- Q1005_Does this project involve the use of identifiable human subjects via contact, data/records and/or survey, or the use of human tissue, serum, or other fluids?
  - Q1006_Does this project involve disclosure/receipt of protected health information to/from sponsor or third parties?
  - Q1100_Is this a multi-site study?
    - Q1091_You have indicated that your proposal includes a multi-site study involving human subjects research. A plan for use of a single IRB (sIRB) may be required. The sIRB is the selected IRB of record that conducts the ethical review for participating sites of the multi-site study. Please review the NIH sIRB policy at the following link. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

Does this proposal require use of a single IRB (sIRB) to review the human subjects research proposed?

- Q1102_Will you use the JHM IRB or an External IRB as the sIRB?

- 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 (http://www.hopkinsmedicine.org/Research/iscro/)?
  - Q1054_Have you obtained review and approval from the Stem Cell Research Oversight Committee (JHU ISCRO)?

- Q1008_Does this project involve use of live vertebrate animals?

- Q1015_Are any administrative costs included in the budget? - Moved to CCQ
• Q1033_Please provide an explanation for the administrative costs requested. - Moved to CCQ

• Q1027_Has the Principal Investigator completed the required effort reporting training? – Removed Completely

• Q1017_Will the project include subawards or subcontracted effort to other organizations?

• Q1019_In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party? - Moved to CCQ

  • Q1036_Please provide the name of the company or institutions with whom you have or may have the material transfer agreement. - Moved to CCQ

• Q1020_Do you anticipate that this project will involve existing JHU intellectual property (yours or another investigator’s), such as inventions, copyrights, etc?

  o Q1037_Please identify the JHU disclosure number.

  o Q1038_Has the proposed use been approved by Johns Hopkins Tech Transfer?

• 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?

• Q1089_Is this a request for a No Cost Extension (NCE)? – Removed Completely

• Q1092_Will the project include or anticipate a Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant in this study?

  o Q1093_Please check the appropriate Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant.
• Q1094_Please provide comments on the Johns Hopkins Clinical Research Network (JHCRN) as a sub site or participant being used.

- Q1095_Is this proposal, in any way, a result of Catalyst or Discovery award funding? - Moved to CCQ

- Q1096_Was it a Catalyst or Discovery award? - Moved to CCQ

• 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?

• Q1099_Please provide a general explanation regarding the activities as defined in the OCI policy.

CCQ

• Q1009_Does this project involve use of bio-hazardous materials, radioactive materials, hazardous chemicals, or recombinant DNA?

- Q1047_Does this project involve the use of biohazardous materials?

- Q1010_Does this project involve use of radioactive materials?

- Q1011_Does this project involve use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)?

- Q1012_Does this project involve use of recombinant DNA?
• Q1013_Will the project necessitate alterations or renovations?
  o Q1031_Please provide an explanation of the required alterations.
  o Q1044_Have the alterations/renovations been approved by the Dean’s Office?

• Q1014_Will additional space be needed in any project location?
  o Q1032_Please add an explanation of the additional space request.
  o Q1042_Has space request been approved by the Dean's Office?

• Q1016_Do you anticipate that program income will be generated under this project? – Removed Completely
  o Q1034_Please provide an explanation for the anticipated program income. – Removed Completely

• Q1026_Is cost sharing or matching required by the sponsor?
  o Q1049_Has cost sharing been approved by the department and/or Dean, as appropriate?
  o Q1045_Please provide cost centers and/or internal orders that will be used for cost sharing.

• Q1018_In this project, will you be utilizing information provided under a confidentiality agreement with a third party? – Ask for SOM contracts only
  o Q1035_Please provide the name of the third party(s) with whom you have the confidentiality agreement. – Ask for SOM contracts only

• Q1015_Are any administrative costs included as direct costs in the budget? – Copied from MCQ
Q1033_Please provide an explanation for the administrative costs requested. – Copied from MCQ

Q1019_In this project, will you be utilizing materials provided under a Material Transfer Agreement (MTA) with a sponsor and/or third party? – Copied from MCQ; Ask for SOM contracts only

Q1036_Please provide the name of the company or institutions with whom you have or may have the material transfer agreement. – Copied from MCQ; Ask for SOM contracts only

Q1083_Science Codes pertaining to University's Strategic Initiatives contained is this research. Select all Codes that apply; select 'None', if appropriate

Q1084_Science Codes pertaining to Medical or Health characteristics of this research. Select all Codes that apply; select 'None', if appropriate.

Q1085_Science Codes pertaining to Funding of this proposal. Select all Codes that apply; select 'None', if appropriate.

Q1086_Science Codes pertaining to the General Purpose of this proposal. Select all Codes that apply; select 'None', if appropriate.

Q1095_Is this proposal, in any way, a result of Catalyst or Discovery award funding? – Copied from MCQ

Q1096_Was it a Catalyst or Discovery award? – Copied from MCQ

Investigator Certifications

Q1076_Have lobbying activities been conducted on behalf of this proposal
- Q1077_Can you certify that the information submitted within this application is true, complete and accurate to the best of your knowledge? Please be aware that any false, fictitious, or fraudulent statements or claims may subject you, as the PI/Co-PI/Co-Investigator to criminal, civil or administrative penalties.

- Q1078_Do you (or your spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that 1) could be affected by the research or 2) is in an entity that could be affected by the research? This applies to current interests/relationships and those within the past 12 months.

  A financial interest or fiduciary relationship includes, for example, receipt or contractual entitlement to royalty, equity, or consulting remuneration, employment, and service as an officer or Board of Directors member.

  If you answer Yes to this question, you must disclose your financial interest or fiduciary relationship in the JHU online disclosure system, eDisclose (http://edisclose.jhu.edu).

- Q1079_Are you currently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from current transactions by a federal department or agency?

- Q1080_Do you agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports?