|  |  |  |  |
| --- | --- | --- | --- |
| Name: | Phone/Pager: | | |
| Department: | E-mail: | Degree: | |
| Additional Contact Person: | E-mail: | Phone: | |
| Project Title: | | | |
| Will this project take place at an SSM facility other than SLUH? | | | Yes  No |
| Did SLU receive funding for this project? | | | Yes  No |
| eRS #: |
| If yes, did SLU receive direct federal funding (e.g., NIH) for this project? \* | | | Yes  No |

\* Note: if SLU is the direct recipient of federal funding for the project and *any site* being paid by the grant/contract is engaged in human research, SLU is considered “engaged” in human research and this form cannot be used.

|  |  |
| --- | --- |
| Is it human research under DHHS Regulations? | |
|  | |
| **A. “Human”** | |
| **1.** Does activity involve human subjects (*living* individuals about whom an investigator  conducting research collects data or biospecimens)? [Click if using PHI for research on deceased persons.](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/notification_of_decedent_research.doc) | Yes  No |
| 1. Does activity involve the prospective collection of information or biospecimens through **intervention** or **interaction** with the individual and uses, studies, or analyzes the information or biospecimens? (**Intervention**:physical procedure by which information or biospecimens are gathered **or** manipulations of the subject or the subject’s environment that are performed for research purposes. **Interaction**:communication or interpersonal contact with the individuals, including electronic interaction.) | Yes  No |
| 1. Does activity involve obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens?(**Private information**:information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or psychological information) or information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. **Identifiable private information**: private information for which the identity of the subjects is or may readily be ascertained by the investigator or associated with the information. **Identifiable biospecimen**:a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.) | Yes  No |
| **If “Yes” to Q1 and Q2 or Q1 and Q3, activity involves human subjects per DHHS regulations.** | |
| **B. “Research”** |  |
| **4.** Is the activity **systematic**? (**Systematic:** activity that involves data collection, either  quantitative or qualitative, and data analysis to answer a question.) | Yes  No |
| **5.** Is the activity an **investigation**? (**Investigation:** activity that involves development, testing,  evaluation, and/or search for information.) | Yes  No |
| **6.** Is the activity designed to **generate or contribute to generalizable knowledge**?  (**Generalizable knowledge:** activity that draws general conclusions (knowledge gained may be applied to other populations outside of study), informs policy, or is universally or widely applicable; contributing to generalizable knowledge normally involves public dissemination of that knowledge.) | Yes  No |
| **If “Yes” to Q4, Q5, and Q6, activity meets the definition of research per DHHS regulations.** | |
| **\* If activity involves “human subjects” and “research” per A & B, STOP. Formal IRB review is required.** | |
| Is it human research under FDA Regulations? | |
|  | |
| **7.** Are any of the following statements true? |  |
| 1. Activity is conducted in the United States and involves use of a drug in one or more human subjects (as recipients of a test article or as controls, patient or healthy, [21 CFR 50.3](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3)), but is **not** the use of an approved drug in the course of medical practice. | Yes  No |
| 1. Activity is conducted in the United States and evaluates the safety or effectiveness of a device in one or more human subjects. | Yes  No |
| 1. Data regarding subjects (including controls) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. | Yes  No |
| 1. Data regarding the use of a device (IVD) on human specimens (including de-identified/anonymous specimens) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. | Yes  No |
| **\*If Yes to any of 7a-7d, the activity is human research per FDA regulations and formal IRB review is required.** | |
| Retrospective Data/Specimen Analysis Considerations | |
|  | |
| **8. Does the project involve retrospective data/specimen analysis?** *If no, skip to next section*  If Yes, provide a data collection sheet to the IRB and check one of the following: | Yes  No |
| 1. The data/specimens to be used in the research do not contain identifiers or the provider of the data/specimens will remove all identifiers, including any codes, before providing data/specimens to the research team. | Yes  No |
| 1. Data/specimens to be obtained qualify as a Limited Dataset (only city/state/zip code, dates, and/or age are being obtained). If the dataset includes health information, provide copy of [internal](https://www.slu.edu/research/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/dua_internal.doc) (if SLU/SSM data) or [external](https://www.slu.edu/research/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/dua_external_slu_recipient.doc) (if non-SLU/SSM data) data use agreement (DUA) for IRB records unless this is quality improvement. By clicking yes, you assure you will not attempt to re-identify any individuals. | Yes  No |
| 1. Data/specimens to be obtained are coded, but the holder of the key to identifiers and the SLU investigator enter into an agreement (such as a code access agreement) prohibiting the release of the key to the investigator. Submit copy of agreement. | Yes  No |
| 1. SLU agent has documentation of written policies from a repository/data source that prohibits the release of the key to SLU agent. Submit documentation to IRB. | Yes  No |
| 1. There are other legal requirements prohibiting release of identifiers to SLU agent or the data (with or without identifiers) are all publicly available. | Yes  No |
| **If “Yes” to any of 8a-8e, the activity may not be human research for SLU agent. Continue with this form.** | |
| Genomic Data Sharing | |
|  | |
| **9. Will you obtain or generate genomic data in this project** (as [defined by the NIH](https://gds.nih.gov/13faqs_gds.html)).  If yes, answer the following: | Yes  No |
| 1. Is the research funded by the NIH through a grant application submitted to the NIH, or contract issued by the NIH, on or after January 25, 2008? | Yes  No |
| **If “Yes” to 9a, you must comply with the National Institutes of Health (NIH)** [**Genomic Data Sharing (GDS) Policy**](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-111.html) **and the** [**Genome Wide Association Studies (GWAS) Policy**](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html)**. Please complete the** [**Genomic Data Sharing Form**](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/genomic_data_sharing_form.docx) **and submit it along with this request.** | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Quality Improvement Considerations | | | | | |
|  | | | | | |
| **10. Does the project involve quality improvement, not research?**  *(If no, skip to next section)*  If Yes, answer the following: | | | | Yes  No | |
| 1. The goal of the project is to inform/improve the performance of the unit/site, not to establish scientific evidence to share beyond the scope of the unit/site. | | | | Yes  No | |
| 1. The unit/site administrators approve this as a QI project to be systematically implemented; activities do not require the consent of individual participants. | | | | Yes  No | |
| 1. If there is a possibility of publishing the outcomes of the QI initiative, the personnel involved will include the following statement with manuscripts, “This project was undertaken as a QI initiative, and as such was not approved by an IRB.” | | | | Yes  No | |
| **If “Yes” to 10a-10c, the activity may not be human research for SLU agent. Continue with this form.** | | | | | |
| Project Description | | | | | |
|  | | | | | |
| **Please provide a brief project description.** State the project’s purpose and explain how you will be gathering or obtaining project information/data/specimens. | | | | | |
|  | | | | | |
|  | | | | | |
| **FOR IRB USE ONLY** | | | | | |
|  | | | | | |
| **THIS DOES NOT REQUIRE SUBMISSION TO THE IRB** | | | | | |
|  | | | | | |
|  | **Signature of SLU IRB Reviewer** |  | **Date** | |  |
|  | | | | | |
| **Justification for IRB Decision (if deemed necessary to provide):** | | | | | |