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

- Revised Common Rule Postponed: DU Policy Changes
- Update on Registering a Protocol on ClinicalTrials.gov
- Certificate of Confidentiality (CoC) applications required for applicable NIH-funded projects
- New Process on Human Subject Research Payments
- New Format Options for IRB Forms

Revised Common Rule Implementation Postponed

As we entered into 2018, the DU IRB was anticipating and preparing to implement new revisions to the human subjects regulations, also referred to as the Common Rule. A bill had been signed that required the revised Common Rule to go into effect on January 19, 2018. This new bill, as mandated by the Federal government, required all IRBs to comply with the new regulations by the January date. The implementation for these new revisions was postponed shortly before the implementation deadline and is now scheduled to go into effect July 19, 2018.

Policy Changes to Expedited Protocol Reporting Requirements

In response to this regulatory postponement, the DU IRB modified its continuing review policy for human subjects research projects. Projects that are approved through an expedited review process and do not receive any federal funds directly or as a federal pass through qualify for the following IRB policy changes:

- **Continuing reviews and expiration dates** have been administratively removed and modified in IRBNet.
- **A two-year approval time period** has been applied to all exempt and non-federally funded expedited projects in IRBNet.
- **A new Post-Approval Monitoring (PAM) Program** will be implemented over the next 12-24 months by the DU IRB Office to help monitor projects that do not have expiration dates.

The IRB Office is currently modifying each human subjects research project in IRBNet that is affected by these new policy changes. Letters are being distributed to notify PIs that their studies have been modified and continuing reviews are no longer required. PIs are not required to take any action due to these changes.

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New DU Process on
Human Subject Research Payments

A new DU procedure has been created to outline the payment process for investigators to use when paying human subjects who take part in research studies. This procedure ensures compliance with subject privacy and IRS regulations.

Reporting Requirements

Due to confidentiality requirements for subjects payments, the payment detail required by the IRS must be stored in the department issuing the payments. DU departments must also obtain a W-9 Tax Identification Form and report the total amount of payment made by DU to individual subjects who receive cumulative payments of $600 or more during a calendar year. This information must be forwarded to Shared Services Center before December 31st every year.

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

Payment Methods

DU allows three acceptable methods for paying human study participants; through issuing a check, gift card, or cash. The PI may select the method most appropriate for each human research study. Regardless of the method of payment chosen, the PI or designee must maintain supporting documentation indicating a receipt by the study participant. The actual payment method must align with the IRB approved protocol and informed consent document.

To review the Human Subject Research Payment Procedure go to: PioneerWeb/Payment Services/Human Subject Research Payments

Continuing Review Renewal Notices

If you are an investigator who has recently received an IRB continuing review renewal notice and your project qualifies under the new IRB policy to not require a continuing review, please disregard the notice. The IRB Office is currently working to administratively change the fields in each individual project in IRBNet to prevent the distribution of these notices.

If you have a federally-funded project or your project was reviewed and approved by the full committee, continuing review reports must continue to be submitted at least 2—3 weeks PRIOR to the project’s expiration date.

If a project expires, the IRB will administratively close the project in IRBNet. No research activity can occur if a protocol has expired. If a continuing review report is not submitted for the project within 10 business days of the expiration date, the project will be permanently closed. For federally-funded projects that are permanently closed, due to no response to the IRB after receiving notification of having an expired project, a non-compliance letter will be issued to the funding sponsor.
ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on public and privately supported clinical studies on a wide range of diseases and conditions.

The final rule by the Health and Human Services Department became effective on January 18, 2017. It clarifies and expands the requirement for the submission of clinical trial registration and results information to the ClinicalTrials.gov database for studies that qualify as an ‘applicable clinical trial’ (ACT).

Applicable Clinical Trial (ACT) is the term used in Title VIII of the Food and Drug Administration Act of 2007 (FDAAA) to designate the sponsor of trials that may be subject to the registration and reporting requirements in FDAAA.

What studies need to be registered?

This final rule considers all interventional clinical trials with one or more arms and with one or more pre-specified outcome measures to be controlled clinical trials.

New NIH Policies

If a NIH-funded study meets the definition of an “applicable clinical trial”, additional requirements must be met.

1. All key personnel on the study must complete Good Clinical Practice (GCP) training and it must be renewed every 3 years. This training is available through DU’s CITI program.

2. The responsible party (sponsor or PI) must register the study on ClinicalTrials.gov and update the project on the website.

3. Effective January 2018, new PHS Human Subject and Clinical Trials forms must be utilized.

4. Utilizing a Single IRB Review process is effective January 25, 2018 for all NIH-funded collaborative projects.

For additional guidance on determining whether a study is an applicable clinical trial, please refer to the ClinicalTrials.gov Checklist (or “ACT Checklist”) and the IRB website.
Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) protects the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. NIH funded researchers are issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies issue CoCs to researchers they fund. Researchers not funded by HHS can continue to apply to NIH or the FDA as appropriate to request a CoC for HHS-mission relevant research.

The NIH updated its policy for issuing CoCs for NIH-funded research, as a result of the 21st Century Cures Act. The policy states that HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected. These Certificates protect the privacy of subjects by limiting the disclosure of identifiable, sensitive information. The CoC also specifies the prohibitions on disclosure of the names of research participants or any information, documents, or biospecimens that contain identifiable, sensitive information collected or used in research by an investigator or institution.

For more information on CoC’s contact the NIH website at: humansubjects.nih.gov

Do you have questions about the IRB process?

- Do you understand what type of IRB review will be done on your project?
- Do you need assistance completing the IRB application?
- Do you know what training is required?
- Do you need help navigating through the IRBNet submission system?

The IRB professional staff is here to help.

To schedule a meeting please submit a request to: IRBAdmin@du.edu or call 303-871-2121.

New Format Options for IRB Forms

The IRB Office has posted new IRB submission forms in both a PDF and Word format on the IRB website and within the ‘Forms & Templates’ section on IRBNet. This change occurred in response to PIs feedback. For some Mac users, some difficulties occurred in completing forms in the Word format. A PDF format has been posted along with the Word format to accommodate both Mac and PC users when completing forms for IRB review.

Please remember to always download the latest version of each form from either the IRB website or within IRBNet. Outdated forms will not be reviewed and will be returned.