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Section 501: Subject Recruitment and Participation

5.1 General Recruitment Guidelines

The information in recruiting materials constitutes the earliest components of the informed consent process. In addition to its review for scientific merit and protection of subjects from unnecessary research risks, the IRB will evaluate all protocols for equitable and non-discriminatory subject recruitment. When inclusion is inappropriate with respect to the safety or well-being of the subjects or the purpose of the research justification, exclusion of particular groups will be considered and approved. The Institutional Review Board (IRB) will also consider the scientific and ethical justification for exclusion of classes of persons who might benefit from the research and determine if exclusion is justifiable and allowable.

There are several questions in the IRB application in which the Principal Investigator (PI) must describe the proposed study population, the number of subjects to be enrolled, and the procedures to be used for recruitment. In addition, all materials used to recruit subjects must be reviewed and approved by the IRB. These would include written advertisements and the amount of reimbursement (See **Section 5.9 Compensation for Research Subjects**) to be given to subjects to compensate for their time and inconvenience, parking, travel, etc. No contact with or recruitment can occur with potential subjects until final IRB approval has been granted.

5.2 Advertisements

The IRB must review and approve the information contained in all advertisements that will be used to recruit subjects for a specific research study and the mode of their communication. Generally, advertisements used to recruit research subjects should be limited to information that a potential subject would need to determine if they are eligible and interested in participating.

More specifically, the advertisements should include information such as:

1. The name and address of the investigator and/or research facility, clearly identifying the research as a University of Denver project.
2. The condition or disease that will be the focus of the research.
3. The purpose of the research with reference to the fact that the study is investigational.
4. If any, a brief list of potential benefits of participation.
5. A summary of the criteria for eligibility to participate.
6. The time and other commitments that will be required of the subject.
7. The location of the study and the office to contact for further information.
8. If the study is conducted by a student investigator, the faculty sponsor's name and contact information should be included.
9. If any, state that reimbursement for time, travel, etc. will be given.
10. Will contain the statement: "This study has been approved by The University of Denver Institutional Review Board."
11. Include the DU logo on any advertisement.

The advertisement should not contain:

1. Emphasize the amount of reimbursement that subjects will receive by bolding or using large fonts. The ads may state that reimbursement for time, travel, etc. will be given.
2. Exculpatory language where the subjects would be required to give up some of their rights.
3. A promise for a favorable outcome or benefits.
4. The concept promoting that the subjects will be receiving medical treatment at no cost (free medical treatment) since the reality is that they will not be charged to participate in a research project.
5. Explicit or implicit claims of equivalency or superiority to other standards of treatments or safety and efficacy.
6. Wording that the study involves "new treatment," "new Medication," or "new drug" without an explanation that the treatment is investigational.
7. Claims, explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling.

Advertisements conforming to the above guidelines may be approved for any advertising format, e.g., posted flyers, newspapers, internet advertisements, radio/television, or slides shown prior to films at movie theaters. However, the IRB must review the final copy of printed and online advertisements to evaluate the relative size of font type used and other visual effects, and must review the script of the final audio or videotaped advertisements. To avoid multiple requests for IRB review and approval, investigators should specify in their original request all advertising formats that are anticipated. If a website is to be used to advertise for a research study, the website address must be identified to the IRB.

When following FDA regulations, the IRB reviews advertising to ensure that advertisements do not allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

5.3 Pre-screening

Some research may require a pre-screening process in which potential subjects are asked for

personal and sensitive health information to determine eligibility for the study. Questions asked during this pre-screening process are subject to IRB review, in particular, to determine if proper procedures are in place for protecting the privacy and confidentiality of the information collected. In addition, if more than the above listed information is present, the IRB must evaluate whether or not the description of potential risks and benefits is presented in a fair and balanced manner. The IRB must also assess the types of incentives, if any, that are offered, whether or not the site clearly states that the study is voluntary, and other subject protection issues.

5.4 Recruitment of Students and Staff

The University students and staff have the same rights as any other potential subjects to participate in a research project, irrespective of the degree of risk, provided all of the following conditions exist:

1. Recruitment should not be conducted in ways that students may reasonably perceive to be undue influence.
2. The research must not bestow upon participating University subjects any competitive academic or occupational advantage over other students or staff who do not volunteer. The researchers must not impose any academic or occupational penalty on those not volunteering.
3. Due to the potential for perceived or undue influence to participate, University students and staff who desire to participate in the research must not be under the direct supervision of anyone who has access to identified data (e.g., researchers, those collecting data).
4. If incentives for participation are offered (e.g., extra course credit), the incentives should not be so large as to cause undue influence. Typically, this means that any credit or extra credit must be only a small portion of the total grade.

5.5 Researchers Recruiting from Their Own Courses

One particular circumstance that raises special ethical concerns involves researchers recruiting students from courses that they are teaching. The primary issue with gathering data from one's own course is the potential for undue influence.

5.5.1 Potential for Undue Influence

Instructors have inherent power over students (e.g., through their responsibility for assigning grades). Because of this power relationship, it is likely that some students will feel pressure to comply with requests made by their instructors. This is true independent of whether the instructors actually try to pressure the students. For example, when instructors ask students to participate in research projects, some students may worry that not participating could influence the instructor's opinion of them or that their grade might be affected. Such potential concerns are problematic regardless of whether the instructor actually should think negatively of nonparticipation or whether the students' grades actually would be affected. Students' perceptions that such negative consequences could happen are enough to make them feel pressure to participate.

5.5.2 Reducing the Potential for Undue Influence

In the rare instances in which recruiting from one's own class is permissible, researchers are expected to minimize the potential for students to feel pressured to participate. There are various strategies for minimizing the potential pressure to participate. One way that researchers have reduced the potential to cause undue influence is to design the study so that the instructor is blind to the identity of the participants (at least until after the final grades have been assigned). For example, a researcher can run the study and keep any identifying information from the instructor.

If a researcher designs a study in this way these points are crucial:

1. Before being asked to participate, potential subjects should be informed that the

instructor will not know who did and who did not participate (at least until after the final grades have been assigned).
2. The research should be designed so that the instructor cannot infer who participated through indirect means (e.g., by seeing who walks into the laboratory, by getting a list of who earned extra credit for participating in the study).

In short, due to the potential for undue influence, researchers generally should avoid recruiting subjects from their own classes. When recruiting from their own class is the only feasible way to do a study, researchers are expected to design the research in such a way that the potential for students to feel pressure is minimized.

5.5.4 Exceptions

There are cases in which the research cannot be feasibly completed without recruiting students from a particular course. For example, if the research project concerns a teaching method that will be implemented in the course, then the only possible subject pool comes from the students enrolled in that course. If a research project has a reasonable chance of yielding benefits, and the only feasible way to complete the study is to recruit in the researcher's course, the research may be permissible if the researcher is able to sufficiently reduce the potential for students to feel pressure to participate.

5.6 Online Recruiting

Online recruiting is used more often today in research since more individuals have access to the Internet. This recruitment method enables investigators to quickly and affordably reach a large number of potential participants across the country. The more traditional recruitment strategies like television, newspaper, radio, or flyers tend to reach only a tiny percentage of a targeted population. Through the use of social media, this type of recruitment can be effective, but as with the other traditional recruitment methods, all scripts and questions must be reviewed and approved by the IRB before they are utilized.

5.7 Subject Pools

A subject pool is a research resource used by some departments and schools in academic settings as a registry of individuals who are interested in participating in research and agree to be contacted for potential participation in a study. These volunteers are used in studies for that school or department. The IRB provides guidance and oversight of departmental subject pools and reviews all research requesting subject pool participation.

Student subject pools serve not only to provide researchers a pool from which to recruit primarily student participants for their studies, but also serve to familiarize students with the research process as subjects and researchers. Student subject pools are composed of undergraduate students enrolled in particular departmental courses that provide credit for participation in one or more research projects. All student participation in subject pool research must be completely voluntary. Departments may provide students with incentives (usually extra credit) to participate in the subject pool. However, reimbursement for participation must not jeopardize the subject confidentiality or anonymity, and subject pools offering extra credit to participating students must provide alternative opportunities to earn the same extra credit for those not wishing to participate in the research. Alternatives to the research subjects should require an equivalent amount of time and effort to complete for extra credit. Subject pools including subjects under 18 years of age are required to obtain parental permission prior to their involvement in research unless those individuals are emancipated. It is up to the student to decide whether to participate in any study; instructors cannot mandate or require student participation. As stated above, instructors are strongly discouraged from recruiting subjects they directly supervise or selecting subjects on such a basis. Subject pool requirements and procedures vary by department, so it is best to consult with your individual departments for specific guidelines and additional requirements.

5.8 Equitable Subject Recruitment

The IRB will only approve studies demonstrating equitable subject recruitment, taking into account the purposes of the research and the setting in which it will be conducted. The IRB evaluates all research applications to verify that investigators have demonstrated equitable selection and recruitment (distributive justice) of all research subjects and have made every effort to ensure diversity of subject selection. In particular, the IRB evaluates any special problems that may occur with proposed research involving vulnerable populations, such as children, prisoners, pregnant women, and decisionally impaired adults. For greater than minimal risk studies, the IRB ensures that proposed sampling efforts do not favor some classes of subjects solely due to ease of availability, compromised positions, or manipulability. IRB reviewers also require researchers to make every effort to include women and members of minority groups, if appropriate to the research purpose.

5.9 Compensation for Research Subjects

5.9.1 General Guidelines

During the initial review of a research protocol, the IRB is required to review both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence. There are guidelines to assist investigators in determining a reasonable amount of compensation that can be given to research subjects and also place some boundaries on what is and is not "reasonable." The "reasonableness" of a particular sum of money or other form of payment should be based upon the time involved, the inconvenience to the subject, reimbursement for expenses incurred while participating, and should not be so large as to constitute a form of undue influence. The guidelines are:

1. For studies involving more than one visit/session, compensation should not be contingent upon the subject completing the study, but should accrue as the study progresses.
2. Unless it creates undue inconvenience or undue influence, compensation to subjects who withdraw from the study should be made at the time they would have completed the study, had they not withdrawn.
3. The amount of compensation and any prorating or scheduling of payments should be clearly described in the informed consent document.
4. Finder's fees and bonus payments of any kind are not permitted (See **Section 5.10**).

5.9.2 Human Subjects Research Payments

Payments made to subjects for their participation in research projects may be provided if the proposed compensation is outlined clearly in the protocol and in the informed consent document.

5.9.2.1 IRB Reporting Requirements

The Internal Revenue Service (IRS) requires human subject payment aggregating $600 or more paid to an individual during a calendar be reported on Form 1099-MISC, Miscellaneous Income.

Due to confidentiality requirements for subjects payments, the payment detail required by the IRS will be stored in the DU departments issuing the payments. University departments are required to obtain a W-9 Tax Identification Form and report the total amount of payment made by the University to individual subjects who receive cumulative payments of $600.00 or more during a calendar year. This information, as well as any payments issued to DU students or DU employees, will be forwarded to Shared Services before December 31st each year. All Principal Investigators are required to submit an annual attestation that provides information for all individual subjects who received cumulative payments of $600.00 or more during a calendar year, as well as any payment

to DU students or DU employees that has been forwarded to Shared Services.

Refer to the Sponsored Programs Participant Payments policy for acceptable methods of payment to human study participants and the requirements for maintaining payment records per DU Shared Services.

5.10 Finder's Fees and Bonus Payments

Finder's fees and bonus payments are generally associated with clinical trials and are offered by the sponsor of the research as an incentive to enhance recruitment. The IRB does not permit the payment of finder's fees and/or bonus payments (monetary or in kind) in any form, due to the potential that such a practice could be perceived as causing undue influence and bordering on unethical research subject recruitment. In addition, several professional associations and groups have stated that this practice is unethical (e.g., AMA, APA).

5.11 Costs to Research Subjects

When appropriate, a statement must be included in the informed consent document alerting the potential subject to any additional costs that may result from participation in the research, specifically if a research subject may have to bear any costs that would be unnecessary if the subject had declined to participate in the research. All potential subjects must be fully informed of the nature and estimated extent of these costs when obtaining consent.

5.12 Protection of Privacy for Subjects and Confidentiality of Subject Data

5.12.1 General

The possibility that research activities may invade the privacy of individuals or result in loss of confidentiality of their private information should always be of concern to researchers involved in human subjects research. In some cases, the risks of serious harm resulting from loss of privacy or confidentiality may exceed the physical or other risks associated with the research activity. In addition, loss of privacy or confidentiality associated with a research activity can be considered a moral wrong and can provide cause for legal actions against the investigator and/or the institution. In this regard, as part of its review of research proposals and protocols, the University IRB considers several issues related to procedures to protect research subjects' privacy and confidentiality.

5.12.2 Considerations and Provisions to Protect Human Subjects Privacy

When the IRB considers whether or not a subject's privacy is adequately and appropriately protected in a particular study, members might consider, but not be limited to, the following:

1. The methods used to identify and contact potential subjects, the nature of the information being sought, and whether or not an invasion of privacy is involved.
2. The setting in which subjects will be interacting with the investigator.
3. The methods used to obtain information about and from subjects.
4. The nature of the information being obtained from individuals other than the "target subjects" that might result in an invasion of subject privacy (e.g., survey information about a family member).
5. Whether or not the information is publicly available.
6. Whether or not information about the subject is recorded in such a manner as to prevent identification.
7. The methods used to limit access to subject logs and signed consent forms.
8. Whether subject consent will be sought and obtained or the requirement to obtain consent meets criteria for waiver.
9. Whether signed consent forms will be kept in locked cabinets or other secure location

separate from subjects' data.
10. For observational studies, chart reviews, or discarded materials studies, the subjects will not be identified.

5.12.3 Confidentiality Data Security Considerations

Whenever researchers promise subjects that their responses and data will be maintained in confidence, all researchers (investigators, directors, transcribers, students, and staff) are required to prevent accidental and intentional breaches of confidentiality. However, all measures used to assure confidentiality of data need to be understood by all research staff before research is initiated, and followed once research is initiated. Confidentiality procedures must be described in research applications that come before the IRB.

Researchers proposing projects that will address sensitive, stigmatizing, or illegal topics or issues must explicitly outline the steps they will take to assure any information linking participants to the study is maintained in confidence. The IRB will require that particularly sensitive data be stored on secure servers such as Redcap, Qualtrics, or another secure server rather than on personal devices. The requirement of signed consent forms is often waived in sensitive studies if the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated in that research. When the IRB considers whether or not subject confidentiality is adequately and appropriately protected in a particular study, members might consider, but not be limited to, the following:

1. The methods used by the investigator to ensure that information obtained is not improperly divulged.
2. The nature and adequacy of the safeguards that will be used to ensure protection of sensitive data.
3. The methods used to de-identify data.
4. Substituting codes for subject identifiers.
5. Removing names from survey instruments containing data.
6. Proper disposal of identified data at the earliest possible time.
7. Limiting access to data in locked file cabinets or password protected computer files.

5.12.4 Protecting Subjects' Health Information

Use or disclosure of subjects' Protected Health Information (PHI) is generally required to have the subject's signed authorization (See **Section 6.8**). Even in circumstances where a waiver of the requirement for written documentation of informed consent has to be approved by the IRB, a signed authorization from the research subject permitting the use and disclosure of their Protected Health Information (PHI), will still be required. The requirement for written documentation authorizing use or disclosure of PHI may also be waived by the IRB under certain circumstances (See **Section 6.9**). Confidentiality is best maintained by anonymous data collection. In the event that the Privacy Rule is more restrictive than the procedures described in the consent requirements, the more restrictive rule must be followed.

5.12.5 Certificates of Confidentiality

Under provisions of the Public Health Service Act, the Secretary of Health and Human Services "may authorize persons engaged in biomedical, behavioral, clinical, or other research … to protect the privacy of individuals who are the subject of such research by withholding, from all persons not connected with the conduct of such research, the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

Protection can be granted only to research activities, i.e., systematic investigations designed to develop or contribute to generalizable knowledge. The protection will be

granted only when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives. Research can be considered sensitive in any of the following categories if it involves the collection of information (including but not limited to):

1. Relating to sexual attitudes, preferences, or practices.
2. Relating to the use of alcohol, drugs or other addictive products.
3. Pertaining to illegal conduct.
4. That, if released, could be reasonably damaging to an individual's financial standing, employability, or reputation within the community.
5. Would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Pertaining to an individual's psychological well-being or mental health.
7. Pertaining to qualify genetics.

For research funded by National Institutes of Health (NIH) that falls into one of the categories described above, the PI is required to obtain a Certificate of Confidentiality. Certificates of Confidentiality are issued by the NIH. Information regarding Certificates of Confidentiality is available on the NIH website at: **http://grants.nih.gov/grants/policy/coc/index.htm**.

It should be noted that the protection offered by a Certificate of Confidentiality is not absolute. It does not restrict voluntary disclosures. For example, it does not prevent PIs from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject threatening violence to self or others, or from reporting a communicable disease. However, if PIs intend to make such disclosure, it should be clearly stated in the consent form. In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

1. The subject or the subject's legally authorized representative consents to the disclosure in writing.
2. Authorized personnel of the Department of Health and Human Services (HHS) request the information for audit or program evaluation or for investigation of HHS grants or contractors and their employees.
3. Release of such information is required by the Federal Food, Drug and Cosmetic Act or regulations implementing that act.

In addition to certificates of confidentiality available from NIH, the U.S. Attorney General is authorized to grant protection for research concerning drug abuse under the Controlled Substance Act. For more information, contact the Drug Enforcement Administration at 14501 I St., NW, Washington, DC 20537.

5.13 Use of Collected Data if a Subject Withdraws from a Study

Current regulatory agencies generally agree that when a subject withdraws from a study or participation of a subject in a study is terminated by the PI, the PI is allowed to retain and analyze already collected data pertaining to the subject. The use and/or analysis of the data must fall within the scope described in the IRB approved protocol and may include identifiable private information relating to the subject.

However, for research not subject to Food and Drug Administration (FDA) review, PIs can choose to honor a subject's request to destroy data relating to the participant or exclude the data from further analysis. PIs are encouraged to consult with the funding agency, if applicable, to assure that requirements of the funding agency are met.

Additionally, PIs are encouraged to consider discussing during the enrollment process, verbally or in the consent form, the use or analysis of collected data if a subject chooses to withdraw from a research study. In deception research, subjects should be permitted to withdraw their data at the

time of the debriefing.

For more detail information on HHS and FDA information see:
http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126489.pdf

5.14 Specimen Collection for Research Purposes

Collection of body fluids (e.g., blood, saliva, urine, etc.) for research purposes must be reviewed and approved by the IRB. Obtaining DU Institutional Biosafety Committee (IBC) approval is also required for any study involving the collection of bodily fluids or tissues. For some studies, the only research intervention is the collection of blood for analysis. Studies involving the collection of blood may be considered minimal risk if the procedures meet certain requirements.

5.14.1 General Requirements

1. There are no special health reasons (e.g., anemia) to contraindicate blood withdrawal.
2. The withdrawal method is by cutaneous sticks (e.g., finger) or by standard venipuncture in a reasonably accessible peripheral vein, and the frequency of punctures does not exceed two per week.
3. The volume of blood drawn from lactating or known pregnant subjects does not exceed 20 ml per week.
4. All blood withdrawals and collections conducted in the State of Colorado must be carried out by certified phlebotomists and investigators must submit a blood draw protocol to the DU Institutional Biosafety Committee (IBC) for review and approval. Any blood withdrawals and collections conducted outside of Colorado will require documentation that the phlebotomist used for the study is certified and must also receive IBC approval.

5.14.2 Additional Requirements for Adults

1. If less than 50 ml is collected, there are no additional restrictions with regard to hemoglobin or hematocrit.
2. If a volume greater than 50 but less than 200 ml is collected for “no-benefit” studies, hemoglobin levels should be >11.0 g/dl for males and >9.5 g/dl for females with a Mean Corpuscular Volume (MCV) >85 femtoliters. The cumulative volume withdrawn or collected may not exceed 450 ml per eight-week period (this maximum includes blood being drawn for clinical purposes) from patients 18 years of age or older in good health and not pregnant.

5.14.3 Additional Requirements for Children

1. No more than three skin punctures are to be made in any single attempt to draw blood, and the frequency of punctures does not exceed twice per week.
2. The volume of blood withdrawn, including blood for clinical purposes, does not exceed the lesser of 50 ml or 3 ml/kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
3. The cumulative volume of clinical and research blood withdrawn per 8 week period does not exceed 6.0% of the child's total blood volume.