Penn State’s Office for Research Protections (ORP) has developed the Continuous Quality Improvement Program (CQI), an initiative driven by receiving Full Accreditation status by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). CQI encompasses the ORP, the Institutional Review Boards (IRB) and related Investigator processes and practices. Penn State has a commitment to continuous quality improvement, which has three hallmarks accomplished through teamwork: focus on “clients” (students, faculty, staff and others), study work processes, and implement information-based decision making. This article focuses on the ORP’s Post-approval Review Program, which is the part of CQI that impacts investigators at all campuses and colleges of Penn State (except for the College of Medicine at The Milton S. Hershey Medical Center campus).

A year in the making, the Post-approval Review Program (PAR) has been developed with information collected internally and externally, on-site and on-line, from beginners in the field of post-approval review and from more experienced practitioners. A particularly valuable resource has been the Post-IRB Approval Review Sub-committee, which is part of the Committee on Institutional Cooperation IRB Administrators Group for the Big Ten universities and University of Chicago. Members of the sub-committee represent new and evolving programs, such as Penn State’s PAR, and other, more established programs.

The ORP is committed to making the Post-approval Review process proactive, educationally-oriented and transparent. Investigators will know what will happen, how it will happen and how it will be followed-up during every step of the process. These are the responsibilities of the Post-approval Reviewer. A climate that facilitates open and honest communication is fostered before, during and after the review. Information about areas that may be of concern is shared in a respectful and educational manner.

The PAR program is composed of four different types of reviews: Routine, Volunteer, Directed and For Cause. Routine visits are selected from a defined pool of recently-approved studies. Criteria such as complexity of the study, population enrolled and risk level are some of the considerations used in the selection. Studies may also be volunteered by the Principal Investigator (PI) for a review. Directed reviews and For Cause reviews are conducted as a precaution or in response to a problem that has arisen with a study or an investigator and are not limited to newly-approved studies. The IRBs determine whether and how these two types of reviews are carried out.

continued on page 2…
shooting for par (cont.)

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The Front Nine: Routine and Volunteer Reviews

Investigators can expect to receive a Preparation Guide (Prep Guide) in advance, which will assist the Investigator in getting ready for the scheduled visit. Generally, the visit starts with an interview, proceeds to record review and observations (by prior arrangement), and ends with a brief conference to summarize the visit. Following the visit, the Post-approval Reviewer compiles the information gathered into a Preliminary Report and reviews it with the Director of the ORP.

To elaborate, the review process begins with scheduling the on-site review with the PI. The PI is provided with the Preparation Guide after the time and date of the review has been confirmed. Before the on-site visit takes place, an internal review of the ORP’s study file and IRB records is completed. When the on-site PAR visit is made, it begins with a discussion among the Post-approval Reviewer, the PI and study team members. The discussion starts with general CQI questions about Investigator interactions with the IRB and ORP and solicits Investigator feedback about education programs offered, as well as other topics. The information gathered in this part of the interview is not associated with the particular investigator – its purpose is for quality improvement only. At the conclusion of this part of the discussion, questions specific to the protocol are asked and that information becomes part of the PAR documentation. An outline of all discussion topics is included in the Preparation Guide.

The Back Nine: Routine and Volunteer Reviews Follow-up

Following an on-site Routine or Volunteered visit, the Post-approval Reviewer compiles the information gathered, drafts a Preliminary Report and reviews it with the Director of the ORP. After their review, the Preliminary Report, which contains information about any actions that may be required and/or optional for the PI to complete, is sent to the Investigator. (Note: Preliminary Reports are not part of the procedure and are not provided for Directed and For Cause Post-approval Reviews.) The Investigator has the opportunity to respond to the Preliminary Report to clarify any information and also to submit documentation of any required actions taken since the visit. After review of the PI’s response, again by the Post-approval Reviewer and the Director of the ORP, the Final Report is composed and sent to the Investigator. Copies of the Final Report are kept in the ORP study file and in the Post-approval Reviewer's confidential files.

If serious or substantive concerns are included in the Preliminary Report draft, the ORP Director will consult the appropriate IRB chair and/or members for further direction. Non-compliance procedures may then be implemented.

Save Strokes!

As investigators and their study teams prepare for, conduct and conclude research investigations, they are invited to refer to the Investigator’s Manual and other sections of the ORP Web site. A wealth of information can be found there about Post-approval Review, policies, regulations, practical tips and more.

continued on page 3...
Go for the Green!

Volunteer your study for a Post-approval Review!

Four advantages to volunteering your study for a Post-approval Review:

- Excellent learning experience for students who are members of the study team
- Demonstrates respect for the research protections processes – set a great example for staff, students and colleagues!
- If a study is volunteered for a visit, that study will be taken out of the selection pool and will not be chosen for a Routine Visit, unless concerns arise about the study.
- Scheduling and scope of the visit is more flexible!

The 19th Hole: Summary

- The PAR Program is designed to be proactive, educationally-oriented and transparent

- When a study is selected for a routine visit, the PI is notified by letter. The PI and the post-approval reviewer will communicate and agree upon a time within about 4 weeks for the visit to take place. The PI will be sent a Preparation Guide to help get ready for the visit. The PI may find that everything is in order and little preparation is needed. Or, the PI may need to spend some time gathering paper and/or electronic documents in one place to help the visit go smoothly.

- If a study is volunteered for a PAR (see sidebar), there is more flexibility in both the timing and the scope. A volunteered visit is conducted like the routine visit.

- Routine and Volunteered visits can take 4-6 hours for record review and discussions, but it varies. If informed consent or study procedure observations are arranged, more time will be needed.

- The PI receives a Preliminary Report to review and respond to after the report is shared with the Director of the ORP. The Preliminary Report includes required and/or optional actions for the PI to complete.

- The Final Report is composed after receiving the PI responses, including any actions completed by the PI. The PI receives a copy of the final report. The Final Report is filed in the ORP study file and in the Post-approval Reviewer’s confidential files.

- If serious concerns are identified, the Director of the ORP will determine whether the IRB should be involved and/or non-compliance procedures will be implemented.

- The IRB determines whether and how For Cause and Directed visits are made.

Course Guide

The CQI and PAR Web areas are still being constructed, but practical information that may be useful upon notification of approval of studies can be found at http://www.research.psu.edu/orp/areas/humans/cqipar/ and in all areas of the ORP’s comprehensive website http://www.research.psu.edu/orp/areas/humans/index.asp.

The “Club Pro”

Josy Lyons is responsible for the Post-approval Review and Continuous Quality Improvement Programs at the Office for Research Protections. Josy joined the ORP team in November, 2006 as an R.N. with 8 years of experience as a research coordinator here at Penn State. This experience, combined with graduate level work in adult education, provides her with a unique
understanding of how research is conducted and the challenges that investigators face. She
would be pleased to talk with you about post-approval review and invites investigators to
volunteer their studies for routine reviews. To talk with Josy, volunteer your study for a post-
approval review or for more information, please call her at 865-1775 or email her at jlm38@psu.edu.

Reference: 1. Penn State’s Planning and Institutional Assessment website at
http://www.psu.edu/president/cqi/cqi/whatis.htm

Josy Lyons

Send Newsletter Feedback to: ORProtections@psu.edu
We want to hear from you!

CROSSWORD

All answers can be found in this issue of the ORP Newsletter. For the answer key, please visit our Web site at:

15. Program introduced in this issue
18. Review and discussion during PAR visits typically fall into a 4-6 _____ time frame
19. Investigators receive one of these before PAR visits
20. ORP has forty-_____ fans on Facebook
21. A PAR visit that isn’t Routine, Volunteered or Directed
22. Person setting a great example to students by volunteering a study for PAR (abbrev.)

Down
1. Parent program of the Post-approval Review program (abbrev.)
2. New ORP Education Specialist
3. ORP’s PAR Club Pro
4. New Education Assistant’s previous stomping grounds
5. The CIC is made up of the Univ. of Chicago and these universities
7. PAR Program is proactive, educationally-oriented and _____
9. New ORP Education Assistant
13. Sporting theme of this issue
14. Lyons’ years of experience as a PSU research coordinator
16. Volunteering a study for PAR removes it from the pool for this type of visit
17. Section added to ORP Web site home page

Across
1. Hobby organization of new Education Specialist
6. A type of client focused on in the three hallmarks of continuous quality improvement
8. Use this for reference in order to save strokes
10. Post-approval Reviewer is qualified as this type of health care practitioner
11. A climate fostering _____ and honest communication is fostered throughout the Post-
approval Review process
12. ORP program area that gained two new employees recently (abbrev.)
In an effort to keep the Penn State research community better informed of the latest developments at the ORP, we have added a new section to the home page of the Web site (http://www.research.psu.edu/orp). This new box, entitled “What’s New?” provides a snapshot of all the latest happenings on the most-visited page of our site. The snippets link either to the news page, or to related Web pages, for further information.

This supplement to our news page is just one way we are improving the ORP Web site. We have also added more options to the navigation to make finding materials easier. If you have other suggestions please send them to ORPprotections@psu.edu. We want to hear from you!

As of press time, the ORP Facebook page keeps 45 fans up to date on the latest events and information from the ORP! Become a fan today!

**Upcoming Events**

**Research Integrity Brown Bag Series**

**SEPTEMBER 12**

*Life Isn’t Always Fair: Copyright in Research and Teaching*
by Matt Jackson, Associate Professor and Head, Department of Telecommunications
12:00 p.m. - 1:00 p.m. / 102 Kern Graduate Building

**OCTOBER 8**

*Data Security*
by Kevin Murphy, Professor of Psychology and IST, Department of Psychology
11:00 a.m. - 12:00 p.m. / 102 Kern Graduate Building

**OCTOBER 30**

*Calculating the Risk-Benefit Ratio for Research with Human Subjects*
by Jim Pawelczyk, Associate Professor, Department of Kinesiology
12:00 p.m. - 1:00 p.m. / 102 Kern Graduate Building

**DECEMBER 1**

*Read ‘em and Reap: Surviving Peer Review*
by Lisa Lattuca, Associate Professor, Education Policy Studies
12:00 p.m. - 1:00 p.m. / 102 Kern Graduate Building

**Survival Skills and Ethics Series for Graduate Students**

**OCTOBER 11**

Topics will include Getting Started in Graduate School, Time Management, Goal Setting, Communicating with your Adviser, Successful Mentor-Trainee Relationship Skills, Facing Cultural Differences and International Student Issues.

*Admission is free, but pre-registration is required. Please visit http://tinyurl.com/survivalskills to register.*
8:30 a.m. - 2:30 p.m. / Nittany Lion Inn
New Faces

Education Specialist: Sharon Shriver

The ORP happily welcomes Sharon Shriver as our new Education Specialist! Coming from the Department of Biology, Sharon’s background in teaching bioethics made her the perfect fit for this challenging position.

She also served on the Academic Integrity Committee for the Eberly College of Science, and, as her popularity among students demonstrates, her strong interest in crafting engaging educational presentations and materials makes her a valuable asset to the Educational Program at the ORP.

In her free time, Sharon zooms between activities for her two children, Carly and Evan, spends lots of time in the outdoors, especially hiking and biking, and sings with new husband Brad in The State College Choral Society.

Please join us in extending a hearty welcome to Sharon!

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Education Assistant: Kara Thomas

The ORP is delighted to welcome Kara Thomas as our new Education Assistant! Kara previously worked at the Office of Sponsored Programs (OSP), which gives her a thorough understanding of the overall mission of the Senior Vice President for Research.

Kara’s work at OSP led to curiosity about the compliance side of research, and she jumped at the opportunity to join the ORP.

She enjoys spending time cheering on friends and family at baseball, football and basketball games, and is daughter MacKenzie’s biggest fan during dance class and swimming lessons.

Please join us in warmly welcoming Kara to the ORP!