NIH Tightens Regulations on Final Conflict of Interest

NIH just issued its final Conflict of Interest Rules which will impact all funded research at USC. The Final COI Rules tighten regulations but have limited public disclosure of financial conflicts.

Federal Register Notice and Summary of Major Changes:
http://grants.nih.gov/grants/policy/coi/

Clarification on Informed Consent Requirements

- **We heard you! TIPS for the Short Form CONSENT Process**

There is a method for subjects who do not understand English/Spanish to provide consent by use of the Short Form Process. In this process, a Short Form is provided in a language understood by the subject while a translator orally translates the study consent in the subject’s language. A Short Form lists all the elements about which subjects must be informed prior to participation.

The Short Form process must be documented with:

- Subject signature on the Short Form
- Witness signature on the Short Form and Study Consent
- Signature from the person obtaining consent on the Study Consent
- Translator signature is not necessary unless the translator is also the witness to the consent process (the consent template will be updated soon)
- Document the use of a translator in the subject’s chart

Short forms are available in eleven languages on the Health Sciences IRB webpage. Click on one of the languages for a direct link: **English; Spanish; Korean; Chinese; Thai; Vietnamese; Russian; Farsi; Armenian; French; Tagalog**

- **More Informed Consent Tips:**

  - Witness signatures are only required if the Short Form Process is used (see above)
Dates of subject signature and that of person obtaining consent do not have to match. If a subject signs the consent later or at home, that is acceptable.

No study procedures may be conducted before obtaining consent from the subject, a legally authorized representative (LAR) or a parent.

If a subject signs the consent on the same day that study participation begins, remember to document in the subject’s study files or medical records that consent was obtained prior to participation in the research.

Signed consents can be faxed or mailed back to the study by subjects or LARs or parents. If faxed, the original signed consent or parental permission is not necessary.

**USC Students Conducting Research Abroad Must Submit Proposals to the IRB... Graduation May be Impacted**

If you plan to conduct Human Subjects research outside of the U.S., you must submit your proposal to a USC Institutional Review Board (IRB) before you initiate any research activities. Failure to follow USC institutional policies regarding Human Subjects research can affect graduation status. For more information check the OPRS/IRB websites or contact the IRB student mentor.

OPRS/IRB websites: [www.usc.edu/oprs/](http://www.usc.edu/oprs/)
IRB Student Mentor: (213) 821-4219 / irbgara@usc.edu
Health Sciences Campus IRB: (323) 223-2340 / irb@usc.edu
University Park Campus IRB: (213) 821-5272 / upirb@usc.edu

**Research Oversight Committee (ROC) and Drug Inventory Forms Discontinued**

The Research Oversight Committee and Drug Inventory Forms are no longer used at the Health Sciences Campus. Please do not include these forms in your IRB applications.

**Articles of Interest**

- **NIH Finalizes Conflict of Interest Rules** *(Nature News Aug 23, 2011)*

  [http://online.wsj.com/article_email/SB10001424052702303627104576411850666582080-IMyQjAxMhEwMDEwMDEwMDAyWj.html?mod=wsj_share_email_bot#sharePrintMode](http://online.wsj.com/article_email/SB10001424052702303627104576411850666582080-IMyQjAxMhEwMDEwMDEwMDAyWj.html?mod=wsj_share_email_bot#sharePrintMode)

- **Useless Studies, Real Harm** *(The New York Times July 29, 2011)*


To Subscribe/Unsubscribe
To receive the USC Human Subjects Newsletter, please send an email request to oprs@usc.edu
To unsubscribe from our list send an email to oprs@usc.edu, specify the email address to be unsubscribed with consideration to accounts that are redirected.

Archives
To view archives of previous USC Human Subjects Newsletters, please visit: www.usc.edu/oprs/news/listserv