

RAMP Readiness Checklist

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)					

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 set forth the conditions of transfer and use, protect proprietary interest in the material, and restrict distribution. Most importantly, the MTA requires the recipient to assume liability which may arise from its use of the material.

[NOTE: MTAs can take 4-8+ weeks to obtain]

MATERIAL TRANSFER AGREEMENT					
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BIOSPECIMEN TRANSFER INFORMATION SHEET

If the material around which an MTA is focused is a human tissue sample collected at Johns Hopkins, including associated data or immortalized cell lines derived from human tissue samples, a [Biospecimen Transfer Information sheet](#) must be submitted to JHTT.

BIOSPECIMEN TRANSFER INFORMATION SHEET					
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RAMP Readiness Checklist

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](#)” 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 with Hopkins. This agreement has specific requirements which are discussed below.

DATA USE AGREEMENT					
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INSTITUTIONAL REGULATORY APPROVALS*

Regulatory approvals are not required for RAMP application submission; in light of the accelerated nature of this program, however, investigators are strongly encouraged to initiate any necessary approvals prior to grant submission.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE APPROVAL

REVISION OF AN EXISTING ACU PROTOCOL					
NEW ACU PROTOCOL NEEDED					

INSTITUTIONAL REVIEW BOARD APPROVAL OF HUMAN SUBJECTS RESEARCH

REVISION AN EXISTING IRB APPLICATION					
NEW IRB APPLICATION					

If approval is also required by an outside IRB (e.g. DoD HRPO, international site Independent Ethics (IE) Committee approval), please explain here including approximate submission and review timeline.

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](#).

RAMP Readiness Checklist

ISCRO APPROVAL					
<p>CLINICAL ENGINEERING CLEARANCES</p> <p>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.</p> <p><u>All applicable equipment, software, and devices</u> 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.</p>					
CLINICAL ENGINEERING CLEARANCE					
<p>RADIATION SAFETY AND USE OF RADIOACTIVE MATERIALS</p> <p>The use of radioactive materials by personnel at JHMI is authorized by a radioactive materials license issued by the Maryland Department of the Environment. All applications for such use shall be submitted to the Radiation Control Committee through the Radiation Safety Officer. Radioactive materials, including what are sometimes called exempt quantities, shall not be used within the JHMI without prior approval of the Committee.</p>					
RADIATION CONTROL COMMITTEE AUTHORIZATION					
CRRC/RDRC APPROVAL					
<p>INSTITUTIONAL BIOSAFETY COMMITTEE</p> <p>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 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. Postdoctoral or Clinical fellows, graduate or undergraduate students, and research associates are covered by the registrations of their Principal Investigator.</p>					
INSTITUTIONAL BIOSAFETY REGISTRATION					

RAMP Readiness Checklist

CLINICAL RESEARCH UNITS

All investigators must submit an application to a Johns Hopkins Institutional Review Board (IRB) before beginning their ICTR [Clinical Research Units](#) (CRUs) application. PLEASE NOTE: Obtaining CRU review and approval can add 2-3 months to your clinical research timeline.

CRU (FORMALLY GCRC) SUBMISSION					
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STATE AND FEDERAL REGULATORY APPROVALS AND CLEARANCES*

Regulatory approvals are not required for RAMP application submission; in light of the accelerated nature of this program, however, investigators are strongly encouraged to initiate any necessary approvals prior to grant submission.

NIH OVERSIGHT OF HUMAN GENE TRANSFER RESEARCH [\(RAC\)](#)

The NIH Office of Biotechnology Activities (OBA) Recombinant DNA Advisory Committee (RAC) provides oversight of research involving recombinant or synthetic nucleic acid molecules.

RAC SUBMISSION					
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Please include any pertinent details regarding the status of RAC submission below:

FDA OVERSIGHT OF INVESTIGATIONAL DRUG AND DEVICE RESEARCH

The FDA Offices of Investigational Drug Research and Evaluation (CDER), Investigational Biologics Research and Evaluation (CBER) and Center for Devices and Radiologic Health (CDRH) 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					
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IND/IDE AMENDMENT TO EXISTING IND/IDE					
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IND/IDE EXEMPTION REQUEST					
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NSR/SR IDE DETERMINATION REQUEST					
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RAMP Readiness Checklist

Please include any pertinent details regarding the status of any FDA submissions below (e.g. Pre-IND meeting already scheduled, etc.)

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 RAMP proposal, will have responsibility for compliance with federal program requirements, or other significant contributions, a subcontract may be required for compensation for work performed. The total requested funds for the subcontract must be listed in the overall project budget. **In this instance, a separate budget specific to the subsite must ALSO be submitted with the overall RAMP 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					
SUBSITE BUDGET WITH INDIRECTS					

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 [JHU Competitive Bidding Policy](#). 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					

RAMP Readiness Checklist

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.)					