

# Compliance Questions

<b>Proposal Number:</b>	
<b>Proposal Title:</b>	
<b>Sponsor:</b>	
<b>Unit:</b>	
<b>Investigator Name:</b>	
<b>Investigator Signature:</b>	
<b>Included Questionnaires:</b>	Personnel Certification Questionnaire CCQ Conditional Compliance Questionnaire MIQ Mandatory International Questionnaire MCQ Mandatory Compliance Questionnaire
<b>Creation Date:</b>	08/04/2023

Personnel Certification Questionnaire		
Q1076_Have lobbying activities been conducted on behalf of this proposal?	Yes	No
Q1077_Is the information submitted within this application 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 an Investigator (PI/Co-PI/Co-Investigator/Key Person) to criminal, civil or administrative penalties. Checking ?Yes? confirms that you have read, understand and are in compliance with the federal agency requirements listed here <a href="https://jhura.jhu.edu/current-and-pending-or-other-support/">https://jhura.jhu.edu/current-and-pending-or-other-support/..</a>	Yes	No
Q1119_Do you hold a paid or unpaid appointment, position or affiliation at any entity other than JHU This includes unpaid positions such as guest, adjunct, honorary, or visitor titles at other institutions.  If yes, has the appointment been disclosed to and approved by your divisional dean's office? All outside appointments require prior approval by your divisional dean's office.  If yes, please ensure that all appointments are listed in your Biosketch and are included in your eDisclose record.  If no, please contact your divisional dean's office to identify next steps for obtaining approvals. See: <a href="https://research.jhu.edu/jhura/compliance/foreign-engagement/">https://research.jhu.edu/jhura/compliance/foreign-engagement/</a> <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1134_Are the paid or unpaid appointments, affiliations, or employment with a foreign institution?  If yes, please remember that you must upload copies of contracts/agreements specific to any foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in your Other Support documents. If the contracts/agreements are not in English, recipients must provide translated copies.  NOTE: The contracts, including the contract for appointments and any other contracts associated with any resources provided resource must first be approved by your divisional dean's office and then uploaded as a single file in Other Support document.	Yes	No
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 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 your organization's disclosure system. For JHU Investigators, use eDisclose ( <a href="http://edisclose.jhu.edu">http://edisclose.jhu.edu</a> ), and include such disclosure in the proposal or progress report (.eg.outside employment in your Biosketch).	Yes	No
Q1115_Are you participating in any investigator program sponsored by a foreign government (e.g. Talent recruitment program)?  NOTE: Many federal funders do not permit researchers participating in such programs from receiving any federal research support.  NOTE: Foreign talent programs are defined as ?any foreign-state-sponsored attempt to acquire US scientific-funded research or technology through foreign government-run or funded recruitment programs that target scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working or educated in the United States.?	Yes	No
<b>If No, advance to the next non-shaded question</b>  Q1116_What country(ies)?		

Q1135_Do you have any visiting postdoctoral fellows, students or scholars involved in research for your lab supported in full or in part by any non-JHU organization, institution, company or government? All visitors must be approved according to the JHU Visitor?s Policy. <b>If No, advance to the next non-shaded question</b>	Yes	No
If yes, was this visitor approved according to the JHU?s Visitor?s Policy?  Note: The visitor?s efforts, including the external funding support for the visitor, are considered ?Other Support? and must be disclosed to federal funders in your Other Support document. <a href="https://research.jhu.edu/jhura/current-and-pending-or-other-support/">https://research.jhu.edu/jhura/current-and-pending-or-other-support/</a>	Yes	No
Q1137_Do you have access to ?in-kind? research resources from any source outside of JHU? This includes resources obtained through a formal or informal collaboration, appointment, or relationship with an outside institution, organization or company. Examples include lab or office space, specialized equipment, research data or materials that are provided without charge to you. See: <a href="https://grants.nih.gov/grants/forms/othersupport.htm">https://grants.nih.gov/grants/forms/othersupport.htm</a>  If yes, you must disclose the details of that resource in your Other Support. Identify any agreements under which you receive these resources. If the research resources are from a foreign institution and related to a foreign appointment or foreign employment (including consulting or research that has not been approved in eDisclose) , you must upload the associated contracts under which you received access to the resource.	Yes	No
Q1079_Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?	Yes	No
Q1080_Do you agree to accept responsibility for the scientific conduct of the project and to provide all required progress reports?	Yes	No
Q1117_I have reviewed the proposal and certify that I have completely and accurately disclosed my current and pending support/other support (both domestic and foreign,) including the amount, type, and source of all support received, or expected to be received, as of the time of this disclosure or will do so at the Just in Time stage of the application process, as may be required by the funder. I understand I am obligated to report in a timely fashion any changes to such disclosures in accordance with University and sponsor policy, and that JHU is required to promptly relay such information to the sponsor.	Yes	No
Q1138_I have been made aware of the requirements under federal law to completely and accurately disclose my current and pending support/other support, and I am aware that any false, fictitious, or fraudulent statements or claims related to my current and pending/other support may subject me to criminal, civil, or administrative penalties under federal law.	Yes	No

CCQ Conditional Compliance Questionnaire		
Q1009_Does this project involve the use of bio-hazardous materials, recombinant DNA/synthetic nucleic acid molecules, radioactive materials, or hazardous chemicals? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1012_Does this project involve use of recombinant DNA?	Yes	No
Q1147_Briefly describe the use of recombinant DNA.		
Q1011_Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals at the NIOSH IDLH level)?	Yes	No
Q1146_Briefly describe the use of hazardous chemicals.		
Q1010_Does this project involve use of radioactive materials?	Yes	No
Q1145_Briefly describe the user of radioactive materials.		
Q1047_Does this project involve the use of biohazardous materials?	Yes	No
Q1144_Briefly describe the use of biohazardous materials.		
Q1013_Will the project necessitate alterations or renovations? <b>If No, advance to the next non-shaded question</b>	Yes	No

Q1044_Have the alterations/renovations been approved by the Dean's Office?		Yes	No
Q1031_Please provide an explanation of the required alterations.			
Q1014_Will additional space be needed in any project location?		Yes	No
If No, advance to the next non-shaded question			
Q1042_Has space request been approved by the Dean's Office?		Yes	No
Q1032_Please add an explanation of the additional space request.			
Q1026_Is cost sharing or matching required by the sponsor?		Yes	No
If No, advance to the next non-shaded question			
Q1045_Please provide cost centers and/or internal orders that will be used for cost sharing.			
Q1049_Has cost sharing been approved by the department and/or Dean, as appropriate?		Yes	No
Q1018_In this project, will you be utilizing information provided under a confidentiality agreement with a third party?		Yes	No
If No, advance to the next non-shaded question			
Q1035_Please provide the name of the any third parties with whom you expect to enter into confidentiality agreements.			
Q1083_Science Codes pertaining to University's Strategic Initiatives contained is this research. Select all Codes that apply; select 'None', if appropriate			
<input type="checkbox"/>	No University Statgenic 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.		
<input type="checkbox"/>	Project involves individualized health research.		
<input type="checkbox"/>	Project involves sustainable energy research.		
Q1084_Science Codes pertaining to Medical or Health characteristics of this research. Select all Codes that apply; select 'None', if appropriate.			
<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.		
<input type="checkbox"/>	Project involves development of a vaccine or testing vaccine effectiveness.		
Q1085_Science Codes pertaining to Funding of this proposal. Select all Codes that apply; select 'None', if appropriate.			

	No Funding Proposal Science Codes apply.	
	Project involves a non-disclosure agreement or Confidentiality Agreement that may be either in negotiations or fully executed. Proposal Type Negotiations Only.	
	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).	
	Proposal will allow an individual to remain on JHU payroll while providing service to a governmental entity. Proposal Type Negotiation Only.	
	Sponsor will approve proposal based on an administrative, not competitive, review.	
Q1086_Science Codes pertaining to the General Purpose of this proposal. Select all Codes that apply; select 'None', if appropriate.		
	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.	
	No General Proposal Purpose Science Codes apply.	
	Open solicitation through a JHU department or center.	
	Proposal requests modification of an award, grant, but only to extend the period of performance.	
	Proposal requests the transfer of an award, grant, from another institution to JHU.	
Q1015_Are any administrative costs included in the budget?		Yes
If No, advance to the next non-shaded question		
Q1033_Please provide an explanation for the administrative costs requested.		
Q1019_In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party?		Yes
If No, advance to the next non-shaded question		
Q1152_Does your transfer of materials involve the procurement of human gametes and/or embryos for use in human embryo research and/or stem cell research?		Yes
NOTE: If yes, additional institutional approval is required. Contact biospecimens@jhu.edu.		No
Q1151_Does your transfer of materials involve the procurement of fresh human somatic cells and/or tissues for the purposes of stem cell research?		Yes
NOTE: If yes, additional institutional approval is required. Contact biospecimens@jhu.edu .		No
Q1148_Is this an incoming MTA?		Yes
Q1149_Does your transfer of materials involve the procurement and/or use of banked and historical human biospecimens, such as cell lines and tissues?		Yes
Q1150_Please verify the following with regard to the banked/historical human biospecimens:		Yes
- There will be no attempt to re-identify biospecimens that have been provided without identifiers.		No
- The biospecimens will not be used for reproductive purposes (e.g., to create embryos from in vitro derived gametes).		
- All required institutional approvals have been or will be secured. See [link to Human Stem Cell and Related Research Guidance] for details about required institutional approvals.		
Q1036_Please provide the name of the company or institutions with whom you have or may have the material transfer agreement.		
Q1095_Is this proposal, in any way, a result of Catalyst or Discovery award funding?		Yes
If No, advance to the next non-shaded question		
Q1142_Will work be conducted off-campus or off-site?		Yes
Q1143_Please confirm that you will comply with the NSF policy for Safe and Inclusive Working Environments Plan for Off-Campus and Off-Site Research and will provide a project-specific plan, disseminated to individuals participating in the off-campus or off-site research prior to departure (see NSF PAPPG Chapter II.E.9).		Yes
Q1133_Was it a Catalyst or Discovery award?		No

## MIQ Mandatory International Questionnaire

Q1055\_Will your project require the involvement of any foreign country, its citizens or organizations?

Yes

No

If No, advance to the next questionnaire

Please select foreign country and activity type where sponsored activity will take place.

Additional Information

[Click here to add additional countries.](#)

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)

[Click here to add additional countries.](#)

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?

Yes

No

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?

Yes

No

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.

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.

Yes

No

If you do not know if a particular country is subject to OFAC sanctions, click on the link at the right of this question. In the window that pops up, use the link provided in the Regulations section. This should instruct your browser to open the OFAC Web page that lists currently sanctioned countries.

## MCQ Mandatory Compliance Questionnaire

Q1005\_Does this proposal involve human subjects? If this proposal includes any of the following, please answer "yes"

- Interventional clinical trial
- Observational clinical studies
- Social/Behavioral intervention
- Collection of data by interview, survey, focus group, educational tests, observation of public behavior
- Review of existing identifiable data including protected health information

If No, advance to the next non-shaded question

Yes

No

Q1100\_Is this a multi-site study?

Yes

No

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.

Yes

No

Q1102_Will you use the JHM IRB or an External IRB as the sIRB?		
Q1006_Does this project involve disclosure/receipt of protected health information to/from sponsor or third parties?	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 Oversight (ISCRO) Committee ( <a href="http://www.hopkinsmedicine.org/Research/iscro/">http://www.hopkinsmedicine.org/Research/iscro/</a> )? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1054_Have you obtained review and approval from the Stem Cell Research Oversight Committee (JHU ISCRO)?	Yes	No
Q1008_Does this project involve use of live vertebrate animals?	Yes	No
Q1017_Will the project include subawards or subcontracted effort to other organizations? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1105_Does any proposed subrecipient employ any immediate family member of a named JHU investigator?	Yes	No
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?	Yes	No
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?	Yes	No
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?	Yes	No
Q1107_Will there be any foreign subrecipients?	Yes	No
Q1020_Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator's), such as inventions, copyrights, etc? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1038_Has the proposed use been approved by Johns Hopkins Tech Transfer?	Yes	No
Q1037_Please identify the JHU disclosure number.		
Q1066_Will any tangible item or information used for, or likely to arise from, the proposed project a) be the product of defense funding, b) be designed, developed, configured, adapted, or modified for a military, space or intelligence application, or c) have potential, military, space or intelligence applications? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1092_Will the project include or anticipate a Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant in this study?	Yes	No
Q1094_Please provide comments on the Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant being used.		
Q1093_Please check the appropriate Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant.		
Q1098_Do you:  - 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? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1099_Please provide a general explanation regarding the activities as defined in the OCI policy.		
Q1108_Does this proposal relate to COVID-19 work? <b>If No, advance to the next non-shaded question</b>	Yes	No
Q1111_Does this proposal require that you use the resources of Johns Hopkins Medicine (JHM), such as access to patients and/or healthcare workers, biospecimens, or data?	Yes	No

Q1110_Will your proposal include any studies exposing animals to SARS-CoV-2 (COVID-19) at JHU?	Yes	No
Q1109_Does this proposal involve funds coming from the Coronavirus Aid, Relief, and Economic Security (CARES) Act?	Yes	No

Proposal Number:	
Proposal Title:	
Sponsor:	
Unit:	
Investigator Name:	

Investigator Signature: \_\_\_\_\_

Included Questionnaires: Personnel Certification Questionnaire

Creation Date: 08/04/2023

Personnel Certification Questionnaire		
Q1076_Have lobbying activities been conducted on behalf of this proposal?	Yes	No
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<p>Q1119_Do you hold a paid or unpaid appointment, position or affiliation at any entity other than JHU This includes unpaid positions such as guest, adjunct, honorary, or visitor titles at other institutions.</p> <p>If yes, has the appointment been disclosed to and approved by your divisional dean's office? All outside appointments require prior approval by your divisional dean's office.</p> <p>If yes, please ensure that all appointments are listed in your Biosketch and are included in your eDisclose record.</p> <p>If no, please contact your divisional dean's office to identify next steps for obtaining approvals. See: <a href="https://research.jhu.edu/jhura/compliance/foreign-engagement/">https://research.jhu.edu/jhura/compliance/foreign-engagement/</a></p> <p><b>If No, advance to the next non-shaded question</b></p>	Yes	No
<p>Q1134_Are the paid or unpaid appointments, affiliations, or employment with a foreign institution?</p> <p>If yes, please remember that you must upload copies of contracts/agreements specific to any foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in your Other Support documents. If the contracts/agreements are not in English, recipients must provide translated copies.</p> <p>NOTE: The contracts, including the contract for appointments and any other contracts associated with any resources provided resource must first be approved by your divisional dean's office and then uploaded as a single file in Other Support document.</p>	Yes	No
<p>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 an entity that could be affected by the research? This applies to current interests/relationships and those within the past 12 months.</p> <p>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.</p> <p>If you answer Yes to this question, you must disclose your financial interest or fiduciary relationship in your organization's disclosure system. For JHU Investigators, use eDisclose (<a href="http://edisclose.jhu.edu">http://edisclose.jhu.edu</a>), and include such disclosure in the proposal or progress report (.eg.outside employment in your Biosketch).</p>	Yes	No
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Q1116_What country(ies)?		
<p>Q1135_Do you have any visiting postdoctoral fellows, students or scholars involved in research for your lab supported in full or in part by any non-JHU organization, institution, company or government? All visitors must be approved according to the JHU Visitor's Policy.</p> <p><b>If No, advance to the next non-shaded question</b></p>	Yes	No



<p>If yes, was this visitor approved according to the JHU's Visitor's Policy?</p> <p>Note: The visitor's efforts, including the external funding support for the visitor, are considered 'Other Support' and must be disclosed to federal funders in your Other Support document. <a href="https://research.jhu.edu/jhura/current-and-pending-or-other-support/">https://research.jhu.edu/jhura/current-and-pending-or-other-support/</a></p>	Yes	No
<p>Q1137_Do you have access to 'in-kind' research resources from any source outside of JHU? This includes resources obtained through a formal or informal collaboration, appointment, or relationship with an outside institution, organization or company. Examples include lab or office space, specialized equipment, research data or materials that are provided without charge to you. See: <a href="https://grants.nih.gov/grants/forms/othersupport.htm">https://grants.nih.gov/grants/forms/othersupport.htm</a></p> <p>If yes, you must disclose the details of that resource in your Other Support. Identify any agreements under which you receive these resources. If the research resources are from a foreign institution and related to a foreign appointment or foreign employment (including consulting or research that has not been approved in eDisclose) , you must upload the associated contracts under which you received access to the resource.</p>	Yes	No
<p>Q1079_Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?</p>	Yes	No
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<p>Q1117_I have reviewed the proposal and certify that I have completely and accurately disclosed my current and pending support/other support (both domestic and foreign,) including the amount, type, and source of all support received, or expected to be received, as of the time of this disclosure or will do so at the Just in Time stage of the application process, as may be required by the funder. I understand I am obligated to report in a timely fashion any changes to such disclosures in accordance with University and sponsor policy, and that JHU is required to promptly relay such information to the sponsor.</p>	Yes	No
<p>Q1138_I have been made aware of the requirements under federal law to completely and accurately disclose my current and pending support/other support, and I am aware that any false, fictitious, or fraudulent statements or claims related to my current and pending/other support may subject me to criminal, civil, or administrative penalties under federal law.</p>	Yes	No