

## Class Project Approval Form

***This form must be submitted to the instructor by each student/group after the instructor's application has been approved by the IRB. The project cannot begin until the instructor gives an individual approval.***

Printed name of student: \_\_\_\_\_

Student Email: \_\_\_\_\_

Printed name of instructor: \_\_\_\_\_

Instructor Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

Class in which the project will take place: \_\_\_\_\_

Instructor's IRB Approval Date: \_\_\_\_\_ IRB Number: \_\_\_\_\_

***Please circle Y for Yes or N for No.***

1. Does the research involve subjects from any of the following categories? If the response to any of the following is "yes," attach an explanation.

Y	N	Under 18 years of age
Y	N	Over 65 years of age
Y	N	Physically or mentally disabled
Y	N	Economically or educationally disadvantaged
Y	N	Unable to provide their own legal informed consent
Y	N	Pregnant females as target population
Y	N	Victims
Y	N	Subjects in institutions (e.g., prisons, nursing homes, halfway house)

2. Does the research involve any of the following? If the response to any of the following is "yes," attach an explanation.

Y	N	Deception of subjects
Y	N	Shock or other forms of punishment
Y	N	Sexually explicit materials or questions
Y	N	Handling of money or other valuable commodities
Y	N	Extraction of blood or other bodily fluids
Y	N	Questions about drug use
Y	N	Questions about sexual orientation, sexual experience, or sexual abuse
Y	N	Purposeful creation of anxiety
Y	N	Any procedure that might be viewed as invasion of privacy
Y	N	Physical exercise or stress
Y	N	Administration of substances (food, drugs, etc.) to subjects
Y	N	Any procedure that might place subjects at risk
Y	N	Examination of subjects' personal behavior
Y	N	Questions about illegal behavior
Y	N	Compensation to subjects in any form; for example, money or course credit
Y	N	Questions about suicidal thoughts or ideas

3. Answer the following questions about the researchers.

- |   |   |   |
|---|---|---|
| Y | N | Are you aware of the University guidelines regarding rights of human subjects code of Federal Regulations - 45 CFR 46, the University of Denver's Federalwide Assurance, and the Belmont Report)? |
| Y | N | Is the research part of a thesis or dissertation?   |
| Y | N | Do you plan to publish or report information based on your research outside of the classroom?   |

4. Answer the following questions about the research.

- |   |   |  |
|---|---|--|
| Y | N | In your opinion, does the research involve <b>more than minimal risk</b> to Subjects: ("Minimal Risk" means that "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")<br><b>If the answer is yes, attach an explanation including the benefits of the research to the subjects and to the discipline or profession.</b> |
| Y | N | Are any <b>emergencies or adverse reactions</b> (physical, psychological, social, legal, or emotional) probable as a result of the research? <b>If yes, then explain how they will be handled.</b>   |
| Y | N | Do subjects leave the study or experiment in approximately the same emotional state as they began? If "no," explain how distress will be handled. In most cases, this means informing subjects that if they become upset, want to talk about the study or related experiences, etc., you or someone else is available. You should provide subjects with your telephone number and your instructor's telephone number.  |

5. Answer the following questions about the informed consent procedures.

- |   |   |  |
|---|---|--|
| Y | N | Are you using a written informed consent form? If so, include a copy. If not, explain why and describe how consent will be obtained. |
| Y | N | Do you plan to identify the subject(s) by name or any other identifiers?   |

6. Identify the subject pool being utilized: (example: random customers at a grocery store.)

7. Describe your sample population, the procedures, measures, and explain the objective of your project. Please limit your description to one typewritten page.

**8. Attach your consent form and/or information sheet to be given to subjects.**

**9. Attach a copy of any survey or measure used in the research.**

**Assurance by Principal Investigator:**

I agree to conduct this research project in accordance with Federal Policy for the Protection of Human Subjects, and with the University of Denver "Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects." No changes in my research protocol will be implemented without the prior review and approval of my instructor.

Student Signature: \_\_\_\_\_

Instructor Signature: \_\_\_\_\_

**ADDENDUM: Protected Health Information (PHI)**

The Health Insurance Portability and Accountability Act of 1996 (**HIPAA**), was written to allow for insurance portability but also as a Privacy Rule to protect the privacy and security of a person's identifiable health information (Protected Health Information or **PHI**.)

**PHI is identified as all individually identifiable health information that is created or received by or from a health care entity that includes information about the past, present or future physical or mental health of a person, the provision of health care to a person, or payment for care is considered Protected Health Information (PHI) and falls under HIPAA regulations. This includes identifiable demographic and genetic information.**

DU's Institutional Review Board reviews the presence of PHI authorizations as part of the IRB application and review process.

Signed permission (**authorization**) is almost always required for the use and disclosure of PHI.

Participants consented into approved protocols before April 14, 2003, or into a protocol which has a waiver of consent, do not need to provide authorization. These subjects are grandfathered under HIPAA. However, if subjects are re-consented for any reason after April 14, 2003, or additional subjects are enrolled after April 14, 2003, authorization is required from those subjects.

If the protocol was approved to have waiver of **consent**, then authorization from subjects is not needed. The waiver of consent is considered to be a grandfathered legal permission to conduct the research without obtaining authorization.

Authorization **must be obtained** in each of these two circumstances:

1. When requesting permission from a patient to have their name, address and phone number or other health information released to an investigator for recruitment into a research study.

**a. Are you requesting permission from a clinical location to contact a patient for recruitment into your study?**

**No**

**Yes**

If your answer to question a. is yes, the site's completed (minus subject signature and name) request for Recruitment Authorization must be Included with this application.

2. When enrolling a subject into a specific research study to request permission to collect their PHI as related to the research study.

**a. Does this research involve the creation and/or use of PHI?**  **Yes**  **No**

If yes, either i. or ii. listed below must be included with this application:

i. A completed (minus subject signature and name) Authorization To Use or Release Health Information For Research Purposes or an Authorization for Enrollment into Research from the health care site **OR**

ii. A completed Request for Waiver of Authorization.

***Please include information about the recruitment site as well as the recruitment and HIPAA authorization process. Explain steps taken at the recruitment site to assure HIPAA compliance. Provide documentation such as Authorization Forms, policies, etc., that verify that the processes in place at the health care site are HIPAA compliant.***