We responded to your concerns . . .

**the IBC Amendment Process has been Modified**

In response to concerns received from our researchers about amending protocols for the addition of new biological materials (plasmids, vectors, etc.), the IBC discussed the current policy at the June meeting. Additionally, the IBC Administrator contacted NIH directly to receive their guidance and interpretations on the current NIH Guidelines for amending protocols. Based on the email response and phone conversation with the NIH’s Biosafety Outreach Consultant, the IBC voted to update the current policy for amendments as follows:

1. The DU IBC will no longer require amendments for plasmids/vectors/genes that do not change the scope or BS level of a project.
2. During the scheduled PAM visits, PI’s will be requested to list the families or class of plasmids that they may use during the next year.
3. Any material that will be used or be requested involving animals will require an amendment.

These changes will be reflected in the IBC Policies and be uploaded into IRBNet and the IBC website. Please contact Tyler Ridgeway, IBC Administrator with any questions.

**Ordering materials from ATCC?**

The IBC Office has been made aware of the issues that investigators have encountered when ordering materials from ATCC. The IBC Administrator has been in contact with ATCC’s support team to understand the best way for updating shipping addresses and end users to avoid these issues in the future. If you are unsure about who has access to order materials for your lab or where these materials are approved to be shipped to, please contact Tyler Ridgeway, IBC Administrator, to review the process or to schedule an in-person meeting.

**Interesting New York Times Article**


Working directly with the Environmental Health & Safety (EH&S) Office, the Occupational Health Program Enrollment process has been streamlined. The Occupational Health Review Form must be completed by all biosafety research staff initially and on an annual basis as part of the Post Approval Monitoring Program.

The completed forms are confidentially reviewed by EH&S for completeness and then forwarded to an Occupational Health Physician at Concentra. Any recommendations received from the Concentra physician will be shared privately with the individual research staff member by EH&S staff. As shown in the flowcharts, EH&S can now give clearance to individuals that show no potential risks based on the project that they are associated with. This step will greatly decrease the time for approval of new staff on a project and for annual follow-ups.

Since June 2018, the EH&S Office has been managing all Occupational Health Review Forms and tracking clearance dates for all IBC researchers and their staff. The flowcharts outline the clearance and approval process for initial enrollments and annual follow-ups. These flowcharts are posted on the DU IBC website and in IRBNet to reference and are hyperlinked directly to the Occupational Health Review Form.
During the annual Post Approval Monitoring (PAM) meetings, the IBC Administrator will confirm that all staff are enrolled in the Occupational Health Program. PAM meeting requests will be sent approximately one month prior to the anniversary month of the protocols approval. This allows time for investigators and their staff to confirm that their training and enrollment in the Occupational Health Program are completed by the time of the meeting. Health Review Forms that show potential health risks may take time to be reviewed by the Occupation Health Physician at Concentra, so please plan accordingly to avoid missing the annual review deadline for your protocol. If you have any questions about the Occupational Health Program, please contact Tyler Ridgeway, IBC Administrator, or Jay Skarda, Biosafety Officer.

The Occupational Health Review Form includes questions regarding Tetanus and Hepatitis B vaccinations. The EH&S Office recommends that individuals with exposure to animals receive the tetanus vaccine or booster before beginning work with animals. If you do not wish to comply with this recommendation, please contact Jay to complete a declination form. Tetanus costs are not covered by DU.

Individuals with exposure to blood or other potentially infectious materials (OPIM) have the option to receive the Hepatitis B vaccine at no cost. This question and option for declination is included in the Health Review Form. If you would like to receive the Hepatitis B Vaccine, please contact Jay to help schedule an appointment with Concentra.