The Annual Survey is completed each fiscal year and required of all WCMC employees. Here are some tips to make your Annual Survey experience run as smoothly as possible.

- Log in at [http://conflicts.med.cornell.edu/](http://conflicts.med.cornell.edu/) using your WCMC CWID and password to fill out your 2010-2011 Annual Survey. The Conflicts Management Office cannot provide assistance for forgotten passwords. If you have forgotten your WCMC password, please contact ITS at x64878.

- To access the site from off campus, use Web VPN: [https://webvpn.med.cornell.edu/dana-na/auth/url_default/welcome.cgi](https://webvpn.med.cornell.edu/dana-na/auth/url_default/welcome.cgi)

- If you are unable to access the site, contact ITS at x64878 for assistance.

- The Conflicts Management Office does not provide hard copies of the survey; all employees are required to log in to the electronic system.

- The Annual Survey must be completed each fiscal year, even if you have nothing to report.

Please note: all employees are required to complete the Annual Survey no later than **April 15, 2011**

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**Study Specific Report Forms**

Investigators participating in IRB protocols must complete a Study Specific Report (SSR) form for each protocol in which he/she is a PI or Co-Investigator. SSRs are required of both WCMC and non-WCMC investigators.

- WCMC investigators can find the Study Specific Report form, along with the Annual Survey, at [http://conflicts.med.cornell.edu/](http://conflicts.med.cornell.edu/). After logging in with your WCMC CWID and password, select “Create Study Specific Report”.

- Once you have submitted your SSR, create a PDF by selecting “View/Print” and then “Print” at the top of the page. Select “Adobe PDF” as the name of the printer and select “OK”. This form should be included along with the protocol documents sent to the IRB.

Co-Investigators from non-WCMC institutions can find the Study Specific Report form here: [http://weill.cornell.edu/research/rea_com/SSR_External.html](http://weill.cornell.edu/research/rea_com/SSR_External.html).

- Choose the appropriate form, either:
  - Financial Interest to Disclose or
  - No Financial Interest to Disclose.

- Create a PDF by selecting “Print” and then “Adobe PDF”. This form should be included along with the protocol documents sent to the IRB.

- The IRB will not review new protocols missing Study Specific Reports.

**NOTE:** If you have dual appointments at NYPH and WCMC, please use [http://conflicts.med.cornell.edu/](http://conflicts.med.cornell.edu/).
Join Us!

- Join CCTEC for pizza and open discussions on resources available to help Cornell inventors start new businesses. The IP & Pizza Event will be held on April 20th from 12-1:30 pm in the Weill Greenberg Center. For more information or to RSVP, contact Laura Cima at LC12@cornell.edu.

- Would you like your technology or startup company showcased to a roomful of entrepreneurs, investors, Cornell alumni, and potential business partners? Please join CCTEC at its annual New Business & Emerging Technology Showcase in Ithaca on April 14th as part of the University-wide, two-day Entrepreneurship@Cornell Celebration for the Cornell Entrepreneur of the Year Award. The two-hour showcase will include poster presentations along with ample networking opportunities. If you are interested in learning more about this opportunity, please contact Laura Cima at LC12@cornell.edu.

NOTE:
An invitation for the IRB Education Seminar will be emailed the first week in April.

The 2011 Radiation Safety training schedule has been posted at: http://tinyurl.com/mfpoo.
The revised Effort Reporting and Tracking plan is now available on the Research Compliance website. Please go to http://weill.cornell.edu/research_compliance/policies to review this policy. If you have any questions e-mail research_compliance@med.cornell.edu or call (646) 962-8218.

Starting March 28th, two monthly effort reports will be sent automatically to the department/division administrators and key effort compliance personnel for each department. These reports are run out of the Grants and Contracts COEUS system; one is for pending projects and the other is for active projects.

If you find discrepancies between your records and the report please contact your Grants and Contracts administrator to resolve.

From the IRB

News and Important Links

- The IRB office has revised the continuing review form to reflect the updated Guidance on IRB Continuing Review of Research, released by the Office of Human Research Protections on November 10, 2010 (http://www.hhs.gov/ohrp/policy/continuingreview2010.html). The form more accurately addresses the information OHRP indicates IRBs need to consider when evaluating research undergoing continuing review.

  This form should be used for the submission of all continuing reviews going forward, and will be required for use as of March 21, 2011. The form can be found on the Research Integrity website at http://weill.cornell.edu/research/for_pol/ins_rev_boa.html

- The IRB HIPAA in Research page can be found here: http://med.cornell.edu/research/rea_com/hip_back.html

- The IRB has added a question to the FAQ section specifically addressing appropriate emailing of patient/research subject information at http://weill.cornell.edu/research/for_pol/irb_faq.html#21

Comprehensive IRB Administrative Training Program

Brought to you by the Office of Research Integrity and Assurance

Presentations geared towards the needs of research coordinators, junior faculty, and anyone who submits protocols to the IRB

A full day of 30-45 minute sessions covering a wide range of IRB policies and their associated administrative procedures

In-depth explanations and a Q&A period for each session

Space is limited and RSVP is required to secure your spot.

Invitations for the April session will be sent the first week of the month.

Never miss an update: Join the RCN (Research Coordinators’ Network) listserv. Send your RCN listserv request to irb@med.cornell.edu.
The much anticipated National Institutes of Health final rule on financial conflicts of interest is expected to be issued in April. The proposed rule would lower the de minimis threshold for reporting financial interests from $10,000 to $5,000 and ask institutions to review the financial relationships of all their investigators to determine whether conflicts exist, establish public websites containing that information, and devise plans to manage the conflicts the institutions identify.

“Since the promulgation of the current regulations in 1995, biomedical and behavioral research and the resulting interactions among government research institutions and the private sector have become increasingly complex. This complexity, as well as a need to strengthen accountability, have led to the proposal of amendments that would expand and add transparency to investigator disclosure of significant financial interests, enhance regulatory compliance and effective institutional oversight and management of investigators' financial conflicts of interest, as well as the agency's ability to ensure compliance,” the unified agenda stated.

An accompanying document, which lists the priorities in the unified agenda, highlights the forthcoming changes to the privacy law which has several research-related provisions designed to streamline the process for obtaining informed consent for clinical trial participation and authorization for use of protected patient data and biological materials.

**The Food and Drug Administration listed several research-related items in the unified agenda, including:**

- Regulations governing good laboratory practices for studies that support or are intended to support applications for research or marketing permits for FDA-regulated products
- Revision of regulations to require that clinical study data and bioequivalence data must be submitted for new drug applications, biological license applications, and abbreviated new drug applications in an electronic format that FDA can process, review, and archive. The NPRM is projected for June
- Revision of post-market medical device reporting regulations to require that adverse events be reported electronically
- Proposed amendment of regulations to require that clinical studies conducted outside the United States in support of a premarket approval application or a humanitarian device exemption application for a medical device be conducted in accordance with good clinical practice (GCP)
- Proposal to expand the scope of clinical investigator disqualification regulations so that when an investigator is ineligible to receive certain investigational products such as drugs (including biologics), new animal drugs, or devices, the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA
- Final rule to affirm an interim final rule's exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency, which would add a requirement that the investigator submit the required documentation to FDA in addition to an institutional review board. Final action is scheduled for June
- Update informed consent regulations to require the insertion of a specific statement in all consent documents that, if applicable, the data from clinical investigation have been or will be submitted for inclusion in the clinical trial registry databank

Source: bna.com
NIH Non-Competing Continuation Requirements for the All Personnel Report

Remember the following requirements whenever completing the All Personnel Report:

- All personnel listed on a grant that are devoting more than 1 CM (8.33%), independent of key personnel status or funding source, must be listed in the All Personnel Report.
- Personnel who are devoting less than 1 CM must not be listed.
- Post-doctoral associates who are devoting more than 1 CM will need to obtain an eRA Commons username, as the report requires its inclusion for each post-doctoral associate listed.

Non-Federal Sponsored Project Submissions Must Include the Sponsor’s Published Facilities and Administrative Cost Rate

GCO/OCTA requires documentation of the sponsor’s published facilities and administrative cost rate, which is usually found in the program announcement guidelines, or on the sponsor’s website.

If the guidelines do not specify a rate, it is the responsibility of the PI or their designee to obtain the rate information from the sponsor in writing.

For current indirect cost rate information, visit: http://med.cornell.edu/research/gra_con/ind_cos_rat.html

Transition to ADOBE-FORMS-B1 at Grants.gov


- On or Before May 7, 2011: To accommodate the transition to the new ADOBE-FORMS-B1 forms in an applicant-friendly manner, NIH, AHRQ, CDC, FDA and NIOSH will accept either ADOBE-FORMS-B or ADOBE-FORMS-B1 packages for deadlines on or before May 7, 2011, with the exception of Ks, Ts, Ds, and Fs which must be submitted using ADOBE-FORMS-B1 on or after January 25, 2011.
Experts Call for Stricter Regulations in Clinical Trials of New Drugs

When most people learn about the results of clinical trials for new medicines, it's either because something very good or very bad happened. "There seems to be two narratives people can handle: Experiments are dangerous and you shouldn't take part, or experimentation is the engine for the next great wonder drug," said Alex John London, an associate professor of philosophy at Carnegie Mellon University who is the co-author of an article in the current issue of the journal PLoS Medicine that looks at this and related issues with clinical trials. "What we need is a more even set of expectations."

That's important, Mr. London said, because if people believe there are only two possible outcomes at either extreme, they might not be willing to participate in clinical studies. "If people don't participate, studies don't happen," he said. Mr. London and his colleague, Jonathan Kimmelman, an associate professor in the biomedical ethics unit at McGill University in Montreal, co-authored the article titled, "Predicting Harms and Benefits in Translational Trials: Ethics, Evidence and Uncertainty." But while arguing that our expectations of clinical trials need to be more realistic and informed, Mr. London and Mr. Kimmelman also believe that the trials themselves need to be proposed, and run, more rigorously. The article, which Mr. London sees as “taking part in a wider conversation” with researchers, funders, review boards and other stakeholders, goes right at what they see as some of the problems in both pre-clinical animal-based trials, and the transitional, first-in-human clinical trials where so many proposed drugs fall apart. They both point out the problems they see in clinical trials, and make proposals for how they could be corrected, with potentially far-reaching implications in drug research.

The co-authors were motivated to write the article, Mr. Kimmelman said, because "only rarely do the effects seen in animal studies translate into human studies." That is, that even though researchers regularly find success with a proposed drug during research on animals, only infrequently do researchers achieve similar success with human test subjects. They note in their paper that one study showed, for example, that only five percent of proposed cancer drugs that enter trials are eventually licensed. "Drug discovery is hard," Mr. London said. "I don't think there's any way of getting around that." And that gets to a central theme to their work, Mr. Kimmelman said: "What we're really trying to do here is check the expectations associated with major clinical findings."

That has important implications not only for possible human test subjects, who need to have a better understanding of potential outcomes, but for organizations that provide research funding "and who would want to move their resources into the most promising areas," Mr. London said. Still, they believe clinical trial outcomes might be improved were it not for two main problems they have found. The first is that most animal studies don't use the same generally accepted methods used in human trials, such as randomization and blinded outcome assessment, to prevent bias by the researcher.

They note that one recent analysis of animal studies found that only 12 percent of those studies used random allocation, where animals are randomly assigned to take the proposed drug or to get a placebo, and only 14 percent used blinded outcome assessment, where a researcher doesn't know which animals were getting the drug and which were getting the placebo. These are important because "researchers have an inherent bias in wanting to see a positive outcome" from the studies, Mr. Kimmelman said.

The second problem they worry about is that they believe that researchers don't look widely enough at other related research in making their predictions about the possible outcome once they begin human trials. They believe that most researchers, when predicting the outcome of their study, only consider other studies involving the particular agent, or drug, they are testing. Mr. London and Mr. Kimmelman refer to this process as "evidential conservatism."

Ultimately, Mr. London said: "We want to make sure we design our trials as well as possible so we can learn from them -- even if it is a failure in outcome. "It's not that we learn from every failure, but it's that when they are well designed, we can learn much more from them."

Excerpted from an article by Sean D. Hamill, Pittsburgh Post Gazette, Published March 14, 2011
President’s Bioethics Commission Names International Research Panel

Washington, D.C. – Dr. Amy Gutmann, Chair of the Presidential Commission for the Study of Bioethical Issues, today announced the formation of an International Research Panel to consider the standards for protecting human subjects in scientific studies. The announcement comes in direct response to a request from President Obama. The President asked the Commission to report on the effectiveness of current U.S. rules and international standards for the protection of human subjects in scientific studies supported by the Federal Government and to assure him that “the current rules for research participants protect people from harm or unethical treatment, domestically as well as internationally.”

This request arose in the wake of revelations last October about U.S. Public Health Service supported research on sexually transmitted diseases in Guatemala from 1946 to 1948, which involved the intentional infection of vulnerable human populations.

The International Research Panel will consider the effectiveness of current federal rules and international standards governing research involving human subjects. The International Research Panel includes experts on medical ethics, science and clinical research who bring wide experience from academia, government, and industry. They hail from many countries, including Argentina, Brazil, China, Egypt, Guatemala, India, Russia, Uganda, Belgium, and the United States. The Panel members will be acting in their individual capacities and are not official representatives of their home nations.

“The members of this International Research Panel will offer a valuable global perspective,” Gutmann said. “Their diverse backgrounds, extensive experience and understanding of global research, and their commitment to the highest ethical standards will be critical to informing the Bioethics Commission’s report to President Obama.”

The International Research Panel will convene in a series of meetings, or Consultation, that will examine:

- The dominant norms, and competing alternatives, driving the ethics of medical research in different global regions outside of the U.S
- The conflicts, if any, between U.S. norms and international standards
- The challenges facing researchers conducting U.S.-funded research in global settings
- How best to address any major differences in regional norms for medical research

The group plans to meet three times, with at least one of the meetings taking place outside the United States. The Consultation proceedings will be distributed publicly. Public comments on these proceedings will be solicited before the Bioethics Commission submits its final report to the President.

In addition, at the President’s request the Bioethics Commission will include a thorough fact-finding investigation into the 1946-48 research. This historical investigation is being conducted by Commission staff, including several senior experts and consultants, and led by Valerie Bonham, the Commission’s Executive Director.

Excerpted from bioethics.gov, Published March 1, 2011
Security of Radioactive Sources

Radioactive material must be secured from unauthorized possession and use.

- All labs must maintain a current and accurate inventory of all their radioactive materials, including waste
- All labs where radioactive materials are used must be kept locked when unattended
- Any radioactive material, including waste, that is stored in a common area must be access controlled
- To maintain security, be aware of any unfamiliar, unescorted person who enters your lab and always ask them to identify themselves and their purpose. If response is questionable, call Security, (646) 746-0911
- Any missing radioactive material must be reported to Radiation Safety IMMEDIATELY, (646) 746-6964, or beeper 17162

Diagnostic Radiation Dosimetry Analysis Services

The senior Imaging Physicists in the Office of Health Physics are available to provide Radiological Dosimetry Analysis (RDA) for procedures currently used to perform diagnostic imaging at the Medical Center.

IRB Protocol Applications which involve the use of radiation producing equipment and/or radioactive materials require that a Radiological Dosimetry Analysis listing organ doses be included.

Our RDA can provide the necessary data to expedite the review and approval process of your application.

Please contact Senior Physicist Irwin Levy (646) 746-2611 or Dr. Leonard Rosenstein (646) 726-4437 in the Office of Health Physics to take advantage of this service.

Institutional Biosafety Committee

New Requirements for Obtaining IBC Approval

On December 1, 2010, the IBC began utilizing a new system to streamline laboratory compliance with IBC policies and procedures using the Research Safety Checklist/IBC Laboratory Registration. This new form allows Weill Cornell Medical College Laboratory Principal Investigators and Core Facility Managers/Directors to submit a single document representing all recombinant DNA, transgenic animal, biohazard or select agent work occurring in the lab. Once your approval is issued by the IBC, it lasts for a two-year period.

It is the Laboratory Principal Investigator’s responsibility to:

- Maintain an up-to-date registration document with the IBC so all applicable work and changes are IBC-approved prior to initiation
- Submit a two-year renewal prior to expiration, for which you and your Lab Safety Coordinator will receive 30-day and 15-day reminder emails with submission instructions, and
- Follow all applicable regulations, policies and procedures associated with the work and in accordance with the IBC’s approval.

The new form is available with comprehensive instructions at http://weill.cornell.edu/research/for_pol/grant_con.html#a

The IBC has revised its Incident Reporting Policy, which specifies immediate reporting and safety procedures for incidents involving WCMC laboratory personnel conducting biohazards, recombinant DNA and select agent research in WCMC owned or leased laboratory facilities.

This document is available at http://weill.cornell.edu/research/for_pol/ins_bio_c om.html under “Biosafety Information”

If you have any questions, please direct them to ibc@med.cornell.edu or (646) 962-8192