STUDENT ISSUE

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UNIVERSITY of DENVER
RESEARCH & SPONSORED PROGRAMS

As a DU student, you may become an research investigator for the first time while you're at the University of Denver. As an investigator, you will need to become familiar with the Institutional Review Board (IRB). For many of you, this will be your first IRB protocol, one of many that you will submit in your research career. With the creation of this new publication, *The Research Compass*, the DU IRB hopes to lay a foundation for you to have a positive experience with the IRB, and view us as a partner and resource. Please use the tips in this newsletter to help you plan your research protocol and move through the IRB process smoothly.

◆ HOW TO GET STARTED IN THE IRB PROCESS ◆

Determine whether your research requires IRB review

Many students, as first time investigators, may submit a research project to be reviewed by the IRB that, per regulatory definition, may not require IRB review because it does not meet the definition of *human subject research*. If your project involves "human subjects" and "research" as defined in the regulations, then it will require IRB review and you must submit an application through the IRBNet system. If you aren't sure if your project needs IRB review, you are encouraged to complete the **IRB Determination Form**. This form will explain the regulatory definitions and ask questions to further assess whether your project should be submitted directly to **IRBAdmin@du.edu** for review. The IRB Determination Form is also accessible on the DU IRB Portfolio site and the Office of Research and Sponsored Programs (ORSP) website. Please allow up to 5 business days for a review and response.

Register in IRBNet and familiarize yourself with the electronic submission system

When creating a new research project for IRB review, organizing your time is essential. Putting together an IRB application takes planning and time and you must allow sufficient time to complete and post all the necessary documentation for IRB review.

All proposed research projects to the DU IRB are conducted online through the IRBNet system. In order to access this system all end-users must register at: **www.irbnet.org** . For detailed instructions on how to register and navigate through the system, please refer to the **IRBNet User's Guide** found on the DU IRB Portfolio site and the ORSP website. If you need additional assistance contact the DU Office of Research Compliance at 303-871-2121 or through **IRBAdmin@du.edu.**

Faculty Sponsor Involvement

As a DU student, you may serve as the PI of a research project but you must have a Faculty Sponsor listed and involved with your proposed project. Your Faculty Sponsor must be registered with the IRBNet electronic submission system in order to have access to your project. This individual is also responsible for providing guidance on creating your research project and must review and electronically sign any IRB package in the IRBNet system before your IRB application is considered complete. Without the appropriate Faculty Sponsor signature, your IRB submission will not be reviewed. As the PI, you are responsible for granting your Faculty Sponsor "full access" to your project in IRBNet.

Plan ahead and be aware of the IRB's review time requirements

IRB review timelines depend on the level of review required of your project (Exempt, Expedited, or Full Board) AND whether the application is complete at the time of submission. The full board meets once a month during the school year and may not meet on a regular basis during the summer. Studies that qualify for exemption or expedited review are reviewed year-round on a rolling basis as they are submitted to the IRB.

Typical review times are as follows:

Exempt: 1—2 weeks

Expedited: 2—3 weeks

Full board: 1—2 months

The DU IRB determines the level of review using federal regulations. In general, the level of risk subjects face and the vulnerability of the population of subjects determines the review level. For an explanation of these different type of review procedures, please refer to the DU Research Compliance Portfolio, the ORSP website (www.orsp@du.edu) or contact the Office of Research Compliance at 303-871-2121 or at: **IRBAdmin@du.edu.**

Complete Human Subjects Protection Training

At DU, all researchers who will be obtaining informed consent, interact with subjects to collect research data, or analyzing identifiable data about human subjects are required to take human subjects protection training. DU students must take the CITI course which contains training modules that satisfy the human subjects training requirement for Social Behavioral & Education Research (SBER) IRB submissions. The required modules are found under the DU curriculum within the CITI program.   For specific information on completing the required training modules, please refer to the following link:

CITI registration instructions.pdf.

The DU IRB requires that CITI training certificates for all researchers be posted in IRBNet under the Training & Credentials feature. For step by step instructions on how to download your training into IRBNet, please refer to the following PowerPoint presentation: Downloading CITI Training to IRBNet Userprofile.pptx

Obtain letters of permission from research sites

Research conducted at schools, hospitals or out of country sites may require a letter of permission from someone in authority and supplementary IRB forms may be required. For research conducted in schools, **Appendix M: Research in Schools** must be completed and posted as part of your IRB application. For international research, you will need to complete **Appendix G: International Research** as part of your IRB submission. Specifically for international research, you will need to demonstrate to the IRB that you have checked on national and local requirements of human subject research and have appropriate permissions. Please refer to the IRBNet Library Guidance: **International Research** for more information for conducting this type of research. For specific requirements for conducting research in foreign countries, please refer to the "International Human Research Standards" article on page 5 of this newsletter.

Plan appropriate data security measures

Think through your data plan carefully to determine how you will keep subjects' data secure. Refer to the IRB Guidance on "Data Security" posted on the IRB Portfolio or contact DU's UTS department for specific recommendations.

Determine the appropriate consent process

Determine whether you will obtain signed consent from your study participants, a waiver of the participant's signature on the consent form (either oral consent or implied consent for online studies), or a waiver/alteration of consent. Make sure you submit the correct forms for requesting a waiver or alteration of particular elements of informed consent. Studies that will use deception or incomplete disclosure must request a waiver/alteration of informed consent and complete Appendix L: Research Involving the Use of Deception.

Prepare consent, assent and parental permission forms

Save time by using the templates found on the IRBNet Library of Forms and Templates as your starting point for developing informed consent forms.

Be thorough in your IRB submission

Your IRB submission documents must explain in detail the "who, what, when, where, how and why" of your study (or with amendments, specific changes you are proposing to your study). Refer to the **Submission Checklists** in the IRBNet Library of Forms and Templates to be sure you have included all the required documents to make your submission complete.

As a final note: Your study has been approved when your IRB Determination Letter, granting full approval, has been posted in IRBNet.

After initial IRB approval is granted, the ongoing requirements

After the initial IRB protocol is approved, researchers are responsible for maintaining IRB approval through Continuing Reviews, Amendments, and on occasion, Unanticipated Problems or Protocol Deviations. An explanation of each is below:

Continuing Reviews: Studies that are exempt do not undergo continuing review. Studies that are approved via expedited review or by the full IRB must undergo continuing review each year until all activities (including data analysis and write-up) are complete. Submit your continuing review application at least 4 weeks before the expiration dated of IRB approvals.   Study expiration reminders are automatically sent in the form of an e-mail to PIs but it is the PI's responsibility to keep track of the study's expiration date. If a study expires, the IRB will administratively close the project

Amendments: When you have received IRB approval for your study, any subsequent changes you make to research procedures, subject population, compensation, recruitment, consent/assent, etc. must be reviewed and approved by the IRB **before** you can implement changes to your study. This requirement applies to Exempt studies as well as Expedited and Full Board studies. Note that there are two parts to an Amendment: 1) Completion of the Amendment/Modification application and 2) changing the protocol and/or other IRB-approved document itself. Please consider what parts of your study are affected by the changes you are making and revise them accordingly and post them in your IRBNet package.

Unanticipated Problems/Protocol Deviations: If something unexpected happens in your research that indicates increased risks to subjects (subjects' data is stolen, a subject becomes upset, etc.), you are required to report this to the IRB. Contact the Office of Research Compliance as soon as possible if this happens. Additionally, if study procedures are modified or changed or events occur outside of the IRB-approved protocol, you are required to report this to the IRB.

International Human Research Standards

Every year, the federal Office for Human Research Protections (OHRP) releases a compilation of laws, regulations, and guidelines from over 100 different countries, as well as standards from a number of international and regional organizations. The IRB encourages investigators planning international research with human participants to consult the 2015 Edition of the *International Compilation of Human Research Standards* to help determine if there are special requirement for informed consent processes, research ethics committee review, reporting requirements, protection of vulnerable populations, and other research-related activities.

Copies of the *2015 Edition of the International Compilation* are available in the following versions:

Microsoft Word Version

Adobe PDF version

For additional information on conducting research in other countries, please refer to DU's IRB Guidance on *International Research*, found on the ORSP website, IRB Portfolio site and the IRBNet Library. If research study materials require information to be translated into a non-English document, for example an informed consent or recruitment script, the Certification of Translation form (Appendix K) must be completed and submitted in the IRBNet package along with a copy of the English version and translated version of the document.

Utilizing IRBNet -

DU's IRB Electronic Submission System

The DU IRB utilizes an electronic submission system called IRBNet to process and manage research proposals from the DU community. This electronic system provides a concise process to store research documents, manage revisions and track and retrieve IRB correspondence and documents. IRBNet also provides the investigators with a resource to store training certificates and to share their project with other research team members, including your Faculty Sponsor.

Within IRBNet, a library of DU-specific forms, checklists and templates have been created and posted for investigators to use when developing their IRB application.

If you have never used the IRBNet system before, contact the Office of Research Compliance at **IRBAdmin@du.edu** to schedule a quick demo or call us at 303-871-2121. A new publication is also available called the *DU IRBNet User's Guide*. This new publication provides additional guidance on navigating through the system, including computer screen shots and step-by-step directions for submitting new studies, amendments, continuing reviews, etc. This guide can be found in the **IRBNet Library**, the **ORSP website** and the **Research Compliance Portfolio** site.

- DU IRBNet Library -

Student Investigators and Faculty Sponsors

As you take on the role of being a Principal Investigator as a undergraduate or graduate student, you owe it to your participants, and the community at large, to be as knowledgeable about the expectations and the requirements associated with assuming this new responsibility.

Investigators, including students affiliated with DU, must agree to accept certain responsibilities before the IRB will review an application. These responsibilities are based on the fact that interactions between the IRB and investigator (and faculty sponsor) do not end with IRB approval of a project; rather interaction must continue for as long as a project remains active.

Who must have a "Faculty Sponsor"?

Investigators who are either (a) graduate or undergraduate students of DU or (b) part-time employee of DU must be sponsored by a full-time faculty member in order to conduct research at DU or at an off-campus location. Faculty Sponsors must electronically sign all IRB submissions through IRBNet for the application to be considered complete. Failure to obtain the Faculty Sponsor's signature will delay IRB review.

What is the Faculty Sponsor's Role?

Faculty sponsors are responsible for guiding student investigators through every phase of the IRB process. They are faculty members who serve as a guiding mentor for a undergraduate or graduate student research project. They are expected to be familiar with various research methods and informed of the rules and regulations governing research at this institution. The sponsor should be the primary resource when student investigators have questions or need assistance with their projects.

Faculty sponsors are responsible for:

- Evaluating whether the student investigator has sufficient knowledge and experience to conduct the proposed research.

- Providing ongoing supervision of the student investigator and monitoring the progress of the project. This includes signing-off on all correspondence between the investigator and the IRB (e.g. responses to conditions, amendments and renewals) via IRBNet.

- Reading and approving the proposed IRB application and supporting materials before it is submitted to the IRB.

- Keeping abreast of the policies and procedures of the DU IRB, the published guidelines for the ethical conduct of research relevant to the field of inquiry, and state and Federal regulations.

- Ensuring that the proposed research is not currently underway, and will not begin until the IRB approval determination letter is officially posted in IRBNet.

- Obtaining valid IRB certification through the on-line training course (CITI).

- Registering in the IRBNet system and having "full access" privileges to the student's research project. The student PI is responsible for granting full access privileges.

Student Investigators are responsible for:

- Conducting the research in accordance with ethical guidelines such that the rights of participants are protected and risks are minimized.

- Keeping abreast of the policies and procedures of the DU IRB, the published guidelines for the ethical conduct of research relevant to the field of inquiry, and state and Federal regulations.

- Ensuring that the information provided in the IRB Application is accurate and complete.

- Maintaining the integrity of the project as it was originally approved by the IRB. Any proposed changes to a project must be submitted through IRBNet, and approved, before they are implemented.

- Informing the IRB upon completion of the research or departure from DU, whichever occurs first. To close a project, investigators must submit a Final Report through IRBNet.

- Ensuring that the proposed research is not currently underway and will not begin until the IRB approval determination letter is posted in IRBNet.

- Obtaining valid IRB certification through the on-line training course (CITI) and ensuring that all personnel associated with their project, including your Faculty Sponsor, obtains certification of on-line training and they are posted in IRBNet.

- Granting Faculty Sponsors "full access" to your research project in IRBNet.

The DU Office of Research Compliance uses the Collaborative Institutional Training Initiative (CITI) Program for web-based training in the ethical conduct of research with human participants. All investigators named on an IRB protocol will be required to have completed the CITI Program within the past four years, as a condition of approval of their protocols that are subject to IRB review. CITI is also utilized by other DU faculty, staff and students required to complete training in animal welfare, responsible conduct of research (RCR), conflict of interest, biosafety, export compliance and health information privacy and security (HIPS).

Investigators and research personnel can access the mandatory training modules through the ORSP website (www.orsp.du.edu) or directly at: **www.citiprogram.org**

End-users must establish a unique username and password to access the DU curriculum and complete the required modules.

Human Subjects Protection Training FAQs   Source: NIH

Q: Who needs to receive required education on the protection of human subjects?

Individuals who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the education requirement. These individuals are considered to be "Key Personnel" on NIH awards and contractors that include research involving human subjects. This includes the Principal Investigator, all individuals responsible for the design or conduct of the study, and those individuals identified as key personnel of consortium participants or alternate performance sites.

Q: Are investigators involved in human subjects research that qualifies under one or more of the exemption categories in 45 CFR 46 required to comply with the education requirement?

Yes. Investigators who conduct human subjects research that is exempt from Institutional Review Board (IRB) review and their research that qualifies under one of the six exempt categories defined in 45 CFR 46.101(b) must comply with the education requirement.