



## IRB Review: What is 45 CFR 46.101(b), Category 4?

There are six categories of research activities involving human subjects that may be **exempt** from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46) which are designated for projects that involve minimal risks where there are no known physical, emotional, psychological risk involved in the proposed study. These studies may not begin until the investigator has received notification that the research qualified for exemption. Be mindful that exemption waives only the need for full IRB review and does not negate the need for the consent of subjects where applicable. In particular, **category #4** is research involving the collection or study of existing archival data, documents, (publicly available or recorded to prevent identity of subjects, anonymous data). Examples of this activity may include:

- Research on publicly available data where the data must be easily accessible **to all**, not just to a limited few.
- A research project involving a retrospective chart review examining pattern of symptoms for X disease.
- A study analyzing data in an already existing de-identified database to evaluate the relationship between BMI and healthy behaviors.
- An anonymous questionnaire/survey that does not involve sensitive topics.
- **ALL** aspects of research activities must involve EXISTING data, specimens, and records. A combination of prospective and retrospective elements (i.e. comparison research study) will not qualify as Exempt.

The scenarios below are non-research activities and may be conducted without completing an IRB application:

- Course-related activities designed specifically for educational/teaching purposes, where data is collected from human subjects as part of a class exercise/assignment. The individual data that will be collected and the project product must not be disseminated outside the institution.
- Searches of existing literature/analysis of aggregate or public data that cannot be linked to a living individual (e.g. data sets available on the web that do not require any sort of confidentiality agreement, census data in public libraries, published school test scores)
- Interviews of individuals where questions focus on things not on people (e.g. questions about policies, general facts about an organization or business). The existing archival data and/or documents could be the results of previously completed questionnaires or surveys that the investigator wishes to publish or present after all identification of the participant is removed. This information must have been previously collected and not prospectively, or ongoing, collection of results.
- Quality assurance activities/evaluation projects designed for self-improvement or program evaluation. (*NOTE: IRB review is needed if your academic program or course curricula requires project submission to the IRB.*)

Remember, even when research is exempt from regulatory requirements investigators still have a responsibility to adhere to the underlying ethical principles for research involving human subjects.

**OCTOBER, 2009**

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## FDA Guidance Cautions Researchers on Delegation of Tasks

Clinical investigators are advised to be especially careful when delegating clinical trial responsibilities, the FDA says in a final guidance that strengthens the language in a 2007 draft. While much of the draft and final guidance language is similar, the FDA is taking a harder line on the relationships between investigators and subinvestigators in multisite trials in the final version, which was posted on the FDA website last week. See final guidance at <http://www.fdanews.com/ext/files/UCM187772.pdf>

## NIH's Proposed Rule Making on Conflict-of-Interest Regulations

The NIH published an Advance Notice of Proposed Rulemaking in May's Federal Register on financial conflict of interest in research. This proposal affects every institution seeking NIH funding. It calls for comments on whether the agency should expand the scope of the regulation. In particular, the definition of Significant Financial Interest; identification and management of conflicts by institutions; assuring institutional compliance; requiring institutions to provide additional information to the PHS; and broadening the regulations to address institutional conflicts of interest. See NIH Guide notice NOT-OD-09-099

## Medical Journals to Publish New Conflict Rules

The International Committee of Medical Journal Editors (ICMJE) has issued a revised Uniform Disclosure Form for Potential Conflicts of Interest. Major biomedical journals such as JAMA, NEJM, Lancet, and Annals of Internal Medicine to name a few, have adopted the ICMJE policy for the disclosure of financial relationships by authors of submitted papers. *The Wall Street Journal* reported that at least a dozen journals have agreed to use the new form, to be phased in over the next few months. The new form to be completed by authors is intended to establish consistency in the disclosure process, which is not currently uniform across journals. "Although efforts are underway to establish uniform reporting systems, there is currently no uniform vehicle for the disclosure of financial associations," said ICMJE leaders in an editorial. The new standardized form, they said, will lessen confusion.

There are four types of information requested on the ICMJE uniform disclosure form:

- Associations at any time with commercial entities that provided support for the work reported in the paper.
- Associations within three years of submission with commercial entities that could be viewed as having an interest in the general paper topic.
- Any similar financial associations involving an author's spouse or children younger than 18
- Relevant non-financial associations such as a researcher who also serves as the unpaid chairman of an advocacy group for a disease.

The form may be downloaded on the computer, completed, and uploaded to the journal Web sites upon submission of a manuscript. The form is posted on the ICMJE Web site at:

[www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) including instructions to help authors complete the information.

A sample completed form is also available to assist authors with the new policy:

[www.icmje.org/sample\\_disclosure.pdf](http://www.icmje.org/sample_disclosure.pdf)

**Primary source:** New England Journal of Medicine

Source reference: [Drazen J, et al "Uniform format for disclosure of competing interests in ICMJE journals" \*N Engl J Med\* 2009; DOI: 10.1056/NEJMe0909052.](#)

## IACUC Announcements...

### \* \* Random Source Animals \* \*

Keep in mind as your planning new research activities that the Institutional Animal Care and Use Program does not procure dogs or cats (alive or dead) from random source (*acquired from a pound, shelter, auction, or veterinarian*) or Class B<sup>2</sup> dealers unless special circumstances apply:

1. The use of these animals and/or tissues is scientifically justified **AND**
2. Approved by the IACUC.

### \* \* Instructions for using **COMMERCIALY AVAILABLE** animal tissues \* \*

A memo must be submitted to the IACUC Office from any principal investigator who wants to use **commercially purchased** (ie grocery store, slaughterhouse, Carolina Biological, etc) animal tissue. The memo should outline briefly the following:

- What is the tissue type?
- 2. Where will it be purchased?
- 3. Who will be working with the tissues (faculty, graduate students, staff)?
- 4. What type of protective equipment will be worn (ie masks, gloves, and/or lab coat)?
- 5. How will it be disposed of?
- 6. Are there any biosafety concerns?

The IACUC will continue to require a **complete animal use protocol** for cat/dog tissue (including blood) obtained from shelters or veterinarians. Protocol amendments to existing protocols will continue to be required for sharing of tissues from animals euthanized on-site (i.e., a PI culls his rodent colony and gives tissue to another PI).

## Semi Annual Inspections: Coming Soon

The time has come for the IACUC to conduct required semi annual inspections. These inspections will occur **November 23-24, 2009**. This process involves an examination of all areas where animals are housed and used for experiments.

✓ A Laboratory Self Evaluation Checklist is located on the IACUC website and should be used to facilitate your preparation.

<http://www.southalabama.edu/researchcompliance/pdf/inspectprep.pdf>

Take this opportunity to discuss any animal program concerns with the site visitor. Open communication benefits the research community, and is an essential component in the semi-annual inspection process.



## Shipping Biohazardous Materials

Up until 2007 shipping bio-hazardous material may have been a confusing situation. In 2006 there was a great reckoning, or technically harmonization, between the federal regulations. Biological materials are now placed in one of two groups for shipping purposes. The first is a "hazmat" shipping group (Category A) that includes materials suspected of actually being harmful. Every biological shipment that isn't in Category A is placed into Category B. While both shipping categories are considered "infectious substances" they are broad, and divided so that the choice of which category to ship under can actually be determined by the shipper instead of flipping through the regulations.

Here is the low down. There is a list of Category A substances provided by the International Air Transportation Association (IATA) following international regulations for shipping items by air. There are also a set of regulations for shipping items by land that are covered by the Department of Transportation (DOT). IATA regulations are more stringent than DOT so following IATA rules means you are covered on all bases (really, DOT is advantageous only when you wish to ship more than 50ml/50g of Category A or 4L/4kg of Category B).

If you have a substance that you are shipping that is "capable of causing permanent disability, life-threatening, or fatal disease in otherwise healthy humans or animals." A list of these substances can be found at: [http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_EPR\\_2007\\_2cc.pdf](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2cc.pdf). If it is a Category A "Infectious substance, affecting humans," assigned UN 2814. So, if you don't have any of that and you are just shipping some other type of biological material then it is a Category B, "biological substance," assigned UN 3373.

Apart from differences that arise from what is actually on the Category A list or not, there is a very different set of training requirements for shipping from each category. Category A is a full and intensive training course which requires knowledge testing at the conclusion. As for Category B, it is simply requested that you view Information about proper packaging, promise to be ethical and not ship something that you might suspect could be harmful.

The Office of Research Compliance is working to develop in-house educational materials on this topic mater. Information has been posted to review if you plan to ship a Category B substance available on the Biosafety website at:

<http://www.southalabama.edu/researchcompliance/biosafety.html>

After having obtained certification for Category A shipping from the Alabama Department of Health, we have the training module in place and are working with the Online Learning Lab to develop a online certification exam for those shippers that require training documentation.

Infectious Substance  
Affecting Humans  
UN 2814



Fill in the volume of the infectious agent.

Volume of infectious material:  ml, or g

UN 4G/Class 6.2/07  
USA/+AA4447

MS130 07w0017

## BIOSAFETY Reminders.....



### The Do's and Dont's of Biomedical Waste Storage and Disposal

Over the last couple of months the Office of Research Compliance has been monitoring and providing guidance on biomedical waste storage and disposal. The majority of research laboratories are making great efforts to comply with these institutional guidelines (<http://www.southalabama.edu/researchcompliance/biosafety.html>, "USA Procedures and Policies"). There are, however, a couple of pointers and clarifications that we would like to reiterate:

#1: You can place more plastic (non-sharps) and paper items into a red biohazard bag than you can a 5 gallon gray bucket. The buckets are expensive, so we ask that you keep the gray buckets reserved for non-regulated sharps such as hard plastic pipettes, sharp tips, or anything that might poke through a bag. Otherwise, regulated sharps to include razor blades, syringes with/without needles, scalpels, lancets must be placed in an FDA approved sharps container.

#2: Full waste containers cannot stay in your lab over seven days (Alabama Department of Environmental Management Land Division—Solid Waste Program Regulations, [Chapter 335-13-7, Medical Waste](#)). Make sure to take all that you used during the week down **before** Monday or Thursday morning when pick up is scheduled.

\*Tip! If you have an odd number of buckets, simply line a red tub with a bio-hazard bag, place your identifying sticker on the bucket and leave the liner untied. "Odds" are, someone else will come down with an odd number of buckets too that can fill up the tub.

#3: Please do not stockpile empty buckets! Take only what you will need for the week.

Questions? Contact us at 460-6509. Make sure to download a flow chart to post in your lab: <http://www.southalabama.edu/researchcompliance/biosafety.html>

### Have You Added Personnel to Your Lab? Changed Cell Lines, Procedures or Investigator(s)?

Any changes in the conduct of your research involving biologicals or recombinant DNA work must be documented on an Amendment form. This information is routed for expedited review by administrative staff or the IBC Chair unless a significant change in the scope of work is proposed. So, as you bring new employees/students on board, others leave, or adjustments need to be made to your approved registration, please be remindful to complete an amendment and submit to Research Compliance, CSAB 134 or email [ahenry@southal.edu](mailto:ahenry@southal.edu) . The link to a downloadable version can be found here: <http://www.southalabama.edu/researchcompliance/biosafety.html>.



## NSF Announces RCR Training Mandate

Beginning January 2010, as required of the America COMPETES Act Section 7009, the University must have an institutional plan in place to provide training in the responsible conduct of research (RCR) to any student (undergraduate or graduate) or postdoc supported with NSF funds. The Office of Research Compliance, with faculty input, is working to develop our institutional plan and will provide updated information later this Fall.

According to the NSF, the federal agency will expect grant submissions to certify that the institution has a plan in place at the time of proposal. Training plans will not be required to be included in submitted proposals, however, they are subject to review upon request at any time.

Instruction in the responsible conduct of research is considered an essential part of preparing long-term development of America's future scientists. Consequently, the University's plan for RCR instruction will extend **beyond** the NSF requirement and apply to all students and postdocs conducting research. Various alternatives to meeting these training requirements will be provided that are suitable for different programs within the institution.

The NSF's proposed implementation procedures can be found in the *Federal Register* at <http://edocket.access.gpo.gov/2009/pdf/E9-4100.pdf>. Questions regarding NSF requirements should be directed to your grant coordinator or to Dusty Layton, Director, Research Compliance.

### \* \* \* Noteworthy News \* \* \*

The DHHS Office of Research Integrity Posts Lab Management 'Video Vignettes' Link at:  
<http://learning.ucdavis.edu/LabAct>

A recent Boston Globe editorial concluded, "The National Institutes of Health, medical schools, journals, and professional organizations all have a role to play in making ghostwriting a clear violation of their ethical codes. Hired-gun wordsmiths have no place in the important process of physicians and patients informing themselves about new treatments."  
<http://lists.aamc.org/t/29011/190525/1083/0/>

DHHS Office of Research Integrity Newsletter, September 2009.  
[http://ori.dhhs.gov/documents/newsletters/vol17\\_no4.pdf](http://ori.dhhs.gov/documents/newsletters/vol17_no4.pdf)

The Business of Mentoring – RCR Online Module developed by Columbia University available at:  
[http://ori.dhhs.gov/education/products/columbia\\_wbt/rcr\\_mentoring/introduction/index.html](http://ori.dhhs.gov/education/products/columbia_wbt/rcr_mentoring/introduction/index.html)

National Institutes of Health (NIH) Director Francis S. Collins, M.D., Ph.D., announces that NIH is now accepting requests for human embryonic stem cell (hESC) lines to be approved for use in NIH-funded research. The NIH Director is also pleased to announce the members of a new working group of the Advisory Committee to the Director (ACD): the Working Group for Human Embryonic Stem Cell Eligibility Review..." The NIH Stem Cell website is located at: <http://stemcells.nih.gov/>