

Project Title - \_\_\_\_\_ PI - \_\_\_\_\_ Sponsor - \_\_\_\_\_

Included Questionnaires: Investigator Certification (FCOI), CCQ Conditional Compliance Questionnaire, MIQ Mandatory International Questionnaire, MCQ Mandatory Compliance Questionnaire

<b>Investigator Certifications</b>		
	YES	NO
Q1076_Have lobbying activities been conducted on behalf of this proposal?		
Q1077_Can you certify that the information submitted within this application is true, complete and accurate to the best of your knowledge? Please be aware that any false, fictitious, or fraudulent statements or claims may subject you, as the PI/Co-PI/Co-Investigator to criminal, civil or administrative penalties.		
Q1078_Do you (or your spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that 1) could be affected by the research or 2) is in an entity that could be affected by the research? This applies to current interests/relationships and those within the past 12 months.  A financial interest or fiduciary relationship includes, for example, receipt or contractual entitlement to royalty, equity, or consulting remuneration, employment, and service as an officer or Board of Directors member.  If you answer Yes to this question, you must disclose your financial interest or fiduciary relationship in the JHU online disclosure system, eDisclose ( <a href="http://edisclose.jhu.edu">http://edisclose.jhu.edu</a> ).		
Q1079_Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?		
Q1080_Do you agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports?		

<b>CCQ Conditional Compliance Questionnaire</b>		
	YES	NO
Q1009_Does this project involve use of bio-hazardous materials, radioactive materials, hazardous chemicals, or recombinant DNA? If no, skip to Q1013		
Q1047Does this project involve the use of biohazardous materials?		
Q1010_Does this project involve use of radioactive materials?		
Q1011_Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)?		
Q1012_Does this project involve use of recombinant DNA?		
Q1013_Will the project necessitate alterations or renovations? If "no," skip to Q1014.		
Q1031_Please provide an explanation of the required alterations in the comments below:  Explanation:		
Q1044_Have the alterations/renovations been approved by the Dean's Office?		
Q1014_Will additional space be needed in any project location? If "no," skip to Q1026.		
Q1032_Please add an explanation of the additional space request below:  Explanation:		
Q1042_Has space request been approved by the Dean's Office?		
Q1026_Is cost sharing or matching required by the sponsor? If "no," skip to Q1018.		
Q1049_Has cost sharing been approved by the department and/or Dean, as appropriate?		
Q1045_Please provide cost centers and/or internal orders that will be used for cost sharing in box below:  Cost Centers/Internal Orders:		
Q1018_In this project, will you be utilizing information provided under a confidentiality agreement with a third party?		

<b>Q1083_Science Codes pertaining to University's Strategic Initiatives contained in this research. Select <u>all</u> Codes that apply; select 'None', if appropriate.</b>		
<input type="checkbox"/> No University Strategic Initiative Science Codes apply. <input type="checkbox"/> Project addresses the needs or extends the promise of cities. <input type="checkbox"/> Project connected to Kavli Neuroscience Discovery Initiative. <input type="checkbox"/> Project connected to learning throughout the lifespan. <input type="checkbox"/> Project invests in Baltimore and its citizens. <input type="checkbox"/> Project involves civil space related activities. <input type="checkbox"/> Project involves data-intensive research. <input type="checkbox"/> Project involves global health inequities research.		
<b>Q1084_Science Codes pertaining to Medical or Health characteristics of this research. Select <u>all</u> Codes that apply; select 'None', if appropriate.</b>		
<input type="checkbox"/> No Medical or Health Related Science Codes apply. <input type="checkbox"/> Participants must sign a HIPAA form (Health Insurance Portability Accountability Act). <input type="checkbox"/> Project involves AIDS/HIV research. <input type="checkbox"/> Project involves cancer research.		
<b>Q1085_Science Codes pertaining to Funding of this proposal. Select <u>all</u> Codes that apply; select 'None', if appropriate.</b>		
<input type="checkbox"/> No Funding Proposal Science Codes apply. <input type="checkbox"/> Project involves a non-disclosure agreement or Confidentiality Agreement that may be either in negotiations or fully executed. <input type="checkbox"/> Proposal Type Negotiations Only. <input type="checkbox"/> Proposal is the initial Negotiated agreement with no dollars specified (Proposal Type Negotiation Only), after which Task Orders will be issued (Proposal Type Task Order). <input type="checkbox"/> Proposal will allow an individual to remain on JHU payroll while providing service to a governmental entity. Proposal Type Negotiation Only.		
<b>Q1086_Science Codes pertaining to the General Purpose of this proposal. Select <u>all</u> Codes that apply; select 'None', if appropriate.</b>		
<input type="checkbox"/> Designed to promote the new research career of PI, for example: NIH K awards, NSF Career awards, ONR Young Investigator awards, or other sponsors such as Beckman Young Investigator Program. <input type="checkbox"/> No General Proposal Purpose Science Codes apply. Open solicitation through a JHU department or center. <input type="checkbox"/> Open solicitation through a JHU department or center. <input type="checkbox"/> Proposal requests modification of an award, grant, but only to extend the period of performance.		
	<b>YES</b>	<b>NO</b>
<b>Q1015_Are any administrative costs included in the budget? If "no," skip to Q1019.</b>		
Q1033_Please provide an explanation for the administrative costs requested in the comments below:		
Explanation:		
<b>Q1019_In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party? If no, skip to Q1095.</b>		
Q1036_Please provide the name of the company or institutions with whom you have or may have the material transfer agreement.		
Name:		
<b>Q1095_Is this proposal, in any way, a result of Catalyst or Discovery award funding? If "no," skip next question.</b>		
Q1096_Was it a Catalyst or Discovery award?		

<b>MIQ Mandatory International Questionnaire</b>		
	<b>YES</b>	<b>NO</b>
<b>Q1055 Will your project require the involvement of any foreign country, its citizens or organizations? If "no," skip to MCQ, the next set of questions.</b>		
Q1056 Will any of the proposed project activity take place within a foreign country?		
Q1057 Please provide the name of the foreign country.		
Name:		
Q1058 Please select the type of activity that you expect to occur in this country. <ul style="list-style-type: none"> <li><input type="checkbox"/> 1 – Subagreement work performed by a foreign university or other foreign entity</li> <li><input type="checkbox"/> 2 – Hiring employees</li> <li><input type="checkbox"/> 3 – Opening a bank account</li> <li><input type="checkbox"/> 4 – Leasing space</li> <li><input type="checkbox"/> 5 – U.S or foreign persons sending or receiving international shipments of tangible items (e.g., equipment/materials, organic/inorganic) or information (e.g., technical data), sent supporting the project</li> <li><input type="checkbox"/> 6 – Travel by project personal to foreign countries or their facilitation of limited-duration activity in them (e.g., conference or meeting)</li> <li><input type="checkbox"/> 7 – University employees or students working in a foreign country for more than ninety (90) days</li> <li><input type="checkbox"/> 8 – Other. Please describe here –</li> </ul>		
<b>Q1070 Do you need additional space to describe the type of activity you expect will take place in this country?</b>		

Q1071 Please describe the Other activity that is expected to take place in this country:		
Other activity:		
	YES	NO
Q1060 Do you need to select another country? <a href="#">Click here to add additional countries.</a>		
Q1061 During the project, will you provide foreign persons access to devices, materials, source code or technical know-how while they are in the United states?		
Q1063_Please provide as much of the following information as you can about any foreign national or foreign organization to which you expect to provide access to project-related devices, materials, source code or technical data during the course of the project: -full legal name, -country of citizenship (or an organization's home country), -connection to the proposed project (e.g., University employee, student-lab assistant, collaborator, vendor, independent contractor, subrecipient), -the parts of the project in which they will be involved and what they are expected to contribute, and -location during project (US and/or named foreign country) Information:		
<a href="#">Click here to add additional countries.</a>		
	YES	NO
Q1090_In addition to the foreign persons whom you described above, do you reasonably expect that other, presently unknown foreign persons will also be provided with access to devices, materials, source code or technical know-how, while they are in the United States?		
Q1064_To the best of your knowledge, will there be any restrictions upon: a) the publication of project results, or b) the inclusion of foreign nationals in some or all project activities?		
Q1065_In the text box below, please describe the kind of restrictions that you believe will apply to the conduct of your project or to the publication of its results. Restriction information:		
Q1067_Are any foreign countries associated with your project subject to sanctions implemented by the Office of Foreign Assets Control (OFAC)? This includes any country that you have disclosed in prior Research Compliance Questions, either because project-related activities are expected to take place within the boundaries of a country, or because one of its citizens will contribute to the project. If you do not know if a particular country is subject to OFAC sanctions, go to: <a href="https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx">https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx</a> .		

<b>MCQ Mandatory Compliance Questionnaire</b>		
	YES	NO
Q1005_Does this proposal involve human subjects? If this proposal includes any of the following, please answer "yes." If "no," skip Q1007. - <b>Interventional clinical trial</b> - <b>Observational clinical studies</b> - <b>Social/Behavioral intervention</b> - <b>Collection of data by interview, survey, focus group, educational tests, observation of public behavior</b> - <b>Review of existing identifiable data including protected health information</b>		
Q1006_Does this project involve disclosure/receipt of protected health information to/from sponsor or third parties?		
Q1100_Is this a multi-site study? If "no," skip to Q1007.		
Q1091_You have indicated that your proposal includes a multi-site study involving human subjects. A plan for use of a single IRB (sIRB) may be required for your federally-funded, human subjects research. The sIRB is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study.  Does this proposal require use of a single IRB (sIRB) to review the human subjects research proposed? Please check with the appropriate JHU IRB if uncertain whether your study may require use of a sIRB.		
Q1102_Will you use the JHM IRB or an External IRB as the sIRB?	JHM's sIRB	External IRB
	YES	NO
Q1007_Does this project involve use of any of the following: human embryonic stem cells (hESCs), somatic cell nuclear transfer (SCNT) involving human cells or other human pluripotent stem cells (hPSCs) that are already subject to oversight by the JHU Institutional Stem Cell Research. If answer is "no," skip to Q1008.		
Q1054_Have you obtained review and approval from the Stem Cell Research Oversight Committee (JHU ISCRO)?		

<b>Q1008_Does this project involve use of live vertebrate animals?</b>		
<b>Q1017_Will the project include subawards or subcontracted effort to other organizations? If "no," skip to Q1020.</b>		
Q1107_Will there be any foreign subrecipients?		
Q1104_Does any named JHU investigator (or any immediate family member of a named JHU investigator) have an ownership or equity interest in any proposed subrecipient? If "no," skip to Q1105.		
Q1106_Has the relevant named JHU investigators disclosed, as required by JHU Policy, all financial interests and employment relationships between the named JHU investigator (and/or their immediate family member) and the proposed subrecipient?		
Q1105_Does any proposed subrecipient employ any immediate family member of a named JHU investigator? If "no," skip to Q1120.		
Q1106_Has the relevant named JHU investigators disclosed, as required by JHU Policy, all financial interests and employment relationships between the named JHU investigator (and/or their immediate family member) and the proposed subrecipient?		
<b>Q1020_Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator's), such as inventions, copyrights, etc.? If "no," skip to Q1066.</b>		
Q1037_Please identify the JHU disclosure number.		
JHU Disclosure Number:		
Q1038_Has the proposed use been approved by Johns Hopkins Tech Ventures (JHTV)?		
<b>Q1066_Will any item or information used or developed during the proposed project a) be the product of defense funding, b) be designed, developed, configured, adapted, or modified specifically for a military, space or intelligence application, or c) have potential, military, space or intelligence applications?</b>		
<b>Q1098_Do you:</b> -have access to non-public information, -or have you performed or do you expect to perform work for the federal government; that may provide you or another member of The Johns Hopkins University with an unfair competitive advantage in applying for federal funding or that could appear to bias its judgement? If "yes," answer Q1099.		
Q1099_Please provide a general explanation regarding the activities as defined in the COI policy below:		
Explanation:		

<b>COVID Questionnaire</b>		
	YES	NO
- Q1108_Does this proposal relate to COVID-19 work?		
Q1109 Does this proposal involve funds coming from the Coronavirus Aid, Relief, and Economic Security (CARES) Act?		
Q1110 Will your proposal include any studies exposing animals to SARS-CoV-2 at JHU?  A COVID-19 Animal Models committee (CAM) tracks all COVID-19 studies that require animal models to assure capacity is available. If your COVID-19 research involves an animal component, you first need to complete a form stating your interest in a COVID-19 animal model. Follow the link here: <a href="https://hub.jhu.edu/novel-coronavirus-information/research-preparedness/coronavirus-research-publications-resources/">https://hub.jhu.edu/novel-coronavirus-information/research-preparedness/coronavirus-research-publications-resources/</a> You will be then contacted by CAM asking for additional information to prioritize requests.		
Does your COVID-19 work include use of JHM resources as explained below:  If you plan to use the resources of Johns Hopkins Medicine (JHM), such as access to patients and/or healthcare workers, biospecimens, or data, you will need to submit a request for approval to the JHM Clinical Research Coordinating Committee here: <a href="https://ictr.johnshopkins.edu/coronavirus/covid-johns-hopkins-clinical-research-coordinating-committee/">https://ictr.johnshopkins.edu/coronavirus/covid-johns-hopkins-clinical-research-coordinating-committee/</a> Approval to proceed with your COVID-19 related research should be secured from this committee before you submit your proposal to your research administration office (ORA, BARA or JHURA) for review and approval. Approval notices/emails should be uploaded into the Coeus proposal development record. Please contact your research administration representative if you have any questions about a timely submission of your proposal.		

PI Signature \_\_\_\_\_ Date \_\_\_\_\_