**PART 1: HUMAN SUBJECTS RESEARCH SELF-DETERMINATION FORM**

This self-determination form is to be used to determine whether a proposed project meets the regulatory definition of being human subjects research and requires formal IRB review.

* If your answers reveal that your proposed project **meets the criteria for being human subjects research**, you must complete and submit a New IRB Application through the [Axiom Mentor system](https://www.smu.edu/OIT/Services/Axiom-Mentor) for review and approval prior to recruiting or having any interaction with potential human participants.
* If your answers reveal that your proposed project is **NOT** human subjects research, you do not need to submit an IRB application, but you should maintain a copy of this form for your records.
* **If you are a student investigator**, your faculty advisor’s signature is required to verify and acknowledge that your proposed project does not require IRB review. The IRB cannot approve research after a project has been implemented or completed so it is important to have your determination verified by obtaining your faculty advisor signature at the end of this form.
* If you are unsure of your self-determination or if you need a formal letter from the Office of Research Compliance documenting that no IRB review is required, upload your completed form, and submit it through the [Axiom Mentor system](https://www.smu.edu/OIT/Services/Axiom-Mentor) by selecting the **review type as Not Human Subjects Research**. Please upload all applicable documents (i.e., survey) with your electronic submission.

**CONTACT INFORMATION:**

**Name of Submitter:** Click here to enter text.

**SMU Position or Title:** Click here to enter text.

**SMU Dept/College:** Click here to enter text.

**If student, Faculty Advisor name:** Click here to enter text. **Faculty Advisor’s email:** Click here to enter text.

**SMU Dept/College:** Click here to enter text.

**Email Address:** Click here to enter text.

**Phone #:** Click here to enter text.

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| **Section A: Summary of Activity** |
| Describe what you hope to learn from this project in 3 – 5 sentences. If this is a QA/QI project, identify the specific process or procedure that this project aims to improve or evaluate.  Click here to enter text. |
| **Activities that typically DO NOT meet the criteria of being human subjects research requiring IRB review. Check any activity that your proposed project may be categorized in.** |
| 1. **Case Report:** A project in this category consists of a case report or retrospective analysis of one, two, or three medical or educational activities/cases. If more than three cases are involved in the analytical activity, the activity will constitute research and may require IRB review. A critical component is that nothing was done to the participant(s) with prior research intent.   **NOTE:** For any case reports that include an individual’s protected health information (PHI), the use of that information must be authorized by the individual per HIPAA regulations. Contact the [Office of Research Compliance](mailto:researchcompliance@smu.edu)  ifan individual’s PHI will be included in a case report to ensure the HIPAA regulations are adequately addressed in the proposed project. |
| 1. **Course-Related Activities:** This category is for a project limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine exercise or curriculum assignment and is not intended for use outside of the classroom.   **NOTE:** IRB approval may be required if an instructor or department has an academic interest in pedagogy, and the classroom is used to test innovations with the goal of contributing to generalizable knowledge about pedagogy. |
| 1. **Program Evaluation/Quality Improvement/Quality Assurance Activities:** A project in this category is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, organization, or other specified setting. The intention of the project is not to generate conclusions that can be applied universally, outside the immediate environment where the project will occur. An example would include distributing a survey to students to provide feedback on library hours on campus to improve and address student needs.   **NOTE:** Requesters or investigators who plan to distribute a survey should ensure that they receive  approval from the [SMU Survey Oversight Committee](https://www.smu.edu/Provost/assessment/Surveys) and if applicable, from committees within their department and the site where the activity will occur. Submit your survey for review and approval at [www.smu.edu/survey](https://smu.az1.qualtrics.com/jfe/form/SV_8zR5ydL2Jmz4NHn). Contact [assessment@smu.edu](mailto:assessment@smu.edu) with questions. |
| 1. **Oral History:** A project in this category is limited to oral history activities, such as open-ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.   **NOTE:** IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories). |
| 1. **Pilot Programs:** A project in this category is a small-scale test of the methods and procedures to be used on a larger scale. Pilot work is not to test hypothesis about the effects of an intervention, but rather, to assess the feasibility/acceptability of an approach to be used in a larger scale study. An example would include testing the feasibility of survey questions before they are used in a large research study. |
| 1. **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Some examples of data sources that qualify as not human subjects research, unless the researcher has received the restricted use data include: data files from ICPSR (Interuniversity Consortium for Political and Social Research), Center for Disease Control, Bureau of Economic Analysis, FBI Uniform Crime Reporting Program, etc.   **NOTE:** IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, an IRB Application would need to be submitted via Axiom Mentor. |
| 1. **De-Identified Private Information or Human Biological Specimens:** A project in this categoryis limited to the use of existing and/or prospectively collected **de-identified** private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:    * 1. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**      2. The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; **and**      3. The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers; **and**      4. Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA; **and**      5. The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA. |
| 1. **Coded\* Private Information and/or Human Biological Specimens\*\*:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if **all** the following conditions apply to the project: 2. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and** 3. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:   (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);  (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or  (c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased, **and**   1. Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and** 2. The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.   From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2003:  \**Coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. |
| 1. **Decedents:** Research that uses only human cadavers, cadaveric tissue, decedent medical record information or discarded decedent specimens from clinical use is not subjects to prior review and approval by the SMU IRB. According to Federal policy, research involving deceased individuals is not considered human subjects research and hence does not require IRB oversight **unless the research study includes both living and deceased individuals.**   If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. Research involving the medical records or specimens of a deceased patient is subject to one of the following:   * Secure a valid research authorization signed by the administrator or executor of the decedent’s estate or the person listed as next-of-kin or * Obtain the approval of a Request to Access Decedent Protected Information (PHI).   NOTE: This exception may not be available for decedent information that contains Psychotherapy Notes or information relating to HIV, metal health, genetic testing or drug or alcohol abuse. |

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| **Defining Research and Human Subjects** |
| **Research**is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” |

**Human subject** is defined in the Code of Federal Regulations, 45 CFR 46.102(f) (1 or 2), as “a living individual about whom an investigator (whether professional or student) conducting research:

* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR
* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”

The Belmont Report states “. . . the term “research” designates an activity designed to test a hypothesis or formal protocol that sets forth an objective and a set of procedures to reach that objective.”

The following activities are specifically deemed **NOT** to be research:

* Scholarly and journalistic activities (i.e., oral history, journalism, biography, literary criticism, legal research and historical scholarship)
* Public health surveillance activities – limited to activities conducted, supported, requested, ordered, required, or authorized by a public health authority.
* information collection for criminal justice purposes
* Operational activities for national security purposes (i.e., activities in support of intelligence, homeland security, defense, or other national security missions)

In general terms, operational activities such as routine outbreak investigational and disease monitoring and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted for services.

**Generalizable knowledge** is information where the intended use of the research findings can be applied to populations or situations beyond that study. Note that publishing the results of a project does not automatically meet the definition of generalizable knowledge.

**PART 2:** **REQUEST DETERMINATION LETTER VERIFYING PROPOSED PROJECT**

**IS NOT HUMAN SUBJECTS RESEARCH**

* If you have conducted a self-determination assessment that your proposed project is **NOT** human subjects research based on one of the categories outlined in Part 1, and you need documentation of this determination, please complete the following sections below and submit both the **Part 1: Not** **HSR Self-Determination Form** along with the **Part 2: Request Determination Letter for Verifying Proposed Project is Not Human Subjects Research** to the Office of Research Compliance at [researchcompliance@smu.edu](mailto:researchcompliance@smu.edu).
* If your self-determination review indicates that your project meets the definition of human subjects research requiring IRB approval, please Create a New Project within the electronic submission system [Axiom Mentor](https://www.smu.edu/OIT/Services/Axiom-Mentor).

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| 1. **Briefly describe the project, and what you expect to do with your findings:** |
| Click here to enter text. |
| 1. **Briefly describe the study population or subject of the research:** |
| Click here to enter text. |
| 1. **Briefly describe the data collection methods used:** |
| Click here to enter text. |
| 1. **If this project is funded or sponsored from an internal SMU or external source, please list the source(s):** |
| Click here to enter text. |
| **5. Does your project involve the distribution of a survey?** |
| If yes, any survey that will be distributed to SMU faculty, staff, or students, must obtain approval from the [SMU Survey Oversight Committee](https://www.smu.edu/Provost/assessment/Surveys) and if applicable, from committees within their department and the site where the activity will occur. Submit your survey for review and approval at [www.smu.edu/survey](https://smu.az1.qualtrics.com/jfe/form/SV_8zR5ydL2Jmz4NHn). Contact [assessment@smu.edu](mailto:assessment@smu.edu) with questions. |