# IRB Newsletter

**University of Florida Institutional Review Boards, [http://irb.ufl.edu/](http://irb.ufl.edu/)**

**IRB-01: (352) 273-9600**

**IRB-02: (352) 392-0433**

## Upcoming Educational Opportunities

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<tr>
<th>Date</th>
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<tr>
<td>03/11/2020</td>
<td>12:00PM</td>
<td>IRB Brown Bag: Informed Consent Training</td>
<td>Shepard Broad Building Room 104</td>
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The IRB Education Program wants to hear from you. Please send in any requests you have for an upcoming Brown Bag topic to arancat08@ufl.edu.

## Media Organizations – Researcher Involvement

FDA has a [guidance on the interaction between researchers and the media](http://irb.ufl.edu/). The guideline is meant to avoid any possible coercion to future potential study subjects and to discourage the release of research data that has not been scientifically scrutinized by the research community.

On the UF IRB’s website you’ll find the [Media Organizations – Researcher Involvement Guideline](http://irb.ufl.edu/) that is consistent with those principles and has been agreed upon by the UF IRB, the UF General Counsel’s Office, and the UFHealth Privacy Office.

## Reminders

### Advertising and Recruiting for Research Subjects

Federal regulations (both DHHS and FDA) require that IRBs make sure that the selection of subjects for a study is equitable. Each protocol submitted to the UF IRB for review must explain how subjects will be identified and recruited for the study. All proposed recruiting tools associated with a recruitment plan must be reviewed and approved by the UF IRB prior to use. For more information, see the [Advertising and Recruiting for Research Subjects Guideline](http://irb.ufl.edu/).

### Revisions to your Research

Federal regulations require that changes to IRB approved research may not occur without prior IRB review and approval, “no matter how minor” unless a change is required to eliminate an apparent immediate hazard to subjects. If the change was made to eliminate an apparent immediate hazard to subjects, it must be submitted to the UF IRB promptly for review. “Prompt” reporting at the University of Florida means as soon as possible, but not later than five (5) working days. When submitting a revision in myIRB, please clearly indicate what the revision is and why this revision is being implemented. For more information, see the [Changes to IRB Approved Research Protocols Guideline](http://irb.ufl.edu/).

### Data Safety Monitoring

As a reminder, if your study has a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Committee (DSMC) you are required to submit those reports to the IRB. You can submit reports to the IRB as you receive them as a Reportable Event in myIRB. You can find out how to submit a new reportable event in myIRB in the [Researcher Manual](http://irb.ufl.edu/) on page 32. Note: Continuing Reviews also require you to submit a copy of the most recent DSMB/DSMC report or correspondence.
### Standardized Text for Informed Consent Forms

As a reminder, if your research includes or utilizes any of the following:

- Genetic Testing (GINA)
- Genetic Data For Future Research (GWAS)
- Certificates of Confidentiality
- Clinicaltrials.gov
- Magnetic Resonance Imaging
- Placebo/Randomization
- Storage of Tissue

Your informed consent form must include the corresponding standardize text. A complete list of standardized text can be found on the IRB website on the page titled Standardized Text for Informed Consent Forms.

### Good Clinical Practice Training

Good Clinical Practice (GCP) describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. **Effective January 1st 2017,** NIH requires that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in GCP.

Although GCP is not an IRB required training, the Institution has determined that UF IRBs will confirm UF researchers’ compliance with this requirement. For more information about training requirements you can reference the Required Training for UF IRBs page on our website and you can also view our GCP Investigator Guideline.