources, you have additional or unanswered questions, please contact the Research Navigators at* ***ICTR\_Navigators@jhmi.edu*** *for further assistance.* **University of Maryland*****College Park****Please see* [***available information***](https://ora.umd.edu/resources/model-agreement#datause) *at the Division of Research Office of Research Administration. For any questions, please contact Cory Whitman, Contract Manager at**oranma@umd.edu****Baltimore County****Please see available information at UMBC’s* ***Office of Sponsored Programs*** *and review the* [***Data Use Agreements FAQ****s*](https://research.umbc.edu/data-use-agreements-faqs/) *linked here for assistance.***JHU Faculty***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://ora.jhmi.edu/i-want-to/sendmaterialsordata/)*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 10 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/2024/01/NCATS-New-Projects-with-Human-Subjects-Research-Addendum-and-Instructions-for-PIs-and-SOs-ver4.3-1.docx) **and/or** [**vertebrate animals**](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fctsa.ncats.nih.gov%2Fwp-content%2Fuploads%2F2023%2F04%2FNCATS-CTSA-Program-Instructions-for-Submitting-Prior-Approval-Requests-of-Planned-Research-Involving-Live-Vertebrate-ver-3.docx&wdOrigin=BROWSELINK). 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**](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwienOuStpSEAxVOEFkFHQB-BsUQFnoECCUQAQ&url=https%3A%2F%2Fgrants.nih.gov%2Fpolicy%2Fhumansubjects%2Fsingle-irb-policy-multi-site-research.htm&usg=AOvVaw3YwkklI0_dbzqRnlcfJlO8&opi=89978449). 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.****Non-JHU Faculty***If you are unsure as to whether your proposal is subject to the NIH sIRB policy and/or to initiate a reliance agreement, please contact your institutional review board for assistance. If after speaking with your institutional resources, you have additional or unanswered questions, please contact the Research Navigators at* ***ICTR\_Navigators@jhmi.edu****for further assistance.* **JHU Faculty** ***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) |  |  |  |  |  |
| [**INSTITUTIONAL BIOSAFETY**](https://www.hopkinsmedicine.org/hse/ibc/regtype2.html)Principal investigators 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 those research materials and describing the research programs and procedures in which they will be used with their institution’s biosafety office. **Non-JHU Faculty***If you are unsure whether or not any materials being used in your proposal will require a registration, please contact your institutional office of health, safety, and environment for assistance. If after speaking with your institutional resources, you have additional or unanswered questions, please contact the Research Navigators at* *ICTR\_Navigators@jhmi.edu* *for further assistance.* **JHU Faculty***Information about all research materials to be registered may be found* [***here****.*](http://www.hopkinsmedicine.org/hse/ibc/regtype2.html)***Please note:***[***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**Some types of research involving human pluripotent stem cells (hPSCs) are subject to institutional oversight. If your proposed project involves materials that require oversight and approval by your institution, please indicate below:**Non-JHU Faculty***If your proposal involves use of hSPSC in any capacity, and you are uncertain as to applicable institutional oversight or approvals required, please contact your IRB for guidance and assistance. If after speaking with your institutional resources, you have additional or unanswered questions, please contact the Research Navigators at* ***ICTR\_Navigators@jhmi.edu******.*****JHU Faculty***More information regarding research activity subject to JHU institutional oversight is available* [***here.***](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/102_4.html) |
| ISCRO APPROVAL  |  |  |  |  |  |
| **RADIATION SAFETY AND USE OF RADIOACTIVE MATERIALS****Non-JHU Faculty***If your proposal involves use of radioactive materials by personnel at your institution, please contact your local radiation safety office for specific guidance about applicable required review and approval processes. If after speaking with your institutional resources, you have additional or unanswered questions, please contact the Research Navigators at* *ICTR\_Navigators@jhmi.edu* *for further assistance.* **JHU Faculty***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.*** ***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/offices-programs/radiation-safety#Our_staff)***.*** *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 |  |  |  |  |  |
| **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 your institution’s purchasing department** and large purchase orders may be subject to your institutions’ competitive bidding policies. **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, if applicable |  |  |  |  |  |
| **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. **Applicants may be asked to provide:*** A second budget and corresponding justification for the sub-award, that contains BOTH the total direct costs AND total indirect costs of the outside facility.
* A scope of work for the outside facility

Subcontracts with outside institutions/facilities should account for no more than 50% of the total requested budget, unless strong justification is provided. **NOTE:** Applicants with questions about the need for a subcontract or with projects they know will require a subcontract should contact the Johns Hopkins 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**.  |
| 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.) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |