**Purpose:** Use this form to help determine 1) if your proposed activities involves regulated research with human subjects and 2) the associated Harvard Research Data Security level for this project. Your responses will assist you in this self-certification only. Points to note:

* This form does not constitute an official IRB determination.
* Do not submit this form to the IRB.
* Contact your respective IRB office if you are unsure about the determination, or if you need a formal determination from the IRB for funding agencies, administrators, or collaborators.
  + [Harvard Longwood Campus](https://www.hsph.harvard.edu/ohra/) (HSPH, HMS, HSDM)
  + [Harvard University Area](https://cuhs.harvard.edu/) (All other Harvard schools)
* Complete all sections of the form and submit it to your negotiating office (i.e., OSP/SPA/ORA) with a new Data Use Agreement review request *only* if IRB review is not planned for the project.

|  |
| --- |
| **Your Name:** |
| **Date:** |
| **Project Title:** |

**Instructions:** Complete the following sections, as applicable. If your responses indicate that IRB review is required, proceed with [submitting an IRB application](https://estrsupport.fss.harvard.edu/creating-new-study) rather than submitting this worksheet to your negotiating office (i.e., OSP/SPA/ORA).

**Section A: Is this project involving Human Subjects under the regulations?**

|  |  |
| --- | --- |
| 1. Research as Defined by DHHS Regulations[[1]](#endnote-2) (Check if “Yes”) | |
|  | **Is the activity a systematic investigation?** *(A* ***systematic investigation*** *is a study or examination that involves a methodical procedure and plan, is theoretically grounded, specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.)* |
|  | **Is the systematic investigation designed to contribute to generalizable knowledge?** *(****Generalizable knowledge******is*** *information that is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:*   * *Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.* * *Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.)* |
| **STOP! If none of the above boxes have been checked** (not Research as defined by DHHS regulations)  IRB review is NOT required. | |
| 1. Human Subject as Defined by DHHS Regulations (Check if “Yes”) | |
|  | **Is the investigator gathering information *about* living individuals?** *(If the focus of the project is on people or their opinions, perceptions, choices, decisions regarding them or how methods, policies, procedures, organizations etc. affect them or their environment, then it is* ***about*** *the individual. If questions are posed so that the individual provides information about something; they are not “about whom” questions but can be thought of “about what” questions, then this is not* ***about*** *the individual.)* |
|  | **Will the investigator obtain information and/or biospecimens through either of the following mechanisms? Specify which mechanism(s) apply, if yes:**  Physical procedures or manipulations of those individuals or their environment for research purposes (“intervention”).  Communication or interpersonal contact with the individuals ("interaction”). |
|  | **Will the investigator obtain information and/or biospecimens that are:**  Identifiable such that the individuals’ identities can be readily ascertained or associated with the information by the investigator (i.e. “Identifiable information”) **AND IS**  Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. “Private information”).  Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will **NOT** be made public, such as a medical record (i.e. “Private information”). |
| **STOP! If any box in this section is checked, you are conducting human subjects research. Contact your respective IRB office. IRB Review is required.**   * + [Harvard Longwood Campus](http://www.hsph.harvard.edu/ohra) (HSPH, HMS, HSDM)   + [Harvard University Area](https://cuhs.harvard.edu/) (All other Harvard schools) | |
| 1. Human Research Under FDA Regulations (Check if “Yes”) | |
|  | **Does the activity involve any of the following?** **(Check all that apply)**  In the United States: The use of a drug[[2]](#endnote-3) in one or more persons other than use of an approved drug in the course of medical practice[[3]](#endnote-4).  In the United States: The use of a device[[4]](#endnote-5) in one or more persons that evaluates the safety or effectiveness of that device.  Data regarding subjects or control subjects submitted to or held for inspection by FDA[[5]](#endnote-6).  Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[[6]](#endnote-7). |
| **STOP! If any boxes are checked, you are conducting human subjects research. Contact your respective IRB office. IRB Review is required.**   * + [Harvard Longwood Campus](https://www.hsph.harvard.edu/ohra/) (HSPH, HMS, HSDM)   + [Harvard University Area](https://cuhs.harvard.edu/) (All other Harvard schools) | |
| **4 Coded Data / Working with Collaborators (Check if “Yes”)** | |
|  | **Will you be receiving information/biospecimens that are coded?** (When identifying information has been linked to a number or a letter and there is a key that connects the code to the identifying information) |
|  | **If coded and there is a key that connects the data to the identity, is there:**  An agreement with the provider prohibiting the release of the key to you  IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to you under any circumstances  Legal requirements prohibiting the release of the key to you |
| **If any of the above boxes (#4) are checked, respond to #5** | |
| 5 Working with Collaborators (Check if “Yes”) | |
|  | **If coded, will you obtain these information/biospecimens from an individual, institution, or provider that is considered a collaborator? *(****An individual, institution, or provider may be considered a “collaborator” if they collaborate on other activities related to the conduct of your research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.)* |
|  | **Will the collaborator collect the information/biospecimens specifically for your research through an interaction or intervention with living individuals?** |
| **STOP! If any boxes are checked under #5, you may be conducting human subjects research. Contact your respective IRB office. IRB Review may be required.**   * + [Harvard Longwood Campus](https://www.hsph.harvard.edu/ohra/) (HSPH, HMS, HSDM)   + [Harvard University Area](https://cuhs.harvard.edu/) (All other Harvard schools)   **If none are marked under #5, you are not conducting human research. IRB review is NOT required.** | |

1. *The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.* [↑](#endnote-ref-2)
2. *The term ‘‘drug’’ means:*

   *articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and*

   *articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and*

   *articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and*

   *articles intended for use as a component of any article specified in clause (A), (B), or (C).* [↑](#endnote-ref-3)
3. *“Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.* [↑](#endnote-ref-4)
4. *The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:*

   *recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,*

   *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*

   *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.* [↑](#endnote-ref-5)
5. *This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.* [↑](#endnote-ref-6)
6. *This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.* [↑](#endnote-ref-7)