Updates from the IRB

University of Denver

Institutional Review Board

November 2017

Here's a snapshot of what's happening in the DU IRB . . .

- ***Introducing our new*** **IRB Research Compliance Administrator—Cami Lind**
- **Town Hall Meetings scheduled on revised Common Rule, and Other Regulatory Changes**
- ***New*** **IRBNet HOW TO: Sheets**
- ***New*** **IRB Submission Forms**
- ***Updated*** **IRB Website**

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UNIVERSITY of DENVER

OFFICE OF RESEARCH & SPONSORED PROGRAMS
Research Integrity & Education

Meet our New IRB Research Compliance Administrator - Cami Lind

In November, Cami Lind joined the DU research compliance team as our new IRB Research Compliance Administrator. Cami has been involved in human subjects research for over 13 years, most recently serving as the IRB Manager for SCL (Sisters of Charity Leavenworth—formerly Exempla Healthcare). She brings years of regulatory experience working directly with investigators through providing advice and assistance in preparing research submissions, conducting workshops and serving as a regulatory resource.

Cami is interested in getting to know our researchers and addressing any issue or problem thoroughly and efficiently.

If you see Cami on campus—please welcome her to our DU research community!

Revised Common Rule & Other Regulatory Changes

Major changes to human subject research regulations, known as the "Common Rule", are expected to become effective **January 19, 2018**. The DU IRB will conduct town hall meetings in January to review the Common Rule changes and address other regulatory changes regarding NIH Clinical Trial Policies and Certificate of Confidentiality revisions.

Additional information on these regulatory changes will be posted on the **IRB website** in January and included in the December IRB Update.

Town Hall Meeting Schedule—ECS Room 357

Thursday, January 11th, 3:00 - 4:00 p.m.

Friday, January 12th, 2:00 - 3:00 p.m.

Monday, January 15th, 3:00 - 4:00 p.m.

New IRB Application & Appendix Forms

Over the summer, the Office of Research Integrity & Education revised the forms used for submitting applications to the DU research compliance boards & committees. New IRB forms were updated to create applications and appendix forms to provide the necessary information for the IRB to conduct a thorough review of a proposed project. The new forms must still be submitted through IRBNet for IRB review and approval. To utilize the new forms, refer to the **IRB website** or download the forms on our website under **IRB Submission Forms, Checklists & Templates.**

For Mac users: The new forms were created using Word; with most features adjusted for Mac users. If you currently utilize the Office Suite for Macs you should not have any difficulties completing the forms. If you don't have Word for Macs and are having trouble filling out a form, please try using the Pages app. The Pages app can be downloaded from the App Store. After downloading Pages, Pages will appear in the iCloud Drive section of your directory system. Drag the form into the Pages folder and edit the form there. Then, save the form as a PDF or Word document. If you continue to have difficulties please contact the DU IRB Office for further assistance.

PLEASE NOTE: ***After January 1, 2018, all IRB protocol applications submitted for review MUST use the most current application, appendix and template***

New IRBNet HOW TO: Sheets

As a DU investigator conducting human subject research, you will need to submit your application electronically through the IRBNet program. To simplify the process for posting documents in IRBNet, **HOW-TO**: Sheets have been created to outline the steps for submitting an IRB application (new projects, amendments, continuing reviews, etc.) through the electronic submission system. A complete list of the **HOW TO:** Sheets are available on the **website** as well as in **IRBNet** under the Forms & Templates section.

Student IRB Workshops

This fall, the IRB Office offered workshops for students who planned to conduct human subjects research. Each session covered a different topic on human subject research ranging from informed consent options to mandatory training requirements. These 30 minute sessions were offered twice a week on a 'drop-in' basis.

The response to these workshops was very positive during first quarter, so additional workshops have been scheduled for the winter quarter.

Winter Quarter Schedule

Offered Wednesdays & Thursdays from
3:00—3:30 pm in the
Anderson Academic Commons, Room 184

January 17 & 18	Getting Started on an IRB Application
January 24 & 25	CITI Program Training Requirements
January 31 & February 1	IRBNet Basic Steps
February 7 & 8	Informed Consents & More
February 14 & 15	Open Session for Q & A