Discretionary Policy

Since June 2015, IRB-01 has been able to approve certain minimal risk research protocols for up to 3 years. Please remember that the approval length will always be up to the discretion of the reviewer and cannot be requested by the Principal Investigator.

In order to be a candidate for up to a 3-year approval, the research must be submitted in myIRB and be determined to be no more than minimal risk by the IRB-01 Reviewer. Mandatory Exclusions to Policy include:

• The study has external funding
• 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

*It is very important that you notify the IRB BEFORE submitting a revision that will exclude your study from the Discretionary Policy. There are important steps that need to be taken prior to submitting your revision.*

What is different?

• Continuing reviews (CR) are submitted by the PI based on approval duration, thus
  o If your protocol is approved for 1 year, your CR is due each year
  o If your protocol is approved for 3 years, your CR is due every 3 years

What is the same?

• You will still receive a 90-day and 45-day reminder prior to your study’s expiration date
• You still need to submit any revisions, changes to study staff, etc. to the IRB prior to allowing those changes to occur.
• You still submit any “serious and unexpected” adverse events within 5 days of being aware of such an SAE
• You still submit any “serious or continuing” protocol or regulatory deviations within 5 days of being aware of such deviation.

How will we know if it has been approved for more than 1 year?

• Your approval letter will indicate “Discretionary Policy in Effect” under the expiration date of your protocol.
As of the June 1, 2016 IRB-01 full Board meeting, the ARE and CRC categories will be removed from the list of full Board agenda groups on all paper forms and Q3.0 of the Requested Review Type SmartForm page in myIRB.

- **CONVERSION STUDIES:** Please remember to submit this year’s continuing review report and have the PI sign and date the form.

- **INFORMED CONSENT FORMS:** Please do not make hand-written changes or cross out information on the ICF. If the information is inaccurate or soon to change, please consent the subject with the current unmarked form, and re-consent the subject after a revision is submitted and approved by the IRB to update the ICF.

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### IRB Full Board Meeting Deadlines 2016

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**Future IRB-01 Brown Bags**

Broad Building, Room 104  
Noon - 1:30 PM  
7/13/16 ~ **Stephanie Gray**  
Assistant Vice President  
Division of Sponsored Programs  
University of Florida  

8/10/16 ~ **B. Dianne Farb J.D., C.H.R.C.**  
Associate University Counsel for  
Research and Health Affairs  
University of Florida  

9/13/16 ~ **Dr. Peter Iafrate, Pharm.D.**  
IRB-01 Chair  
Assistant Director Research  
Programs and Services  
University of Florida  

*Objectives TBA*