Department of Linguistics, University of Arizona

Guidelines and Tips on How to Get Permission to do Research with Human Subjects
(updated June 2018)

This document is written for people in the Linguistics Department at the University of Arizona. If you are in a different field or department, many of the points in this document may not apply to you, and you should seek guidance from the University Human Subjects Protection Program (HSPP).

Important links:

Linguistics department website for human subjects information This has information about Human Subjects Protection specific to members of the linguistics department.
Human Subject Protection website This has forms and other resources. Other links here are subparts of this website.
Human Subjects Protection forms Use forms from this site for making your application. To open these, make sure you are using Adobe Acrobat Pro (see below). The forms most commonly used by linguists at UA are the following:
Application for Human Research. This is the main application form.
List of Research Personnel. You list your research team and their CITI dates on this form.
Amendment to Approved Human Research. If you make any changes in protocol, personnel, etc., you need to submit this form.
Determination of Human Research. This form is *not* required. You can use it to help figure out whether or not you even need to get Human Subjects Protection approval.

The UA's Human Subject Protection website also has consent document templates and forms to fill out for various appendices, if needed. (In general, an attachment to your application that has an official form is an Appendix. The list of personnel is called an attachment, but has an official form. Other documents are simply attachments.)

Important information on the 2018 forms: the PDF files that you need to fill out will not work with Adobe Acrobat Reader. You will need to use Adobe Acrobat Pro, which you can acquire free of charge in different ways depending upon whether you are a student or a faculty member. If you are a student: visit https://adobe-student.arizona.edu/, fill out the online survey, and within a couple days you should have access to Adobe Creative Cloud, including the Adobe Acrobat software. You are allowed to put it on only one computer so choose carefully! If you are a faculty member: submit a work request to SBS Tech, and request access to Adobe Creative Cloud, including Adobe Acrobat. For questions about acquiring this software, please contact the University of Arizona 24/7 IT Support Center.

Advice from the HSPP office: At the website for the Human Subjects Protection Program there are some resources and forms with advice about how to go through the human subjects application submission process. These can answer many questions for you about certain terms, definitions, and what is or is not allowed. However, these resources are meant to cover all fields, so they are sometimes not specific enough what we need as linguists. The current Application for Human Research form as downloaded from the HSPP website also contains text explaining the questions on the form. The HSPP website changes frequently in how it tries to make information available to investigators, so look around the website for advice. The guidelines below are more specific to linguistic research.

Note on terminology: The general term for the organization that oversees research with human subjects is "IRB", which stands for "Institutional Review Board". This is a university-level organization, and at the University of Arizona, the IRB is part of the Office of the Vice President for Research. Its other name is the "Human Subjects Protection Program", abbreviated HSPP, and in these guidelines you may see the terms "HSPP" and "IRB" used interchangeably. At the department level, the Department of Linguistics has its own Human Subjects Committee, or Departmental IRB Committee, typically composed of 3-4 faculty members. The current list of committee members is available at the department website for human subjects information. Any time you have a question regarding research with human subjects, or need to send a submission to the department committee, be sure to always include ALL members of the committee on your email.

I. Overall process/steps

1. Start by taking the CITI test, which you can reach from the university IRB website and keep a careful record of the date you passed it; you'll need to include that date each time you submit a project/application for approval for yourself and any other personnel listed on your project/application. You are required to take the CITI renewal test every 4 years thereafter, and keep track of your most recent pass date, which must be recorded on any List of Research Personnel submitted with any proposal.
2. When you start planning a research project, determine whether it counts as using human subjects or not. (You can use the Determination of Human Research form on the HSPP site, but *you do not have to complete that form.* You can see II below instead.) If your project counts as using human subjects, go on to step 3.
3. **Students**: You may be able to do your research under an already-approved project your advisor or another faculty member has, in which case you won't have to submit anything, though whoever the PI is will need to add you as personnel to their project. See III below. Otherwise, proceed to step 4.

4. Download the most recent version of the Application for Human Research on the HSPP website (usually under a category like "Forms"; in 2018, the HSP Office will be updating the form without changing the version number as typos, etc. are found. Your job will be easiest if you use the most recent form, which has the most things fixed in it!) Read the parts of the document below that apply to your work, read some of the sample recently approved forms on this website, and write a draft of your form. You will need some appendices and attachments as well, and there are forms and templates for you to use on the same site. See IV below. Pro tip on filling in text boxes: As you fill in the text boxes, you will be able to see only one line of text. If you click away from the text box, it will spring to the full necessary size. If you then type again, it won't expand until you click away from the text box.
5. Check the HSPP website for what the current requirements are for file formats and signatures. The new forms available beginning in January 2018 are "smart PDF forms" and will no longer require a signature image to be inserted into the form; rather, **you will need to email the completed form to the relevant people and receive approval confirmation by email – this will serve as a signature**. The new form has a button to click in order to generate an email, which should be sent to all current members of the department IRB committee. However, those email addresses will not be automatically filled in; you'll need to put them in yourself. **Important**: the PDF files that you need to fill out will not work with Adobe Acrobat Reader. You will need to use Adobe Acrobat Pro, which you can acquire free of charge in different ways depending upon whether you are a student or a faculty member. If you are a student: visit https://adobe-student.arizona.edu/, fill out the online survey, and within a couple days you should have access to Adobe Creative Cloud, including the Adobe Acrobat software. If you are a faculty member: submit a work request to SBS Tech, and request access to Adobe Creative Cloud, including Adobe Acrobat. For questions about acquiring this software, please contact the University of Arizona 24/7 IT Support Center.
6. Download the "checklist" document from the departmental Human Subjects web page, make sure you can check all the boxes, and include a copy of this document as an attachment in your email to the department IRB committee, along with the rest of your forms. We have added this requirement in order to catch a lot of the common problems we see in many proposals.
7. Send your draft Application for Human Research by email attachment, along with all relevant appendices and other supporting documents to **all the members of the departmental Human Subjects Committee (Adam, Diana, Janet, Masha, as of Fall 2017).**
8. One member of the committee will get back to you either with an approval, or with a list of changes you need to make to your form(s). If you don't hear back within a week, please check in to see who is handling your form and when they think they can finish working on it. Make any requested changes, and send your revised form, appendices, and attachments to that person by

email attachment. Always resend all of the forms, even those that did not change, in this subsequent email.

9. The departmental committee will decide whether your research is exempt or not (see V below). **Note: "exempt" does not mean "exempt from requiring permission from the IRB"**. "Exempt" means "exempt from annual review"; exempt projects are typically those that pose very low or no risk to participants, those that involve no physical contact with participants (therefore, EEG and ultrasound studies cannot be categorized as exempt), and those that do not involve participants from certain populations. In most cases, if a project is determined to be exempt, it can be reviewed and approved within the department, and may not need to go to the university IRB. If you have made all the necessary changes based on feedback from a department IRB committee member, and your project is determined to be exempt and doesn't fall into a few special categories, the departmental committee will notify you that your project has been approved and is exempt, and will send you an approval email along with a letter assigning your project an IRB project number and its designation as exempt. Make sure to keep this email and approval letter. Proceed to step 16. Otherwise, go to step 10. Recall from above that you will receive email approval in lieu of a signed form from the committee member.
10. If your work is not exempt, or cannot be given final approval by the departmental committee, the departmental committee will give you feedback that may require changes prior to giving departmental approval. Once you have departmental approval, your next step will be to submit your forms to the University IRB for final approval..
11. Look up the current instructions for how to submit documents to the HSPP office. Follow the instructions to submit your forms.
12. Wait about 10 days and then if you haven't heard back from them yet, call the HSPP office and ask **very politely** whether you could check on how it's going with your proposal.
13. You will likely get an email back asking you to make some changes to your forms. Make them immediately, and send the forms back in. There is a new policy (as of 3/2016) that **if you do not get the final version of the forms resubmitted to the IRB, and possibly approved, within 30 days from your initial submission, the IRB will cancel your project, and you will be required to start over with a new submission**. Please note that this means not 30 days from receiving the list of revisions from the IRB, but rather 30 days from your initial submission.
14. You will get an email notifying you that your project is approved (with stamped consent form if applicable). It will also tell you whether your project is exempt or not. Then go to steps 15 and 16.
15. If your research is not exempt, you need to file annual review paperwork once per year (see VI below).

16. **Amendments**: If you ever need to get permission to do something you didn't put in your original proposal, you may need to file an amendment, even if the project is exempt. See VII below for details.

II. Do you need human subjects approval in order to do your project?

If you are going to talk to humans or do anything involving humans in order to get the information in your paper, you almost always need human subjects approval.

Cases where you do NOT need human subjects approval:

- **Class work ONLY:** You are doing the work for a class (including term papers), and you are not going to use the data for anything else, **ever**. If you do the work without human subjects approval, you cannot even use the data as pilot data for a conference or workshop abstract submission (with plans to do the full experiment before the conference or workshop) or as pilot data for a grant proposal. The only use of the data can be for class purposes. You **cannot** get retroactive approval later.
- **Casual, occasional asking another linguist for a judgment:** If you ask a linguistics graduate student or faculty member who happens to be a native speaker of a particular language for a grammaticality judgment of a couple sentences of that language, or ask them how to say some sentence in that language, you do not need human subjects permission. (However, if they are a graduate student in some other field, not a linguist, you do need permission. If you are going to elicit data more systematically from a friend in Linguistics, for half an hour with a prepared sentence list, then you do need permission.)
- **Grammaticality judgments by yourself:** You do not need permission to ask yourself whether sentences of your native language are grammatical.
- **No humans involved:** You do not need human subjects approval for research that uses exclusively computational modeling with no human data or uses only data that appears in past published literature (e.g., a grammar).
- **Publicly available recordings and corpora:** You do not need human subjects approval to analyze publicly available recordings, for example old TV broadcasts. You do not need approval to analyze corpora from LDC, TalkBank, Childes, Buckeye, etc.
- **Asking people non-data academic questions:** You do not need human subjects approval to ask other academics' opinions about theories or background literature or to get advice on your paper. You do not need human subjects approval in order to cite something in the past literature.

Cases where you DO need human subjects approval:

- Any **experimental work** where you present people with stimuli or put them in some situation and record something about their reaction. These typically

are now categorized as “Benign Interventions” and require human subjects approval, and in some cases will be determined to be exempt.
- Any **elicitation work** where you ask native speakers how to say things and record their response or write them down (exception for linguistics friends you ask casually and briefly; see above).
- Any situation where **you record (audio or video)** people's naturally occurring language behavior, even in a public location.
- Any **experiment** where you physically manipulate the subject in some way (EEG, oral/nasal airflow, ultrasound, etc.).
- Data collection for research purposes through Qualtrix, Amazon Mechanical Turk, or other **crowdsourcing** methods.

Non-obvious cases where you **still need approval**:
- **Self-experimentation:** Doing experiments on yourself (exception for grammaticality judgments; see above).
- **Experimentation on family members:** Collecting data (recorded or written) from your own child or your friend's or relative's child.
- **Public facebook data:** Data collection from Facebook or other social media, even if the people who posted it made it publicly viewable. (The line between publicly available data on random websites that you don't need permission for and publicly visible social media data you do need permission for is unclear, and may depend on whether the data is sensitive and whether individual posters can remove it later. Data from an online dating site needs permission, data from an online newspaper as a corpus doesn't. Ask the department IRB committee if you unsure.)
- You still need approval if you are not a U.S. citizen or if your previous university approved the project and now you’re continuing it. Authority for human subjects protection is based on your affiliation with the university.

Anything with kids, clinical populations, Native American languages, or anything you're worried about: check with the departmental IRB committee or the instructor of the course the work is for, even if it seems like it shouldn't need approval, just to be sure. Remember, you cannot obtain retroactive approval for data collected without human subjects permission.

III. Can I do my research under someone else's already approved project?

This is most often relevant for graduate and undergraduate students, whose advisor (or some other faculty member) may already have a larger project approved, where the student's planned work is a sub-part of the larger project.

Check with your advisor: do they have an already approved project your work might fit under? If they do, does their approval cover ALL the things you're planning to do

(e.g., what language you will work on, what population of subjects you will use, how you will recruit and consent them, what methods you will use with them, how subjects will be compensated, where you will do the research)? And is your advisor OK with having you do your work under their approval? (They may want you to learn how to submit a human subjects proposal, so they may want you to do your own.)

If your advisor's project covers all the things you're planning to do, and your advisor is OK with you doing your work under their project, your advisor needs your CITI pass date, and must document the personnel change in their records in case of a future audit on their project. Personnel changes do not require an amendment, unless the PI is changing from one person to a different person, in which case the appropriate amendment forms must be submitted to the departmental committee and in some cases to the university IRB. If the project uses a consent form, your advisor needs to give you copies of the project's consent form to use with your participants.

Once you are added as personnel and have the correct consent form, you can go ahead and do your research, and it is approved under the larger project's approval. Do NOT do this if your advisor's project does not have permission for all the things you are going to do (location, consent, recruitment procedures, population, etc., not just methods), unless your advisor files an amendment to get permission for the additional thing(s) you want to do.

Turn in your filled out consent forms to your advisor when you finish running subjects and make sure they go to the correct storage location (currently, Douglass 218A). Give back or destroy any extra blank copies of the consent form.

IV. Guidelines and suggestions for filling out the Application for Human Research form (main application form) and appendices and attachments

Because the new form is a “smart form”, your path through it will depend on the answers you give. We have tried to make our bold headings match the headings in the form, so you can search this document to find our notes on what to do with a given question. The HSPP will make adjustments to the form throughout the year as they find out what does and does not work. This means some wordings or page numberings may differ between their form and our guidelines. The HSPP said they will not be changing version numbers during this time, so any 2018 form will be accepted. Please alert us to any discrepancies you find so we can modify our guidelines.

Let us know if there are gaps. The way we created this was by trying to come up with all combinations so we would find all the questions and then put relevant

guidelines in an appropriate place. But we may have missed something -- your help will be appreciated!

Finally, the 2018 Application for Human Research is new to us as well as to you. We are open to suggestions for improving your experience as a user of these guidelines in filling out the 2018 Application for Human Research.

As you fill out your form, ***keep track of the appendices and documents*** that you need to attach! The form is not smart enough to give you a helpful list at the end.

In using these guidelines, **items in bold, flushleft** are major sections, typically in gray in the Application for Human Research. *Italic items* are subcategories within each major section. Page numbers refer to the form available online on January 8, 2018.

Title (If funded, provide exact title of funded project). This begins on p. 1 of the untouched Application for Human Research.
Project title: Make your project title *very broad*, so you won't have to file an amendment if you change your topic slightly later. For example, instead of "Relative clauses after agentive verbs in Language X," title your project "Structures of Language X." Instead of "Perception of Voice Onset Time in Japanese," title it "Perception of Japanese Speech." **Exception**: If you have a grant that went through Sponsored Projects, the Human Subjects project has to have the same title as the grant.

*Alternate contact information***:** You are not required to include anything here. Do not list one of the members of the departmental Human Subjects committee on this without their permission.

General Information. This begins on p. 1 of the untouched Application for Human Research.

Answer the questions succinctly and briefly, and check the appropriate boxes. You are required to provide the following details:

What is the expected length of this project? For the expected length of the project, put a *long duration of time, like 5 years*. This amount of time needs to cover all analysis and publication of the data, not just collection of it. When your project ends, you should not be intending to touch the data again. Do not put a short time period like "2 months" simply because you think that's how long you have to get the data collected.

Will the University of Arizona be the coordinating center for a multi-site study? Will the University of Arizona be the IRB of Record for multiple sites? The answer is “yes” if you are doing the work at another location besides the UA, and a collaborator at the other location is really involved in the work (e.g., consenting subjects, helping you

plan the research), and their university is not having them submit a separate human subjects project there. It is also "yes" for some more obvious reasons.

Is this an investigator-initiated study? The answer here is typically "yes", unless some company has hired you to do the work. Ignore the message about Banner that pops up.

Funding Information. This is on p. 1 of the untouched Application for Human Research.

Check the appropriate box regarding federal funding. Note: *even exempt projects must be reviewed by the university-level IRB if federal funding is involved.*

Location of Research. This is on p. 1 of the untouched Application for Human Research.

Check the appropriate box(es). If you select "other" you will need to give an explanation in the text box that is exposed.

Check all locations at which you will run subjects or conduct research, then fill in the textbox with specifics: "Douglass Building Rooms 316 and 318A," "public locations in Tucson convenient to the subjects, such as public libraries," "an office or empty classroom at X university in Y country," or "subjects' homes." If the locations aren't on the UA campus, explain where they are, e.g., "in Phoenix," "at University of Victoria in Victoria, Canada," etc. The reader needs to get an idea of what things will be like where you'll be doing the research. If you will conduct research with *different groups of subjects at different locations* (e.g., native Dutch speakers at a research institute in the Netherlands, native Spanish speakers at a community center in Tucson, and native English speakers in a lab on campus), clearly explain what the different groups are and which locations apply to each.

If you check "other"... a textbox will pop up.

Site Authorization: If you are doing research at some other university campus or other official location, such as a business, in the U.S. or elsewhere, you need a site authorization. This can be a very brief letter from a faculty member at the other university, on letterhead, stating that you are welcome to conduct research at their university and they will arrange for a quiet space/office/empty classroom for you to use. If you are doing research at some location where someone has authority over what happens there (e.g.,. a work site, a preschool, a Native American festival, etc.), you also need a site authorization. If you need a site authorization, *put it in an attachment and mention that attachment*, and who the authority is, here. You do not need a site authorization for subjects' or experimenters' homes or for public locations. You do need site authorization for locations at the UA outside of your home department.

Submitting site authorization later: If you can't get the site authorization until after you get to the country or to the fieldsite, explain the location and who you will need a site authorization from, and why you can't get it until you get there. Add a statement such as "Once the site authorization is obtained, a copy will be faxed or emailed to the Human Subjects Office. No research will be conducted until the site authorization has been faxed/emailed."

Financial Conflict of Interest Disclosure. This is on p. 2 of the untouched Application for Human Research.

You have to do your Financial Conflict of Interest training and pass it, and submit your Disclosure of Significant Financial Interests (none for most of us) before you can file a Human Subjects proposal.

Project Abstract. This is on p. 2 of the untouched Application for Human Research.

This discussion pertains to the three questions in this section. Please try to keep these narrative answers *short, and readable for non-linguists,* even though the next question asks for a lay summary. If your research is extremely low risk (no risk greater than that encountered in daily life), and on non-sensitive topics, then you do not need to prove that your research is extremely novel and fascinating. For the lay summary, write this summary *so that people who know no linguistics at all can understand it easily*. **Use NO TECHNICAL TERMS AT ALL**. For instance, "processing" is a technical term, and so is "verb phrase." We find that many people write an excellent lay summary of the topic of the research in their debriefing script, but the lay summary in the first draft is completely unreadable to non-linguists. One strategy is to start from the debriefing script you would use to tell subjects what the research is about after they finish the experiment, although you do need to add information about what methods you will use. Also add information about where you are conducting the study and with what group of people. Another strategy is to call a friend or relative who is not a linguist, and ideally not an academic, and explain your project to them. Write the lay summary the way you would explain the project out loud, not in academic register prose. You do not have to (and should not) explain all the details. Note: as you discuss your project, you do **not** need to include a power analysis. This is important for studies with substantial risk.

Population and Recruitment. This is on p. 2 of the untouched Application for Human Research.

Fill out your responses and check the appropriate boxes.

Maximum number of participants to be enrolled in the study: Explain how many participants you plan to have, using the *maximum number* you might ever want to run, so you don't have to file an amendment and wait for it to be approved in order to run more people on your last day of fieldwork (or just so you don't have to file

more amendments). You can write "up to X subjects will participate" or give a range (e.g., 20-50 subjects).

Check all the categories of participants that will be included in the research: Depending on your population, you may be required to submit additional forms; e.g., if you check "Children" you will be prompted to complete and submit the Appendix for Vulnerable Populations along with your application (see guidance for specific groups on the HSP website). For recruitment methods, check all the boxes that might apply. You need to explain here how you're going to locate your subjects and how you're going to contact them, and how you're going to ask them to participate (recruitment), and also how you will explain the experiment and the privacy for data and so on to them and ask if they would like to participate (consent). If you are recruiting subjects from introductory linguistics classes, make sure to *get permission for any method of recruitment you might eventually want to use* (e.g., announcements in classes made by the instructor; visiting classes in person to make announcements; posting on a course d2l site; email sent by instructor; passing around sign-up sheets in class; etc.). If you are recruiting a small number of native speakers of some language who live in Tucson, and you are hoping that the few you know have more friends who they can put you in touch with, include permission for recruiting through *word of mouth*, or through introductions through mutual friends. If you want to post messages on social media (e.g., Facebook) or send them to email listservs or have members of other departments forward them to departmental listservs, mention that. If a local person at a remote location (e.g., a university in a foreign country) will help you by recruiting through their friends, posters on bulletin boards, listserv messages, and announcements in classes, make all of that clear.

What are the inclusion and exclusion criteria for study participation? Explain your *subject pool* (especially if recruiting from classes or using the Psych pool), or explain how you have access to the kinds of participants you need (e.g., you know several speakers of Brazilian Portuguese through your soccer team, and they know additional speakers).

Indicate age range, gender, and ethnicity of your research population. Explain generally what group of people the subjects will be, e.g., "students enrolled in introductory Linguistics classes," "native speakers of Japanese," "native speakers of English who are learning Spanish," "native English speakers above age 60," etc. Your response must include a *statement addressing ethnic and gender distributions* among your subjects. If you are recruiting from introductory Linguistics classes, include a statement like "The ethnicities of subjects will reflect the distribution of ethnicities among students enrolled in introductory Linguistics courses." For any research that both men and women can be in, state "Both men and women will be equally encouraged to participate." If the subjects have to be native speakers of, for example, Mandarin Chinese, you should write something like "Because nearly all native speakers of Mandarin are Asian, it is expected that all subjects will be Asian." (Put this even if you're running the experiment in China, where this group is the majority. Modify this sentence depending on how native speakers of the language

you are studying identify themselves to use the terms they prefer.) One reason for this is that scientists used to do medical research only on men, and then found that the results didn't apply to women.

Age of subjects, vulnerable populations: If you are not collecting data from children, state that all subjects will be 18 years old or older. If you are not collecting data from children or members of other vulnerable populations, state that no members of vulnerable populations will be included.

Female subjects: If there will be women among your subjects, include a statement like "Because some of the subjects will be women of childbearing age, it is possible that a subject could be pregnant at the time of the study. However, because of the entirely non-medical nature of the study, pregnant women are not a vulnerable population for the purposes of this study." (If this is true, that is.)

Separate populations: If you are testing two separate populations (e.g., native Burmese speakers who you recruit in Phoenix through a community center and native English speakers who you recruit at the University of Arizona from introductory Linguistics classes), you need to *make it very clear* what populations are involved, and what the characteristics of each group are.

Please select the methods that will be used to recruit individuals. Provide copies of documents, as applicable.

Oral recruitment ("In Person" and "Face to Face"): In Person is a more formal presentation to a larger group of people (2 or more, depending on formality; this includes any class presentations for recruitment purposes); Face to Face is informal, often one-on-one. If you plan to do one type but might want to do the other, check both to give yourself the options. Include a "Sample recruitment script" in an attachment and mention the attachment here. If any recruiting through classes is involved, mention "only in classes where the instructor gives permission."

Email/online/social media recruitment: If you will post announcements electronically or send them by email, you need to include a "Sample recruitment script/message" as an attachment and *mention the attachment here*.

Recruitment posters/flyers: If you will post posters, the actual poster has to be approved by Human Subjects.

PRO TIPS ON RECRUITMENT

Compensation and recruitment: Recruitment announcements/messages/etc. *cannot mention the specific amount of compensation*, if there is monetary compensation. They can state "If you decide to participate, you will receive a small monetary compensation" (or a candy bar, or a small gift, if that's the case). If prospective subjects ask you directly how much the compensation is, you can tell them, but you can't announce it. This is considered coercive.

Separate populations/methods: If your project involves two separate populations, or separate groups that will participate in separate methods, or

anything like that, *make it very clear* how each group is recruited (e.g., "The native Mandarin speakers will be recruited among Mandarin-speaking students of the UA by word of mouth through the PI's friends. The native English speakers will be recruited from introductory linguistics classes through class announcements by d2l, email, and oral announcement by the instructor.").

When will recruitment occur? Give a time frame that is significantly longer than you think it will take, so you don't have to come back with a modification to your protocol.

Where will recruitment take place? See comments above about site authorization if you plan to recruit in a "private" space (e.g., a business).

Informed consent. This begins on p. 3 of the untouched Application for Human Research.

Check the appropriate boxes. Some will require that you provide an appendix to explain.

Describe in detail the consent processes checked above. ***This is long because there is a lot of focus on the consent process.***

Type of consent: To explain consent, explain whether you will be using a written consent form or obtaining oral consent. If you plan to obtain oral consent, explain how you will record the information about which subject was consented when (recording this in fieldnotes is an option). Also state here that you will explain to subjects that they are not required to participate, and that there will be no negative consequences for them if they choose not to, and that if they participate, they can stop at any time. It is typical to state that you will explain these things orally, and that they will also be stated in the consent form. Explain everything about how you will do consent that isn't obvious, such as what language the consent forms will be in if not English, how oral consent will be recorded or noted down, why you are using what method to consent subjects, etc.

Oral consent: We can now often use *oral consent (no signature) for no-risk or extremely low-risk experiments*. If you plan to do this (no signed consent forms), then explain in Question 7b why this is adequate for this study, based on the low-risk nature of the study. (If there is no audio or video-recording and you don't keep subject's names except for reporting for extra credit, and don't keep the names in any way attached to the data, you may want to state that you are not using a consent form partly because it would be the only record of subjects' names.) It is usual to have a written sheet that contains the same information as a consent form (but shorter), that you can show to subjects while you discuss consent with them and possibly give them a copy of. This may be called a disclosure form, but it is not clear if there is a rule about this. This will go in an

Appendix for Alterations/Waivers of Consent or PHI form from the HSPP website, which justifies the waiver of signed consent.

Oral consent and consent forms: If you are using oral consent with no signed consent forms, *then do not write back in Section 2 Qu. 4a that you will be storing the consent forms* in some particular location, since you won't have any. Write "N/A" there.

Reasons to use signed consent forms: Use signed written consent *if there is any danger that someone might be worried about whether you have adequate permission and good informed consent*; e.g., for work with Native American tribes, with children, for any relatively medical-like work like EEG, or for anything even mildly dangerous.

Video-recording consent: If you would normally want written consent but your *subjects will not be literate in any language*, you can video-record the consent procedure. Explain this in Qu. 7b.

Consent in other languages: You can translate consent forms/oral disclosure forms *into whatever language your subjects read comfortably*. If they will not be able to read English easily, do not use the English form; translate it instead. There are Spanish templates on the HSPP site. Provide an English version as well as the actual version in the language in the attachments.

Writing your own consent form vs. using existing templates: There are template consent forms on the HSPP web site, but *you can actually write your own consent form that's in a much more conversational style*, and is shorter and not threatening. It has to include at least the *legally required elements* of informed consent. The HSPP website has some helpful material about consent here but we can't currently find a list of the federally required elements of consent on it. We have found them before by googling "required elements of consent" or such and finding them on a U.S. federal government website. You do not have to mention alternative procedures or treatments for a non-medical study; just skip that. Most of the required points are things you would want to tell your subject anyway, like how long the experiment will take and what you'll have them do if they decide to be in it. So you could write your consent script or form the way you would actually explain it in person, in conversational style.

Assent for children: If your study involves children (= anyone under the age of 18 years), you need to get *signed consent from a parent or legal guardian, and assent from the child if they are old enough to understand*. For example, you could say "If you want to do this, we're going to play a game where you hear the computer say some words and then you say them back again. Would you like to do this? If you would, can you take that marker and make a mark on this paper?" (This is an abbreviated example to show how you could do assent with a 2.5 year old; modify to your type of study and age of children.)

Consent form not culturally appropriate: If a standard consent form is culturally inappropriate in the country or cultural group where you will be doing the

research, do not use it. *Write your own conversational style consent form or use oral consent.* (See above.)

***No coercion, and recruitment from your own classes*:** You should *never coerce a potential subject* to participate if they don't want to. If your work involves any situation where subjects might feel coerced or obligated to participate, explain why, and explain how you will prevent that. If you are recruiting students from classes and you will not recruit from classes you are teaching, state "Subjects will not be recruited from any classes the PI is teaching so that they do not feel coerced." If you are recruiting from your own classes, explain how you will make it very clear to potential subjects that they do not have to participate and that you will not hold it against them and their grade won't suffer if they don't.

Where will original signed consent and PHI Authorization documents be stored (building name and room)?: If you will be using written consent forms and submitting your application through the Department of Linguistics, you have to write *Douglass Room 218A* here. That's a closet under the stairs by the side door on the east side of the Douglass Building. When you're done consenting subjects (or once each year or so if your study is ongoing), take your signed consent forms to Marian in a folder with your name and the name of the study and the year on it. Marian will store them in Douglass 218A, the closet under the stairs. This is our approved/designated official storage location for Linguistics consent forms. Many low- and no-risk projects do not need written, signed consent forms, and if you're not using a signed form, you can enter "N/A" here.

How long will consents be maintained after conclusion of the project: The default of 6 years is fine unless you have reason to do something else. This is only for storage of consent forms, not of data.

Data Collection Procedures. This is on p. 3 of the untouched Application for Human Research.

Select all applicable methods based on the checklist. There is a checkbox for a new category called “Benign Interventions”: this will typically be checked for linguistics research.

Does this project involve the administration of a Drug or use of a Device for research purposes? Typically, linguistic research answers “no” to this.

Please provide details of the research procedures and include the study population who will be completing them. Explain your methods here.

Explain *all methods* you are going to use with your subjects. For example, if you're going to run a main perception experiment and then do a language background questionnaire, you need to explain both methods. If you will use four different methods plus a language background questionnaire, and each subject can choose whether to do just one, more, or even all four, of the main methods, but everyone does the language background questionnaire, *make all of that clear.* If subjects can

do some methods only if they are literate in the language, but all subjects can do other methods, explain this.

Writing style: *Explain the methods in a conversational style, avoiding technical terms,* e.g., "Subjects will sit in a sound-protected booth and will hear real words and nonsense words over headphones, and will press a button to say whether the thing they heard was a real word or not" as opposed to "subjects will perform an auditory lexical decision task." Explain where the subject will be and what they will do in what order, so that the reader can understand how the experiment will feel from the subject's perspective. If someone other than the PI will be doing the work with the subjects, explain this (e.g., a local assistant at a field site).

Methods not too detailed: Make your methods *as general as possible*. Do not list details that do not affect protection of subjects. If you state "subjects will be audio-recorded using a head-mounted Countryman E50P5l microphone," and you decide to use a different microphone one day because someone else borrowed the usual one, or you decide that a lapel mic will work better, you don't have permission to use any other microphone model. Get permission in the first place for everything you think you might reasonably want to do, and make it as general as possible (e.g., simply "subjects will be audio-recorded"). People may feel like including a lot of detail shows that they know what they're doing, but it is not necessary here. For perception/psycholinguistics tasks, if you can say "subjects will hear stimuli over headphones or see stimuli on a computer screen, and subjects will respond about what they heard, for example pressing a button to say whether the stimulus was a real word or not, or whether the stimulus contained the sound "t," or whether a sentence-long stimulus is a possible sentence in English or not" then that gets you permission for auditory and visual lexical decision, phoneme monitoring, and grammaticality judgment all at once, and you won't have to submit a new proposal or an amendment for a slightly different task.

What is measured: State what will be measured *in lay terms*, such as "how long it takes subjects to press the button (reaction time)," or "various acoustic characteristics of the sounds will be measured." For things like syntactic elicitation or discourse studies, you may be able to make this less specific, e.g., "how the subjects say the sentences will be analyzed."

Recording: Make it clear if subjects will be audio-recorded or video-recorded.

Syntactic elicitation is usually considered to be an interview.

Data collection instruments: Refer to an attachment of "Sample stimulus items" or "Sample interview questions" or whatever else you might be using. Putting "sample" means you can change the exact items later, as long as you stay within the same type of questions/stimuli.

Personnel: Make it clear in the procedures section who is doing the work with subjects, especially if you have a research assistant or a local assistant at the

fieldwork site. (Also make this clear if someone is helping you recruit or helping you analyze data, in the relevant section.)

Please state the estimated time commitment for subject participation. Explain how long the activities in the procedures will take. You can use a *range*, e.g., "subjects will be recorded for 20-40 minutes" *or a maximum* "no subject will be interviewed for more than 4 hours total, in approximately 1-hour sessions." Put the *longest time range* you might want to use, within reason, so you don't have to file an amendment to make the elicitation sessions 5 minutes longer. This has to be on the consent form too, and *must match what you put here*.

Benefits, Costs, Compensation & Risks. This begins on p. 4 of the untouched Application for Human Research.

Describe the anticipated benefits of this study to society, academic knowledge or both. The benefit to society is the *benefit to the scientific field,* so you should state something like "The benefit to science is that we will gain a better understanding of …(very general statement of your topic)…."

Describe any benefits that individuals may reasonably expect from participation. For almost all linguistic research, there is *no direct benefit to the subjects*. If you list a very minor benefit like "increased awareness of their language," you will have to include that in the consent form too and explain it to your subjects. *There is no need to show a direct benefit to subjects as long as the risk is low, as it typically is*. So just state "There is no direct benefit to subjects" unless there's a good reason to say something else. ***Compensation does not go under benefits.*** Do not list compensation (money, extra credit, candy bars, etc.) in the Benefits section.

Describe any costs, monetary and non-monetary, that subjects may incur. Most linguistics projects can write "The only cost to subjects is their time" or "The only cost to subjects is their time and transportation costs to the research location." If appropriate, you can add something like "Because most subjects will be students who are at the university anyway, most will have no transportation costs."

Please describe all physical, psychological, social, legal, and or economic risks you feel are associated with participation in this research. For most linguistic research on non-sensitive topics, there are *"no risks greater than those encountered in daily life,"* and you should use that phrase. Risks include *social risks* as well as physical risks, though. If you are recording open conversation, there is a small risk that subjects could say something that they would rather not have recorded because it is sensitive, even though they knew they were being recorded. (This could include a student talking about drug use or an endangered language community member saying negative things about another community member.) For discourse and sociolinguistic research, you might be asking subjects interview questions that could elicit sensitive information, such as questions about sexual orientation. Research on sensitive topics poses a small risk in that subjects could be recorded saying something sensitive. If there are risks like this, state them here; however, do not try to come up with risks to describe if "no risks greater than those encountered in daily

life" is accurate. Do not add things like "The only risk is that subjects could become bored during the experiment": you could be bored in daily life too, and if you add that, you will have to put it in the consent form and explain it to all your subjects during consent. See also question 12b below about risk of audio/video-recorded data becoming public.

Discuss what steps have been taken to minimize risk to subjects/data. **If your work really does have risks:** If you have any risks beyond daily life, explain how you will minimize those risks. For the risk of accidentally saying something during a recording that one does not want recorded, state that if the subject expresses concern about anything they said, or if the researcher judges that something sensitive was said, *you will delete that recording* (or that portion of the recording). If you're especially concerned about this risk, you could state that you will *allow subjects to review the entire recording* afterward and to have you destroy the recording if they have any concerns. (This practically never happens in real life, and most people wouldn't want to spend the time to listen to the whole recording.)

Provide a brief <u>lay</u> discussion of the plan to monitor for subject safety. Avoid jargon!

Discuss the amount of compensation (monetary and/or non-monetary). If you are giving subjects money, a candy bar, a small UA souvenir (sometimes appropriate when running subjects in another country, e.g., a UA pen), or anything like that, specify what you will be giving them, including the dollar amount if it is money. If subjects will get extra credit in their course, specify that (e.g., "Subjects will receive a small amount of extra credit in their course if their instructor allows this.") You may want to write this to be a little general, for example "Subjects will receive a small gift such as ….. or …. as compensation for their time."

> <u>*No coercion through compensation*</u>**:** Compensation should not be enough to coerce subjects to participate if they don't want to. Linguistics experiments don't usually have a problem with this.
>
> <u>*Bonus for multi-visit studies*</u>**:** You can pay a bonus (extra monetary compensation) for completion of a multi-visit experiment, as long as the bonus isn't enough to be coercive.
>
> <u>*Compensation in other cultures and economies*</u>**:** Monetary compensation should be an amount appropriate to the local economy for field research. Explain how you determined the amount and how you know it is appropriate (e.g., your local collaborator advised this amount) if it would be unusually high or low here. Compensation that seems unusual here because of what it is (rather than money) is fine if that's what's appropriate in the culture, just explain it.

Describe the provisions for medical care and available compensation in the event of research related injury. Linguists typical say they have no such provisions because the research does not pose injury risks.

Privacy and confidentiality. This begins on p. 4 of the untouched Application for Human Research, and continues to p. 5. Data security is a new issue. See the UA Library and Unviersity IRB websites: http://data.library.arizona.edu/, https://rgw.arizona.edu/sites/researchgateway/files/data_storage_and_retention_v2015-05.pdf, http://rgw.arizona.edu/sites/researchgateway/files/storing_research_information_for_future_use_v2015-05.pdf

Will the research team be accessing medical records, educational records or employee records during the research? The usual answer for linguistics research is "no".

Where will the data be stored? Check the appropriate boxes. Note that "other" requires an explanation, and "my personal laptop hard drive" is not a good answer here unless you can justify it.

For each of the storage locations checked above, discuss the type of data to be stored (including if the data is identifiable), who may have access to the data, and how long the data will be kept. The key issue is here about identifiable data that presents some risk to the participants. If data is not identifiable or presents no personal risk, then just say what you are going to do. If the data is identifiable and presents risk, then it needs to be behind a UA firewall, e.g., UABox. Please see the UA's Data Classification and Handling Standard for more information (identifiable Human Subject Research data is classified as "confidential".)

Will you be transmitting/receiving any subject data to/from an outside group? This is primarily to protect personal health information and/or limited data sets (both technical terms; links provided to both if you need to check).

Discuss how, when and why subjects/data may be removed from the study. This is about you deciding to stop a subject's participation part-way through, not about the subject deciding to stop. This is rare for linguistics projects except possibly in multi-visit experiments (if the subject is missing a lot of appointments or does not pass a criterion test, for example). If you wouldn't stop a subject mid-way through, just state "The PI does not expect to withdraw any subjects from the study." Otherwise, explain.

Describe steps, if any, to protect the privacy of the subjects throughout their participation in the Human Research (e.g., during the recruitment process, consent process, and/or research procedures). Privacy refers to *keeping the fact that the subject signed up and participated private (if need be)*. For a study on a sensitive topic, people might actually not want others to know that they participated in it, but this is rare for linguistic research. For most studies, you can write something like "Because of the non-sensitive nature of the research, the recruitment and experimental procedures described above are sufficient to protect the subject's privacy during recruitment and participation." Or if sign-up is through a website where names are not displayed, or through private emails, such as the Linguistics subject pool, you could write "The recruitment and sign-up procedure incorporates privacy during recruitment."

Use of Data/Specimens. This begins on p. 5 of the untouched Application for Human Research.

Check the appropriate boxes. Depending on what you check, some other options may pop up. Here are some pointers on how to fill in some of the text boxes.

In which of the following formats will the data be kept? This question is working to protect subjects' identities. If you plan to keep identifiable data (either by name or because a face or voice can be recognized from the data), explain why this does not put the subject at risk. Some tips:

> *Not identifiable data vs. audio/video recordings.* If you aren't going to keep subjects' names and there is no audio- or video-recording, then you can just point out that even if data were to become public, it would not be possible to identify any subjects based on it. For any non-sensitive data with audio- or video recordings, add a statement such as "Because of the non-sensitive nature of the data, even if the data were to become public, it would pose no risk to the subjects." The human subjects office assumes that a listener could identify speakers by hearing an audio recording, so audio recordings are always considered to carry the risk that someone could steal them and recognize the subjects. Therefore, you need to state that the content is non-sensitive and would pose no risk even if this happened. It's often best to state this both under Risk and here.
>
> *Names not kept.* If you are going to keep subjects' names only to report so that they get their extra credit, and the names will not be tied to the data in any way, and you are not using any audio- or video-recording, state this.
>
> *Sensitive information.* If your research includes potentially sensitive information, like asking about family history of mental illness, explain how you will keep information like this safe, or whether it won't be identifiable because you won't keep names at all and there will be no recording. This may also need to be explained in the discussion of risk in the appropriate section.

Will data/specimens be kept for future research, including unspecified future research and/or genetics? If "yes", explain who will have access to the data and how the data will be kept private, and mention whether or not your data include genetic information. For example, you might say "Only the PI and research assistants working with him/her will have access to the data, and the data will be kept on a password-protected server." This replaces the old question about destroying data; for most linguistics projects, do not destroy data, and explain *"Data will not be destroyed because of the no-risk nature of the data."* **Exceptions:** If you are working on a Native American language and the community requires that data be destroyed afterward, or that data be stored only in the community's archive and you will not keep a copy; or if your data actually is dangerous to participants, then you need to state when you will destroy it.

Also explain all of the ways you might use the data, especially if that would allow other people to hear/see recordings. For example, if you would like to be able to post brief clips from the recordings on the web as examples, or to play brief clips in teaching or in research talks, specify that. If you would like to be able to share the data with another researcher you might collaborate with in the future, state that data may be shared with other researchers. If you would like to post the entire set of data you collect on the web and make it publicly available, or if you would like to make it available to other interested researchers who might request it in the future (following typical NSF Data Management Plan procedures), state this. The consent form needs to cover this as well, and *must match what you put here*.

Will the data/specimens be kept in a repository? Although this sounds like they're looking for information about biospecimens, this is also a good place to address future uses of linguistic data, especially audio-/video-recordings. If you are making audio-recordings, you might want to share them with some other researcher later who can answer a different question from them. You might want to post all your data online (audio-recording or just unidentifiable perceptual data). See question 12b above for more discussion, and discuss any such future uses of data, archiving, or making data available to others here as well as in 12b. Make sure your statements here, in 12b, and in the relevant part of the consent form are *consistent*.

Will the data/specimens be shared with collaborating entities? For work with some indigenous language communities, you may be planning to file a copy of all the data with the community or tribal library, the tribal community center, etc. The community may require this, and it is often a good idea even if they don't. This definitely affects privacy and risk (if conversations are recorded), since another community member could go to the community library and hear the content of the recordings. If this applies, explain it here (and in the risk section and the sharing of results with subjects section).

Please discuss the information management plan if your funding agency requires such a plan to manage data. You definitely need to answer this question if you have or are applying for NSF funding (and thus have a Data Management Plan). If you do not, the form is ambiguous about whether you need to discuss this here. Most of this information is covered above in Questions 12b, 18, and 19. If you are going to share data with other researchers or archive it, it may be best to address all of this again here. *It is OK to be redundant. Make sure your answers here match those in related questions and match the consent form.*

If appropriate, discuss how immediate and/or long term study results will be shared with subjects, families, and/or the institution. It's often considered good practice to offer to let the subject know how the research turned out when it's done. You can do this for most experiments by stating that at the end of the study, you will ask the subject to let you know if they would like to receive a copy of papers or talks about the study when they are done, and that you will collect the email address of anyone who asks for copies and will send them. For work with some endangered language communities, you may be required to visit the community to explain the outcomes

of the research. If so, you should explain this here. If you will be storing a copy of the data with a community or tribal library or archive, you should mention that here as well.

Signatures

Check the attestation box and type in your name and date, then send it to the department committee.

This is the end of the Application for Human Research, except for the appendices and attachments referenced as you filled out the form, and submitting it at the department level for evaluation and/or approval. If your proposal needs to go to the University level, remember that you must submit your documents *from a UA email account.*

Make sure to include all your appendices and attachments.

Appendices for most linguistics projects:

1. A "vulnerable populations" appendix if you are recruiting a vulnerable population.
2. A "no written, signed consent" appendix if you want to not have signed consent.

Attachments:

1. The *List of Research Personnel*: All CITI pass dates on the List of Research Personnel must be less than 4 years old. Sometimes it's hard to tell from the procedures and all the information in the Application for Human Research who on the project is doing what, and then when we get to the List of Research Personnel we're surprised to find out there's a research assistant. *Try to make this sort of thing clear within the Application for Human Research.*

   ***Collaborators/assistants who are not at the UA and the List of Research Personnel training problem*.** If you will have a collaborator or assistant at another university in the U.S., not affiliated with UA, they may not be able take the UA CITI test. Their own university probably requires them to do some sort of Human Subjects training, so list the name of that training (and date if possible) on the List of Research Personnel. If your collaborator or research assistant is based in another country, and they have some type of training, list that. If they are based in country with little human subjects protection or at the remote field site, state that you will train the collaborator/research assistant in the ethical treatment of human subjects yourself, if they cannot do the CITI test. Explain what issues you will focus on

in training them, such as not coercing subjects to participate, keeping data private and not discussing data with others, etc. On the List of Research Personnel, you can just list something like "local collaborators: names not yet known" (if that's the case).

People not officially affiliated with the UA actually CAN take the UA CITI test, even though it says it's only valid for people affiliated with the UA. It turns out that "affiliated with" is different for human subjects training purposes than for anything else, and all it requires is that they do the UA CITI test and click the right things. So if you have a collaborator at another university or in another location for whom the CITI test wouldn't be an unreasonable imposition, and their university doesn't require any human subjects training, you can have them do the CITI test and just have them click the thing saying they are affiliated with the UA. However, if it's more appropriate, train them yourself as discussed above.

2. *CVs of all PIs and Co-PIs* (including advisor for student PIs).
3. *Data collection tools.* This includes sample survey questions, interview questions, stimulus items, etc. for each type of procedure you will use.
4. *Consent documents.* Whatever consent form or consent script or consent document you will use (not a sample, the real final one). Please make sure all the *details in your Application for Human Research match the same details in your consent form* and any other appendices. If your Application for Human Research says the procedure will take up to 30 minutes, the consent form should not say 30 minutes to 1 hour. *If you say there is a risk in the Application for Human Research, you cannot tell subjects there is no risk on the consent form.* This is one of the most common errors encountered by the department human subjects committee.
5. *Recruitment documents*. Sample recruitment script and final versions of posters or flyers if you will use them.

You do not need to include a copy of your grant proposal, even if it is funded.

V. Is my project exempt, and can it be approved by the Departmental committee?

"Exempt" means that once approved, a project does not need to undergo annual review and renewal, and that in most cases it does not require amendments (see Section VII for details) . Exempt projects are still subject to potential audit by the university Human Subjects Protection Office (HSPP). "Exempt" does not mean that a researcher has permission to carry out research with human subjects without going

through the approval process for human subjects. The Departmental Human Subjects committee for Linguistics has permission to approve most human subjects projects that are exempt. Note that **you still have to submit the proposal exactly as you would do if it were not exempt, and the forms still have to be filled out exactly as they would be if it were not exempt**. PIs are not allowed to decide on their own whether their projects are exempt, and the departmental committee has to do the same review of the same paperwork that the HSPP office would do if you were submitting an exempt project there.

If your project can be approved by the departmental committee, the approval will probably be faster than if you have to submit it to the HSPP office, because there is one less level of review.

Typical linguistics research projects are usually exempt if:

- they *do not use any children* or other vulnerable populations
- they do not use any methods where *physical contact* with the subjects is required (e.g., ultrasound, EEG, and articulatory phonetics methods where you have to put something on the subject all involve physical contact).
- AND either the data collected is *non-sensitive* or there is *no way subjects could possibly be identified* from the data.

Audio and video recording are considered exempt as long as the data is non-sensitive.

There are a few categories of research that are exempt, but that nonetheless the departmental committee does not have authority to approve, so those have to go to the university HSPP office for approval after the departmental committee has given its approval:

- work with *children* that uses methods that could be used in an educational setting, and that is very low risk;
- any exempt research funded by a *federal funding agency*. So this means that **if you get an NSF grant, the human subjects proposal for that research has to go to the HSPP office after the departmental committee approves it**, but it may still wind up getting classified as exempt by the office. This means it will take longer, and NSF can't award the grant until it's approved, so be sure to allow time.
- research where you have a collaborator at another university (a collaborator who is really involved with the project, like in consenting or running subjects or in designing the experiment, not just someone who lets you use space there to do your experiment), and their university either chooses to have the UA be responsible for the project without them reviewing it, or their university has no human subjects process at all.
- research that involves endangered languages regardless of whether you do language documentation research on tribal land or survey language attitudes in a language class (as long as your research involves endangered languages

in some way, your project has to go to the university HSPP office after it was reviewed by the departmental committee)

You do not have to figure out whether your project is exempt. The departmental committee will determine whether your project is exempt. *If you think the project might be exempt, when you submit it to the departmental committee, please state in your email that you think it may be exempt*.

You do not have to figure out whether or not the project can be approved within the department, but **the criteria above give you an idea of whether your project is likely to need to go to the university HSPP office, and therefore will need more time**. If the departmental committee determines that your project needs to go to the university HSPP office, the committee will provide you with the necessary signatures for the HSPP review but will ***not*** review your project internally.

If you have affiliations in two departments (e.g., faculty with split appointments, ANLI students), or if your project has a collaborator in a different department: Most departments do not (yet) have permission to approve exempt projects at the departmental committee level, so all of their projects have to go to the university HSPP office for review. If you have a choice of submitting your likely-to-be-exempt proposal through Linguistics or another department, and the other department does not have this system, it will be faster to submit it through Linguistics.

VI. Annual renewal paperwork

If your project is *not* exempt, it has to be reviewed by the University IRB once each year to make sure no new risks to subjects have been discovered. For medical research, it might be found in the meantime that an experimental drug has side-effects that were not known before, and they need to check whether to stop the study. For linguistics projects, it is extremely unlikely that a new risk will ever be discovered. The only situation we can think of where this might happen would be if you are doing field research on a minority group language in some country, and a new government takes power and starts persecuting the members of the ethnic group that speaks the language you study, so that it becomes newly dangerous for it to be known that one is a speaker of this language. In this situation, we hope that you will have taken measures to avoid endangering your subjects long before your next annual review, like only doing research with speakers who have immigrated to the U.S., for example. However, all non-exempt projects have to be reviewed every year.

Annual review paperwork is not very hard, and the form is relatively short. Some tips for this process:

- For the **literature review,** the purpose is to show you have reviewed the research literature to find out if anyone has discovered a new risk for your

research method in their own research. This is extremely unlikely for most linguistic methods. You may be able to put something like "A Google search on the terms 'research AND recording AND speech AND (language you're working on) AND risk' returned only 3 hits, none of which were relevant to the current research method."

- The Human Subjects Protection Office (HSPP) will *probably* send you a **notification to remind you** about your annual review, but don't count on it. Keep track of your expiration date yourself.
- HSPP sets the deadline for renewal paperwork very early, well before the expiration date on the project, so that they have time to review it. **Do not let your project expire, and do not submit your renewal after the deadline they give you: the university IRB will cancel your project and you will have to start over, possibly with complications about using your earlier data.**

VII. Amendments

If you have received approval for a research project, and you realize you want to modify it to have permission to do something slightly different, you may need to file an amendment.

Amendments for exempt projects (regardless of whether the projects were declared exempt by the HSPP office or by the departmental IRB committee):

Amendments for exempt projects are only required if the change you're requesting is one of the following:

- Changes in PI/Co-PI's
- Research involving prisoners
- New knowledge that increases the risk level
- Removal or addition of funding
- Addition of a B–UMG site
- Survey or interview procedures that involve children (i.e., individuals under the age of 18) that do not fall under exempt category 1 which describes research in commonly accepted educational settings
- Observational research of children that involves participation by the researcher
- Research subject to FDA regulations
- The use of any methods described in the Expedited review categories that do not meet the exempt criteria (e.g., blood draws). For information about Expedited review categories, please refer to this link: http://www.hhs.gov/ohrp/policy/expedited98.html.

- Change in the way identifiers are recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that subjects can be identified
- Records review that involve prospective collection of data
- Addition of an instrument, survey, etc. from which information obtained is recorded in such a manner that (i) human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
- Addition of vulnerable populations and research activities that may pose more than minimal risk to the participant.

If the change you're requesting is on the list above, you need to file an amendment with the HSPP office with the appropriate form(s). To do so, please follow the procedure for non-exempt projects described below.

All other changes to exempt projects do not require an amendment. However, you must keep a record of any changes to the protocol (e.g., type of change you made and date of change) as you may be asked to produce such documentation if your project is audited by the university IRB.

Procedure if your project is not exempt:
You have to file an Amendment form to the HSPP office. Check the website for the current correct form, fill it out, obtain signatures from the departmental committee, and file it by emailing it to the HSPP Office.