

THE FOLLOWING IS A REVISED VERSION OF THE UNIVERSITY OF DENVER'S "APPLICATION TO THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS" (IRB). THIS APPLICATION IS NO LONGER APPROPRIATE. ALL RESEARCH PROTOCOLS/STUDIES INVOLVING HUMAN SUBJECTS MUST BE SUBMITTED VIA DU'S NEW ELECTRONIC SUBMISSIONS SYSTEM, e-PROTOCOL. THE QUESTIONS INCLUDED IN THIS APPLICATION ARE SIMILAR TO WHAT YOU WILL FIND IN THE ELECTRONIC VERSION.

Human subjects are involved in a project if it utilizes data derived from human responses, observations of human beings or human materials (records, pathological specimens, diagnostic specimens, etc.) whether such data is obtained directly from the human source or utilizes secondary data.

- 1. Are there persons or materials involved in this project that could be considered human subjects?**

Yes No

The IRB also reviews Protected Health Information for deceased persons (decedents.)

- 2. Are you collecting Protected Health Information on decedents?**

Yes No

If the answers to Questions 1 and 2 are **No, STOP HERE**. Regulations regarding human subject use in research do not apply.

In addition to the completed application, please assemble your application in the following order:

1. If you have applied for (or received) funding, please attach a copy of "methods" and "human subjects" sections of your grant proposal. In referring to methods when answering questions, please indicate the page number where the reference may be found.
2. Attach any questionnaires or instruments to be used.

➤ *Incomplete applications will be returned.*

The University of Denver's assurance with the Department of Health and Human Services is available from the Office of Sponsored Programs Office or at: <http://www.du.edu/osp/multipleproject.html>

NOTE: If you have not completed DU's Education Program for the Protection of Human Subjects in Research, you (and your advisor) are required to do so prior to review of your application.

***To facilitate timely review,
please be sure your application is complete***

If you have any questions, please contact Sylk Sotto-Santiago at ssottosa@du.edu or 303.871.4052.

University of Denver
(Colorado Seminary)

OSP Use Only	
IRB Protocol #	_____
OSP Proposal #	_____
OSP Grant #	_____
Date Received	_____
IRB Board:	_____
_____DU	_____ERI

**APPLICATION TO INSTITUTIONAL REVIEW BOARD FOR THE
PROTECTION OF HUMAN SUBJECTS**

SECTION A: PROTOCOL INFORMATION

Highest Completed Degree: Doctorate Master's
 Baccalaureate

Principal Investigator (P.I.): _____

- Program Director
 Appointed Faculty
 Undergraduate
 Staff
 Non-appointed Faculty
 Graduate Student
 Research Staff

Department: _____

Email: _____ Phone: _____ Fax: _____

Home or Campus Address: _____

Associated Investigators and/or Faculty: _____

Exact Title of Project: _____

Location/Site of Research and Recruitment: _____

Begin Date: _____ End Date: _____

Purpose of Research: (Check all that apply)

- Sponsored Agreement (list below)
 Faculty Research
 M.A. Thesis
 Psy.D. Doctoral Paper
 Ph.D. Dissertation
 Classroom Research
 Undergraduate Research
 Creation/Use of Protected Health Information (PHI) (see Section C)
 Other: _____

If sponsored agreement, agency to which it will be submitted (if any): _____

<p>I have read the departmental procedures for Research Proposal Review and the applicable <u>Principles for the Conduct of Research with Human Participants</u> and will abide by them, including the requirement to send feedback to subjects within six months, if applicable.</p> <p><i>I have completed DU's Education Program For The Protection Of Human Subjects in Research provided by the Office of Sponsored Programs at workshops or through Blackboard.</i></p>			
_____	_____	_____	_____
P.I. signature	Date	Faculty Sponsor Signature	Date

If P.I. is not tenure track faculty, advisor, departmental chair/dean or department director signature is required:

THIS PROTOCOL WAS APPROVED BY THE DEPARTMENT ON _____
Date

THIS PROTOCOL MEETS MY APPROVAL and **I have completed DU's Education Program For The Protection Of Human Subjects in Research:**

Faculty Sponsor or Dept. Director signature Date Printed Name

Faculty Sponsor or Dept. Director's email address

SECTION B: PROTOCOL METHODOLOGY

An individual is considered to be at risk if he/she may be exposed to the possibility of harm - physical, psychological, sociological or other - as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his/her needs.

The most obvious examples of placing subjects at risk include the experimental use of the following procedures: surgical and biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of unusual physical exertion; subjection to deceit, public embarrassment and humiliation. There is however, a wide range of medical, social, and behavioral projects in which, although there may be no immediate physical risk, procedures are introduced which involve discomfort, anxiety, harassment, invasion of privacy, or constitute a threat to the subject's dignity through the imposition of demeaning or dehumanizing procedures. Finally, the risk element will be examined for those studies dependent upon stored data, or information, which might have been obtained for quite different purposes.

If an activity will expose an individual to risk, then the committee will wish to assure itself that (a) the rights and welfare of the individual are adequately protected, (b) the methods used to obtain informed consent are adequate and appropriate, and (c) the risks to the individual are out-weighed by the potential benefit to him/her or by the importance of the knowledge to be gained.

With respect to the above criteria, research participants will be exposed to the following risk level (Check one):

- 1. The proposal requires use of human subjects at no risk to the subjects.
- 2. The proposal requires use of human subjects with no more than minimal risk.
- 3. The proposal requires use of human subjects at risk but provides adequate methods for avoiding risks.
- 4. The proposal requires use of human subjects at risk but provides adequate means for acquiring legal, informed consent.
- 5. The proposal requires the subjection of human beings to risk for which no consent can be obtained but which are far outweighed by the possible benefits that may accrue to the subject or society.

CHECK ONE:

- (1) DU students will be used as subjects YES NO
- (2) Experimental drugs will be used YES NO
- (3) Experimental devices will be used YES NO
- (4) Subjects who are non-English speaking will be used YES NO
- (5) Minors will be used (less than 18 years) YES NO
- (6) Subjects who are cognitively disabled will be used YES NO
- (7) Prisoners and/or incarcerated subjects will be used YES NO
- (8) Subjects will be compensated.
If yes, clarify in what form: _____ YES NO
- (9) Pregnant women YES NO
- (10) Uses **Protected Health Information (PHI)** (see Section C) YES NO

Confidentiality – pertains to personal, identifiable information that a subject has shared with the researcher with the expectation that it will not be shared with others in ways that are inconsistent with the understanding of the original disclosure without permission of the subject.

Anonymity – means that no one, including the researcher, will be able to identify an individual subject. Names, other identifiers, and even demographics can potentially identify subjects. Any information that uniquely identifies someone eliminates anonymity.

My research project is anonymous.

My research project is confidential.

If your study is anonymous, please include a copy of the “Project Information Form” you will use.
(See link for Attachment B in the IRB Application Checklist.)

If your study is confidential, please include a copy of the “Informed Consent Form” you will use.
(See links for Attachments C and D in the IRB Application Checklist.)

SECTION C: PROTECTED HEALTH INFORMATION (HIPAA)

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.*

The gathering or use of any one of these identifiers requires IRB review. This includes the following demographic and genetic information:

- Names
- All geographic subdivisions smaller than a state
- All elements of dates (except year) for dates directly related to an Individual, Including birth date, admission date, discharge date, date of death; and all ages over 89
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- VIN and serial numbers, Including license plate numbers
- Device Identifiers and serial numbers
- URL's
- Internet protocol (IP) address numbers
- Biometric Identifiers, Including fingerprints and voiceprints
- Full-face photographic Images and any comparable Images
- Any other unique Identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-Identification

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.

- **Are you requesting permission from a clinical location to contact a patient for recruitment into your study?** Yes No

If your answer 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.*

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

If yes, one of the following listed below must be included with this application:

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**

A completed Request for Waiver of Authorization (Attachment A)

Please insert your answers to the following questions.

- (1) *What is the rationale for this study? Briefly explain what makes the study worth conducting.*
- (2) *Describe the subject population and explain the rationale for using in this population special groups such as prisoners, children, the mentally disabled or groups whose ability to give voluntary informed consent may be in question. How and from where will subjects be recruited? Include information about the recruitment site as well as the recruitment and HIPAA authorization process, if appropriate. 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.)*
- (3) *What will the procedure be like from the subject's point of view? Indicate what will happen from initial contact to final briefing. Indicate who is conducting the research and how they are being supervised.*
- (4) *Describe and assess any potential risks - physical, psychological, social, legal or other - and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe why these methods are considered the best available and other methods, if any, that were considered and why they will not be used.*
- (5) *Describe consent procedures to be followed, including how and where informed consent will be obtained. If a school or other institution is involved, indicate how permission from institutional authorities will be obtained. Once obtained, a copy of the approval must be submitted to the IRB. Also, see question #12.*

- (6) *Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks and an assessment of their likely effectiveness.*
- (7) *In studies that involve clinical trials (biomedical and behavioral intervention studies), describe the plan for data and safety monitoring of the research to ensure the safety of subjects.*
- (8) *Assess the potential benefits to be gained by the individual subject as well as benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits of doing this research are more important than the risks experienced by the subjects.*
- (9) *Give specific details for any stressful or potentially stressful procedures or methods which might place a subject at risk. For example, if electric shock is used state intensity in milliamps per cm, the anatomical area(s) of application and duration. If drugs are used, state types, dosages, intended effects, duration and authority for their purchase, use and control. (The most obvious examples of procedures which place subjects at risk are: surgery and biopsy, drug administration, exposure to radiation, requirement of physical exertion, subjection to deceit, public embarrassment and humiliation). In addition to the obvious, there is a wide range of procedures which may be of little or no physical risk but may involve discomfort, anxiety, harassment, invasion of privacy or threaten the dignity of an individual through the imposition of demeaning or dehumanizing procedures. There may be an element of risk to subjects when stored data is used for purposes for which it was not originally obtained.*
- (10) *Describe the source of materials being used in the research; i.e., specimens, records, data, whether to be obtained or already existing.*
- (11) *Describe provisions made for any medical care which may result from the participation of the subject in the experiment.*
- (12) *How and when do you intend to provide feedback to subjects, participating organizations, etc.*
- (13) *What effects, desirable or undesirable, might this study have on the Department, the University, or the profession?*
- (14) *If you have answered yes to any of Section B items (1) through (10), a consent statement must be included as part of this application. The consent must be given either by the research subject his/herself or by his/her legally authorized representative, such as a parent or guardian. Whenever feasible, it is always best to obtain formal consent (i.e. a signed form) from subjects. If formal consent is not feasible, submit a complete and detailed statement of justification. If a formal consent is to be obtained, compose a SPECIFIC INFORMED CONSENT FORM and/or script of any oral explanation to be given, whenever possible. A copy of the script should be given to and signed by the subject. Provide WRITTEN JUSTIFICATION for omission or modification of any of these elements. The Informed Consent Form should be written in simple lay language and may not include any exculpatory language through which the subject is made to waive or appear to waive any of his/her legal rights.*

Note: Use the attached Informed Consent checklist when completing #14. See also Attachments A, B, C.

- (15) *Attach any recruitment advertising. The advertisement should be limited to:*
 - a. *the name of the investigator*

- b. the purpose of the research and eligibility criteria to admit subjects into the study
- c. description of benefits (e.g. payments or free treatment)
- d. a phone number for further information regarding the study

(16) Are there any conflicts of interest or potential conflicts of interest between the P.I. (and his/her co-investigators, if any) and the involved funding source or device provider?

yes no

(17) (a) Is this project being reviewed by another IRB? If yes, who? Submit a copy of their review/approval with this application.

(b) If your answer to #17 (a) is yes, please explain why another board is reviewing your application.

(18) If any Instrument is being used, which asks questions regarding suicide or homicide, a response to this standard question is required:

"If collecting information regarding suicide and homicide, provide an explanation/description of the reporting procedures that will take place. When indicators are positive, what time schedule will be followed?"

Please use the following as a checklist for inclusion of all elements if applicable and return with your application.

THE BASIC ELEMENTS OF INFORMED CONSENT ARE AS FOLLOWS:

<u>Included</u>	<u>N/A</u>	
<input type="checkbox"/>		1. An invitation to participate
		2. A statement that:
<input type="checkbox"/>		a. the study involves research,
<input type="checkbox"/>		b. an explanation of the purpose of the research,
<input type="checkbox"/>		c. the expected duration of the subject's participation, and
<input type="checkbox"/>	<input type="checkbox"/>	d. identification of any procedures which are experimental.
		3. A statement of:
<input type="checkbox"/>		a. the name, highest degree, and telephone number and Department of i) the faculty supervisor (if applicable) and ii) the individuals actually conducting the research, and
<input type="checkbox"/>	<input type="checkbox"/>	b. the sponsoring agency
		4. A description of:
<input type="checkbox"/>		a. any reasonable foreseeable risk or discomforts to the subject,
<input type="checkbox"/>		b. steps to minimize risks or discomforts, and
<input type="checkbox"/>		c. steps taken if discomforts arise, for example: if study involves children and the child gets upset, the procedure will be discontinued.
<input type="checkbox"/>		5. A description of any benefits to the subject or others which may reasonably be expected from the research.

6. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject.
7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, including video records. If confidentiality is promised, or implied, the following statement shall be included:

“I understand that there are two exceptions to the promise of confidentiality. If information is revealed concerning suicide, homicide or child abuse and neglect, it is required by law that this be reported to the proper authorities. In addition, should any information contained in this study be the subject of a court order or lawful subpoena, the University of Denver might not be able to avoid compliance with the order or subpoena.”

8. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if any injuries occur, and if so, what they consist of, or where further information may be obtained. 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.

“No informed consent may include any exculpatory language through with the subject is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.” – 45 CFR 46.116.

Examples of **unallowable** wording:

- I voluntarily and freely donate any and all blood, urine, and tissue samples and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of language:

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This institution is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This institution makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research.

9. a. An explanation of whom to contact, including phone #, for answers to pertinent questions about the research and research subjects’ rights, and

- b. inclusion of the following statement regarding whom to contact in the event of a research related injury to the subject:

If you have any concerns or complaints about how you were treated during the research sessions, please contact

(if submitting to the DU IRB) Dr. Dennis Wittmer, Chair,
Institutional Review Board for the Protection of Human
Subjects, at (303) 871-2431,

(if submitting to the ERI IRB) Dr. Clarence Snelling, Chair,
Institutional Review Board for the Protection of Human
Subjects, at (303) 871-4050

or Sylk Sotto-Santiago, Office of Sponsored Programs at (303)
871-4052 or write to either at the University of Denver, Office of
Sponsored Programs, 2199 S. University Blvd., Denver, CO
80208-2121.

10. A statement that:
- a. participation is voluntary,
 - b. refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and
 - c. the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

11. If subject is to be compensated, a clear statement as to whether or not subject will receive this compensation if the subject chooses to withdraw his/her participation.

12. If the subject is a minor (less than 18 years of age) at least one parent/guardian must sign the consent form. The signature of both parents(s)/guardian(s) should be obtained whenever possible. Depending upon the nature of the project, the IRB may require that both parents sign.

13. If the subject is between the ages of 12 and 18, provisions should be made for him/her to sign in addition to his/her parents(s)/guardian(s) where appropriate. Depending upon the nature of the project, the IRB may require subjects under 12 to provide assent.

14. The following signature paragraph shall be **included** in all consent forms:
- I have read and understood the foregoing descriptions of (name or research project). I have asked for and received a satisfactory explanation of any language that I did not fully understand. I agree to participate (or to have my child participate) in this study, and I understand that I may withdraw my consent at any time. I have received a copy of this consent form.

Signature

Date

15. If video taping is involved, a separate consent check off and signature line placed below the consent signature shall be included as follows:

- I agree to (have my child) be video taped
 I do not agree to (have my child) be video taped

Name

Date

16. If audio taping is involved, a separate consent check off and signature line placed below the consent signature shall be included as follows:

- I agree to (have my child) be audio taped

I do not agree to (have my child) be audio taped

Name

Date

17. Consent forms for research involving blood sampling of subjects by venipuncture is to include a statement similar to:

Approximately 3 teaspoons of blood will be removed from your arm by venipuncture. This is the standard method used to obtain blood for routine hospital laboratory tests. You can expect to experience some discomfort at the moment the needle goes into your arm.

Risks should be stated as follows:

Risks: Other than this momentary pain, the discomfort of venipuncture should be minimal. However, in about 10 percent of cases a small amount of bleeding under the skin will produce a bruise (hematoma). The risk of more serious complications including temporary clotting of the vein, infection of a hematoma, or significant external blood loss, is less than one in 1,000.

In addition, a form is to be provided for the subject to sign at the time procedure is done, stating that the seal on the needle was broken in front of them.