

newsletter

Issue 3, March - September 2004

Spring Edition

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Announcements

Changes Made to IACUC, IBC, and UIC Applications

Notice: Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and University Isotope Committee (UIC) applications have all been revised. New applications are available to download on the ORP website (<http://www.research.psu.edu/orp>). As of February 29, 2004, expired applications are no longer being accepted.

Notice: A new IACUC application document entitled "Research Protocol Preparation Help" is now available for downloading. The Help document includes links to additional information you may use to complete your application accurately and completely. Download the application at http://www.research.psu.edu/orp/ANI/APPS/prep_app.rtf.

Notice: Some modifications to IACUC protocols can now be submitted via email. The list of modifications that may be submitted via email includes 1) title change, 2) funding source change, 3) personnel additions with some restrictions, 4) housing changes unless biosafety concerns exist, 5) animal source change, 6) requests to add up to 10% more animals to the study, and 7) requests to add a new strain. Be sure to review the modification application for additional information prior to making your email submission (<http://www.research.psu.edu/orp/ANI/APPS/modification.pdf>).

Notice: Modifications to IACUC Breeding Colonies should now be submitted using the standard IACUC modifications application. The IACUC breeding colony modification application should no longer be used.

Notice: University Isotope Committee (UIC) applications are now only accepted electronically. Submit UIC applications to Erica Kresovich at emk128@psu.edu.

Notice: The ORP is now accepting Institutional Biosafety Committee Annual Review forms electronically. Submit electronic forms to Erica Kresovich at emk128@psu.edu.



US Export Control Laws: Is Your Research Affected? *Part Two of Two*

In our last issue, we discussed how to determine if your research is subject to the US Export Control laws. In this issue, we continue by addressing some additional considerations you must take into account if you do determine your research is regulated by the International Traffic in Arms Regulations (ITAR) or the Export Administration Regulations (EAR). It is important to remember that if you are in doubt or need assistance identifying if your research is regulated and, if so, to what restrictions you must adhere, you should contact the Office of Sponsored Programs for guidance.

Participation of Foreign Nationals/Persons in Your Research

The export control regulations do not allow foreign nationals/persons who are not full-time employees of the University to participate in your research if it is regulated by ITAR or EAR. Foreign nationals/persons might include faculty, staff, post-doctoral scholars, visiting faculty, graduate students, research or teaching assistants, among others. If you want to involve a foreign national/person in your regulated research, you should contact the Vice President for Research prior to involving such person(s) in your research in any way. The Vice President for Research will refer you to someone who can help determine if such person(s) can be involved in your research in any capacity.

Hiring or Using Foreign Nationals/Persons

In order for any foreign national/person to be considered for participation in regulated research, he/she must be willing to sign certain agreements prior to involvement in the research. Foreign nationals/persons who are:

- Hired to be, or are, bona fide, full-time employees of the University, and
- Who are not citizens of a country to which exports are prohibited, and
- Whose duties include the performance of sponsored research
- Who may have access to technical data (as defined in the ITAR)

must sign a statement that they will maintain a permanent residence in the United States during their period of employment. Additionally, they must also agree that they will not disclose, export, or transfer technical data to any other foreign national/person without written approval of the U.S. Department of State unless the recipient has executed a similar statement for the University, is a full-time employee of the University, and has a need to know.

Presentation of Previously Unpublished Research Data at Conferences

When you are conducting research regulated by ITAR or EAR, you must consider certain restrictions on presenting your unpublished research data at professional conferences prior to delivering your presentation. Generally the determination depends on the location of the conference and whether or not it is open to the public.

Allowable Presentations for ITAR Regulated Research

You may present previously unpublished regulated research data at conferences held within the US that are generally open to the public. When the conference is to be held outside of the US or is not generally accessible to the public, you must contact the Vice President for Research for guidance prior to making your presentation.

Allowable Presentations for EAR Regulated Research

You may present previously unpublished EAR regulated research data at open conferences held in any location, nationally or internationally. If the conference is not an open conference, you must contact the Vice President for Research for guidance prior to making your presentation. EAR considers a conference to be open "if all technically qualified members of the public are eligible to attend and attendees are permitted to take notes or otherwise make a personal record (not necessarily a recording) of the proceedings and presentations." [15 CFR 734.7(4)]



The Oral History Debate: Is it Research?

In recent years, as Institutional Review Boards (IRBs) have faced increasing governmental scrutiny they have struggled to apply the letter of the law to social science research in ways that are not overly restrictive and onerous to researchers. One such area of social science research that has been contentiously debated is in the field of oral history. For years, oral historians have argued that much of the work they perform should not be categorized as research, as the federal government defines research. 45 CFR 46.102(d) defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Oral historians have argued that interviews conducted with individuals about events of the past do not fall into this definition of research since they are designed to document a specific historical event or the experiences of individuals and are not intended to draw conclusions or contribute to generalizable knowledge. The Oral History Association sent a letter and proposed policy to the Office of Human Research Protections (OHRP) in August of 2003 making just such an argument.

The OHRP responded in September of 2003 with a letter concurring with the proposed policy, which stated that oral history interviews do not fall within the federal definition of research in that, generally, they do not serve the purpose of contributing to generalizable knowledge. Essentially, OHRP’s concurrence indicates that oral history interviewing work does not in some cases require IRB review. OHRP has not yet issued a formal policy statement, however, and clearly indicates that the agency has not accepted the policy put forth by the Oral History Association as its own.

In December of 2003, at the Applied Research Ethics National Association (ARENA) annual meeting in Washington, DC, an OHRP representative, Michael Carome, discussed the current status of the oral history debate. The discussion outlined three principles for evaluating oral history activities, all of which rest upon a decision as to whether generalizable knowledge will be created.

1. Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute “research” as defined by 45 CFR 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute “research” as defined by 45 CFR 46.

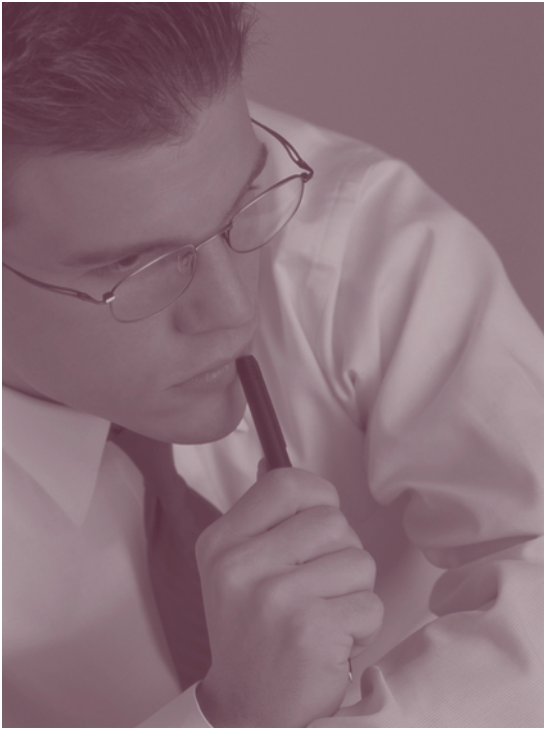
Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

3. Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of an archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR 46, the creation of an archive WOULD constitute research under 45 CFR 46.

Example: Open-ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR 46 since the intent is to collect data for future research.

The Penn State IRBs concur and have adopted this guidance information. This policy and a decision tree will be available in the near future on ORP’s website to assist investigators in determining if their oral history work would constitute “research” as defined by 45 CFR 46.

If you have questions about the three principles and how your project may be categorized, please do not hesitate to contact the ORP to discuss your work with one of the IRB administrators.



About the ORP Review Process...

Q: I dropped off a new “Application for the Use of Human Participants” to the Office for Research Protections (ORP) and didn’t hear anything back about approval until nearly 3 weeks later. I thought my study was a simple one involving little to no risk to participants/subjects and I was just performing simple tasks. Why does it take so long?

A: As a rule of thumb, a new “Application for the Use of Human Participants” generally takes 3 weeks for review. The 3-week review time applies to those studies that are designated as “exempt” or “expedited”. Studies determined to be full reviews are evaluated by the full Institutional Review Board at their monthly meeting and require a longer review. For further guidelines on Full Review Submission for human participants, please visit http://www.research.psu.edu/orp/HUM/othr/mtgs_04.htm (for submission deadlines) and <http://www.research.psu.edu/orp/HUM/othr/types.htm> (for an explanation of the criteria for the different levels of reviews).

The Review Process

In the beginning...

- The process involves a step-by-step review starting with prescreening at the ORP to check for complete applications, proper signatures, correct number of copies and an initial determination of the type of review.
- Once these criteria have been met, a reviewer is assigned to the protocol.

Exempt Reviews...

- Human Participant Protocols that fall under the “exempt” level of review are exempt from 45CFR46, the federal regulations governing human participant research. However, these regulations indicate that a researcher cannot determine for him/herself that their research is exempt. A third party not involved in the research must determine the protocol exempt. At PSU, that determination is made by the ORP. Therefore, researchers must still submit an Application for the Use of Human Participants. The review time for an exempt protocol is three weeks.

Who are these “reviewers”?

- Reviewers are members of the two Institutional Review Boards (IRB) that are administratively supported by the ORP. Committees consist of a minimum of 5 members comprised of at least one scientist, at least one non-scientist and at least one person not affiliated with the Institution (e.g., a community member). The membership of these committees is comprised of Colleges and Units throughout the University. This allows the committees to have expertise in many areas.

What do these “reviewers” do with my protocol?

- Each reviewer is granted 2 weeks to review a protocol and is given a copy of the protocol along with a reviewer sheet. Upon completion of the review, the reviewer then sends their comments back to the ORP. Depending on the committee, this is done in various ways (i.e. email, fax, US Mail or Campus Mail).

Then what...?

- Once the review sheet has been returned to the ORP, the IRB Administrator composes a list of necessary revisions as a result of the review. This list is compiled in an email, which is sent to the Principal Investigator (PI) and copied to other personnel as applicable.

Back to the investigator...

- Upon receipt of this email, the PI has the opportunity to respond to the revisions requested and reply with any items necessary for approval.

Back to the ORP...or...“The Final Lap to Approval”

- When the ORP receives correspondence from the investigator and assuming all the necessary information is contained therein, approval is granted. The ORP sends an email to the investigator indicating that they may begin their research. Occasionally, the reviewer may ask to see the response from the investigator, in which case the review period may be extended.

At last!

- Shortly after the approval email is sent, a hard copy of the formal approval letter and any pertinent accompanying documents (e.g., the approved informed consent form, etc.) are sent to the investigator and copied to other personnel as applicable.

Continued on pg. 5...

About the ORP Review Process Continued...

Further information regarding the review timeline

- With the exception of full reviews, the review time is generally about 3 weeks.

Yes, but...

- This timeline can be affected by the content of the study, the completeness of the application and the amount of time it takes for the investigator to respond to any revisions requested by the ORP and/or reviewer.
- Generally, a response from the investigator is expected within 30 days from the date of the email request for additional information. If additional time is needed, the investigator should contact the ORP to extend the deadline.
- If a response is not received within the 30-day time period, a reminder will be sent to the PI, Co-Investigators (Co-PI), Advisor and Project Coordinator. The reminder indicates a response must be received within 2-weeks from the date of the reminder notice or the application will be withdrawn from consideration. If additional time is needed, the investigator should contact the ORP to extend the deadline.
- Submissions may be reviewed and approved in a shorter time frame due to the nature of the studies, but the ORP asks investigators to allow for 3 weeks for each study due to the workload of the committees and the ORP (over 2,600 human participant submissions are processed annually!).

Proceed with caution, please...

- To ensure a quality review, the ORP asks investigators to allow 3 weeks for the review process. Continued requests for quick turnarounds, though handled on a case by case basis at the ORP, do not permit the reviewers, who volunteer their time as committee members, adequate time to deliver a quality review.
- Federal regulations guide this important process and are in place for good reasons. For further information on the background of these regulations, please visit <http://www.research.psu.edu/orp/HUM/train/history.html>.

Good news ahead!

- The ORP is continually working to improve the submission procedure for investigators. Work is presently in progress to develop and implement an online application wizard that will provide a more streamlined process and allow investigators to complete the application based on their specific research design.

Looking at this process from a different angle...

- We have developed the flow chart on page 6, Diagram 1, of this newsletter to help investigators visualize the review process in a more concise manner for all areas of research administratively supported by the ORP.

As always...

- Never hesitate to contact the ORP with any questions about this process – we're here to help you! To obtain contact information, please visit: <http://www.research.psu.edu/orp/Directory/contacts.htm>.

Continued on pg. 6 (diagram 1)...

ORP Staff Member In the Spotlight!

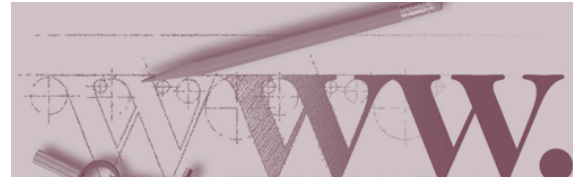
CIP Certified



Jodi Mathieu - "In the Spotlight!"

On December 17, 2003, Jodi Mathieu, IRB Administrator for the ORP, became a Certified IRB Professional (CIP). Jodi's efforts entailed the extensive review of the federal rules and regulations for human participant research and the completion of a four-hour exam composed of 250 multiple choice and objective questions. Jodi's certification has allowed her to advance her knowledge in human participant scientific methods, government regulations and ethical principals. As a result, the quality of the protection of human participants will continue to be enhanced. In order to maintain certification, continuing education requirement must be maintained or the CIP exam must be retaken every three years.

ORP Available Services...



There is Still Room Available!

Every three months, the ORP offers the service of listing active, Institutional Review Board (IRB) research studies currently recruiting on their website. Any investigator wishing to use the ORP website as a form of advertisement for recruiting should submit a Study Listing Form, located at the following URL: http://www.research.psu.edu/orp/STUDY_LIST/form.rtf and send to Jenn Stewart at jas72@psu.edu. Only a total of 25 full review studies and 25 exemption/expedited studies can be posted on the ORP website at this time. Please note that Hershey Medical Center (HMC) investigators must go through the HMC IRB for approval to post their ad on the ORP website.

The ORP will accept study listings on a first-come, first-serve basis; however, the policy still stands that investigators who currently have studies listed are given the courtesy of renewing their listing first. Once your study is listed on the ORP website, you will have the option to continue having your study posted until you choose to remove it. A notice is sent approximately every three months and a response is required in order to continue with the ORP service of listing your research study.

If you are interested in adding your approved IRB study to the ORP website, please contact Jenn Stewart at 814-865-1775 or email the Study Listing Form (located at the above URL) to jas72@psu.edu. If you are not familiar with this service and would like to see a list of the current studies, please visit: http://www.research.psu.edu/orp/STUDY_LIST/intro.htm.

ORP LISTSERV

protocol deadlines
announcements research-related information

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The ORP recently developed a listserv, L-ORP-Research-L, to disseminate announcements on protocol deadlines, changes in protocol submissions, upcoming ORP events, office hours during the holidays, distribution of newsletters and other important research-related information. The listserv will be used sparingly and only to disseminate information that is important for all active researchers to know. Unlike most listservs, only the ORP has the ability to send notices to the listserv; thus, preventing any unnecessary information from being distributed.

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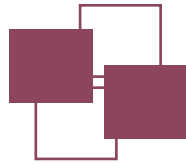
Essential announcements will only be distributed to the ORP listserv and will no longer be sent out to all active Principal Investigators in the ORP database. Principal Investigators who were active until at least February 13, 2004 were added to the ORP listserv automatically. New Principal Investigators who became active after February 13, 2004 may not have been added to the listserv. If you did not receive the welcome message about being added to the listserv, it is possible that you were not added automatically. A notice has also been added to the application approval letters, providing information on how to subscribe and unsubscribe from the list.

The ORP encourages all Principal Investigators and Co-Investigators to subscribe to the ORP listserv. If you are interested in subscribing or being removed from ORP listserv, send an email to: L-ORP-Research-L-subscribe-request@lists.psu.edu to subscribe or L-ORP-Research-L-unsubscribe-request@lists.psu.edu to unsubscribe. There is no need to add any text in the subject line or in the message body of the email.



Change in Maintaining Informed Consent Records...

Subjects must receive a copy of any informed consent documentation that was submitted to the Office for Research Protections for review. The principal investigator is expected to maintain the original signed consent forms along with the IRB research records for this research at least three (3) years after termination of IRB approval. **For projects that involved protected health information (PHI) and are regulated by HIPAA, records are to be maintained for six (6) years. Additional requirements apply for FDA and sponsored trials, which the investigator should determine when applicable.**



Addition to the ORP Staff



New ORP Associate Director, Jackie Gardner

Jackie is very enthusiastic about joining the ORP team and states "I am looking forward to the opportunity to move the ORP into the future by enhancing the current educational and electronic efforts, while elevating the department's "benchmarking" status. I am excited about working to improve collaborative efforts with the College of Medicine located at Hershey Medical Center and other PSU campus locations. Additionally, I am committed to promoting the ORP as a place that continues to attract and retain the best people, while providing a workplace environment that allows them to do their best work."

The Office for Research Protections (ORP) is pleased to announce our new Associate Director, Jackie Gardner, M.S. Jackie received a Bachelor of Science in Health and Physical Education and a Master of Science in both Human Resource Management and Exercise Science. In addition, Jackie is a certified Exercise Specialist. Jackie possesses the skills, knowledge and experience in project management, administration and research.

Coming from a diverse clinical background and merging into the position of Project Coordinator and Laboratory Manager for a \$1.4 million 3-year NIH-funded project in the Department of Kinesiology/ Noll Physiological Research Center, Jackie has gained the skills and expertise needed to fulfill the responsibilities of an Associate Director. This dedicated, high energy, detail-oriented individual is capable of attracting, directing, motivating and supporting various levels of staff while demonstrating an exceptional customer-service focus. Jackie's unique combination of clinical research and managerial experiences and skills are a great benefit to the research community and the ORP staff.

Outside of work, Jackie enjoys spending time with her son and husband, remaining physically active, and volunteering for the American College of Sports Medicine, American Heart Association and the Corl Street Elementary School.

Upcoming responsibilities that Jackie will be faced with as the Associate Director of the ORP include staff management, supporting and enhancing the current efforts of the ORP, helping to elevate the current benchmarking status, maintaining a customer-service focus, monitoring the operation of five compliance committees and providing leadership in compliance oversight.

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