Acceptable Recruitment Methods

Identification, initial contact, screening and recruitment of potential human subjects form the foundation of the informed consent process. The research team, the study sponsor, and the IRB share the responsibility for creating a recruitment environment that is not only effective but is also ethical and that complies with the federal regulations and guidance. Both the screening and the recruitment process should demonstrate and reflect respect for the dignity and autonomy of the potential participants by avoiding any potential undue influence and by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment and/or screening purposes.

In preparing recruitment materials the researcher should consider the purpose of the research, the setting in which the research will be conducted, and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

The following methods for recruiting subjects have been used in studies being conducted at UF and are generally acceptable. There may, however, be extenuating circumstances in which one of the methods might not be appropriate for a particular study. This is not an exhaustive list. One study may employ more than one method of recruitment. The method(s) of recruitment should be discussed within your protocol and the Recruitment myIRB Methods section of your myIRB application. All recruitment materials must also be attached to your electronic application for review.

- **Advertisements, flyers, information sheets, notices, internet and/or media postings.**
- **Direct recruitment of potential study participants.** Examples are physicians talking to their own clinic patients about the study, and contact between the study team and potential subjects in person or by phone.
- **Recruitment letters.** Ideally, the recruitment letter should come from someone or some agency or clinic known to the prospective participant. Preferably, the letter would ask the person to call for additional information or if interested in participating in the study; or return a post card or send an e-mail.
- **Referrals.**
- **Another IRB-approved screening and/or recruitment protocol/recruitment database.** This protocol describes how potential research participants will be asked for and will give their formal consent for future contact. Investigators contact these potential subjects about particular studies in accord with their protocol and the (typically signed) consent of the prospective subject. In many cases, prospective participants may have given permission to be contacted for future studies by means of a check-off box in a previous banking/registry consent form.
- **Review of medical records to identify potential research participants.**
- **Review of publicly available records.**

Unacceptable Recruitment Methods

- **Cold calling.** An unrelated party (no previous clinical or research relationship) is initiating telephone calls based on knowledge of confidential information.
- **UF listservs.** UF listservs cannot be used for recruitment purposes. Please refer to the policy at [https://ufhealth.org/health-science-center/communications-and-listservs](https://ufhealth.org/health-science-center/communications-and-listservs) for more information.
- **Recruitment from previous research studies where subjects have NOT agreed/consented to be contacted for future research (You may recruit for two separate protocols simultaneously, but you cannot use personal information collected for one study to recruit for another protocol later without formal subject agreement/consent).**
- **Payment from research participants.**
- **Compensation for participation in the form of a coupon for a discount on the test article to be...**
used after the product has been approved for marketing.

- **Finder’s fees/ bonus payments.** Payments in exchange for referrals of potential participants or designed to accelerate recruitment.

### Retrospective (Medical) Chart Reviews: Case Reports or IRB Review?

The mission of the IRB is to protect the rights and welfare of human research subjects. The Federal Policy for the Protection of Human Subjects (45 CFR 46.102(d)) defines research as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. Retrospective (medical) chart reviews are considered research when they attempt to answer a research question. These chart reviews include a “systematic investigation” that usually begins with a hypothesis. The process of “testing and evaluating” the data that is generated through the retrospective chart review is what defines this activity as research. Therefore, retrospective chart reviews that incorporate data collection and data analysis to answer a research question must undergo IRB review. Many of these research projects can be approved without the informed consent of the subjects.

In general, the review of medical records for publication or “case reports” of typically three or fewer patients is **NOT** considered human-subject research and does **NOT** typically require IRB review and approval because case reporting on a small series of patients does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systemically for publication or presentation.

When larger series of patients are being reported, investigators usually begin to ask specific research questions and formal systemic collection of data occurs, moving these activities closer to prospectively designed research. The boundaries between case reporting and formal medical records review research may be unclear for a series of one’s own patients. Researchers are advised to consult with the IRB or submit larger case series reports for IRB review when uncertainty exists about whether formal and systematic collection of human subject research is occurring.

### IRB Education Opportunities

~ *February Brown Bag Series* ~

Broad Building, Room 104  
Noon – 1:30 p.m.  
February 11, 2015

“Deviations, Waivers, and SmartForms, Oh My!”  
By  
Renée Collins, HIPAA Coordinator, IRBs;  
Kim Foli, QA/QI Coordinator, IRBs;  
And  
Tiffany Danielle Pineda,  
Education Coordinator, IRBs  
University of Florida

**Objectives:**

- To understand the different review types of studies  
- To understand the different types of Waivers and when they are needed  
- To understand the different types of audits available through the IRB  
- To understand the different forms of deviations  
- To understand the different types of non-compliance  
- To become familiar with the different myIRB terminology and the information available in the myIRB User Manual  
- To become familiar with common IRB submission mistakes

**RSVP:** Tiffany Danielle Pineda  
tiffany.danielle@ufl.edu

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**Banking Protocol Reminder**

Please track **ALL** acquisitions and release of data and/or specimens for reporting to IRB-01 at continuing review.