A Note from the Director

Welcome to the first issue of The Research Compass for Faculty and Staff. This newsletter has been created by the Office of Research Compliance as a tool to increase communication between the DU IRB and the research community. The goal of this publication is to present topics of interest to investigators on regulatory issues and provide a platform for sharing ideas and updates from the DU IRB.

This spring I joined the DU research community as your new Director of Research Compliance. With almost 20 years experience working in the research compliance field and managing IRBs, I am very excited to have the opportunity to work with the DU faculty and student investigators on their research endeavors.

Since my arrival I have been busy meeting with investigators around the campus. I have been evaluating the current IRB processes in order to improve IRB efficiency and decrease turn-around time without compromising our compliance requirements. The number of protocols the DU IRB received this summer was at a record high for the DU full board, reviewing nine full board protocols at the August meeting alone. Working closely with Tim Sisk, our IRB Chair, and the committed group of IRB members and dedicated administrative staff, the review and approval of those full board submission and other IRB submissions could not have been reviewed and approved as efficiently and timely as they were.

I will continue to meet with faculty, staff and students in the DU research community to help prioritize and streamline the IRB processes. Working together, and with your input, I know that the experience that new and/or skilled investigators will have in the future with the IRB will be positive. Your input is always welcome in creating a valuable and resourceful IRB. I hope this newsletter will be a positive step in further opening the communication between the DU IRB and the research community.

Mary Travis
Director of Research Compliance
Office of Research & Sponsored Programs
The University of Denver 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.

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 are new to DU, have never used the IRBNet system before or need a refresher on how to use the system, please contact the Office of Research Compliance at 303-871-2121. A new publication called the DU IRBNet User’s Guide has also been created to provide additional guidance on navigating through the system. The User’s Guide includes 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.

New IRB Submission Checklists, Forms and Templates

Within the IRBNet Forms & Templates Library, new submission checklists, forms and templates have been recently posted for investigators use in preparing and submitting research projects to the DU IRB.

The following checklists have been developed to provide a list of the documents required to create a complete IRB application for review. Submissions that are considered incomplete will not be reviewed until all mandatory and supplemental documents, as applicable, have been posted in IRBNet.

- **CHECKLIST:** Initial Submissions for Full Board and Expedited Review
- **CHECKLIST:** Exemption Application
- **CHECKLIST:** Continuing Review/Progress Report
- **CHECKLIST:** Amendments/Modifications

The IRB continues to develop and post new guidance documents and templates in IRBNet in response to investigator requests. If you require specific information or guidance on one of your current or proposed research projects contact one of the research compliance staff members for assistance.
Collaborating with Researchers at Other Institutions—What You Need to Know

Collaborative research projects are those projects that involve more than one institution (e.g., PI working with another PI at an institution other than DU). In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants. If you’re planning to conduct a research activity at a site other than DU, for instance, studies that may occur in schools or other organizations or as a collaborative project with other universities, additional steps may be required in the approval process. If you wish to avoid duplicate IRB review, an Inter-Institutional Authorization Agreement (IAA) may be arranged to establish one institution’s IRB as the designated or primary IRB to review and approve the research. This process is known as ceding. If the other institution has an IRB, DU may be willing to review documents from other institutions or, in some cases, relinquish IRB oversight to another institution. IAA’s need to be negotiated at each institution, on a case-by-case basis, and must be signed and authorized by the Institutional Official. Please contact Mary Travis, Director of Research Compliance, at mary.travis@du.edu or 303-871-4049 to discuss the conditions under which an IAA may be an option for your project.

For more information on research involving non-DU entities in collaborative projects, please refer to the guidance documents “Collaborative Projects” and “Guidelines for Ceding IRB Review” found in the IRBNet Library of Forms and Templates at www.irbnet.org.

Ceding - to relinquish, abandon; to yield or formally surrender to another

Your Input is Valued & Requested

The Office of Research Compliance wants you and your students to have the resources to be successful investigators. If there is a topic that you would like to have featured in an upcoming issue of the newsletter, need a new research guidance created or have suggestions or comments for improving the IRB process, please submit your ideas to: IRBAdmin@du.edu or contact one of the staff members directly.

Classroom Presentation Requests

Research Compliance staff members are available to conduct classroom presentations on a variety of topics. Common requests have included topics ranging from how to utilize the IRBNet system to creating appropriate recruitment materials. If you are interested in having a research compliance staff member come to your classroom, please send your request to: IRBAdmin@du.edu and include the following information:

- Requested date for presentation
- Class Title/Instructor name /contact information
- Location of classroom
- Target audience & their experience in research
- Length of presentation requested
- Requested topic(s) to be addressed
Terminology Used in IRB Determination Letters

After a research project has been submitted and reviewed by the DU IRB, a determination letter is generated and posted in the IRBNet system. To clarify the actions taken by the IRB, a list of words and their definitions are provided below:

**Approved**: Full approval has been granted; no further action is required by the PI. Recruitment and study procedures may begin.

**Approved with Conditions**: Conditional approval has been granted by the IRB requiring that certain stipulations or revisions must be addressed by the PI before full approval is granted. No recruitment or study procedures may begin until full approval has been issued. In most cases, an administrative review may be allowed and approved by the Board to grant full approval for projects that involve minor revisions.

**Deferred**: IRB approval has been delayed or withheld due to a project lacking sufficient information or if significant modifications are required. Projects will need to be re-reviewed by the Full Board before full approval will be granted.

**Exemption Granted**: A project has been issued exempt status qualifying under one of the federal regulatory exempt categories. No further action is required by the PI and study procedures may begin.

**Acknowledged**: An IRB submission was administratively reviewed and does not require a formal IRB review. As an example, a project has been completed and a final report has been issued. Final reports do not require a full board or expedited review.

**Administratively Closed**: The IRB may administratively close a study if the PI has been unresponsive to IRB requests or has allowed a study to lapse in approval.

**Closed**: The PI has submitted a final report to close the study.

**Suspended**: The IRB Chair or Full Board authorizes a study be stopped immediately in response to a specific safety or increased risk or noncompliance issue that has been reported or identified. All research activities must stop until the IRB issues a determination letter indicating the study may continue.

The Establishment of the IRB

Institutional Review Boards (IRBs) were established in 1974, as part of the **National Research Act** passed by Congress in response to growing concern about the ethics violations in research. The **Belmont Report of 1974** established the following three foundational principles which guide IRBs in their review and approval of research projects:

**Respect for persons.** This principle includes both respect for the autonomy of human subjects and the importance of protecting vulnerable individuals.

**Beneficence.** More than just promotion of well-being, the duty of beneficence requires that research maximize the benefit-to-harm ratio for individual subjects and for the research program as a whole.

**Justice.** Justice in research focuses on the duty to assign the burden and benefits of research fairly.
IRB Approval Stamps & Footers on Consent Documents

For IRB-approved research protocols utilizing informed consents, the DU IRB applies approval stamps in the header of each document indicating the IRB approval and expiration dates. Investigators should only use the consent forms with a valid IRB approval stamp when enrolling participants in their research projects. Forms used beyond the expiration date (valid for use through) stamped on the document are not considered valid.

| DU IRB Approval Date: 01/29/15 | Valid for Use Through: 01/30/16 |

For research projects that are granted an exempt status by the IRB and utilize an Exempt Information Sheet, the DU IRB will apply a stamp in the header of the form indicating the date the IRB exemption was issued. Exemptions are granted a five-year time period. At the end of the five-year period, the study will be administratively closed unless the PI contacts the IRB and requests an extension on the exempt project.

| DU IRB Exemption Granted: 01/29/15 |

To help investigators effectively manage and use the most current IRB-approved informed consent document, the IRB strongly recommends the use of footers on consent documents. Using footers will help investigators easily identify and utilize and track version numbers and/or dates and clearly identify the title of each consent if a study utilizes multiple consents.

<table>
<thead>
<tr>
<th>IRBNet#</th>
<th>Document Type</th>
<th>Version #</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>445566</td>
<td>Informed Consent, Control Group, v. 1, dated 09/01/15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 requirements 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 here:

- 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 Certificate 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. The IRB also requires all research that will be conducted outside of the United States include Appendix G: International Research in the IRB application.
Historical Reflection on Human Subject Research

The Research Compass newsletter will dedicate a page in each issue highlighting a study in the Historical Reflection on Human Subject Research section. This section will review an historical event that had a significant impact on how human subject research is conducted today and will emphasize the importance of complying with the federal regulations and the ethical principles governing human subject research. The Tuskegee Syphilis Study is the first research study to be presented as part of this Historical Reflection on Human Subject Research section.

The Tuskegee Syphilis Study

In Macon County, Alabama, beginning in 1932, the Public Health Service (PHS) started working on a syphilis study during the Great Depression in collaboration with the Tuskegee Institute. Investigators enrolled a total of 600 impoverished sharecroppers as study participants. The intent of the study was to record the natural history of syphilis in Blacks. When the study was initiated there were no proven treatments for the disease.

The men were offered medical care and survivors insurance. They were enticed and enrolled in the study with incentives including: medical exams, rides to and from the clinics, meals on exam days, free treatment for minor ailments and guarantees that provisions would be made after their deaths in terms of burial stipends paid to their survivors.

Since that time, “Tuskegee” has become a word that is known for an infamous research study: a forty year endeavor on the part of the PHS to not treat African-American men with late stage and presumably non-infectious syphilis.

When penicillin became the standard treatment for the disease in 1947 the medicine was withheld as part of the treatment for the study participants, both the experimental and control groups.

The men were never told about or offered the research procedure called informed consent. The researchers had not informed the men of its purpose, the potential consequences of the treatment or non-treatment that they would receive, or the life threatening consequences of the treatment they were to receive, and the impact on their wives, girlfriends and children.

On July 25, 1972, the Associated Press broke the story that appeared simultaneously in New York and Washington that there had been a 40-year nontherapeutic experiment called “a study” on the effects of untreated syphilis on Black men in the rural south. In October of 1972, the Tuskegee Study was officially declared closed.

In 1997, after much organizing from citizens and politicians, then President Bill Clinton apologized to the six remaining men from the study and to all African Americans.
Faculty Sponsor Responsibilities

When a faculty member takes on the role of serving as a Faculty Sponsor (FS) for a student investigator the responsibilities for being a FS are equivalent to those for a PI and should not be accepted lightly.

The FS must be actively involved in the research, from the protocol design to the data analysis and report preparation.

Faculty Sponsors are responsible for:

- Understanding the research hypotheses, goals and methodology
- Assisting the student with protocol preparation and research descriptions for the IRB
- Staying apprised of the status of each protocol or award under their sponsorship
- Assuring that the student understands the underlying ethical principles for conducting research with human subjects
- Assuring the student follows the protocol approved by the IRB and seeks regulatory approval of all proposed changes and implement such changes only after regulatory approval is granted.
- Be available to review drafts and answer questions.
- Review and edit each IRB submission BEFORE the project is formally submitted to the IRB.

Faculty Sponsors are required to:

- Complete the mandatory Human Subjects Protection Training through CITI.
- Register in IRBNet and have “full access” capability to the student’s research project. Obtaining “full access” enables IRBNet to automatically notify all persons with full access e-mails on reviews, IRB determination letters and renewal notices for the study project but this must be initiated by the student investigator.
- Electronically sign ALL IRB submission packages prepared by the student investigator. Signing the submission confirms that the submission was reviewed and approved by the FS. If a FS does not electronically sign an IRB package for a student, the submission is considered incomplete and will delay the review process. Notification will be sent directly to the student investigator requesting the FS’s signature.

Research Compliance Website

Research Compliance is getting a new website. A new website is currently being created to provide information on the DU IRB, IACUC and IBC along with other relevant research compliance topics. The estimated launch date is December 1st. The new Research Compliance website will be linked directly to the Office of Research and Sponsored Programs (ORSP) website as well as the DU Research & Scholarship website.

This site will include human and animal research regulatory forms, templates, and policies that our research community can refer to and use in order to submit new research projects to the appropriate committee(s) for review.

DU IRB Application Form

As part of every IRB application submitted through the IRBNet system, an on-line document known as the DU IRB Application Form is required. This form provides valuable study information to the IRB reviewers by identifying the key study personnel, the funding source, type of research proposed and many other areas that are required as part of the submission process. This form is currently being revised to streamline the process and eliminate duplication during the IRB submission process. The anticipated “go live” date is January 2016. More information will be provided in the next issue of this newsletter.