



Research Compliance Questionnaire User Guide

A comprehensive explanation of all research compliance questions
and their origins in JHU policy or Federal Regulations

NOTE:

***“Branched logic” limits questions users are asked based on previous answers
given: users are asked only RELEVANT questions.
Therefore, users will not typically be asked every question in this guide.***

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Access instructions for Coeus Lite and Premium can be found at the ORIS website at:
<http://jhuresearch.jhu.edu/oris.htm>

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1. **Does this project involve the use of human subjects via contact, data/records, and/or survey, or the use of human tissue, serum, or other fluids? If yes, be sure to complete the Special Review tab.**

Explanation:

Federal law (53 FR 45660, 45 CFR 46 and 21 CFR 50) and institutional policy require assurance that the rights and welfare of human subjects of research are protected.

2. **Does this project involve disclosure/receipt of protected health information?**

Explanation:

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR §160 and §164, Subparts A and E, provide protection for confidential health information. Prior to releasing and/or receiving any confidential health information JHU may be required to enter into an agreement that contains certain restrictions on the use and disclosure of the information.

3. **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 (<http://www.hopkinsmedicine.org/Research/iscro/>)?**

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:

- All research using human embryonic stem cells (hESCs);
- All research involving somatic cell nuclear transfer (SCNT) involving human cells;
- Other hPSCs (e.g., human induced pluripotent stem cells [iPSCs], human embryonic germ cells [hEGCs]) where the research involves:
 - Introduction of the cells into humans;
 - Introduction of the cells into the central nervous system of non-human primates;
 - Introduction of the cells into non-human animals and there is a reasonable possibility of the cells giving rise to gametes; or,
 - Creation of gametes or embryos.

4. **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/>

5. **Does this project involve use of live vertebrate animals? If yes, be sure to complete the Special Review Tab.**

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).

6. **Does this project involve use of bio-hazardous materials, radioactive materials, hazardous chemicals, or recombinant DNA?**

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 Registration of Research 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 <http://irb.jhmi.edu/Forms/index.html>. The manual may be obtained at <http://www.hopkinsmedicine.org/hse/manuals.html>.

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.

7. Does this project involve the use of biohazardous materials? If yes, please be sure to complete the Special Review tab.

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.

8. Does this project involve use of radioactive materials? If yes, be sure to complete the Special Review Tab.

Explanation:

Application for an authorization to use radioactive material is made through the RCU, Ext. 5-3710. 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 <http://irb.jhmi.edu/Forms/index.html>. The manual may be obtained at <http://www.hopkinsmedicine.org/hse/manuals.html>.

9. Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)? If yes, please be sure to complete the special review tab.

10. Does this project involve use of recombinant DNA? If yes, please be sure to complete the Special Review tab.

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.

11. Will the project necessitate alterations or renovations?

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

A. Please provide an explanation of the required alterations.

B. Have the alterations/renovations been approved 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 modifications include changes to electrical systems, HVAC, plumbing, reinforcement of an existing structure to support special equipment, etc.

12. Will additional space be needed in any project location?

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.

A. Please add an explanation of the additional space request.

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

13. Are any administrative costs included in the budget?

Explanation:

OMB Circular A-21 states that salaries of administrative and clerical staff and items such as office supplies, postage, local telephone cost and memberships should normally be treated as F&A. If this proposal is a "major project," defined by A-21 as requiring "an extensive amount of administrative or clerical support, which is significantly greater than the routine level of such services provided by academic departments," and requests any of the above items, please provide an explanation.

A. Please provide an explanation for the administrative costs requested.

14. Do you anticipate that program income will be generated under this project?

Explanation:

Program income must be managed in accordance with sponsor policies/regulations. Program income is defined as “gross income earned by a recipient from activities part or all of the cost of which is either borne as a direct cost by a grant.” Examples of program income include:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased from grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients where such reimbursement occurs because of the grant-support activity.
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.

A. Please provide an explanation for the anticipated program income.

15. If this proposal is funded, will you need multiple accounts?

16. Is cost sharing or matching required by sponsor?

Explanation:

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 the text box provided.)

A. 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.

B. Please provide cost centers and/or internal orders that will be used for cost sharing.

17. Has the principal investigator completed the required effort reporting training?

Explanation:

See Comptroller’s Office Policy on Effort Reporting:

<https://www.controller.jhu.edu/policyapp/displayEntry.do?entryId=01&entryType=PL&guidId=EFF&deptAbbr=FRC>

This training is a mandatory requirement of the university that is periodically audited by internal audits.

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

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.controller.jhu.edu/policyapp/displayEntry.do?entryId=01&entryType=PL&guidId=SUB&deptAbbr=SP>

19. Will human subjects be involved in research by the subcontractor, via contact, data/records, and/or survey, or the use of human tissue, serum, or other fluids.

Explanation:

Federal law (53 FR 45660, 45 CFR 46 and 21 CFR 50) and institutional policy require assurance that the rights and welfare of human subjects of research are protected.

The subrecipient and/or JHU will require the use to be approved by the Institutional Review Board.

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

Explanation:

If a confidentiality agreement exists with a third party, JHU must assure that any information required to conduct the research under this proposal is not restricted in use.

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

Explanation:

This will assist us in identifying any existing restrictions.

21. In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party?

Explanation:

The terms of the MTA may affect the terms and/or conduct of this research project.

A. Please provide the name of the company or institutions with whom you have or may have the material transfer agreement.

22. Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator's), such as an invention, copyright, etc.?

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.

A. Please identify the JHU disclosure number, if applicable.

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.

23. Has the proposed use been approved Johns Hopkins Tech Transfer?

Explanation:

JHTT will need to approve the use to avoid licensing conflicts.

24. Will your project require the involvement of any foreign countries, their citizens or organizations?

NOTE ONE: It is acceptable to answer "No" if the only anticipated foreign involvement consists of foreign nationals reading or hearing unrestricted publications of project findings.

NOTE TWO: If uncertain how to answer this or any other Compliance Question, follow the help link next to each question within Coeus, or use this guide, which can be found with other Coeus User Guides (via the Help Menu in Coeus Premium, or via the link on the CoeusLite home page).

NOTE THREE: If at any time (even after your proposal is awarded) your answer to this question changes from No to Yes, please contact your research administration office.

Explanation:

This question helps us decide whether there is any possibility that your project will involve international transactions, including “exports”.

The U.S. government thinks of exports differently than the average person, and it has restrictions on what we can export and to whom.

To the U.S. Government, an export can involve the familiar shipment of a commodity from the U.S. to another country by cargo ship. When a U.S. citizen travels outside the United States, the contents of his/her suitcase are considered exports. If a Hopkins faculty member provides technical data or software source code to a non-US citizen - even if the transfer takes place in the United States - such a transaction is considered to be a “deemed export” (the Federal Government deems the transfer to have been made to the home country of the person receiving the data or software).

Given such a broad definition of exports, and given the international nature of JHU's students, employees, and our work, you can imagine how many exports are made by Hopkins employees every day. Depending upon the items exported, their destinations, end users and how the items will be used, some exports cannot be made without a license from one or more Federal offices.

The percentage of Hopkins exports requiring licenses is quite small, but exporting without required licenses can result in steep civil and criminal penalties being applied to JHU and/or to its employees. Answering these Research Compliance Questions carefully and completely will help JHU decide whether a license is required for exports necessary for the completion of your proposed project.

ADDITIONAL NOTE: If some of your project work will involve doing business overseas (e.g., opening a foreign bank account or leasing space abroad), there are additional JHU policies and Federal regulations that apply to such activity. Some of these Compliance Questions will not only look for export-control issues; they will also provide information to JHU's Global Compliance Officer, who can help ensure that your project activity is in compliance with the additional requirements.

Regulation:

Several bodies of Federal regulation tell us what can be exported to other countries and/or to their citizens. However, the following three bodies of regulation are those that have the most frequent impact on exports from JHU:

[Foreign Assets Control Regulations](#) (Department of the Treasury)

[Export Administration Regulations](#) (Department of Commerce)

[International Traffic in Arms Regulations](#) (Department of State)

25. Will any of the proposed project activity take place within a foreign country?

26. Do you need to list more than 5 countries? If so, please indicate the number of countries in the box provided.

Explanation:

Coeus can presently handle a maximum of five countries per proposal. If your project activity will take place in more than five countries, please contact JHU's Export Control and Global Compliance Officers:

Export Control: Frank Barker, 410-516-0415, fwb@jhu.edu

Global Compliance: Sunanda Holmes, 443-997-5325, sholmes8@jhu.edu

27. Please select a foreign country (you will have the opportunity to select additional foreign countries).

Explanation:

Select the line in the pop-up window that corresponds to a country that will be associated with your project, and then click on the “OK” button.

28. Please select the type of project activity that you expect will occur in this country.

Explanation:

Select the line/category in the pop-up window that corresponds to your planned activity, and then click on the “OK” button.

Category 8 can be used for any “Other” activity that is not described elsewhere in the pop-up window. You will be given an opportunity to request that additional space (a text box) be provided so that you can describe activities covered by Category 8.

29. Please describe the type of activity that you expect will take place in Country.

Explanation:

Please describe in the provided text box the “Other” project activities that will take place in the country you have selected.

30. Do you need to select another country?

Explanation:

It is important that you disclose each country in which you expect project activities will occur. Answering “Yes” to this question will allow you to select a new country and activities that will take place in it.

31. During your project, will you provide foreign nationals with access to devices, materials, source code or technical data while they are in the United States?

Explanation:

A foreign national is a person who: a) is not a U.S. citizen, b) does not have a green card or c) has not been given some protected status by the U.S. Government (e.g., refugee status).

Foreign nationals are at JHU as students, post-docs, visiting scholars and other JHU staff. Visas allow them to legally study or work with us in labs, technology transfer offices and other Hopkins offices.

If we provide a foreign national with access to source code or technical data while the foreign national is in the United States, the U.S. Government considers that act to be a “deemed export” to the foreign national’s home country.

32. 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, sub-recipient),
- 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)

NOTE ONE: 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.

NOTE TWO: At the proposal stage, it may be difficult or impossible to identify all foreign persons and entities that will be involved with your project. At a minimum, please provide a description of your general expectations. For example, you could write: “We expect to collaborate with Company X, which is organized in Country Y”, or “We expect to provide access to a number of foreign national graduate students, who have not yet been identified”

NOTE THREE: Information about individuals that is supplied in response to this question (including citizenship) will be used discretely by your research administration office and/or the Office of Export Controls to perform database searches designed to ensure compliance with Federal law and regulation.”

Explanation:

The Federal Government wants to keep certain items and information away from certain people, organizations and countries. The sooner we can identify those to whom we will provide access to items or information, the more likely we will be able to avoid unauthorized exports.

33. You indicated that foreign countries, their citizens or organizations will play some role in the completion of the proposed project, but you have also indicated that no project activity will take place in a foreign country AND that no foreign nationals will play a role in the project in the United States. Did you enter Yes to "will any of the proposed project activity take place within a foreign country" when the answer should have been No? If so, please return to the question and change your answer. If your answers to the questions are accurate, please describe in the box below how foreign countries, their citizens or organizations will play some role in the completion of the proposed project.

34. 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?

Explanation:

Accepting publication or access restrictions on our funded work is not only at odds with JHU’s commitment to unrestricted research and dissemination of research results, but doing so can also make it necessary for the University to submit to time-consuming licensing procedures before it can allow foreign persons to participate in its research or other activities, or before it can broadly share the results of its work.

Policy:

[JHU's Policy on Classified or Otherwise Restricted Research](#)

A. 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.

35. Is any item or information that will be used or developed during the proposed project the product of defense funding or specifically designed, developed, configured, adapted, or modified for a military or space application?

Explanation:

The University needs to know if the proposed project will use, develop or provide any defense articles or services, as defined and regulated by the State Department’s International Traffic in Arms Regulations (“the ITAR”).

The “Regulation” information provided for this question consists of a section taken from the ITAR, which describes the kind of items that are typically designated as defense articles and services.

Regulation:

ITAR Section 120.3 describes the State Dept. policy on designating and determining defense articles and services:

An article or service may be designated or determined in the future to be a defense article (see 120.6) or defense service (see 120.9) if it:

Is specifically designed, developed, configured, adapted, or modified for a military application, and (i) Does not have predominant civil applications, and (ii) Does not have performance equivalent (defined by form, fit and function) to those of an article or service used for civil applications; or

Is specifically designed, developed, configured, adapted, or modified for a military application, and has significant military or intelligence applicability such that control under this subchapter is necessary.

36. Are any foreign countries associated with your project subject to sanctions listed by the Office of Foreign Assets Control (OFAC)?

Explanation:

This includes any country that you have disclosed in prior Research Compliance Questions, either because project-related activities are expected to take place within that country's boundaries, or because one of its citizens will contribute to the project.

Click MORE to the right of this question, then read the Regulation information which provides a link to OFAC's list of current Sanctions Programs.

TIP: The "Regulation" information provided for this question contains a link to OFAC's list of current Sanctions Programs.

Regulation:

[Sanctions Programs of the US Department of the Treasury, Office of Foreign Assets Control \(OFAC\)](#)