myIRB is an electronic submission system that allows Principal Investigators to submit their research proposals. All the tools you need to assist you with registration and training, the Researcher Manual, review types, technical assistance, etc. can be found in the myIRB section of the IRB-01 website at http://irb.ufl.edu/myirb.html; however below is a quick “survival guide”:

1) **What should be submitted through myIRB?**
IRB-01, IRB-02 and IRB-03 now require new study submissions in myIRB; whereas,

- **IRB-01** (medical research with/without collection of PHI involving the UF Gainesville Health Science Center (HSC) faculty, staff, students and patients in Gainesville) require **all** new NON-HUMAN, EXEMPT, EXPEDITED and FULL BOARD medical research for review; new submissions in paper are no longer accepted;

- **IRB-02** (behavioral, social, educational research; no PHI) requires study submissions for EXPEDITED and EXEMPT (including non-human subjects and existing de-identified data) review in myIRB; Greater than Minimal Risk (GMR) studies that require full Board review must still be submitted in paper; and

- **IRB-03** (medical research with/without collection of PHI involving UF HSC Jacksonville faculty, staff, students and patients) requires study submissions for EXEMPT (including non-human subjects and existing de-identified data), EXPEDITED, and RETROSPECTIVE CHART REVIEW to be submitted in myIRB; GMR studies that require full Board review will continue to be submitted according to the current process (electronic submission to IRBSubmission@jax.ufl.edu - hard copy to IRB office).

*Please ensure that you choose the correct IRB Review Committee for your proposal before submitting so that your study will not be returned to you by IRB staff.*

2) **Registration and training.** In order to use the online myIRB system all users must register and complete all required training. Users outside of the Gainesville HSC must use a secure network connection and download the VPN Client (Cisco AnyConnect) to access the system. Please refer to the myIRB Registration, myIRB Training Requirements and Accessing myIRB links for more information.

**Training note:** If you have taken the mandatory training for IRB-01, you have fulfilled the training requirements for IRB-02 and IRB-03. However, completing the training requirements...
for IRB-02 and IRB-03 does not fulfill the training requirements for IRB-01.

3) **Familiarize yourself with the system.** Please read through the [myIRB Researcher Manual](#) to learn how to create and submit a new study; add study staff; navigate through the SmartForms; respond to reviewer requested changes; submit revisions, continuing reviews/study closures, and reportable events; etc.

4) **Prepare your materials before you create your study.** Although most of the study submission prompts you to provide study-specific details on the individual SmartForms, you may still be required to upload a protocol, ICFs, advertisements, phone/email scripts, Confidentiality Agreements, etc. Also, it helps to start with your protocol (if required) because your responses to the questions on the SmartForms will be based on it.

5) **Why your submission may be returned by IRB Staff pre-review team.** As directed by the full Board, IRB-01 pre-review staff has been instructed to return submissions if the incorrect requested review type was selected; all of the appropriate “study types” were not selected; the protocol does not contain sufficient detail; an old ICF template was uploaded, incorrect attachments, etc. Please refer to the [Selecting the Requested Review Type](#) and [myIRB Acceptability Standards](#) for more information.

6) **Play in the Sandbox.** Our developers created the [Sandbox site](#) to help researchers learn to use myIRB. The site works just like the real myIRB system, but research does not actually get processed or reviewed.

7) **myIRB Technical Support.** For assistance with registration, logging in, training, etc. please contact our [myIRB Technical assistance](mailto:myirbtech-l@lists.ufl.edu).

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**8) General myIRB research related questions.** Please direct general research related questions to the following:

- **IRB-01** ~ Email [ufirb-l@lists.ufl.edu](mailto:ufirb-l@lists.ufl.edu) or call (352) 273-9600
- **IRB-02** ~ Email [IRB02-Investigators-L@lists.ufl.edu](mailto:IRB02-Investigators-L@lists.ufl.edu) or call (352) 392-9234
- **IRB-03** ~ Contact Sheila Austin, Sheila.austin@jax.ufl.edu, (407) 244-9427; or Belinda Carlton, Belinda.carlton@jax.ufl.edu, (407) 244-9746

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**NOTICE**

**To IRB Investigators and Staff:**

If you have a study approved under the [Discretionary Policy](#) (i.e. approved for longer than one year), please contact the IRB office before you begin to prepare a revision which may make your study ineligible to remain under this approval policy. Following is the list that would disqualify a study from remaining under this policy:

- The study is externally funded
- Any studies involving the VA Medical Center
- Student projects for which faculty sponsor received federal funding
- Federal sponsorship, including federal training grants
- Studies with FDA-regulated components (any drug, device, or biologic, or food or herbal being used to treat, prevent, or ameliorate a disease)
- Studies with contractual obligations or restrictions that preclude eligibility in this policy
- Studies using prisoners as subjects
- Studies using wards of the state
- Studies seeking or obtaining Certificates of Confidentiality

*Failure to do so may result in a revision that has to be withdrawn. .and resubmitted.*
LEARNING OBJECTIVES:

Upon completion of this activity, participants should be able to:

- Explain why research is regulated
- Register and learn training requirements for submitting a study to myIRB
- Distinguish between different review types and how they are submitted to myIRB
- Describe how to create a new study, effectively navigate SmartForms, and appropriately handle attachments
- State how to track progress and respond to the reviewers

For additional information, or to RSVP, contact Ivana Simic at 352-273-9604 or e-mail isimic@ufl.edu.

**myIRB CONVERSION CORNER**

1. Remember to answer question 2.0 and 2.1 on the **Legacy Paper Conversion** Smartform page to indicate what phase of the study you are currently doing, if different from the initial paper review.
2. Do not include the paper IRB# in the title of the myIRB study.
3. Remember to update all documents as clean, unstamped MS Word documents (ICFs, flyers) with the new myIRB study ID#. so they may receive new approval stamps.

*~ May Brown Bag Series ~*

**Susan A. Blair, MSJ, MBA**

UF HIPAA Privacy Officer
Office of Vice-President for Health Affairs

Broad Building, Room 104
Noon - 1:30 PM
May 11, 2016

*Objectives TBA*
Common myIRB Terminology

**Activity:** These are the actions you are able to take in myIRB. The activities available to you are determined by your role and the current state of the submission.

**Agree to Participate:** This activity replaces the signature on Addendum A. Each person on the study team *must* perform this activity including the Principal Investigator. If there are outstanding Agreements, the submission cannot be submitted.

**Assigned to IRB Meeting:** This state indicates the study has been assigned to a Meeting and Reviewers. No action is required by you when the study is in this state.

**Changes Requested by ?** This state indicates changes are necessary to your submission. The changes may be necessary based on IRB office pre-review or may be the result of a Reviewer determination.

**Hide/Show Errors:** This selection is located in the menu bar on each SmartForm page. It is used to list the required fields that still need to be completed. The study cannot be submitted if there are errors left in the study.

**In Exempt Review:** This state indicates the study has been assigned to an Exempt Reviewer. No action is required by you when the study is in this state.

**In Expedited Review:** This state indicates the study has been assigned to an Expedited Reviewer. No action is required by you when the study is in this state.

**IRB Staff Review:** This state indicates a member of the IRB staff is performing a pre-review of the submission. You may receive questions you need to respond to before it moves past this state. No action is required by you when the study is in this state.

**My Home:** This is where you will be able to access and work with your studies. This is the only location where a new study can be created. This is where your inbox is located. Your home view is determined by your current role which is located in the *orange* bar.

**PI Proxy:** This is a Co-Investigator that has similar or the same credentials as the Principal Investigator and in theory should be able to perform the same study functions/responsibilities as the Principal Investigator.

**Reportable Events:** These submission types include Serious Adverse Events, Deviations (Regulatory and Protocol), and Miscellaneous items.

**Reviewer Notes:** Specific items located on SmartForm pages that require a response. Please note in most instances this will also require a revision to the associated SmartForm question.

**Role:** This determines your authority for viewing myIRB submissions and determines the activities you will be able to execute.

**SmartForm Pages:** The individual pages of the electronic submission.

**State:** This is the current submission status. It is found in the upper left hand corner of the study workspace.

**Study Workspace:** This is the actual study which replaces the previous paper submission. It is study specific and this is where you will submit any submissions (Continuing Reviews/Closures, Reportable Events, or Revisions) specific to the study. You can also access the current state of the study or its associated submissions. The study history is available for review in the first tab. In addition, you will find approval letters and the associated stamped documents in this area.