Renewals

A HOW-TO

Objectives

1. Why are renewals necessary?
2. What projects require a renewal?
3. How do I find the form?
4. How do I fill out the form?
5. What are the required documents with submission?
6. When do I submit the renewal?
7. Where do I submit the renewal?

Why are renewals necessary?

- Renewals are required under the regulations
- Renewals are necessary to ensure the continued protection of the rights and welfare of research subjects.
- Provides the IRB with a “snapshot” of the project within a year period.

What projects require a renewal?

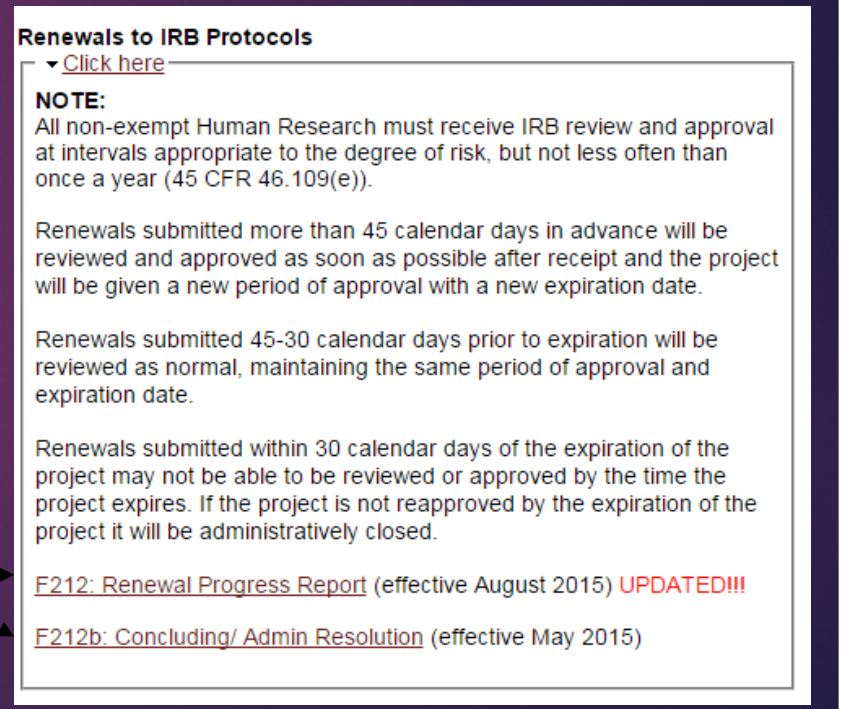
- All non-exempt Human Research.
  - i.e. Expedite research and full committee
  - Reference your IRB approval letter for determination to verify!

How do I find the form?

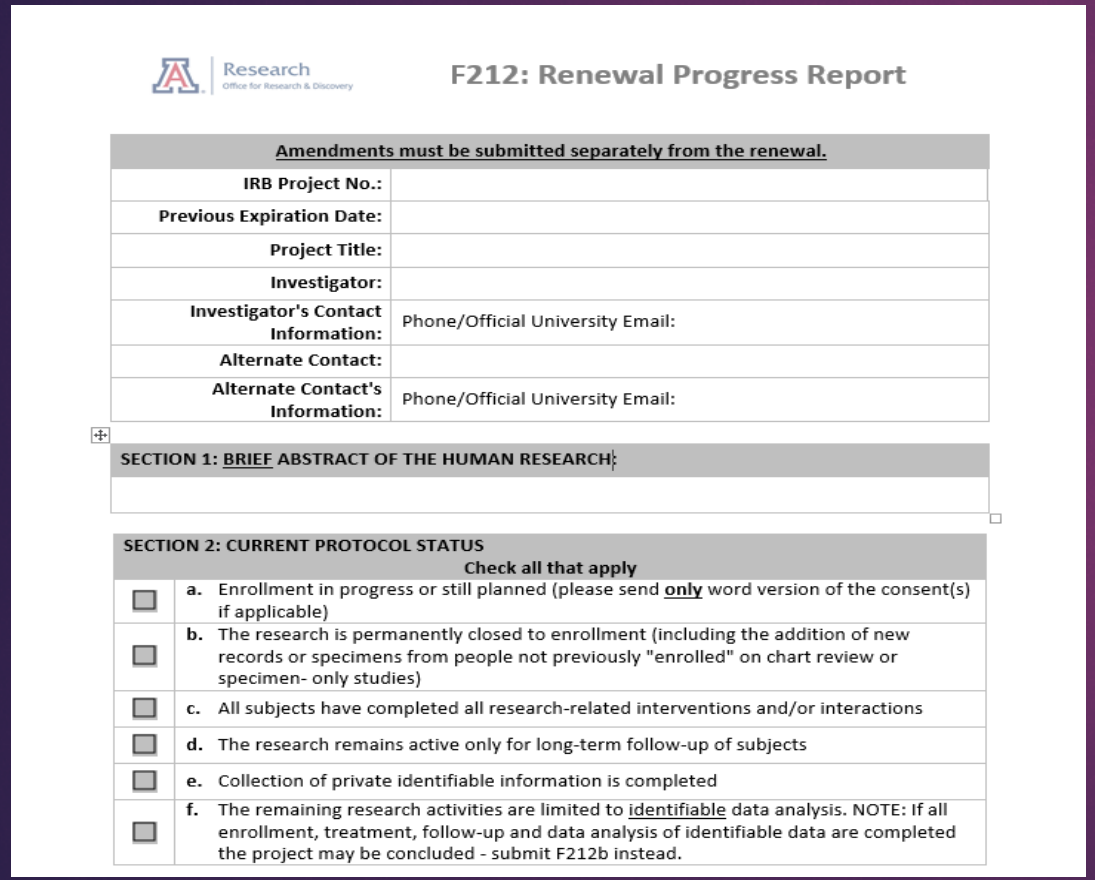
Go to our website, under forms: http://orcr.arizona.edu/hspp/forms.
Download the appropriate renewal form, under "Renewals to IRB Protocols":

- F212- used when research is ongoing. This includes enrollment, closed enrollment, data analysis, follow-up, etc.

- F212b- used when research is concluding. This Includes analyzing only de-identified data.



How do I fill out the form?



Research
Office for Research & Discovery

F212: Renewal Progress Report

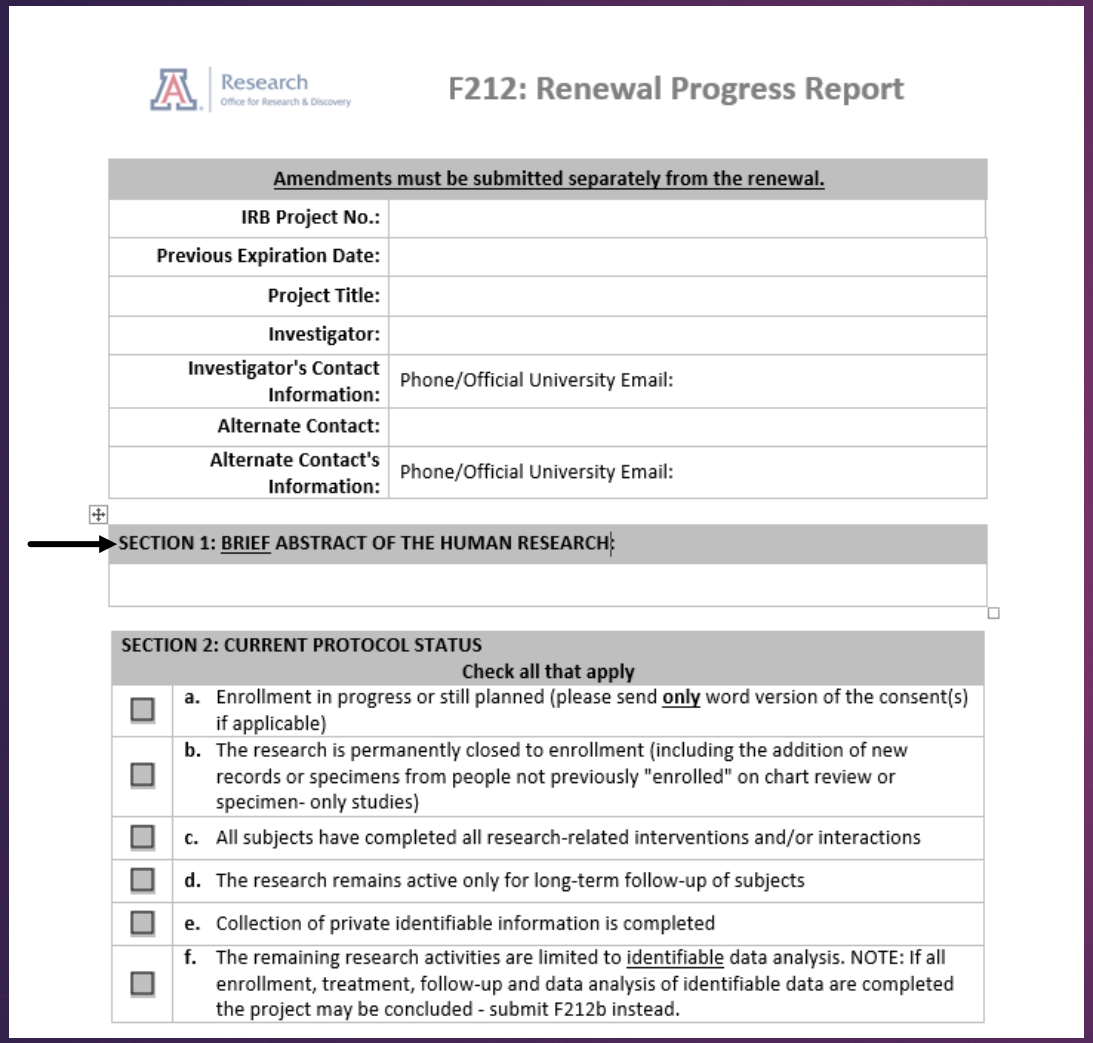
Amendments must be submitted separately from the renewal.	
IRB Project No.:	
Previous Expiration Date:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: BRIEF ABSTRACT OF THE HUMAN RESEARCH

SECTION 2: CURRENT PROTOCOL STATUS Check all that apply	
☐	**a.** Enrollment in progress or still planned (please send **only** word version of the consent(s) if applicable)
☐	**b.** The research is permanently closed to enrollment (including the addition of new records or specimens from people not previously "enrolled" on chart review or specimen- only studies)
☐	**c.** All subjects have completed all research-related interventions and/or interactions
☐	**d.** The research remains active only for long-term follow-up of subjects
☐	**e.** Collection of private identifiable information is completed
☐	**f.** The remaining research activities are limited to identifiable data analysis. NOTE: If all enrollment, treatment, follow-up and data analysis of identifiable data are completed the project may be concluded - submit F212b instead.

Let's break it down by section...

Both the F212 and F212b ask very similar questions, we will use the form F212 for example purposes.



Research
Office for Research & Discovery

F212: Renewal Progress Report

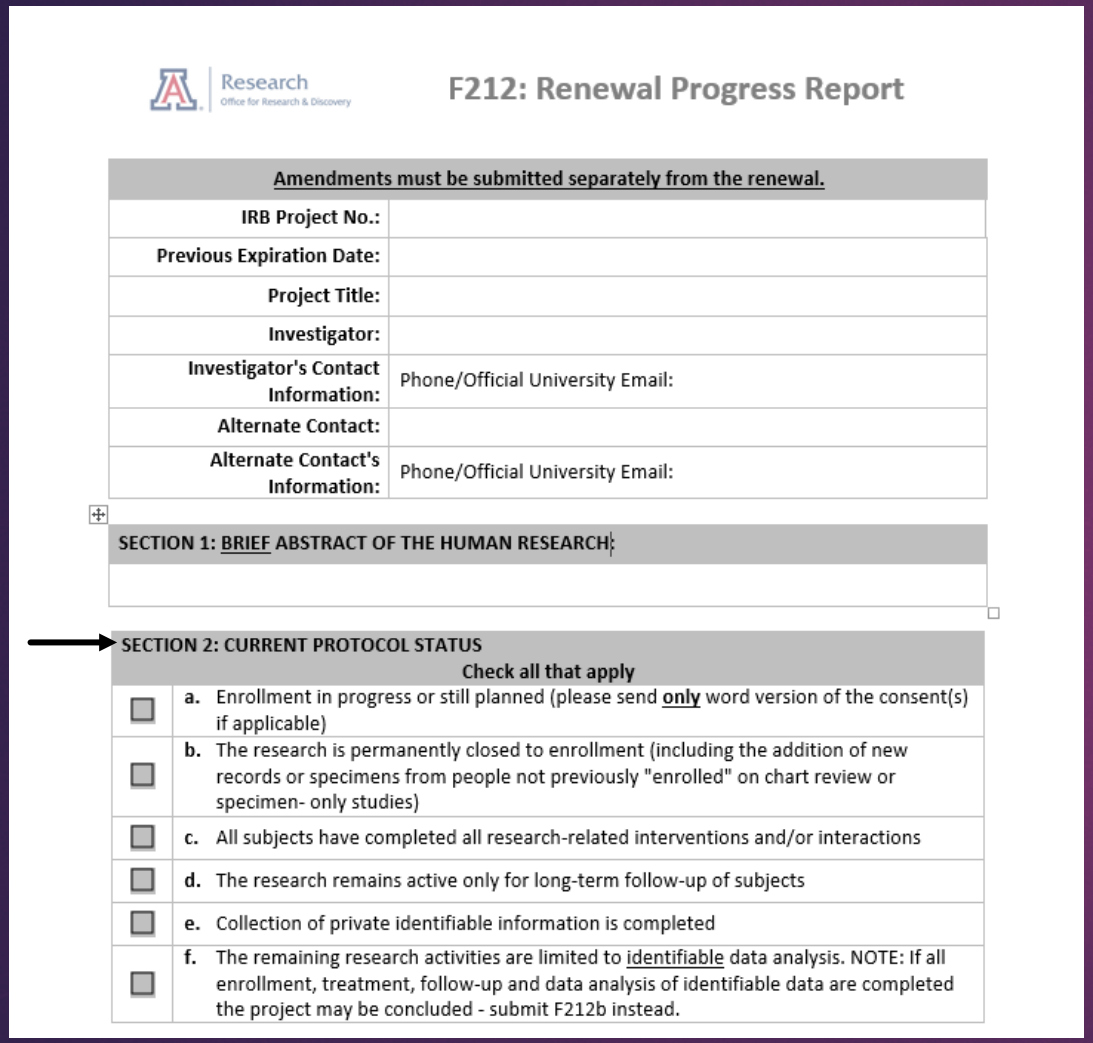
Amendments must be submitted separately from the renewal.	
IRB Project No.:	
Previous Expiration Date:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: BRIEF ABSTRACT OF THE HUMAN RESEARCH

SECTION 2: CURRENT PROTOCOL STATUS Check all that apply	
☐	**a.** Enrollment in progress or still planned (please send **only** word version of the consent(s) if applicable)
☐	**b.** The research is permanently closed to enrollment (including the addition of new records or specimens from people not previously "enrolled" on chart review or specimen- only studies)
☐	**c.** All subjects have completed all research-related interventions and/or interactions
☐	**d.** The research remains active only for long-term follow-up of subjects
☐	**e.** Collection of private identifiable information is completed
☐	**f.** The remaining research activities are limited to identifiable data analysis. NOTE: If all enrollment, treatment, follow-up and data analysis of identifiable data are completed the project may be concluded - submit F212b instead.

Section 1

Give us an abstract of your research. This can be cut and pasted from your currently approved IRB application.



Research
Office for Research & Discovery

F212: Renewal Progress Report

Amendments must be submitted separately from the renewal.	
IRB Project No.:	
Previous Expiration Date:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: BRIEF ABSTRACT OF THE HUMAN RESEARCH

SECTION 2: CURRENT PROTOCOL STATUS

Check all that apply

☐	**a.** Enrollment in progress or still planned (please send **only** word version of the consent(s) if applicable)
☐	**b.** The research is permanently closed to enrollment (including the addition of new records or specimens from people not previously "enrolled" on chart review or specimen- only studies)
☐	**c.** All subjects have completed all research-related interventions and/or interactions
☐	**d.** The research remains active only for long-term follow-up of subjects
☐	**e.** Collection of private identifiable information is completed
☐	**f.** The remaining research activities are limited to identifiable data analysis. NOTE: If all enrollment, treatment, follow-up and data analysis of identifiable data are completed the project may be concluded - submit F212b instead.

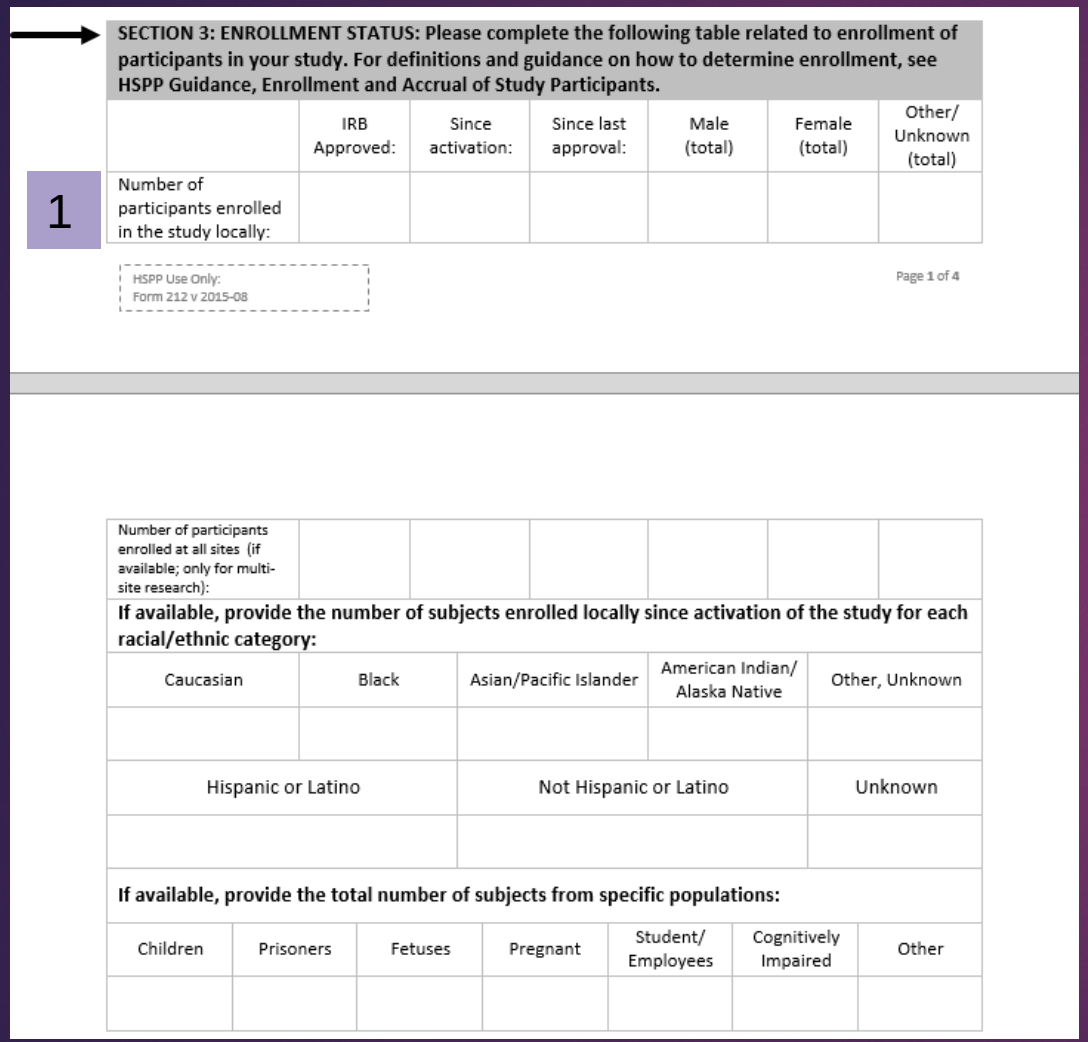
Section 2

This is the section where you update the IRB on what you plan to do for the next year.

Please note: Whatever option you chose will be what we note in our system. To change the status, an amendment would be necessary, otherwise it can be changed at the next year's renewal.

Hints:

- if you are planning on enrolling, **only** check option "a".
- If you are planning to only perform identifiable data analysis, **only** check option "f".
- Options "b-e" allow multiple options to choose.



SECTION 3: ENROLLMENT STATUS: Please complete the following table related to enrollment of participants in your study. For definitions and guidance on how to determine enrollment, see HSPP Guidance, Enrollment and Accrual of Study Participants.

		IRB Approved:	Since activation:	Since last approval:	Male (total)	Female (total)	Other/ Unknown (total)
1	Number of participants enrolled in the study locally:						

HSPP Use Only:
Form 212 v 2015-08

Page 1 of 4

Number of participants enrolled at all sites (if available; only for multi-site research):						

If available, provide the number of subjects enrolled locally since activation of the study for each racial/ethnic category:

Caucasian	Black	Asian/Pacific Islander	American Indian/ Alaska Native	Other, Unknown

Hispanic or Latino	Not Hispanic or Latino	Unknown

If available, provide the total number of subjects from specific populations:

Children	Prisoners	Fetuses	Pregnant	Student/ Employees	Cognitively Impaired	Other

Section 3

- This is the section where you update the IRB enrollment numbers.
- This is the most complicated part, so let's break it down.

Part 1:

Number of participants enrolled in the study locally: this indicates participants that are enrolled under UA IRB's approval.

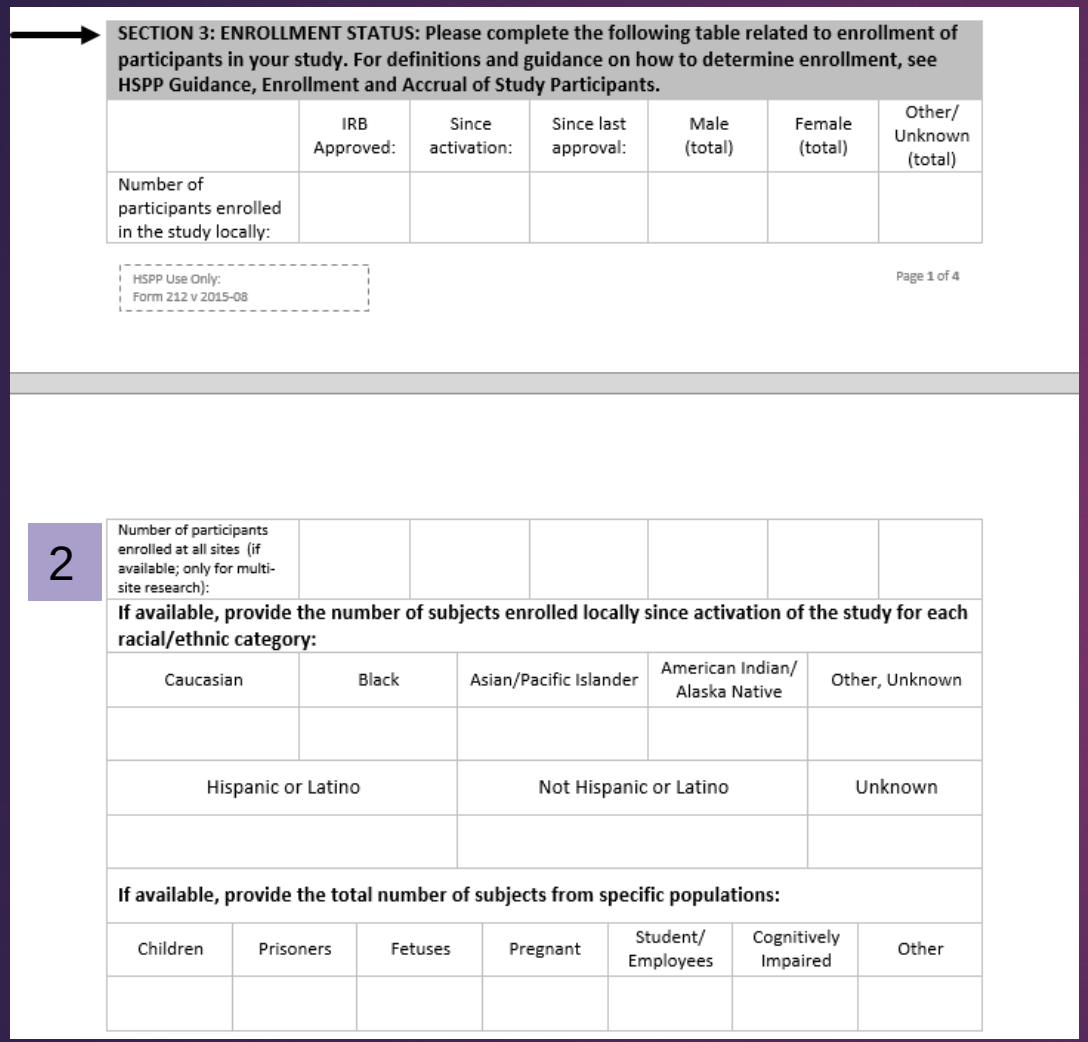
IRB Approved: What is your IRB approved limit to enroll? Find this on your most currently approved IRB application (F200 or F203).

Since Activation: How many subjects have you enrolled since the original project approval?

Since Last Approval: How many subjects have you enrolled since your last renewal? If this is your first renewal, list your "since activation" number here, as well.

Male/Female/Other: Breakdown your numbers for us based on sex. Unsure? Mark in the "other/unknown" box.

Section 3 cont.



SECTION 3: ENROLLMENT STATUS: Please complete the following table related to enrollment of participants in your study. For definitions and guidance on how to determine enrollment, see HSPP Guidance, Enrollment and Accrual of Study Participants.

	IRB Approved:	Since activation:	Since last approval:	Male (total)	Female (total)	Other/ Unknown (total)
Number of participants enrolled in the study locally:						

HSPP Use Only:
Form 212 v 2015-08

Page 1 of 4

2

Number of participants enrolled at all sites (if available; only for multi-site research):						

If available, provide the number of subjects enrolled locally since activation of the study for each racial/ethnic category:

Caucasian	Black	Asian/Pacific Islander	American Indian/ Alaska Native	Other, Unknown

Hispanic or Latino	Not Hispanic or Latino	Unknown

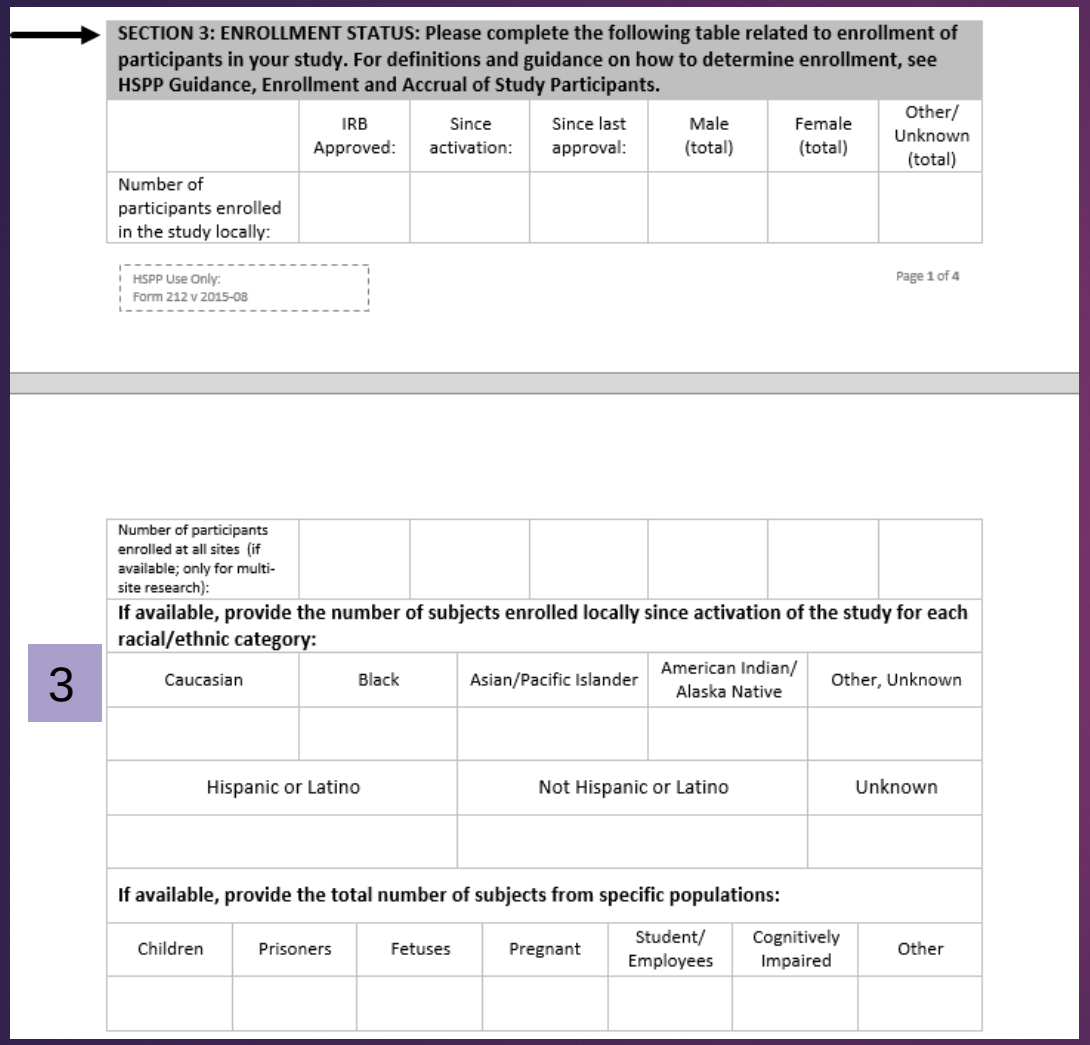
If available, provide the total number of subjects from specific populations:

Children	Prisoners	Fetuses	Pregnant	Student/ Employees	Cognitively Impaired	Other

Part 2:

Number of participants enrolled at all sites: this applies for multi-site studies- meaning other sites that are collaborating on the said research **yet** under another IRB's approval. This doesn't apply to a lot of our currently open research projects.

Same instructions apply as mentioned in the previous slide…



SECTION 3: ENROLLMENT STATUS: Please complete the following table related to enrollment of participants in your study. For definitions and guidance on how to determine enrollment, see HSPP Guidance, Enrollment and Accrual of Study Participants.

	IRB Approved:	Since activation:	Since last approval:	Male (total)	Female (total)	Other/ Unknown (total)
Number of participants enrolled in the study locally:						

HSPP Use Only:
Form 212 v 2015-08

Page 1 of 4

3

Number of participants enrolled at all sites (if available; only for multi-site research):						

If available, provide the number of subjects enrolled locally since activation of the study for each racial/ethnic category:

Caucasian	Black	Asian/Pacific Islander	American Indian/ Alaska Native	Other, Unknown

Hispanic or Latino	Not Hispanic or Latino	Unknown

If available, provide the total number of subjects from specific populations:

Children	Prisoners	Fetuses	Pregnant	Student/ Employees	Cognitively Impaired	Other

Section 3 cont.

Part 3:

Racial/Ethnic Category: This section is for those projects that collect demographics. If your project does not collect demographics, this section is not mandatory!

4

If available, provide the total number of subjects from specific populations:						
Children	Prisoners	Fetuses	Pregnant	Student/ Employees	Cognitively Impaired	Other

SECTION 4: STATUS REPORT ON THE PROGRESS OF THE HUMAN RESEARCH:
1. Status of subjects consented into this study (describe if subject consenting is completed, number of and whether any subjects were screen failures, or whether any subjects withdrew from the research and the reason why):
2. Status of achieving the aims of the human research:
3. Expected progress to be made during the next approval period:
4. A thorough summary of any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research, please note N/A is not accepted by the IRB ("Last IRB review" means an initial or continuing review, whichever is most recent):

Section 3 cont.

Part 4:

Specific Populations: This section covers the vulnerable populations that may be enrolled in your project. **Only** fill out the sections that apply to you (if any).

If available, provide the total number of subjects from specific populations:

Children	Prisoners	Fetuses	Pregnant	Student/ Employees	Cognitively Impaired	Other

SECTION 4: STATUS REPORT ON THE PROGRESS OF THE HUMAN RESEARCH:

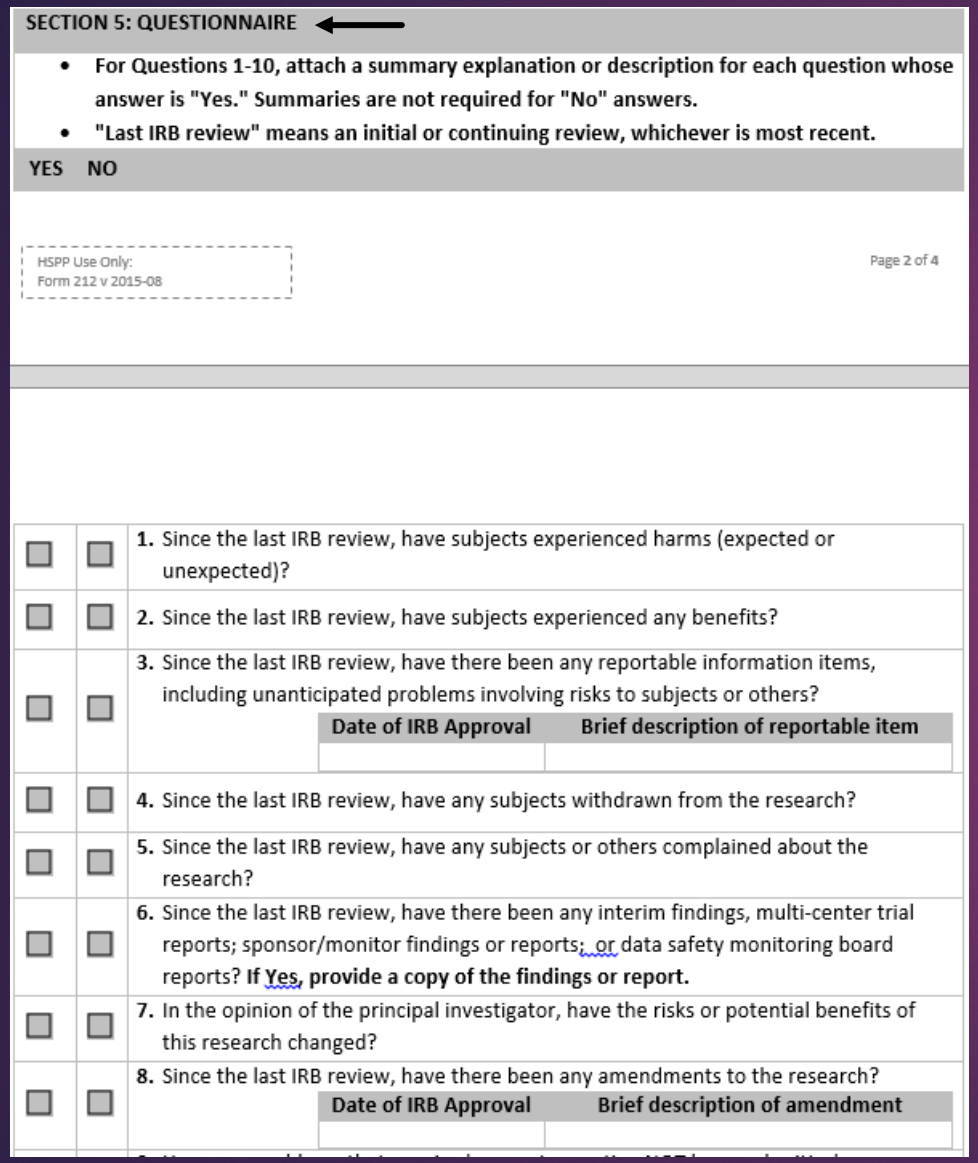
1. Status of subjects consented into this study (describe if subject consenting is completed, number of and whether any subjects were screen failures, or whether any subjects withdrew from the research and the reason why):
2. Status of achieving the aims of the human research:
3. Expected progress to be made during the next approval period:
4. A thorough summary of any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research, please note N/A is not accepted by the IRB ("Last IRB review" means an initial or continuing review, whichever is most recent):

Section 4

This section is where you inform the IRB of the progress of your research.

Tips:

- The chair will not accept the answer “N/A”.
- Question 4 seems to cause the most issues. The Chair wants to know if any new literature on your topic demonstrates an increase in risks to subjects. If no new risks are identified, tell the chair where you searched.



SECTION 5: QUESTIONNAIRE

- **For Questions 1-10, attach a summary explanation or description for each question whose answer is "Yes." Summaries are not required for "No" answers.**
- **"Last IRB review" means an initial or continuing review, whichever is most recent.**

YES NO

HSPP Use Only:
Form 212 v 2015-08

Page 2 of 4

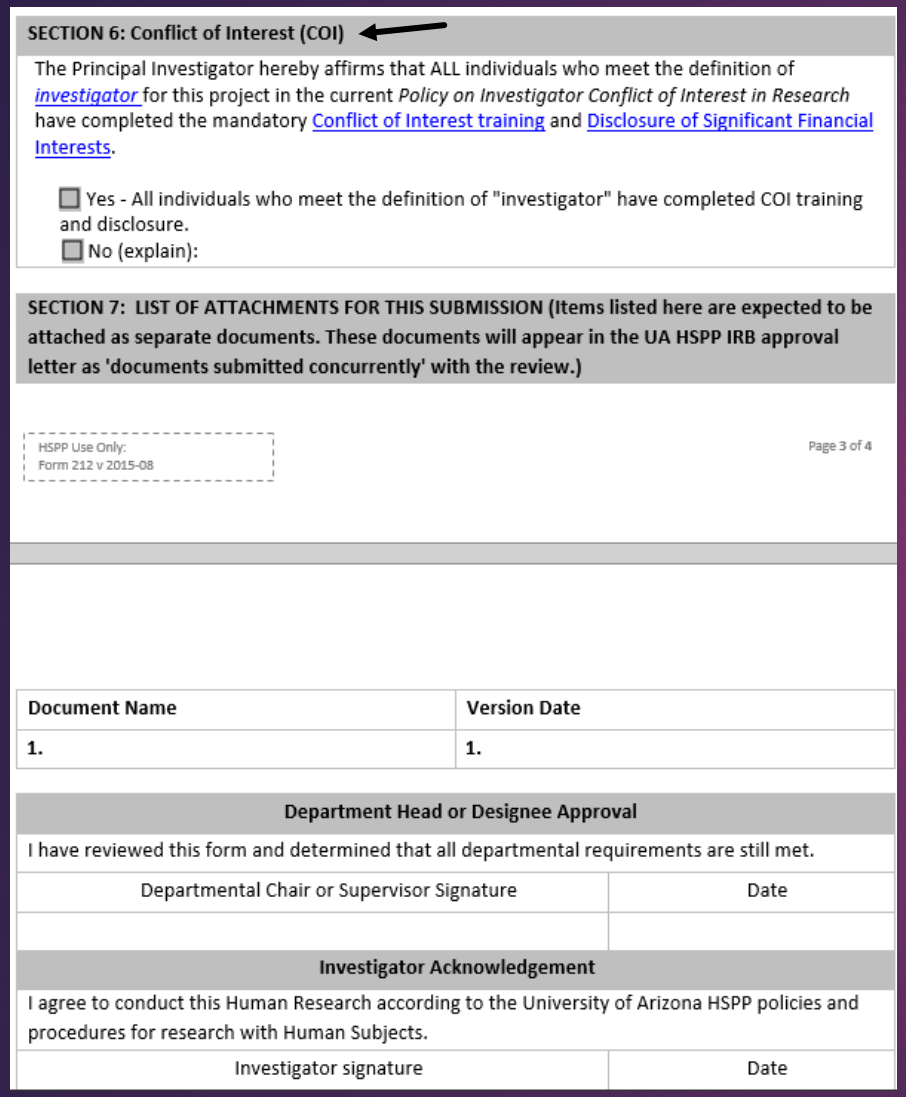
YES	NO	
☐	☐	**1.** Since the last IRB review, have subjects experienced harms (expected or unexpected)?
☐	☐	**2.** Since the last IRB review, have subjects experienced any benefits?
☐	☐	**3.** Since the last IRB review, have there been any reportable information items, including unanticipated problems involving risks to subjects or others? **Date of IRB Approval** / **Brief description of reportable item**
☐	☐	**4.** Since the last IRB review, have any subjects withdrawn from the research?
☐	☐	**5.** Since the last IRB review, have any subjects or others complained about the research?
☐	☐	**6.** Since the last IRB review, have there been any interim findings, multi-center trial reports; sponsor/monitor findings or reports; or data safety monitoring board reports? **If Yes, provide a copy of the findings or report.**
☐	☐	**7.** In the opinion of the principal investigator, have the risks or potential benefits of this research changed?
☐	☐	**8.** Since the last IRB review, have there been any amendments to the research? **Date of IRB Approval** / **Brief description of amendment**

Section 5

This section consists of “yes” or “no” questions. Anytime you check “yes”, the chair will require an explanation. This can be done via a separate attachment, or an explanation within the same box.

Tips:

- Every question must be answered.
- Question 8 seems to cause the most trouble. This question asks if any amendments have been made, if “yes”, please list each amendment approval date and description in the boxes provided. No additional attachment necessary. Keep track of your amendments!



SECTION 6: Conflict of Interest (COI)

The Principal Investigator hereby affirms that ALL individuals who meet the definition of *investigator* for this project in the current *Policy on Investigator Conflict of Interest in Research* have completed the mandatory Conflict of Interest training and Disclosure of Significant Financial Interests.

☐ Yes - All individuals who meet the definition of "investigator" have completed COI training and disclosure.
☐ No (explain):

SECTION 7: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)

HSPP Use Only:
Form 212 v 2015-08

Page 3 of 4

Document Name	Version Date
1.	1.

Department Head or Designee Approval	
I have reviewed this form and determined that all departmental requirements are still met.	
Departmental Chair or Supervisor Signature	Date

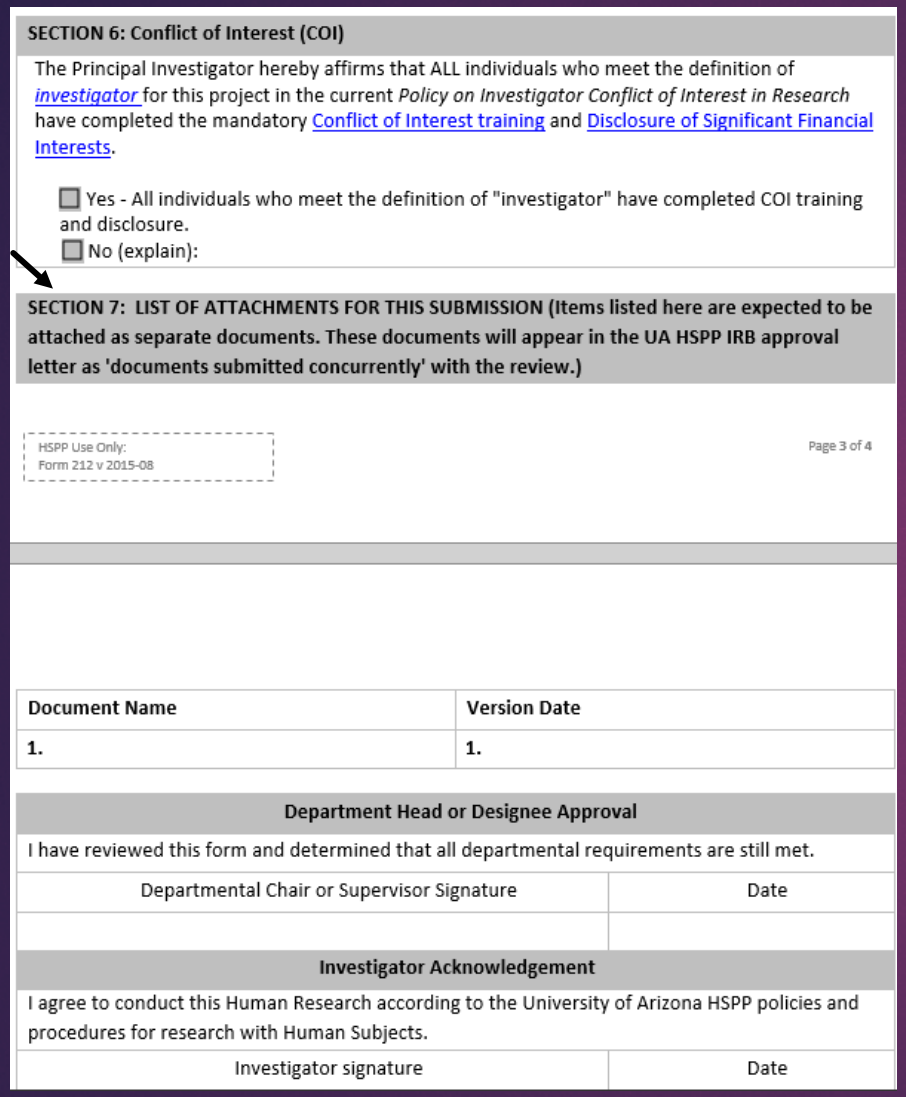
Investigator Acknowledgement	
I agree to conduct this Human Research according to the University of Arizona HSPP policies and procedures for research with Human Subjects.	
Investigator signature	Date

Section 6

This section simply wants to know if you have completed your COI training.

Tips:

- The answer must be “yes”, because this training is a requirement!



SECTION 6: Conflict of Interest (COI)

The Principal Investigator hereby affirms that ALL individuals who meet the definition of *investigator* for this project in the current *Policy on Investigator Conflict of Interest in Research* have completed the mandatory Conflict of Interest training and Disclosure of Significant Financial Interests.

☐ Yes - All individuals who meet the definition of "investigator" have completed COI training and disclosure.
☐ No (explain):

SECTION 7: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)

HSPP Use Only:
Form 212 v 2015-08

Page 3 of 4

Document Name	Version Date
1.	1.

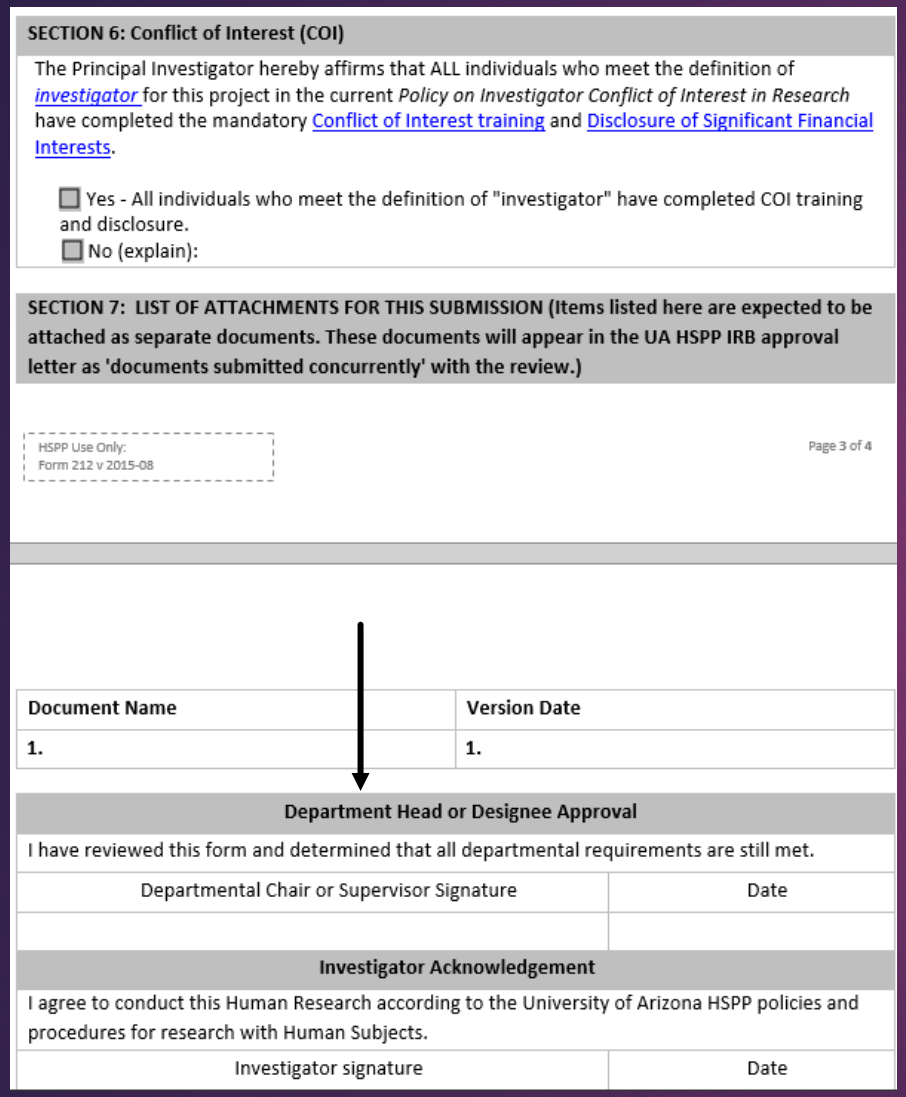
Department Head or Designee Approval	
I have reviewed this form and determined that all departmental requirements are still met.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
I agree to conduct this Human Research according to the University of Arizona HSPP policies and procedures for research with Human Subjects.	
Investigator signature	Date

Section 7

This section is where you list all of the documents that you have submitted with your submission.

Tips:

- A lot of researchers leave this blank! This is the number one "pre-review" comment! So, please be sure to fill this section out in order for the IRB to ensure we have all proper documentation.



SECTION 6: Conflict of Interest (COI)

The Principal Investigator hereby affirms that ALL individuals who meet the definition of *investigator* for this project in the current *Policy on Investigator Conflict of Interest in Research* have completed the mandatory Conflict of Interest training and Disclosure of Significant Financial Interests.

☐ Yes - All individuals who meet the definition of "investigator" have completed COI training and disclosure.
☐ No (explain):

SECTION 7: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)

HSPP Use Only:
Form 212 v 2015-08

Page 3 of 4

Document Name	Version Date
1.	1.

Department Head or Designee Approval

I have reviewed this form and determined that all departmental requirements are still met.

Departmental Chair or Supervisor Signature	Date

Investigator Acknowledgement

I agree to conduct this Human Research according to the University of Arizona HSPP policies and procedures for research with Human Subjects.

Investigator signature	Date

You are near the end!

Do not forget signatures!

What are the required documents with submission?

See HSPP website for submission requirements

Provide 1 copy of the following:

- Consent documents (in Word) to be used in the next approval period (including HIPAA authorization documents, if applicable). This may be omitted if the research is permanently closed to enrollment and if re-consent is not needed.
- A script of information to be provided orally to subjects if consent will not be documented in writing. This may be omitted if the research is permanently closed to enrollment and if re-consent is not needed.
- Summary regarding any "Yes" answers from Section 5; questions 1-12 above.

- See the last page of the form!

Hint: The most common error is a submission that is missing the "word" versions of the **last approved** consent form(s). Don't forget to submit these!

When do I submit the renewal?

Submit renewal documents between 30 and 45 calendar days prior to the expiration of the study.

Email reminders are sent to investigators 60 calendar days prior to expiration. Reminders are sent to the PI and contact person listed on the IRB application.

Hint: Avoid having your project assigned a new expiration date. Renewals submitted over 45 days prior to the expiration date will be issued a new expiration date.

Where do I submit the renewal?

- Please submit the renewal with all required documentation to our departmental email account: VPR-IRB@email.arizona.edu
- You will know the email went through if you receive an immediate “IRB Submission Receipt”.
- An IRB Associate will complete a “pre-review” on your submission, in which you will receive a reply for revisions- not to worry, 9 out of 10 submissions require revisions.
- Be prompt in your response! The faster you are, the faster the submission will go to the chair or committee for review!

Confused?
Want to talk?

- We love to talk to our investigators!
- Reach out to us!
- Whenever you are on our website, our contact
- Information is always found on the right-hand side under “HSPP Contact”.