

Compliance Questions Explained

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

Investigator Certifications

**Important Note - These five Investigator Certification questions must be answered by all key personnel involved with the research proposal. A signed copy of this certification for each person must be uploaded into the Coeus record prior to approval.*

Q1076 Have lobbying activities been conducted on behalf of this proposal?

Explanation and Frequently Asked Questions:

<http://web.jhu.edu/administration/gca/political%20activities%20guidelines%20and%20lobbying%20and%20advocacy/Political%20Activity%20Guidelines/Political%20Activity%20Guidelines%20Documents/LobbyingFAQ.pdf>

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.

Explanation:

<https://www.jhu.edu/university-policies/>

Then follow the click path below:

Policy and Document Library - University Research Integrity (GEN007)

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 (<http://edisclose.jhu.edu>).

DID YOU KNOW?

Only answer, "yes" to this question if the financial conflict of interest pertains to this proposal.

Explanation:

http://web.jhu.edu/conflict_of_interest/JHU_Policies

<https://research.jhu.edu/jhura/compliance/conflicts-of-interest/>

https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Q1079 Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?

Explanation:

Reference - Uniform Guidance 2 CFR § 200.213 - Suspension and debarment

<https://www.jhu.edu/university-policies/> -Then follow the click path below:

Policy and Document Library / Suspension and Debarment (PRO002)

Q1080 Do you agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports?

Explanation:

<https://www.jhu.edu/university-policies/> -Then follow the click path below:

Policy and Document Library / University Research Integrity (GEN007)

CCQ Conditional Compliance Questionnaire

Q1009 Does this project involve use of bio-hazardous materials, radioactive materials, hazardous chemicals, or recombinant DNA? If no, skip to Q1013

Explanation:

JHU's Biosafety Office (working within the Department of Health, Safety and Environment) provides advice and information concerning the Institutional Biosafety Committee (IBC), the current status of regulations which pertain to the use of recombinant DNA molecules in The Johns Hopkins Institutions, and information concerning guidelines for research with biological agents that can cause disease in humans, plants, or animals.

The Institutional Biosafety Committee reviews research involving recombinant or synthetic nucleic acid molecules as well as agents or materials identified as moderate to high risk such as potential pathogens/infectious agents and biological toxins. Research involving materials that require IBC review cannot proceed without IBC approval. New investigators, and those whose research is subject to NIH recombinant DNA guidelines, must complete a *Registration of Research with Recombinant DNA* form, and be approved by the IBC prior to the initiation of such research. Investigators who wish to use a potential pathogen/infectious agent or biological toxin in their research program must complete an *Infectious Agents, Pathogen, or Biological Toxin* form, and be approved by the IBC prior to the initiation of such research. Investigators who wish to use human-derived materials in their research program, including human-derived cell lines, must complete a *Human Tissue, Cell Line, or Body Fluids* form and be approved by the Biosafety Office prior to the initiation of such research.

The forms noted above and a copy of the latest *NIH Guidelines for Research Involving Recombinant DNA Molecules* may be obtained from the Biosafety Officer, Ext. 5-5918, or may be downloaded from the HSE Web Site (www.hopkinsmedicine.org/hse).

The JHMI HSE policies 901-916 contain current institutional policies regarding use of radioactive materials and radiation producing machines. These policies are located at: <https://hpo.johnshopkins.edu/hse/>. Specific questions may be directed to the Radiation Control Unit at 410-955-3710.

Information for human subjects research, including that which involves radiation exposure to human subjects is available at: <https://www.hopkinsmedicine.org/research/resources/offices-policies/human-subjects-research.html>. Specific questions may be directed to the Radiation Control Unit at 410-955-3710.

Forms for registration of Hazardous and Toxic Chemicals and the criteria for chemicals meeting HSE requirements for registration are available at www.hopkinsmedicine.org/hse/.

U.S. export control regulations may require JHU to have a license before it includes citizens of certain countries in work that involves organic or inorganic materials capable of causing harm to living things (as well as technology associated with them).

Q1012 Does this project involve use of recombinant DNA?

The Johns Hopkins Institutional Biosafety Committee, a subcommittee of the Joint Committee for Health, Safety and Environment, shall monitor the conduct of all research involving recombinant or synthetic nucleic acid molecules.

<https://www.jhu.edu/university-policies/> - Then follow the click path below:

Policy and Document Library / Health, *Safety and Environment* in the Policy & Procedures Categories (HSE503) Recombinant or Synthetic Nucleic Acid Molecules

Explanation:

The Institutional Biosafety Committee, reviews research registrations involving recombinant DNA. New investigators and those whose research is subject to NIH recombinant DNA guidelines are to complete a Registration of Research with Recombinant DNA Form prior to the initiation of such research. The form and a copy of the latest NIH Guidelines for Research Involving Recombinant DNA Molecules may be obtained from the Biosafety Officer, Ext. 5-5918 or downloaded from the HSE Web Site, www.hopkinsmedicine.org/hse.

Q1011 Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)?

It is the policy of Johns Hopkins to encourage the minimization of hazardous waste generated from patient care, research, and teaching activities.

<https://www.jhu.edu/university-policies/> -Then follow the click path below:

Policy and Document Library / (HSE704) Registry of Highly Hazardous Chemicals
<https://www.jhu.edu/university-policies/> - Then follow the click path below:
Policy and Document Library / (HSE703) Management of Hazardous Chemicals

Q1010 Does this project involve use of radioactive materials?

Explanation:

Health, Safety and Environment (HSE), located at 2024 East Monument Street, is responsible for providing information and advising research investigators concerning the approved methods for the handling and disposal of radioactive materials, recombinant DNA, infectious agents and toxic chemicals. Certain hazardous agents and materials require approval prior to use at these institutions. The HSE maintains a certification list of those university Principal Investigators who have registered their recombinant DNA and potentially pathogenic/oncogenic agents or materials. A copy of this registration list is on file in the Office of Research Administration. If a project will involve organisms pathogenic to humans requiring safety practices, equipment, and facilities at Biosafety Level II and above (e.g., HIV, HVB, TB, legionella, CMV, shigella, etc.), or hazardous or highly toxic chemicals, the Health, Safety and Environment (HSE) must be notified and HSE approval obtained well in advance of submitting the application to the Office of Research Administration. If the number and/or date of approval is not provided on the special review tab, or if the approval is listed as "pending," signature of the sponsored project application will be delayed until we get HSE confirmation that the project will not pose unacceptable risks or requirements.

All applications for such use shall be submitted to the Committee through the Radiation Safety Officer.
https://www.hopkinsmedicine.org/hse/radiation_safety/index.html

<https://www.jhu.edu/university-policies/> -Then follow the click path below:

Policy and Document Library / Health, *Safety and Environment* in the Policy & Procedures Categories

Q1047 Does this project involve the use of biohazardous materials?

Explanation:

The Biosafety Officer of HSE provides advice and information concerning the guidelines for research with agents which can cause disease in man, plants or animals. The Institutional Biosafety Committee reviews and approves research with agents or materials identified as moderate to high risk. The Biosafety Officer provides review and containment guidelines for low risk agents. A Research of Registration with Human Tissue, Infectious Agents, Pathogens, Oncogenes or Toxins Form, is to be submitted to the Biosafety Officer. The JHMI Radiation Safety Manual contains a copy of the form which must be completed and the current institutional policies regarding radioactive materials. Forms for projects that involve radiation exposure to human subjects are available at https://www.hopkinsmedicine.org/institutional_review_board/forms/. Forms for registration of Hazardous and Toxic Chemicals and the criteria for chemicals meeting HSE requirements for registration are available at www.hopkinsmedicine.org/hse/. The Biosafety Officer of HSE provides advice and information concerning the current status of regulations which pertain to the use of recombinant DNA molecules in The Johns Hopkins Institutions. The Institutional Biosafety Committee, reviews research registrations involving recombinant DNA. New investigators and those whose research is subject to NIH recombinant DNA guidelines are to complete a Registration of Research with Recombinant DNA Form prior to the initiation of such research. The form and a copy of the latest NIH Guidelines for Research Involving Recombinant DNA Molecules may be obtained from the Biosafety Officer, Ext. 5-5918 or downloaded from the HSE Web Site, www.hopkinsmedicine.org/hse.

<https://www.jhu.edu/university-policies/> -Then follow the click path below:

Policy and Document Library / Health, *Safety and Environment* in the Policy & Procedures Categories

Q1013 Will the project necessitate alterations or renovations? If no, skip to Q1014.

Alterations or renovations to university property is a concern of your school's business office and may require approval by the Dean's Office.

Explanation:

Any alterations or renovations to existing space, as well as agreement to the cost and funding of those alterations/renovations, require appropriate institutional approvals prior to proposal submission. These

DID YOU KNOW?

Only answer, "yes" to this question if the alterations or renovations require funding.

modifications include changes to electrical systems, HVAC, plumbing, reinforcement of an existing structure to support special equipment, etc.

Q1044 Have the alterations/renovations been approved by the Dean's Office?

Q1031 Please provide an explanation of the required alterations in the comments below:

Q1014 Will additional space be needed in any project location?

Additional space is a concern of your school's business office and may require approval by the Dean's Office.

Explanation:

Requests for space should be forwarded through your Department Director to the appropriate dean. Resolution of such space requests must be accomplished well in advance of submitting the application to your divisional research administration office for institutional signature. Failure to do so may result in refusal to process the application or conditional signature pending approval of the space request.

Q1042 Has space request been approved by the Dean's Office?

Q1032 Please add an explanation of the additional space request below:

Q1026 Is cost sharing or matching required by the sponsor? If no, skip to Q1018.

The University's goal is to ensure that cost sharing is proposed, accounted for and reported consistently with guidelines established in the Office of Management and Budget (OMB) Uniform Guidance 2 CFR 2.306 & Subpart E – Cost Principles.

<https://www.jhu.edu/university-policies/>

-Then follow the click path below:

Policy and Document Library / Cost Sharing (SP003)

DID YOU KNOW?

Cost sharing must be reflected in your budget and approval documentation must be attached to the Coeus record.

Explanation:

Cost sharing: Answer "Yes" if key personnel effort is not fully funded by the project. (If other than sponsor caps on salary or any other project costs are going to be supported by other funds", explain in text box provided).

Q1045 Please provide cost centers and/or internal orders that will be used for cost sharing in the comments.

Q1049 Has cost sharing been approved by the department and/or Dean, as appropriate?

Explanation:

Cost sharing commitments require budgetary support by the department or the school, as appropriate. The divisional research administration office will require documentation of this commitment prior to approving the proposal.

Q1018 In this project, will you be utilizing information provided under a confidentiality agreement with a third party?

Explanation:

By answering this question, you will help us determine whether the terms of a confidentiality agreement would undermine JHU's commitment to sharing its research activities and results to the widest extent possible. It will also help us to determine whether a license will be required before we can involve citizens of all or certain foreign countries in certain aspects of our work.

Q1035 Please provide the name of the third party(s) with whom you have the confidentiality agreement.

Q1083 Science Codes pertaining to University's Strategic Initiatives contained in this research. Select all Codes that apply; select 'None', if appropriate

- No University Strategic Initiative Science Codes apply.
- Project addresses the needs or extends the promise of cities.
- Project connected to Kavli Neuroscience Discovery Initiative.
- Project connected to learning throughout the lifespan.
- Project invests in Baltimore and its citizens.
- Project involves civil space related activities.
- Project involves data-intensive research.
- Project involves global health inequities research.

Q1084 Science Codes pertaining to Medical or Health characteristics of this research. Select all Codes that apply; select 'None', if appropriate.

- No Medical or Health Related Science Codes apply.
- Participants must sign a HIPAA form (Health Insurance Portability Accountability Act).
- Project involves AIDS/HIV research.
- Project involves cancer research.

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.

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.

Q1015 Are any administrative costs included in the budget? If no, skip to Q1019.

The salaries of administrative and clerical staff should normally be treated as F&A costs. Direct charging of these costs may be appropriate only if certain conditions are met.

<https://www.jhu.edu/university-policies/> -Then follow the click path below:
Policy and Document Library / Administrative Costs, Sponsored Projects (SP001)

Reference - Uniform Guidance 2 CFR 200.413

Q1033 Please provide an explanation for the administrative costs requested in the comments below:

<https://www.jhu.edu/university-policies/> -Then follow the click path below:
Policy and Document Library / Administrative Costs, Sponsored Projects (SP001)

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.

<https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>

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? If no, skip next question.

For more information:

<https://research.jhu.edu/major-initiatives/catalyst-awards/>

Q1133 Was it a Catalyst or Discovery award?

MIQ Mandatory International Questionnaire

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

Q1058 Please select the type of activity that you expect to occur in this country.

- 1 – Subagreement work performed by a foreign university or other foreign entity
- 2 – Hiring employees
- 3 – Opening a bank account
- 4 – Leasing space
- 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
- 6 – Travel by project personal to foreign countries or their facilitation of limited-duration activity in them (e.g., conference or meeting)
- 7 – University employees or students working in a foreign country for more than ninety (90) days
- 8 – Other. Please describe here –

DID YOU KNOW?

Foreign involvement includes travel to international conferences and meetings even if the location is unknown at this time.

Explanation:

Select the numbered line item in the pop-up list that corresponds to the expected activity. Your options will be as follows:

1. University employees or students working for more than ninety (90) days
2. University employees or students working for less than ninety (90) days
3. Work performed by U.S. subrecipients or subcontractors
4. Work performed by foreign subrecipients or subcontractors
5. Incoming or outgoing shipments or transmission of tangible items (e.g., equipment or materials, either organic or inorganic) or project-related information (e.g., exchanges of research data or technology).
6. Hiring employees
7. Opening a bank account
8. Leasing space
9. Other. Please request below additional space to describe this activity.

After you have selected your line item(s), click on the “OK” button.

Q1063: Please provide as much of the following information as you can about any foreign person (an individual or entity) to which you expect to provide access to project-related devices, materials, source code or technology, during the course of the project:

- full legal name
- country of citizenship (or in which an entity was organized)
- role in the proposed project (e.g., as a university employee; student lab assistant; visiting student, scholar, or faculty member; vendor; or subrecipient)
- the parts of the project in which they will be involved and what they are expected to contribute
- location during project (U.S. and/or a particular foreign country)

Explanation:

This information is not being requested simply because an individual is “foreign.” Depending upon other aspects of this project, including the countries that will be visited and/or represented, some or all of the information may be needed to determine whether a license would be required to involve a certain person in all or just some project activities. JHU greatly values the inclusion of persons from around the world in its various missions and intends to use this information discreetly, and only as needed to ensure its compliance with U.S. export controls and economic sanctions.

It is not always possible to identify, at the time a proposal is submitted, all foreign persons to whom we are likely to release items and information. It is acceptable to answer this question by providing not only detailed information associated with presently known, foreign persons, but also to write something like “We expect to share Technology A with a certain number of foreign national graduate

students, but we have not as yet selected them." If you do so, it is important that you contact the Export Control and Facility Security Office (ECO@jhu.edu) when you ultimately choose for project involvement certain foreign persons who have not been specifically identified in this proposal.

Do not assume that individuals with access to project-related items in another country are citizens of that country. It is possible, for example, for an Iranian graduate student to be working in the London-based lab of a British collaborator.

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 technology, while they are in the United States?

Q1055 Will your project require the involvement of any foreign country, its citizens or organizations? If no, skip to next set of questions.

Explanation:

In the interest of promoting national security, economic strength and foreign policy, the U.S. Government has implemented certain policies, laws, and regulations that limit how we may include foreign persons (individuals or entities; see definition below) in our work, both in the U.S. and in other countries. By identifying connections that this project is likely to have to other countries, we can determine whether any steps must be taken to lawfully collaborate with persons in or from them. Here are some examples of connections to other countries that would warrant an answer of "Yes" to this question:

- a. Citizens of other countries will contribute to your project's objectives, while either in or outside the U.S.
- b. A foreign organization will be funding your project.
- c. A foreign organization will be supporting your project in ways other than directly providing funds, such as by offering materials, lab space/equipment, or by supporting individuals (regardless of citizenship) who will work with or for you.
- d. A component of your project will take place in another country. This would include JHU project personnel and/or subrecipients or subcontractors being either physically present in the country, or working with persons in the country via phone or Internet while located in another country. It would also include persons in another country receiving or sending shipments for the benefit of the project.

Definition of "foreign person": A person who: a) is not a U.S. citizen, b) is not a lawful permanent resident or c) has not been assigned protected status by the U.S. Government (e.g., as a refugee).

Please err on the side of over-disclosing connections that you foresee to foreign countries. The Export Control and Facility Security Office (ECO) will determine whether any connections present issues that should be addressed, prior to the initiation of funded work.

Projects that involve activity in other countries must comply not only with U.S. laws and regulations, but also with foreign countries' laws and regulations. If some of your project work will involve doing business in other countries and will require things like opening bank accounts, leasing space, or hiring foreign individuals, then thoughtfully answering this and other Research Compliance Questions can help us anticipate issues associated with foreign law that must be considered, prior to work beginning in those countries.

If at any time your answer to this question changes from "No" to "Yes," please notify your research administration office.

Regulation

U.S. Export Controls

This question is asked in part to help us comply with several bodies of U.S. regulation that were enacted to promote national security, economic strength and foreign policy. Some of the regulations are collectively referred to as "export controls," and two examples are as follows:

1. The *Export Administration Regulations*, which are implemented by the Bureau of Industry and Security, from within the Department of Commerce.
2. The *International Traffic in Arms Regulations*, which are implemented by the Directorate of Defense Trade Controls, from within the Department of State.

Export Control regulations center around certain tangible items and information that may not be shared with persons who are in or from certain countries. Answers to this and other Research Compliance Questions help

us identify projects at JHU that are likely to involve such items and information and determine whether a license will be needed to share them with certain foreign persons.

Economic Sanctions

Other regulations contemplated by this question are those that collectively represent economic sanctions programs implemented by the Office of Foreign Assets Control, from within the Department of the Treasury. The aim of sanctions programs is generally to block certain governments', entities', and individuals' ability to access resources, in order to prevent them from acting in ways that threaten U.S. interests.

Some sanctions programs focus upon certain countries or regions. A handful of them are so comprehensively restrictive as to generally forbid us to do business with *any* person in or from certain regions/countries. The remainder of the programs are more narrowly restrictive and forbid us to do business only with *certain* persons (individuals or entities) that have been formally linked to particular regions/countries. One should note that numerous federal agencies, including those that implement the export control and sanctions regulations, publish lists of persons, to which certain restrictions apply (i.e., we may not be allowed to work with them at all, or without a license). Answers to this and other Research Compliance Questions help us to identify instances in which we may need to avoid doing business with such persons.

Q1056 Will any of the proposed project activity take place within a foreign country? (e.g., will members of the project team, subrecipients or subcontractors be present in the country or interact with persons in the country from a location in another country?)

Explanation:

An answer of "Yes" is appropriate for more than just situations in which JHU personnel will be physically present in a foreign country. The answer would also be appropriate for instances in which other persons will be contributing to project objectives in another country, for instance as subjects, participants, or collaborators. For example, if your project were to involve the research team establishing a physical presence in Turkey, never entering Syria, but collaborating with subrecipient personnel (from any country, including the U.S.), who will collect survey information from persons in Syria, then, for the purpose of answering this question, this project would be regarded as taking place within both Turkey and Syria. The same would hold, if the project team, never leaving the U.S., were to interact with subjects, participants, or collaborators located in either Turkey or Syria.

Q1070 Do you need additional space to describe the other types of activity that you expect to take place in this country?

Q1071 Please describe the Other activity that is expected to take place in this country:
Other activity:

Q1060 Do you need to select another country?

Q1061 During the project, will you provide foreign persons* access to devices, materials, source code or technology while they are in the United States?

* Individuals who: a) are not U.S. citizens, b) are not lawful permanent residents or c) have not been assigned protected status by the U.S. Government (e.g., as refugees).

Explanation:

The U.S. Government deems the release of source code or technology* to foreign persons in the U.S. to be exports to their home countries. U.S. export control regulations tell us when a license would be required to release certain items to citizens of certain countries, when they are studying/working with us at JHU. Thoughtful answers to these Research Compliance Questions help us determine what we must do (e.g., apply for a license) to achieve project objectives while also complying with federal laws, such as those associated with export controls.

*Information that a person would need to develop, produce or use (at an advanced level) any devices, materials, or other items associated with their work at JHU in general, or with your project in particular.

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 persons in some or all project activities?

Explanation:

By answering this question, you will help us determine whether the imposition of certain kinds of publication or access restrictions upon your funded work would be a) inconsistent with JHU's commitment to sharing its research activities and results to the widest extent possible, and/or b) would render some of the project content subject to export restrictions.

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 economic 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 or more of its citizens will be involved in the project. If you do not know if a particular country is subject to OFAC sanctions, go to:

<https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>.

Regulations

U.S. Department of the Treasury, Office of Foreign Assets Control, Sanctions Programs List:

<https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>.

MCQ Mandatory Compliance Questionnaire

Q1005 Does this proposal involve human? If this proposal includes any of the following, please answer "yes." If answer is "no," skip to Q1007.

- **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**

Explanation:

Federal law (45 CFR 46 and 21 CFR 50) and institutional policy require assurance that the rights and welfare of human subjects of research are protected.

<https://www.jhu.edu/university-policies/> -Then follow the click path below:
Policy and Document Library / IRB Authority (GEN002)

Q1100 Is this a multi-site study? If answer is "no," skip to Q1007.

The goal of this policy is to enhance and streamline the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/

DID YOU KNOW?

Only answer this question if the project involves multiple sites involving human subjects.

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.

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5166

Reference - 45 CFR 46.114

https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/jhmirb_serving_as_the_sirb.html

Q1102 Will you use the JHM IRB or an External IRB as the sIRB?

For more information:

https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/jhmirb_serving_as_the_sirb.html

Q1006 Does this project involve disclosure/receipt of protected health information to/from sponsor or third parties?

Explanation:

Federal law (45 CFR 46 and 21 CFR 50) and institutional policy require assurance that the rights and welfare of human subjects of research are protected.

Policies.jhu.edu – <https://www.jhu.edu/university-policies/> -Then follow the click path below:

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.

Explanation:

It is the policy of the Johns Hopkins University (JHU) 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. Covered research includes: A. All research using human embryonic stem cells (hESCs); B. All research involving somatic cell nuclear transfer (SCNT) involving human cells; C. Other hPSCs (e.g., human induced pluripotent stem cells [iPSCs], human embryonic germ cells [hEGCs]) where the research involves: 1. Introduction of the cells into humans; 2. Introduction of the cells into the central nervous system of non-human primates; 3. Introduction of the cells into non-human animals and there is a reasonable possibility of the cells giving rise to gametes; or, 4. Creation of gametes or embryos.

Q1054 Have you obtained review and approval from the Stem Cell Research Oversight Committee (JHU ISCRO)?

Explanation:

Approval by ISCRO is required. See <http://www.hopkinsmedicine.org/Research/iscro/>

Q1008 Does this project involve use of live vertebrate animals?

Explanation:

Federal law and Institutional policy require humane care and use of all vertebrate animals (see P.H.S. Policy on Humane Care and Use of Laboratory Animals, revised September, 1986 and USDA The Animal Welfare Act, 7 USC, 2131 et seq). See JHU Policy and Guidance at:

DID YOU KNOW?

Only answer, “yes” to this question if the project involves outgoing subs that JHU will fund from this award.

<http://web.jhu.edu/animalcare/policies/index.html>

Q1017 Will the project include subawards or subcontracted effort to other organizations? If answer is “no,” skip to Q1020.

Explanation:

If yes, a commitment from this organization that they will enter into the appropriate agreement is required.

See the University Policy on Subrecipient Monitoring:

<https://www.jhu.edu/university-policies/> -Then follow click path below:
Policy and Document Library / Subrecipient Monitoring (SP010)

Subrecipient/Vendor Determination Form: This mandatory [form](#) is used to document the characteristics of the relationship between an external entity and the University to **determine** that the entity is properly treated as a **subrecipient** as opposed to a vendor/contractor. The University follows the requirements in the UG to determine subrecipient or contractor status as part of required subrecipient monitoring. See 2 CFR sec. 200.330

Q1105 Does any proposed subrecipient employ any immediate family member of a named JHU investigator?

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?

https://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/conflict_interest.html

Reference - 2 CFR § 200.112 - Conflict of interest

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?

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?

https://www.hopkinsmedicine.org/som/faculty/policies/facultypolicies/conflict_interest.html

Reference - 2 CFR § 200.112 - Conflict of interest

Q1107 Will there be any foreign subrecipients?

Q1020 Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator's), such as inventions, copyrights, etc.? If the answer is "no," skip to Q1066.

JHU Policies - policies.jhu.edu / Governance/Compliance / Policies / Intellectual Property (GOV012)

Explanation:

JHU must determine rights and limitations to use the existing intellectual property to assure that the work under this proposal can take place with minimal restrictions. Link to JHU IP Policy - https://www.jhu.edu/assets/uploads/2014/09/intellectual_property_policy.pdf

Q1038 Has the proposed use been approved by Johns Hopkins Tech Ventures (JHTV)?

Explanation:

JHTV will need to approve the use to avoid licensing conflicts. <https://ventures.jhu.edu/technology-transfer/reports-of-invention/>

Q1037 Please identify the JHU disclosure number.

Explanation:

All inventions must be disclosed to Johns Hopkins Office of Technology Transfer. Upon filing of the Report of Invention, a disclosure number is issued.

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?

For more information: <https://research.jhu.edu/jhura/compliance/export-controls/>

Explanation:

Your answer to this question will help us determine whether your project will involve the use or creation of tangible items or technology that the U.S. Govt. believes could be used by other countries in ways that would undermine national security or foreign policy. Some such items/technology are those that are created primarily, or which are being used, for critical military, space, or intelligence applications ("defense articles"). Others are those that are normally used for benevolent, civilian purposes, but which also could be used for military purposes or to harm U.S. persons or interests ("dual-use items").

Regulation

There are several bodies of regulation that are bundled together as "U.S. export controls," but these are the two that most frequently apply to research activities at JHU:

- 1) The Export Administration Regulations ("EAR"): Implemented by the Department of Commerce and its

Bureau of Industry and Security, these regulations contain a Commerce Control List, which contains multiple categories of two general types of controlled items:

- a. Dual-use items, which are tangible goods, source code, and technologies normally used for benevolent, civilian purposes, but which also could be used for military purposes or to harm U.S. persons or interests; and
- b. Certain military items that are not considered critical to the U.S. maintaining a military or intelligence advantage.

Depending upon a number of factors, including countries represented, the EAR may require that we have a license before we may include a foreign person in work that involves items found on the Commerce Control List.

Here is a link to additional information on the EAR: <https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear>

2) The International Traffic in Arms Regulations (“ITAR”): Implemented by the Department of State and its Directorate of Defense Trade Controls, these regulations contain a U.S. Munitions List (“USML”), which is broken into multiple categories of controlled items that are referred to as “defense articles.” Technology associated with defense articles is referred to as “technical data.” Unlike the EAR’s dual-use items, defense articles are typically designed, developed, configured, adapted, or modified for critical military, space, or intelligence applications.

Overall, the ITAR is more restrictive than the EAR. For instance, the release of technical data described on the USML is generally forbidden to citizens of any country, in the absence of a license or an applicable license exemption. Additionally, the ITAR forbids the provision of “defense services” to foreign persons. Defense services involve the furnishing of assistance (including training) to foreign persons, whether in the United States or abroad, in the design, development, engineering, manufacture, production, assembly, testing, repair, maintenance, modification, operation, demilitarization, destruction, processing or use of defense articles, even if the assistance involves the use of only public-domain information.

Q1092 Will the project include or anticipate a Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant in this study?

The Johns Hopkins Clinical Research Network’s collection of organizations and clinicians coordinate and support clinical trials that offer researchers the opportunity to collaborate with other purpose-driven researchers to advance and improve the practice of medicine.

<https://ictr.johnshopkins.edu/collaboration/collaborations/johns-hopkins-clinical-research-network-jhcrn/>

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? If the answer is “yes,” answer Q1099.**

DID YOU KNOW?

***This question refers to
Organizational Conflict of Interest.***

Explanation:

The JHU and divisional disclosure and professional commitment policies require that investigators disclose to the institution those financial interests that reasonably appear to be related to their institutional responsibilities.

https://pages.jh.edu/news_info/policy/institutional-coi.html

A covered party must disclose any services to U.S. government agencies and/or financial interests that reasonably appear to be related to his/her institutional responsibilities. All employees in all units of The Johns Hopkins University. Includes officers, faculty, staff, and others who are compensated or otherwise supported by the University for their services or who appear to act as agents of the University in using, controlling, or assigning to others the use of University facilities and resources.

Q1099 Please provide a general explanation regarding the activities as defined in the COI policy below:

Explanation:

http://web.jhu.edu/conflict_of_interest/overview_of_policies

COVID Questions

Q1108 Does this proposal relate to COVID-19 work?

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?

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:

<https://ictr.johnshopkins.edu/coronavirus/covid-johns-hopkins-clinical-research-coordinating-committee/>

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 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.

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:

<https://hub.jhu.edu/novel-coronavirus-information/research-preparedness/coronavirus-research-publications-resources/>

You will be then contacted by CAM asking for additional information to prioritize requests.

Q1109 Does this proposal involve funds coming from the Coronavirus Aid, Relief, and Economic Security (CARES) Act?

COMMON MISINTERPRETATIONS OF THE COMPLIANCE QUESTIONNAIRES

1. Only answer questions that apply to your proposal. There are many dropdown questions that need to be answered when parent questions apply. Skip to the next parent question as specified in the directions following each question.
2. 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.

Many investigators answer, "yes" to this question if they have ever reported to eDisclose, but this question only refers to the project proposal being presently submitted.

3. Q1017 Will the project include subawards or subcontracted effort to other organizations?

This question has been marked, "yes" when the proposal is an incoming subgrant, but it should only be marked, "yes" when there are outgoing subs that JHU will be awarding using the funding from the proposal.

4. sIRB or single IRB questions only apply when there are multiple sites which requires the use of an sIRB. Many investigators have marked, "yes" to sIRB when there is only one site.
5. Cost sharing must be clearly indicated in the budget and approval from the appropriate department authority must be documented in the Coeus record.