Introduction to the myIRB Platform for Social and Behavioral Science Researchers

Introduction

Several years ago, the University of Florida implemented an online system for submitting and processing proposals for human-subjects research, called myIRB. Created with the assistance of the developer, Click Commerce, myIRB is a web-based, interactive package of “SmartForms” that provides paths for submission of new studies, revisions, and continuing reviews.

The University of Florida has three IRBs (along with a fourth, commercial IRB called Western IRB). The biomedical and health IRB01 adopted myIRB in stages, starting with exempt protocols, followed by expedited and then recently full-board studies. IRB02 (the social and behavioral science IRB) and IRB03 (Jacksonville) are now completing the phased adoption (or “roll-out,” as it’s called) of myIRB.

During the past year, we have been working with the IRB-01 myIRB functional team in an effort to assure that the IRB02 “path” will be appropriate for social, behavioral and educational science research, and comprehensible for UF’s IRB02 researchers, while compatible with the overall regulatory requirements common to all IRBs. Last October, we went “live” with optional submission of exempt protocols. As of May 1, 2016, submission of all new studies via myIRB is mandatory. Revisions and continuing review of studies approved under the legacy paper system will continue for now to be reviewed “offline.”

What’s New?

**Online versus paper.** The online system is web-based, which has many advantages for both the IRB and researchers, including more efficient workflow and better tracking of studies as they move through the review process (so, for example, you’ll be able to check on the status of your study on your own “home page”). All study materials remain electronic during submission, review, revisions when needed, and final approval.

**Free-text versus check-box.** The paper traditions in IRB01 and IRB02 evolved quite differently, with IRB01 adopting a largely Q&A, checkbox format, while IRB02 adopting a more free-text, “guided” narrative format. The myIRB system is closer to the former, although researchers often (may) respond with text at various points. UF has seen a growing need to get metrics data from all of the research being done at the university, and the SmartForms of myIRB can more readily be queried for various reporting
requirements. Still, the core of the IRB02 submission – description of the purpose and methods of the research – is provided in free-text, as the “study protocol.”

**Explicit versus implicit information.** One important feature and advantage of the myIRB system is the explicit nature of the description of study details that have possible regulatory implications. For example, the paper system had no explicit request to confirm that 1) potentially vulnerable subjects are *not* being recruited, 2) that no international sites are being targeted, or 3) that no protected health information is being accessed. We have relied on researchers’ protocol narratives to raise these concerns when appropriate, and a large portion of our feedback to researchers in preliminary reviews has been due to a lack of clarity on one or more of these concerns.

In contrast, myIRB explicitly requests the full range of needed information. The result is that for many social and behavioral science studies, you’ll be explicitly indicating that something is not the case or irrelevant. On the other hand, as a conditional-branching platform, some SmartForms which are irrelevant for your study are never presented. So from a broad perspective, the system remains very efficient for the researcher to work through. At the outset, it may make the online system seem more cumbersome than our paper system for study submission, but with a little practice the system will seem efficient and thorough.

### Preparing to use myIRB

Before you can create and submit a study via myIRB, you’ll need to do the following:

**Have computer access to myIRB.** If you will be using a computer outside of the Health Science Center, as most of you will, the Cisco AnyConnect VPN will need to be installed and running on your machine, and *connected* to either the Health Science Center (HSC) or Gatorlink systems. This connection also allows access to MyIRB off campus through your personal computer or tablet. (Many of you will already have the VPN software on your computers, as it’s the same system used by the UF libraries and elsewhere.)

You can obtain and download the AnyConnect client software from the Gatorlink Anyconnect VPN Service. For UF-managed machines, you’ll need your administrator to install and configure the VPN client.

**Register with myIRB.** To access the system as an investigator and begin the process of creating a study submission, you need to register with myIRB as a researcher. It may take several days for the application to be processed, so be sure to register as soon as possible.
**Do the Required Training for Researchers.** As of July 1, 2016, researcher training is being certified within myIRB, and you won’t be able to create a study submission until that happens. [Researcher training and certification](#) can be accomplished either through the NIH Extramural Training course, or the CITI basic training.

*The auto-check for training will be specific to which IRB the study is directed;* assuming that’s IRB02, you’ll need certification for either the [CITI basic course](#), OR the [NIH Extramural course](#). Unless you direct a study to IRB01, you will **NOT** need the HIPAA training, nor the IRB01 “Local” Training.

**Note** that neither the NSF “Responsible Conduct” course (which is more addressed to research integrity than human subjects protections), nor [the CITI Behavioral/Social Science course or modules](#) (Group 3 in the CITI listings), will satisfy the training requirement. Only NIH course or CITI Group 1, IRB-01 Mandatory Training – BioMed will apply. Detailed instructions on “navigating” to the appropriate CITI course are provided on our website.

We know that the title of the required CITI course is a bit awkward for IRB02, referring both to IRB01 and “biomed” training, and the examples are drawn largely from health and biomedical work, rather than social and behavioral (See the Cheat Sheet, page 5 in particular), but the content is appropriate for all human-subjects research (after all, the regulations are the same, and the commission that produced the Belmont Report was charged with the “Protection of Human Subjects for Biomedical and Behavioral Research”). Worth remembering too that many researchers have studies under both IRBs.

**Read about using myIRB.** Read at least the first two sections (Getting Started and New Studies) of the [myIRB Electronic Submission Researcher Manual](#). This explains in broad terms how to access myIRB, create a study, navigate the SmartForms, and submit it to the IRB.

**Creating a Study with myIRB**

Between the [Researcher Manual](#) and hands-on use with the system, you should be able to navigate through the creation and submission of a study. But here are some tips, reminders, and suggestions that should facilitate that first encounter:

**Prepare your materials before creating the study.** Although much of the study submission takes the form of either forced-choice selections or brief text responses to questions, you’ll still need to have on hand all the documents, in electronic form, that are likely to be needed for submission. **Even for exempt protocols, these materials may include 1)**
informed consent and assent documents, 2) any fliers, emails or (social) media ads to be used for recruitment, and 3) other supporting documents that might need to be provided.

Along with those materials, it would be helpful (at least at first) to have written what you traditionally have put in the various sections of the submission, in separate sections for uploading to various SmartForms. You will see entry requests for the purpose, the methods and procedures to be used, an evaluation of risks and benefits, and the recruitment and consent procedures, depending on the nature of your study. Even for exempt studies, for example, you’ll be asked for a detailed description of procedures.

Accessing your home page. Some confusion may occur between the “myIRB Home Page” where you land after you’ve logged in to myIRB, and your own Home Page as researcher (or other roles). On the myIRB Home Page, you’ll see a small My Home button, located in tiny print in the upper right part of the MyIRB homepage banner, linked to your home page. You’ll know you’re on the right page when you see your name in a large font size, tabs for your inbox, studies, and templates, and a “Create: New Study” on the left:

Studies awaiting action on your part (studies in pre-submission, or returned from the IRB for revision) are in the INBOX, while all studies that you’re associated with (as PI, supervisor, or other staff) appear in the Studies tab.

Study Staff Registration and agreement. Although the PI is the person submitting the protocol, and is the only one who can submit or revise studies in myIRB (unless you
designate a proxy; see below), all other study staff (i.e., co-PIs and co-investigators, research assistants and coordinators, etc.) must be registered with myIRB and will need to have agreed to participate in the study before they can be listed on your study.

When you first create a study, you’ll be asked for basic information about the study (title, brief description, study staff, and roles) and to which IRB your study is to be directed. The second form is Requested Review Type. The specific forms that are subsequently presented will depend on the choice of Board and Study Type.

Choosing a Study Type. Read through the description of the various types of studies on the IRB02 website, as well as advice on selecting Review Type on the myIRB website.

Uncertain about Exempt Status? You may already have a good sense of whether or not your research might qualify for one of the exemptions under the regulations (45 CFR 46.101(b)), but try to be “liberal” in making the call for new studies.

Studies of existing data records. Within myIRB, studies that may qualify for the “existing-data” exemption are considered a separate category of “Review Type” from other exemptions, and should be submitted as Retrospective Data / Chart Review. See the myIRB description of different Review Types for more guidance.

Expedited versus Full Board studies. Very few IRB02 studies (around 1% to 2%) are judged to be potentially greater than minimal risk, and hence needing review by the convened Board. If we deem your study to be in need of Full Board review, we will take the appropriate steps to implement that review.

Navigating the SmartForms. As you proceed, make use of the “pull-down menu” in the upper tool bar that says “Jump to:” and indicates what forms will be presented given your choices so far. On each form, take note of what sections are obligatory (marked with a red asterisk *) and which are optional (so you could proceed with submission without responding or entering any information). Together, these actions will give you a good sense of what the study submission will require.

PI Proxy. The Researcher Manual describes the process of identifying a “PI Proxy,” one other study staff who will be able to access your study in MyIRB, creating, submitting or revising it. You should consider carefully if a proxy will be needed or appropriate for you, study by study. (Other co-investigators or staff can make changes to the study submission, but the revisions can only be submitted by the PI or proxy.)

Agree to Participate. Before the “submit study” button appears, the PI and all listed study staff will need to agree to participate in this particular study, even if they’ve registered with MyIRB and have the required training certifications.
Conclusion

The transition to myIRB for IRB02 has been under development for some time, and we’ve labored over the last year to try and make the system “researcher-friendly.” But as with any complex software, it should be viewed as a work in progress, with modifications and improvements to the system being implemented on a regular basis. Send any comments or questions via email to our researcher listserv, IRB02-Investigators-L@lists.ufl.edu.