

PSYCHOLOGY DEPT. HUMAN SUBJECTS PROCEDURES – Spring, 2016

To: Department Members

From: Department Human Subjects committee

For instructions on submitting applications to the IRB:

- <http://rgw.arizona.edu/compliance/human-subjects-protection-program/submitting-documents-irb>

To access the most recent versions of IRB forms:

- <http://rgw.arizona.edu/compliance/human-subjects-protection-program/HSPF-form/forms-index>

There are three distinct steps to submitting a new study with human subjects for approval. They occur in this order:

- 1) Review by the Psychology Human Subjects Committee (mandatory)**
- 2) Review by the University of Arizona Institutional Review Board (mandatory)**
- 3) Request to use the PSY 150A1 subject pool (necessary only if you want to draw subjects from that pool)**

Proposals to conduct research with human subjects are reviewed by one of four Institutional Review Boards (IRBs) at the U of A. The Human Subject Protection Program (HSPP) serves as the interface between the researchers and the IRBs. Forms for proposals to the IRB, guidelines for filling those out and a manual for investigators are available at <http://ocr.arizona.edu/hspp/procedures>.

The departmental Human Subjects Committee serves as an interface between investigators in Psychology and the HSPP. Our job has two components:

- 1) Review each application to determine if the scientific or scholarly validity of the project has been assessed and found to be appropriate.
- 2) Protect the department's reputation among the population of potential subjects, particularly the PSY 150A1 pool, and the general community.

The general process for submitting the 'F200: Application for Human Research, or an annual F212: Continuing Review Report is below.

- 1) Consult the IRB website for current forms: <http://ocr.arizona.edu/hspp/forms>. Do this even if you are quite experienced in preparing applications, because the forms are updated regularly.

If you are a faculty member supervising a graduate student, an undergraduate student, or a staff member who prepares an application, you must review the document prior to submission. Training in preparing the application is the responsibility of all faculty members, not only the department committee.

If you are a faculty member and have questions about how to complete your application, you may want to consult with one of the department's committee members for advice (or if you are a graduate student whose advisor is unavailable). Or, you can contact the IRB representatives directly. Every regular faculty member (and their grad students) has been matched to one committee member as a primary contact and another committee member as a secondary contact if the primary person is unavailable. Email your contact person, but realize that they may need a couple days to get back to you while juggling their other jobs.

- 2) Submit your F200 application or F212 Continuing Review Report via email with the associated documents

attached and listed in the email, to the Departmental Coordinator in room 334 in the Psychology Administration Office. Digital copies of all relevant documents are mandatory (these should be sent as an email attachment to the following email address <dschoonover@email.arizona.edu>). Please note that any page that requires signatures needs to be printed and submitted separately to the Departmental Coordinator along with the first page that states the name and project. When completed, your proposal will be logged, and if it is a new application, assigned to one of the department committee members for review. *Note that you need not worry about which member(s) of the committee will read and/or sign your proposal, simply drop it off.* Continuing Review Reports will go to the Department Head for signature. For periodic reviews, we strive for a quick turn-around of one to two days. For new applications, allow three to five weekdays for departmental review. **Please include your email address on the first page under “PI contact information”.** Please do **not** leave an application in a committee member's mailbox, or hand it to him/her in the hall: the centralized system allows us to keep track of paperwork, and ensures equitable workload among the committee members.

- 3) If the departmental reviewer(s) finds your document meets the criteria listed above, they will sign it, and return to the Departmental Coordinator, who will then ask the department head to sign and will email it to the University IRB. The Departmental Coordinator will be able to tell you when/if your form has been emailed on request.

If the departmental reviewer thinks your application can be improved with regard to the two criteria listed above, they will suggest revisions to you by email.

If you revise your application and resubmit it to the department committee, please include a brief cover letter summarizing the changes. Consult the email from the department committee member to determine how you should submit your revised application; they may suggest direct return to the committee member's mailbox, or routing through the Departmental Coordinator.

Most revisions suggested by departmental reviewers are **advisory**; the IRB makes the final decisions about proposals. It is within your prerogative as an investigator to decline suggested changes. If so, please note this in your email accompanying revised proposals. An important exception to this general principle concerns the subject population specified in your application. If you specify use of the PSY 150A1 subject pool, the Psychology Human Subjects Committee (in consultation with the Head) retains the right to deny use of that pool, if we believe that the proposed research has a significant risk of harm to individual participants in the pool, and/or degradation of the pool for future use (i.e., if your experiment might inspire fear and loathing of doing experiments in general).

After your application has been submitted to the Human Subject Protection Program office the application will be reviewed by staff and further emails may be sent seeking clarifications. The final approval letter will be sent via email with an attached PDF document.

After your project is approved:

- 1) When approved, your project will be assigned a Project Approval Number. **Keep track of this number.** You will need to provide it when requesting access to the department's human subject pool (PSY 150A1 students). You will also need it when filing consent forms.
- 2) As people participate in your study, keep track of their sex --the Periodic Review Form from the IRB will request the male/female proportion of participants. (If your project is funded by NIH, you likely know that you should also keep track of participants' racial group and whether they are Hispanic or non-Hispanic).
- 3) **At least once per semester**, gather the signed consent forms from subjects who participated in the previous month. Place these in an envelope or manila folder clearly labeled with: a) the name of the principal investigator of the project, b) the name of the advising or cooperating Psychology faculty member if the PI is not a Psychology faculty member, c) the project approval number assigned by the IRB, and d) the month and year of the consent forms. Give these to the Departmental Coordinator in the Psychology Administration Office, room 334; they will file them in the university-approved location for Psychology's consent forms (Room 312 of the building). [Some projects have a different approved location for storage of consent forms, in which case the filing system is up to you] **Filing consent forms in a timely manner is**

the responsibility of the Principal Investigator; you will not be reminded of this requirement.

4) As your project proceeds, you might want to make small changes to the approved protocol. All changes to a previously approved project must be handled by completing one of the forms available in the forms section of the IRB website as these change frequently <http://ocr.arizona.edu/hssp/forms>. There are two different forms corresponding to two types of changes:

a) **F213: This form is for changes that the IRB considers “major” changes** such as:

- Changes in the study personnel, such as departure of one undergraduate research assistant who is replaced by a different RA.
- Adding a new questionnaire to a battery of questionnaires
- Change in the amount of time required to complete the experiment.
- Change to the title of the project
- Changes in the eligibility criteria
- Changes in the total planned enrollment

F213 forms must be processed through Dale and reviewed by the Dept. IRB Committee.

b) **F215: This form is for changes that the IRB considers “minor” changes** such as fixing typos, translations to documents where the English version has already been IRB-approved, or the addition of a new funding source.

F215 forms can be submitted directly to the VPR and do not need to go through Dale or the Dept. IRB committee.

5) Change in the location of an experiment. Any change in location must also be requested from the IRB. **If** the change means moving an experiment from one building to a different building (not just a room change), this will also require pre-approval from the Psychology Human Subjects Committee. Write your letter to the IRB requesting a building change, but submit it to Dale a co-signature from the committee. Dale will then forward your letter to the IRB.

6) Sixty days prior to the expiration of your study be alert for the appearance of a request for a ‘F212: Continuing Review Report.’ In order to continue your research project the Continuing Review Report must be reapproved by the expiration date of the project. You can decide to conclude your study at this time as well. The forms are due at the HSPP 45 days prior to the expiration of your study. Please allow at least three weekdays for departmental review to allow time for the department head’s signature.

6) If there are adverse reactions to the study protocol, those must be reported.