HUMAN SUBJECTs RESEARCH (HSR) Determination Form  
(formerly Appendix E)

**Complete this form only if you think your project does NOT require IRB review, and you need a formal determination letter.**

**Per the federal regulatory definition of “human subjects research,” a project meeting the definition of BOTH “research” and “human subject” requires IRB review and must be submitted through IRBNet.**

* **Please allow at least two weeks for a formal review and a response to be issued.**
* Submit completed form to **HSRrequest@du.edu**. Do not submit this form through IRBNet or to IRBAdmin@du.edu.
* Forms that are incomplete, handwritten, submitted directly to the IRB Office staff email accounts, or attached as part of an IRB submission in IRBNet will NOT be reviewed.

# SECTION A: CONTACT INFORMATION

**Protocol Title of Proposed Research:** Click here to enter text.

**Name:** Click here to enter text., Click here to enter text.

**Credentials:** Click here to enter text.

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

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

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

**IF A STUDENT, list Faculty Sponsor (FS) Name**: Click here to enter text.

**FS Position/Title:** Click here to enter text.

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

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

**Student Project:** Thesis Dissertation Capstone Other

(If “Other,” please describe) Click here to enter text.

# SECTION B: SUMMARY OF ACTIVITIES

## B.1

**B.1.1. Purpose of the project:** 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.

**B.1.2. Describe all project procedures:**

Click here to enter text.

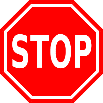
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| **B.1.3 Activities that typically do NOT represent “human subjects research” requiring IRB review.**  Please check the appropriate activity that your project fulfills. |
| * 1. **Case Report:** The project consists of a case report or a retrospective 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 will 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 includes an individual’s protected health information (PHI), the use of that information must be authorized by that individual per HIPAA regulations. Contact the IRB Office if an 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:** The project is 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 class exercise or 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. **Decedents:** Research that uses ***only*** human cadavers, cadaveric tissue, decedent medical record information or discarded decedent specimens from clinical use is not subject to prior review and approval by the DU 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 Health Information (PHI).   **NOTE:** This exception may not be available for decedent information that contains Psychotherapy Notes or information relating to HIV, mental health, genetic testing, or drug or alcohol abuse. |
| * 1. **Oral History:** The project 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. **Program evaluation /Quality Improvement/Quality Assurance Activities:** The project 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 of the immediate environment where the project occurred.   **NOTE:** Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur. |
| * 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  IRBNet. |
| * 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** of the following conditions apply to the project:      1. (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(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, 2008:**  *\*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. **De-Identified Private Information or Human Biological Specimens:** The project is 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. |

**Please note: Depending on the type of data being shared with the Investigator, a Data Use Agreement (DUA) may be required.**

* A Data Use Agreement (DUA) is a written agreement that is used to govern the transfer of research data between institutions. It describes the data being transferred or shared and addresses the ownership of the data, the permitted uses of the data, publication of results, development of inventions, disposal of the data, and any liability.
* Are you transferring data from or to an outside entity or a researcher at another institution? If so, . Please complete and submit the [Data Agreement Request Form](https://www.du.edu/techtransfer/faculty-staff/agreement-review.html) (sending data) or **Data Agreement Request Form (receiving data)** respectively to [datacontract@du.edu](mailto:datacontract@du.edu).

**Please note: If there is the transfer of biological materials between two insitutions, a Material Transfer Agreement (MTA) may be needed.**

* A Material Transfer Agreement (MTA) is a contract that governs the transfer of materials between institutions for use in research. These agreements address issues such as ownership of the transferred material and modifications and derivatives made by the recipient. They also may limit the use and further dissemination of the material by the recipient, address publication rights and confidentiality as well as rights to inventions and research results.
* Are you receiving or transferring tangible research mateirals (i.e. biological specimens, cell lines, plasmids, nucleotides, proteins, transgenic animals, plant varieties, bacteria, pharmaceuticals and other chemicals) from or to a researcher at another institution? If so, please contact [techtransfer@du.edu](mailto:techtransfer@du.edu).

****If your activityfalls into a category described in Section **B.1.3**, submit the Human Subject Research Determination Form to [HSRrequest@du.edu](mailto:HSRrequest@du.edu) for formal review and determination.

If your activity **did not** fall into a category described in Section **B.1.3**, continue to Sections C and D to assess if you are engaged in human subjects research per the regulations set forth by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

# SECTION C: defining research & HUman Subjects

**Research** is defined in the Code of Federal Regulations, 45 CFR 46.102(d), as a systematic investigation designed to develop or contribute to generalizable knowledge.

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.

**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.

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| 1. **SECTION C. Activities subject to HHS human subject research regulations (45 CFR 46)** |
| **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**  TIP: If the investigation is characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, lab, department, organizational setting), then the activity meets the definition of research.  Yes, Go to #2  No, Go to Section D |
| **Does the research involve obtaining information about LIVING individuals?**  Yes, Go to #3  No, Go to Section D |
| **Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact between investigator and person) with the individuals?**  Yes, IRB review required  No, Go to #4 |
| **Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?**  Yes, Go to #5  No, Go to Section D |
| **Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)**  Yes, IRB review required  No, Go to Section D |

# SECTION D: Activities subject to FDA REgulations

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| **SECTION III. Activities subject to FDA human subject regulations: If your answer is “yes” to any of the 3 questions below, IRB approval is required and the FDA regulations apply to your study.** |
| 1. Is this is an experiment that involves a test article\* and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A subject is an individual (either health or a patient) who is a recipient of the test article or a control.   \**Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.  Yes, IRB review required  No |
| 1. Is this is a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.   Yes, IRB review required  No |
| 1. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.   Yes, IRB review required  No |

**Instructions:**

If you have **NOT** answered a question that indicates “IRB review required,” please proceed by submitting the completed form to [HSRrequest@du.edu](mailto:HSRrequest@du.edu) for formal assessment.

If you have answered a question that indicated “**IRB review required**,” please proceed by submitting your study protocol documents via IRBNet.