



Research Regulator

Promoting Responsible Conduct in Research



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Office of Research Compliance

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Research Regulator Expands Content

-Newsletter to Promote Responsible Conduct in Research-

The Research Regulator was developed in December 2006 as a means to provide our research community with up-to-date information about research involving human participants. It was also created to provide researchers with another option to earn Continuing Research Education Credits (CRECs). While we still believe that human research protections is of utmost importance on our campus, it has become clear that the wide variety of research conducted here and at our affiliated hospitals would benefit from expanding its content to cover all nine areas of Responsible Conduct in Research or RCR (see following article). As a result, CREC will not be offered for each issue; rather one issue per year will be devoted solely to human research protections allowing us to offer 4 CREC for completion of the related online quiz. More information about that upcoming issue will be released in the Spring.

Thank you to our current readership, your input has been invaluable. Please continue to forward this newsletter to your colleagues, students and staff. We hope these changes will expand our readership, promote the ethical conduct of research and provide an impetus for open discourse within our community. To request a free electronic subscription please e-mail Tracy.Wilson-Holden@case.edu.

Christian LaMantia
Office of Research Compliance

What is Responsible Conduct in Research?

"In general terms, responsible conduct in research is simply good citizenship applied to professional life. Researchers who report their work honestly, accurately, efficiently, and objectively are on the right road when it comes to responsible conduct. Anyone who is dishonest, knowingly reports inaccurate results, wastes funds, or allows personal bias to influence scientific findings is not.

However, the specifics of good citizenship in research can be a challenge to understand and put into practice. Research is not an organized profession in the same way as law or medicine. Researchers learn best practices in a number of ways and in different settings. The norms for re-

sponsible conduct can vary from field to field. Add to this the growing body of local, state, and Federal regulations and you have a situation that can test the professional savvy of any researcher.¹"



Illustration by David Zinn

The Public Health Service (PHS) through the Office of Research Integrity (ORI) has defined RCR to include the following core instructional areas:

- Data acquisition, management, sharing and ownership,
- Mentor/Trainee Responsibilities
- Publication practices and responsible authorship
- Peer Review
- Collaborative Science
- Human Subjects
- Research Involving Animals
- Research Misconduct
- Conflict of Interest and Commitment

Research Compliance operationalizes regulations, Federal guidance, sponsor requirements, and University policy to create programs to

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2008 RCR Seminar Series

Join us for this series of presentations outlining the important aspects of each RCR instructional area.

All seminars will be held on Friday mornings, 9-10 am or 10-11 am, in the Wolstein Research Building Auditorium, Room 1413

Friday, January 25

- Research Misconduct
- Animal Research

Friday, February 1

- Authorship
- Responsible Mentoring

Friday, February 8

- Human Subjects Research
- Conflict of Interest

Friday, February 15

- Data Management
- Peer Review and Collaborative Science

[Click here to register.](#)



2008 Conflict of Interest Update

Do You Have Any "Significant Financial Interests"?

Soon it will be time for faculty and investigators to submit the Case annual conflict of interest form to the Case COI Committee (COIC). This year, the form has a new name: "The Case Faculty and Sponsored Research Significant Financial Interest Report."

Significant Financial Interest vs. Conflict of Interest: In the past, investigators have often included on their annual forms a disclaimer to the effect of, "Yes I have a financial interest in a company that sponsors my research, but this does not represent a conflict." The change in terminology on this year's form is taking the onus away from the investigator to decide whether there is a COI, i.e., whether his or her consulting salary, equity interest, royalty income or other financial interest in an outside entity could appear to directly or indirectly unduly influence his or her sponsored research.

Now investigators are being asked to list all "Significant Financial Interests" (SFIs) where there is a relationship with sponsored research, and to leave to the COIC the judgment as to whether a given relationship could constitute a COI. As in the past, the questions on the annual form will define the SFI information that is required. [The Case COI Procedures Manual](#) also provides a definition of "significant financial interest."

Reporting vs. Disclosure: The term "reporting" will be used where the institution internally collects confidential, detailed information on financial interests, as opposed to "disclosure," in which the affected individual publicly provides information (with confidential details removed) on publications, to staff, on informed consent documents, etc.

The Case COI Committee (COIC): The COIC is a body that includes Case faculty and investigators, University officials, and representatives from the affiliate/partner hospitals--UHCMC, MHS, LSCVAMC, and CCF. The COIC collects and reviews the annual forms; drafts research COI Management Plans; and develops COI policy for the University and in conjunction with affiliate/partner hospitals. The COIC participates in the national dialogue with academic medical centers regarding COI issues. The change in terminology from "COI disclosure" to "significant financial interest reporting" at Case resonates with best practices at peer institutions.

Get Ready: 2008 Significant Financial Interest Reports
The requests for the annual SFI reports will be distributed in May to Case faculty and to investigators working on sponsored research. Online disclosure will be the preferred method via the SpiderWeb portal. Please update your Case Faculty and Sponsored Research Significant Financial Interest Report at any time via SpiderWeb. For instructions, or to obtain or activate your Case network ID, check out the Case Office of Research Compliance COI web page, which includes contact information for the COIC: <http://ora.ra.cwru.edu/research/orc/coi/index.cfm> ❖

2007 SFI Reports

Forms Collected

Faculty	2434
Non-Faculty	444
Total Collected	2878

SFI Reported

Faculty	439 (18%)
Non-Faculty	50 (11%)

**In the past, the Case COIC has followed up with approximately 10% of significant financial interests disclosed.

- ~ Eliminate
- ~ Reduce
- ~ Manage

How the COIC Creates a Management Plan

- The COIC learns of the potential need to create a management plan via 1) the investigator's annual reporting form; 2) the IRBs; 3) the Institutional Animal Care and Use Committee (IACUC); 4) the Office of Sponsored Projects Administration; or 5) the Office of Technology Transfer.
- The COIC interviews the investigator to determine if a plan is necessary.
- The COIC, working with the investigator, creates a plan.

Examples of Management Strategies for Individuals

For research not involving human subjects:

- Disclosure on publication/presentations
- Provisions to protect advisees from conflicts of mentoring
- Provisions to ensure equitable utilization of institutional facilities

For research involving human subjects:

- Recusal from the IRB protocol

If the COIC finds compelling circumstances for the conflicted investigator to remain on the IRB protocol, then:

- Disclosure to prospective research participants
- Recusal from subject selection and informed consent process



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ensure compliance. But many of these core areas are not governed by specific regulations or clear codes of conduct.

Even if there were compliance programs for each of these areas, compliance alone does not ensure RCR.

What are the requirements?

The 1989 National Research Service Award training grant mandate from NIH requires that trainees funded under such an award receive RCR instruction. Case satisfies this requirement through the IBMS 500 course.

In 2000, ORI tried to mandate that institutions require documented RCR training through the *Policy on Instruction in the Responsible Conduct of Research*. The requirement was suspended, however, because institutions throughout the country expressed great concern about applicability to diverse scientific disciplines, as well as a lack of financial resources.

NIH was the only agency to mandate training for research involving human subjects, which resulted in the creation of our local CREC Program. Today, despite the lack of formal RCR policies, funding agencies like the National Science Foundation (NSF) are requiring researchers and their institutions to show evidence of appropriate RCR instruction before awarding new or renewing current research grants. Specifically, study sections are looking for programs that provide periodic (versus one-time only) RCR instruction for trainees, and that such instruction is conducted at least in part by the faculty mentors.

What RCR resources are available?

The Office of Research Compliance (ORC) hosts an [RCR website](#) that provides links to a variety of excellent resources.

A seminar series (see Page 1) covering the nine core areas was developed to provide postdoctoral trainees and third and fourth year graduate students with more advanced training. Everyone is welcome to attend these sessions. Registration is through the [Seminar Calendar](#).

The University utilizes the online Collaborative Institutional Training Initiative (CITI) program for human subjects training. CITI has also developed an online RCR training program. The University has subscribed to this program and offers it free to the campus community. Instructions on how to access this tool can be found on the [RCR Resource](#) website.

Each upcoming issue of the Regulator will include information on one or more of the core instructional areas. This issue provides information on conflicts of interest (Page 2), peer review and collaborative science (Page 4). Future issues will also include relevant case scenarios which we hope will spur formal and informal discussion/debate between mentors and students. In fact, fostering an open dialogue about RCR may be the best “teacher” of all.

Reference

1. Steneck, Nicholas H. ORI Introduction to the Responsible Conduct of Research, HTML Version September 2006 Available at: (<http://ori.dhhs.gov/education/products/RCRintro/>). Accessed January 18, 2007. ❖

CREC Program Updates

There is a new, more streamlined look to the CREC webpage.

The website still provides you, the investigator, with “everything you ever needed to know” about the CREC Program, the training opportunities available and how to access them. Now, by just a **click of a mouse**, you can find exactly what you need from a menu.

Need to be “Core” certified in the CREC Program?

Click [Entering the CREC Program \(Initial certification\)](#): This section provides pertinent information on how to register for the CITI Basic Course, the criteria required for successful completion, account set-up, and the link to the CITI Online Education Program.

Need to obtain continuing CREC and prefer online web options?

Click [Online Continuing CREC \(Recertification\)](#): Here you'll find a list of the CITI courses available for Continuing CREC as well as the online training options provided by the Office of Research Compliance. Please notice we have taken out some “old” and brought in some “new” web streamed videos and quizzes just for you.

Another item of interest: The Collaborative Institutional Training Initiative Program (CITI) also offers the Responsible Conduct of Research (RCR) course. Please be aware that this training option

*is **not eligible for Continuing CREC**. More information on the CITI RCR course and other RCR training options can be found in the article above.*

Need to obtain continuing CREC and prefer a more conventional training format?

Click [Other Continuing CREC \(Recertification\)](#): Our Research Seminar Series has proven to be a very successful format, providing training in a variety of research related topics. Many of the presentations offered focus on the ethical conduct of human subjects research and qualify for CRECs.

The calendar page is updated continuously offering the latest available information on best practices and covering all types of research at Case and the affiliated hospitals. The site provides the date and time of the event, a title and brief description of what will be covered, how many CRECs are allotted, the location, and once again with a click of a mouse, easy registration.

So check out our new look at <http://ora.ra.cwru.edu/research/orc/crec/index.cfm>.

We welcome your feedback. Send an email to tracy.wilson-holden@case.edu, and let us know what you think! ❖

RCR Instructional Areas In Depth: Peer Review/Collaborative Science

Peer Review

The assessment of articles and grant applications to determine their worthiness for publication or funding generally includes an in depth review of the science by a researcher who specializes in a similar area.

With the privilege of being asked to review another scientist's work, however, comes a set of responsibilities and ethical challenges.

- *How quickly must the review happen?*
- *What if your previous publications will be discounted by the results?*
- *Can you show the manuscript or application to others?*
- *What if the information clearly shows your current path of research will not work?*
- *What if there is a really good idea in the proposal that you would like to pursue?*

Michael Kalichman, Director of the Research Ethics Program at the University of California, San Diego, wrote that peer reviewers should follow these guidelines:

- Be sure you can thoroughly review the submission in a timely fashion before agreeing.
- Only review submissions when you possess the scientific knowledge and skill to assess the study appropriately.
- Be objective in the review. If a personal or professional conflict of interest or bias exists, the reviewer should decline to participate.
- Treat all unpublished work you are reviewing as confidential. It is inappropriate to share the paper with colleagues or students unless permission is granted by the editor or funding agency.
- Should you determine, through the review, that it is prudent to discontinue a current line of research, it is acceptable to do so. It is recommended that you inform the editor or agency, however.
- On the other hand, peer reviewers should keep in mind that the DHHS Office of Research Integrity considers "the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review" to constitute **plagiarism**.

Further guidance and interactive case studies of challenging ethical issues in peer review can be found at the following sites:

http://ccnmtl.columbia.edu/projects/rcr/rcr_authorship/

http://ori.dhhs.gov/education/products/niu_peerreview/index.htm

<https://www.citiprogram.org/default.asp> ❖

Collaborative Science

Academic institutions and funding agencies have recently been encouraging researchers to collaborate on projects with faculty members from other departments, other institutions, and even with industry partners. This multidisciplinary approach capitalizes on the unique skills of individual researchers working together to collectively advance science.

While the overall benefits of the collaboration can be great, the potential exists for disagreements to arise later if researchers "hit the ground running" when a partnership is suggested.

Multidisciplinary Research. Disparate scientific fields may have differing views when it comes to the use of technical jargon, presentation style, standards for designating authorship, and expected timelines for completion of projects, to name a few. In addition, typically only one researcher will be designated as the principal investigator.

Multi-institutional Research. In general, one institution will need to be designated as the primary site for the research. This could potentially have implications for the amount of funding each institution receives. In addition, if the project is successful there may be media recognition for the institutions and investigators.

Partnering with Industry. Industrial/academic partnerships can be very rewarding for both parties. The collaboration can provide industry with access to some of the world's academic experts. The academics, in return, receive funding and support that may not otherwise be accessible. On the other hand, individuals coming from these backgrounds may have differing opinions about when and if to publish results and ownership of ideas and processes.

Communication is key. Regardless of the type of collaborative science, the best way to avoid problems during the project is to ensure that all parties have a clear view of what is expected. See the "Research Prenup??" panel for more ideas on what to discuss with potential collaborators.

Additional resources:

http://ori.dhhs.gov/education/products/columbia_wbt/rcr_science/index.html

http://ori.dhhs.gov/education/products/niu_collabresearch/

<https://www.citiprogram.org/default.asp> ❖

Research Prenup??

What will you do when the honeymoon is over and the visions of you and your collaborator gracing the front cover of Science or Nature have given way to the daily frustration of trying to get the guy to return your phone call or send you the results of the experiment he was supposed to do last month...



Advanced planning and discussion, as well as a **written agreement between researchers**, can eliminate much of the discord that may occur once a project is underway. Examples of points to discuss and clarify with your collaborators at an early stage are listed below.

- What are the goals and anticipated outcomes from the project?
- What are the expected contributions of each collaborator?
- How will decisions be made to alter the path of the research?
- How will authorship be handled?
- How will credit be given to each collaborating institution?
- Who will present research results at meetings?
- How will you handle intellectual property and patent applications?
- When will the project be over?
- Who will own the data and how will it be stored after the project?

For more information about pre-nup agreements between scientists, the Office of Research Integrity (ORI) website has the following link: http://ori.dhhs.gov/education/preempt_discord.shtml