

HHS Releases Notice of Proposed Rulemaking

The Department of Health and Human Services (DHHS), through the Office for Human Research Protections (OHRP) and 15 other federal departments and agencies, released a Notice of Proposed Rulemaking (NPRM) on September 2, 2015, containing proposed changes to the Common Rule. DHHS' stated goal is to strengthen and modernize the Common Rule. Given the NPRM's proposal to significantly expand the scope of the Common Rule and the other extensive changes it proposes, it should be of interest to everyone involved in human subject research. DHHS has requested public comments regarding the proposed changes be submitted by December 7, 2015.

The NPRM proposes several major changes to the Common Rule, including:

- Extend the Common Rule's jurisdiction to trials conducted at U.S. institutions, regardless of the funding source of the specific clinical trial.
- Include biospecimens in the definition of a "human subject" regardless of presence of identifiable information.
- Consider use of one-time broad consent for the storage or maintenance of biospecimens.
- Additional required elements of informed consent.
- A new list of 11 specific activities that would be "excluded" from the Common Rule's requirements.
- Eight categories of research exempt from certain Common Rule requirements
- Require researchers to implement reasonable safeguards for protecting against risks to the security or integrity of biospecimens or identifiable private information.
- Require reliance on a single IRB as reviewing IRB for cooperative research.
- Eliminate continuing review for minimal risk studies.

[A copy of the NPRM and instructions on how to submit comments to DHHS can be found here.](#) The NPRM proposes many changes to the Common Rule and it would be impossible to list them all in our newsletter. As such, the HSRO is highly recommending that

researchers access the original document and familiarize themselves with the many changes being proposed. DHHS is soliciting comments on the NPRM, which are due December 7, 2015. This comment period provides everyone ample opportunity to be part of the final rulemaking process.

The HSRO intends to hold educational presentations on the changes proposed in the NPRM. In the interim, stakeholders should continue to monitor NPRM-related releases from DHHS that may have an impact on their research practices.



Where do the regulations come from?

CITI Research Ethics and Compliance Education Guidebooks

New! The [CITI Program](#) at the University of Miami now offers the following research ethics and compliance education guidebooks:

- Human Subjects Research (HSR) Guide for Social, Behavioral, and Educational Research
- Good Clinical Practice Guide
- RCR for Engineering: An Introduction to Ethics and Engineering Research
- Conflicts of Interest (COI) Guide, Second Edition
- Clinical Research Coordinator (CRC) Guide (coming soon)



The books are available for purchase through the online bookstore: www.citiprogram.org/publications
For more information on bulk orders, contact citisaless@med.miami.edu

Good News from RCQA (Research Compliance and Quality Assurance):

- 7 out of 23 audits conducted in 2015 and focused on the informed consent process only, had no significant findings. Congratulations to Drs. Benatar, Luca, Wright, Askari, Avisar, Namias and Punnen and their study teams.
- Clinical Trials Disclosure: From the records reviewed in clinicaltrials.gov, non-compliant records decreased from 64% in December 2013 to 15% in June 2015. Congratulations to UM researchers and thank you for your fast responses to queries.
- Corrective and Preventative Action (CAPA) Program: Since the start of the university-wide CAPA program in September 2014, 2 CAPA plans have been successfully closed (all corrective and preventative actions implemented).
- During the first semester of 2015, over 110 staff and faculty members attended research related compliance training conducted by RCQA.

eProst Mentoring

Do you have questions related to IRB forms, policies/requirements, or review procedures? If yes, please sign up via ULearn to attend a help session intended to provide assistance to anyone who needs help preparing an IRB submission. You are encouraged to bring all of the necessary documentation on a jump drive so that an HSRO staff member may assist you with completing the submission. Sessions are available on alternate Thursdays and prior registration via ULearn is required as space is limited.

2015 HSR Community Conference — *Charting the Course for Quality*



More than 320 members of the South Florida research community gathered on September 10 and 11 for the **2015 Human Subject Research Community Conference** at the

Shalala Student Center on the University of Miami's Coral Gables Campus. The event offered researchers in every facet of a human research protection program a unique learning and networking opportunity.

Presentations were offered by institutional leadership, representatives from federal agencies (National Institutes of Health, U.S. Food and Drug Administration and the Office of Human Research Protection under the U.S. Department of Health & Human Services), national and international speakers.

Community partners included representatives from area medical and academic institutions, including Baptist Health System, Miami Children's Research Institute, Miami Veterans Affairs Medical Center, Florida International University, Florida Atlantic University, Mount Sinai Medical Center, Carlos Albizu University and Jackson Health System.

The University of Miami's Human Research Protection Program is committed to quality and improving efficiency throughout its operations. To this end, communication and collaboration are the pillars to achieve the program's collective success. Opportunities such as this allow for industry colleagues to exchange ideas and work together on future initiatives for the protection of human subjects and the advancement of research.



Prize Drawings to Incentivize Participation in Research Studies

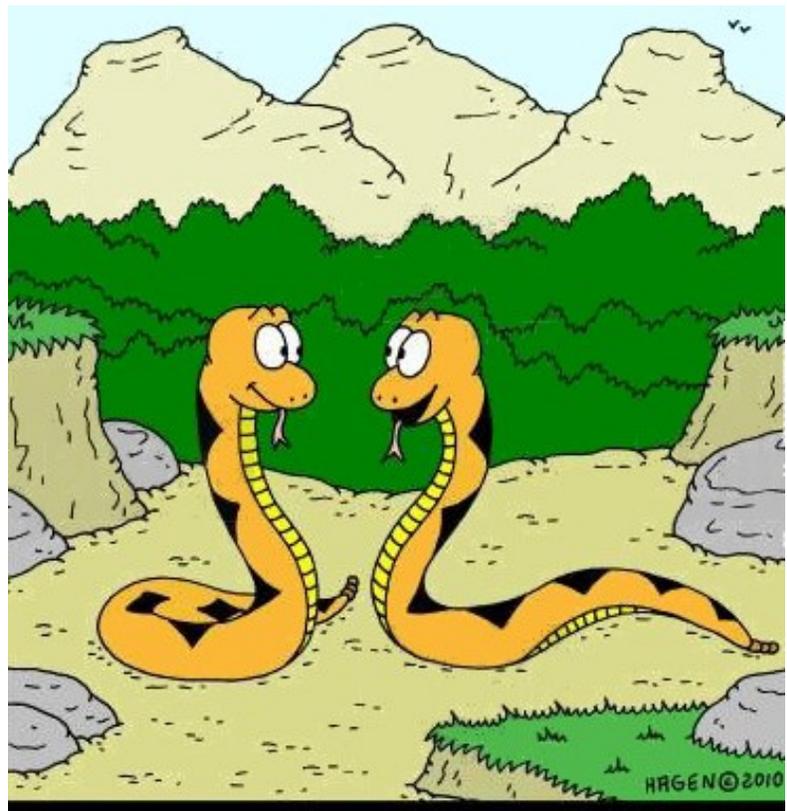
The Office of General Counsel has advised that the use of prize drawings is likely illegal as an incentive for participation in research studies; thus, this is not an option for an incentive in research at the University of Miami. Amendments in 2013 to Florida's game promotion law (849.094) made it illegal for not-for-profit institutions to run contests or sweepstakes. A separate Florida law (849.0935) enables not-for-profit institutions to run raffles if certain criteria are met, including that the raffle be open to all members of the public and not be conditioned on consideration or contribution by an individual in order to be eligible to win the prize. With respect to research studies, it appears that we would be conditioning prize eligibility by requiring participation in surveys/studies, and potentially violating other requirements of the raffle law.

Several other Florida universities have similar rules or procedures in place with respect to rewarding research participants through prize drawings:

- **University of Florida:** “[Y]ou may not use random drawings for money or prizes as incentives for participation”; “The General Counsel’s office has recommended that IRBs not approve studies that involve games of chance.” (Sources: <http://irb.ufl.edu/irb02/forms-templates-guidelines/doform.html>; <http://irb.ufl.edu/irb02/forms-templates-guidelines/games-of-chancelottery-as-compensation.html>)
- **University of Central Florida:** “Use of a lottery presents additional ethical concerns.... Payment of large prizes to a very small number of participants violates this balance of subject participation and compensation, creating serious concerns about undue inducements to participation. The only time the IRB will consider allowing a lottery is if the research is specifically studying lotteries” (Source: http://www.research.ucf.edu/compliance/IRB/Investigators/PI_Manual/appendices_faq.html)

- **Florida Atlantic University:** “FAU researchers are not able to use lotteries for prizes or cash as incentives for research participants. Instead, consider incentives that can be given to every participant, such as a candy bar, a scratch-off lottery ticket, a Starbucks gift card, or some other nominal item.” (Source: http://www.fau.edu/research/researchint/irb_fags.php)

This will be incorporated into the UM IRBs’ guidance documents for compensation of research participants.



It's so ironic: I finally win a prize at a raffle and it has to be a free pedicure!