Amendments

A HOW-TO

Objectives

1. What is an amendment?
2. What projects are required to submit an amendment?
3. How do I find the form?
4. How do I fill out the form?
5. When do I submit the amendment?
6. Where do I submit the amendment?

What is an amendment?

An Amendment is a change you wish to make to a previously approved research project prior to implementing the change*.

Examples:

- Title change
- Updates to key personnel
- Change in study procedures
- Addition or revision of recruitment text or locations
- Addition or revision data collection measures, or eligibility

*The only exception to this policy is when a change is needed to eliminate apparent immediate hazards to human subjects. If this occurs, then the IRB must be notified within five (5) days.

What projects are required to submit an amendment?

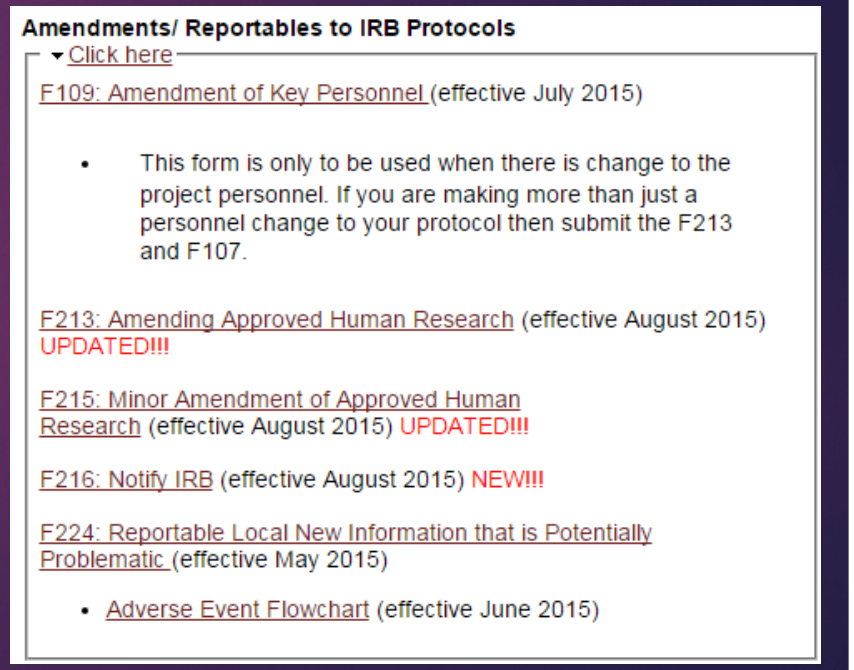
- All non-exempt Human Research.
  - i.e. Expedite research or full committee research
  - Reference your IRB approval letter for determination to verify!

Please note: There are instances in which exempt research requires an amendment. See our guidance: http://orcr.arizona.edu/sites/orcr.arizona.edu/files/Exempt%20Research%20v2015-08.pdf

How do I find the form(s)?

- Go to our website, under forms: http://orcr.arizona.edu/hspp/forms
- Download the appropriate amendment form, under "Amendments/ Reportables to IRB Protocols":

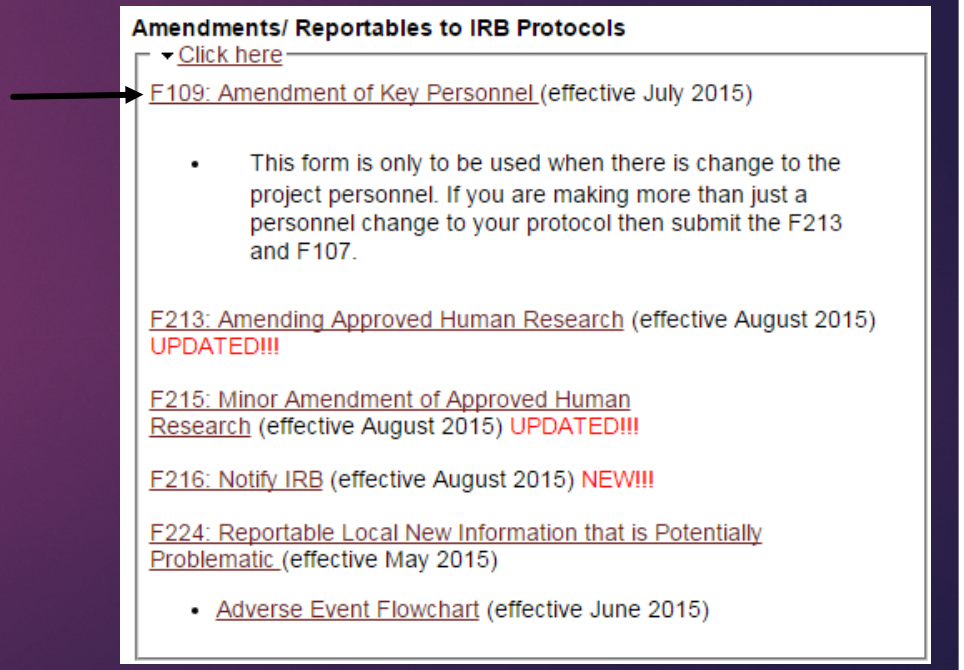
There are multiple types of forms. Let's break them down to find the form that best represents the amendment you wish to make.



F109

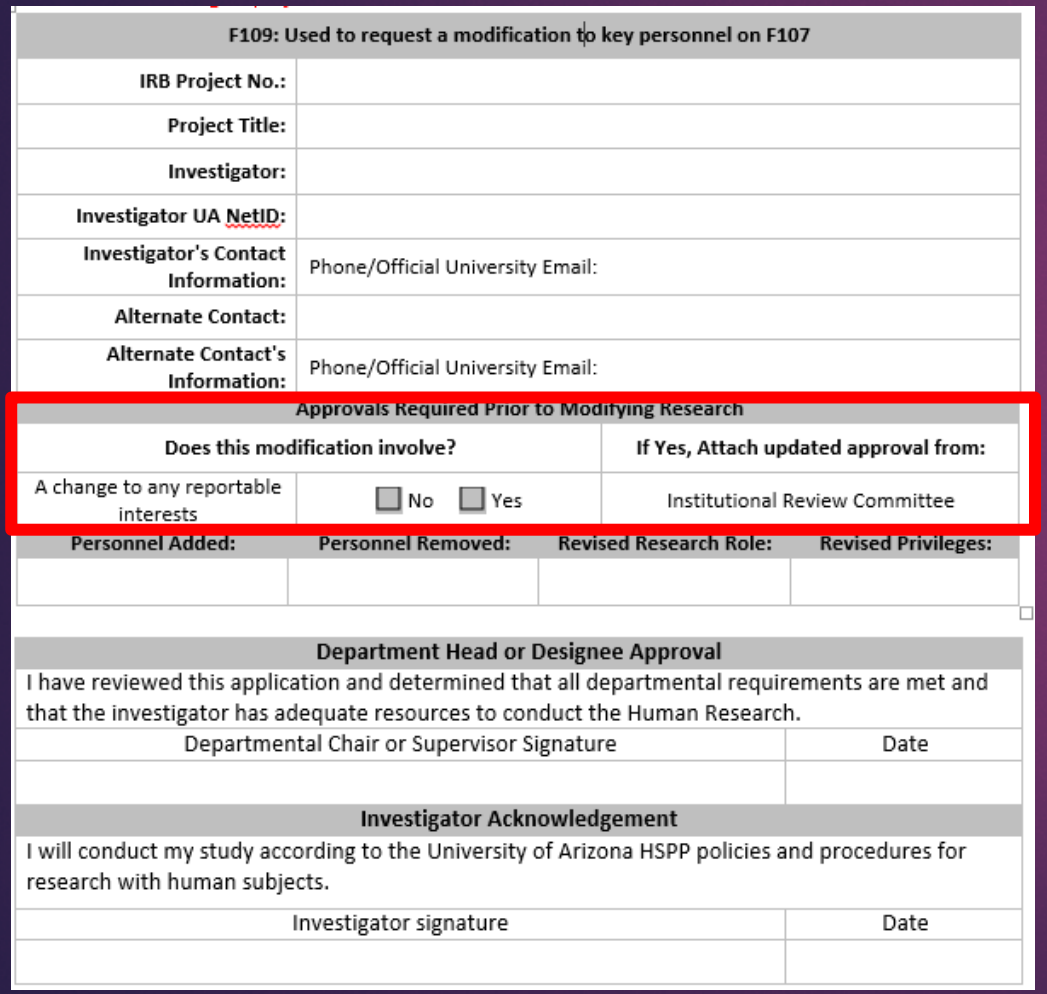
This form is used to add/remove/revise the "key personnel" listed on your protocol*.

> *Key Personnel: the PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation" I.e. those that are recruiting, consenting, have access to identifiers, and interacting with subjects.*



*If you are making more than just a personnel change, you need to use a F213 and provide only the updated F107 portion in addition to the F213.

How do I fill out the F109?



F109: Used to request a modification to key personnel on F107	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

Approvals Required Prior to Modifying Research		
Does this modification involve?		**If Yes, Attach updated approval from:**
A change to any reportable interests	☐ No ☐ Yes	Institutional Review Committee

Personnel Added:	Personnel Removed:	Revised Research Role:	Revised Privileges:

Department Head or Designee Approval	
I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date

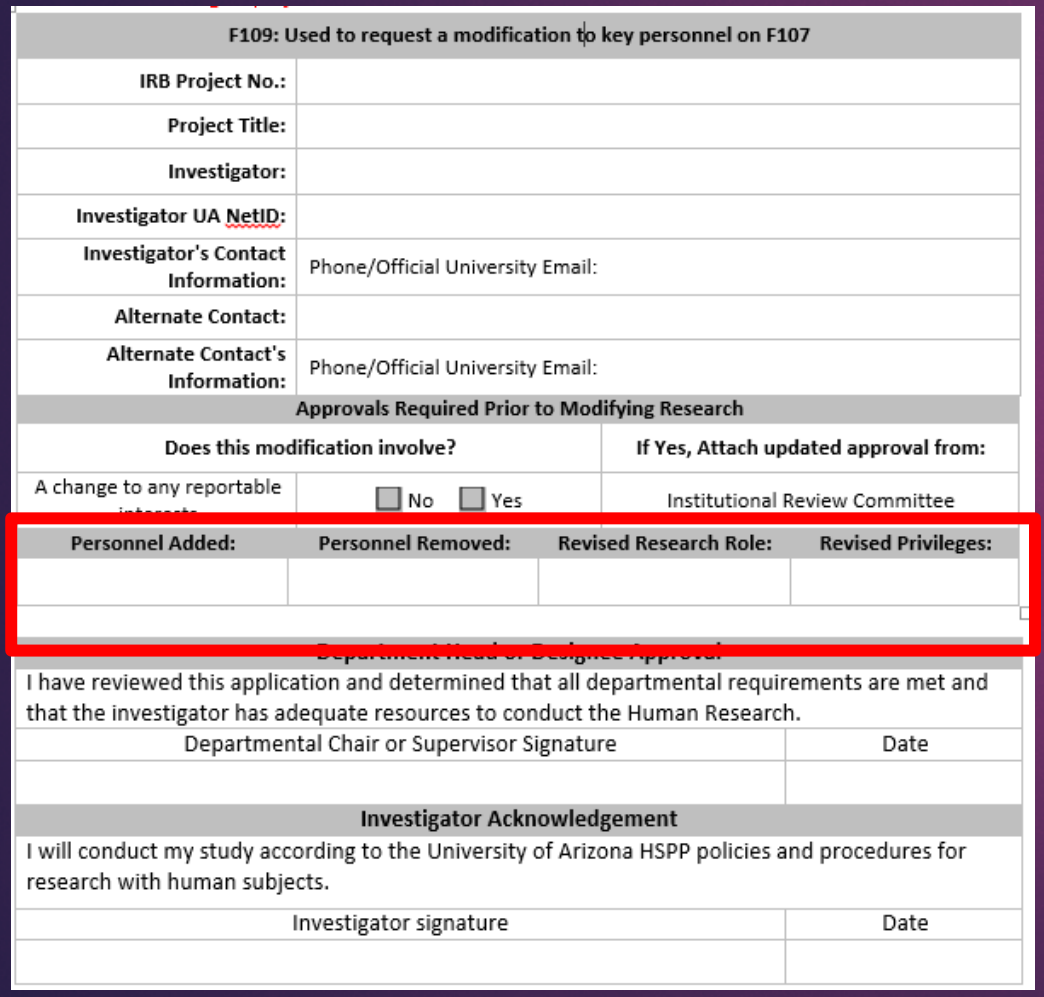
Investigator Acknowledgement	
I will conduct my study according to the University of Arizona HSPP policies and procedures for research with human subjects.	
Investigator signature	Date

Let's break it down by section...

Are there any changes to your conflict of interest reporting?

If you mark "yes", we do require approval from the IRC.

F109 continued…



F109: Used to request a modification to key personnel on F107	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

Approvals Required Prior to Modifying Research		
Does this modification involve?		If Yes, Attach updated approval from:
A change to any reportable	☐ No ☐ Yes	Institutional Review Committee

Personnel Added:	Personnel Removed:	Revised Research Role:	Revised Privileges:

Department Head or Designee Approval	
I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date

Investigator Acknowledgement	
I will conduct my study according to the University of Arizona HSPP policies and procedures for research with human subjects.	
Investigator signature	Date

This is the section where you break down exactly what is changing.

Personnel Added: Who are you adding? State specific names!

Personnel Removed: Who are you Removing? State specific names!

Revised Research Role: This section is for any changes to the research role of an existing personnel. (Example: "John Smith has changed from the research coordinator to Co-PI.")

Revised Privileges: This section is where you can change consenting privileges to an existing personnel. (Example: "John Smith can now consent.")

F109 continued…

F109: Used to request a modification to key personnel on F107	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

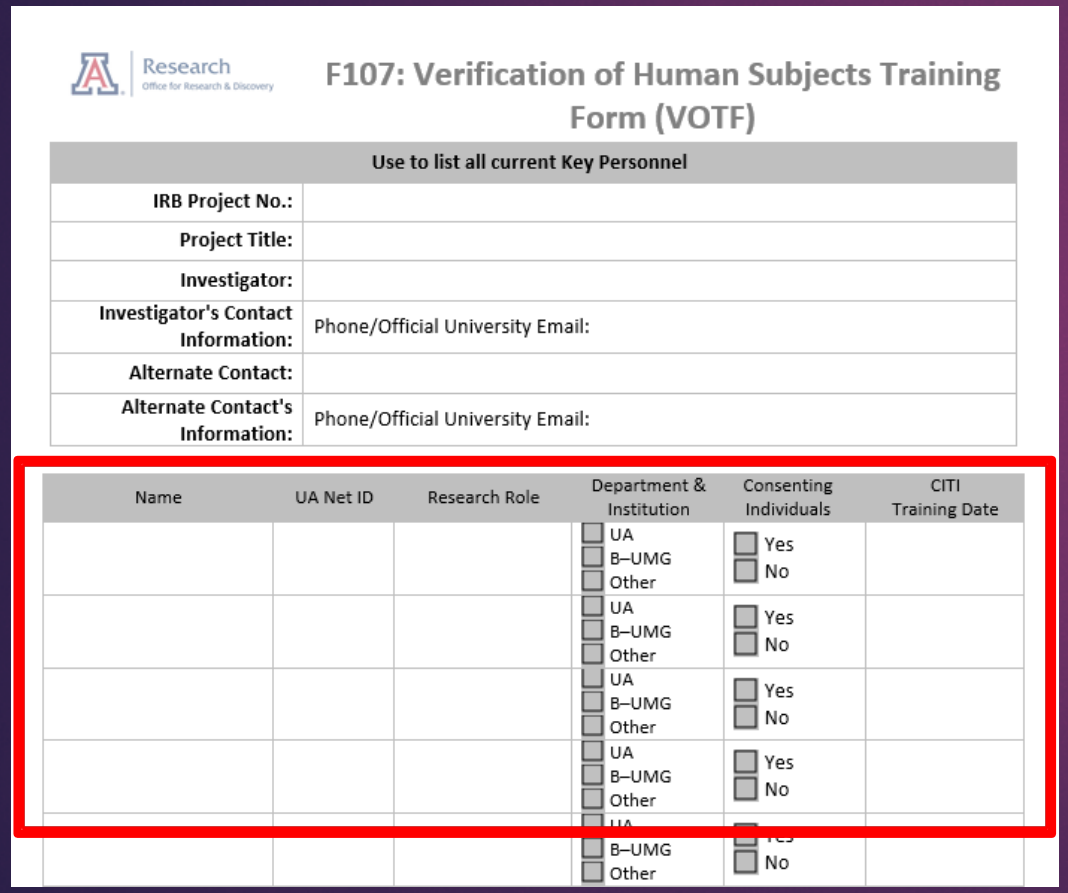
Approvals Required Prior to Modifying Research		
Does this modification involve?		**If Yes, Attach updated approval from:**
A change to any reportable interests	☐ No ☐ Yes	Institutional Review Committee

Personnel Added:	Personnel Removed:	Revised Research Role:	Revised Privileges:

Department Head or Designee Approval	
I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
I will conduct my study according to the University of Arizona HSPP policies and procedures for research with human subjects.	
Investigator signature	Date

Signatures are required!

F109 continued…



Research
Office for Research & Discovery

F107: Verification of Human Subjects Training Form (VOTF)

Use to list all current Key Personnel	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

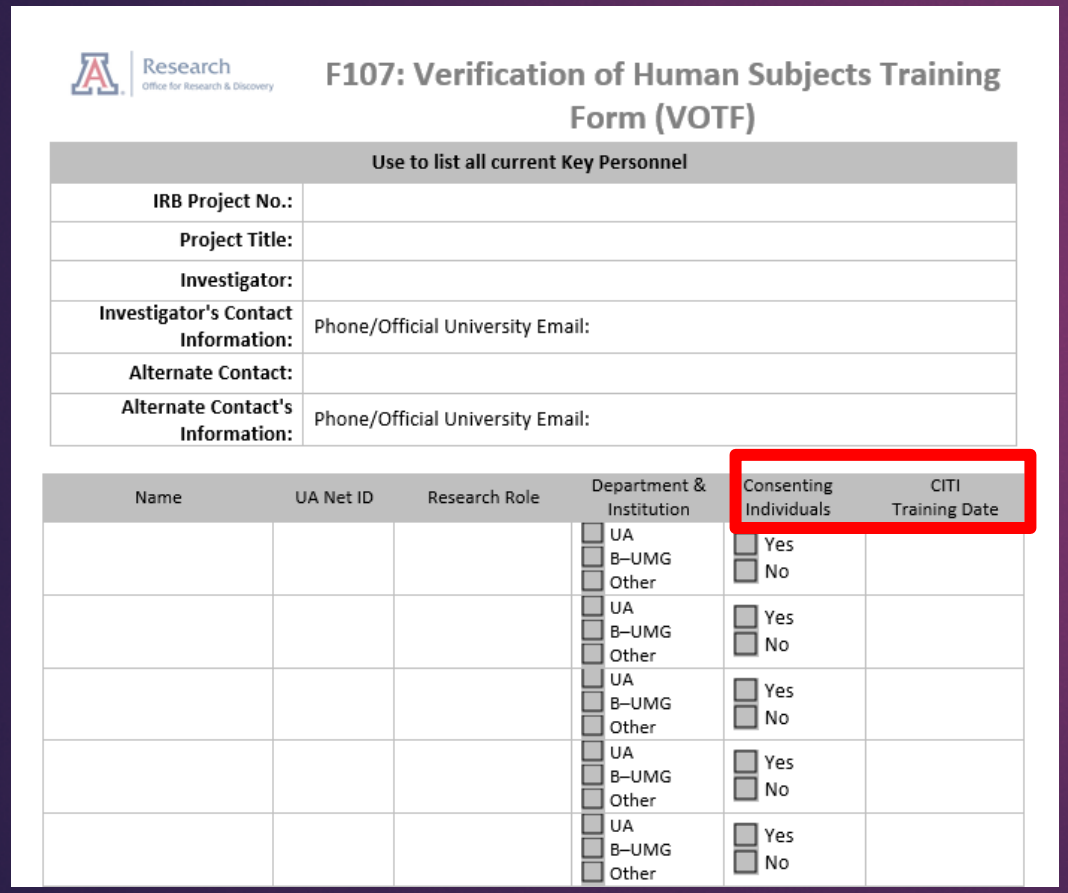
Name	UA Net ID	Research Role	Department & Institution	Consenting Individuals	CITI Training Date
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	

Now, we are at the F107 portion of the form.

- This must include all previously approved personnel **AND** newly added or revised personnel.
- It is easiest to "cut" and "paste" your last approved F107 on this form(or just edit off your last approved one).
- Revise your F107 based on what you have stated in the F109 portion.

TIP: if you are adding a PI or Co-PI, their CV is required with submission.

F109 continued…



Research
Office for Research & Discovery

F107: Verification of Human Subjects Training Form (VOTF)

Use to list all current Key Personnel	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

Name	UA Net ID	Research Role	Department & Institution	Consenting Individuals	CITI Training Date
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	
			☐ UA ☐ B–UMG ☐ Other	☐ Yes ☐ No	

The following boxes are the most commonly confused sections:

- **Consenting individuals:** Is this individual going to consent subjects? Yes or no?
- **CITI training date:** What is the date that CITI training was completed? Please note: CITI training is only good for four years!

F213

This form is used to make "**major**" changes to your project.

Examples include (but are not limited to):

- Title change
- Change in study procedures
- Addition or revision to data collection measures, or eligibility
- Increasing enrollment numbers
- Closing enrollment

How do I fill out the F213?

Request to amend previously approved research See HSPP Guidance, Amending Approved Human Research	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Approvals Required Prior to Amending Research		
Does this amendment involve any changes to:		**If Yes, Attach updated approval from:**
Use, type, or frequency of radiation, laser, or MRI	☐ No ☐ Yes	Radiation Safety Committee
Use of any biohazards	☐ No ☐ Yes	Biosafety Committee
Any reportable interests	☐ No ☐ Yes	Conflict of Interest Institutional Review Committee

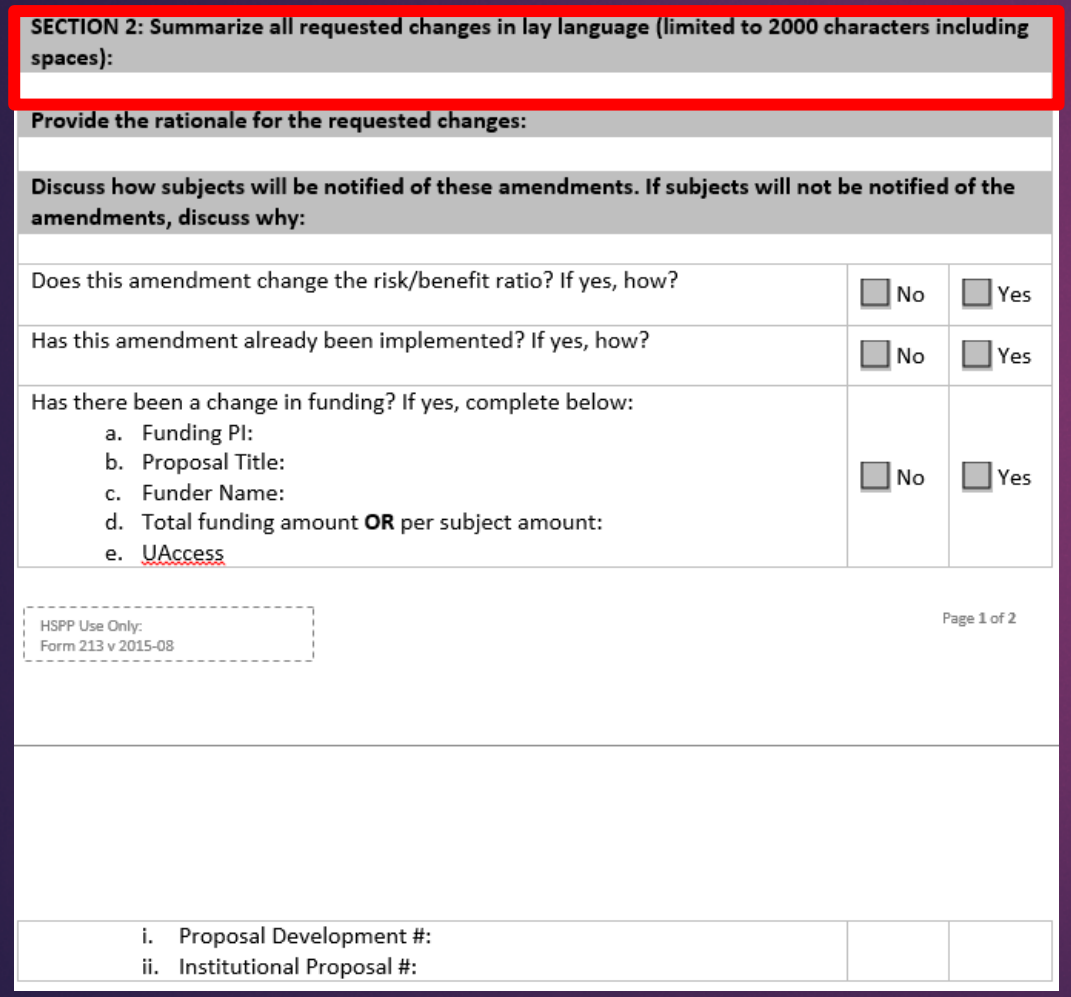
Section 1:

This is the section where you update us on any new changes involving:

-radiation
-biohazards
-Reportable interests

Please note: a “yes” answer, requires additional “approval” documentation.

F213 continued…



SECTION 2: Summarize all requested changes in lay language (limited to 2000 characters including spaces):		
Provide the rationale for the requested changes:		
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes

HSPP Use Only:
Form 213 v 2015-08

Page 1 of 2

i. Proposal Development #: ii. Institutional Proposal #:		

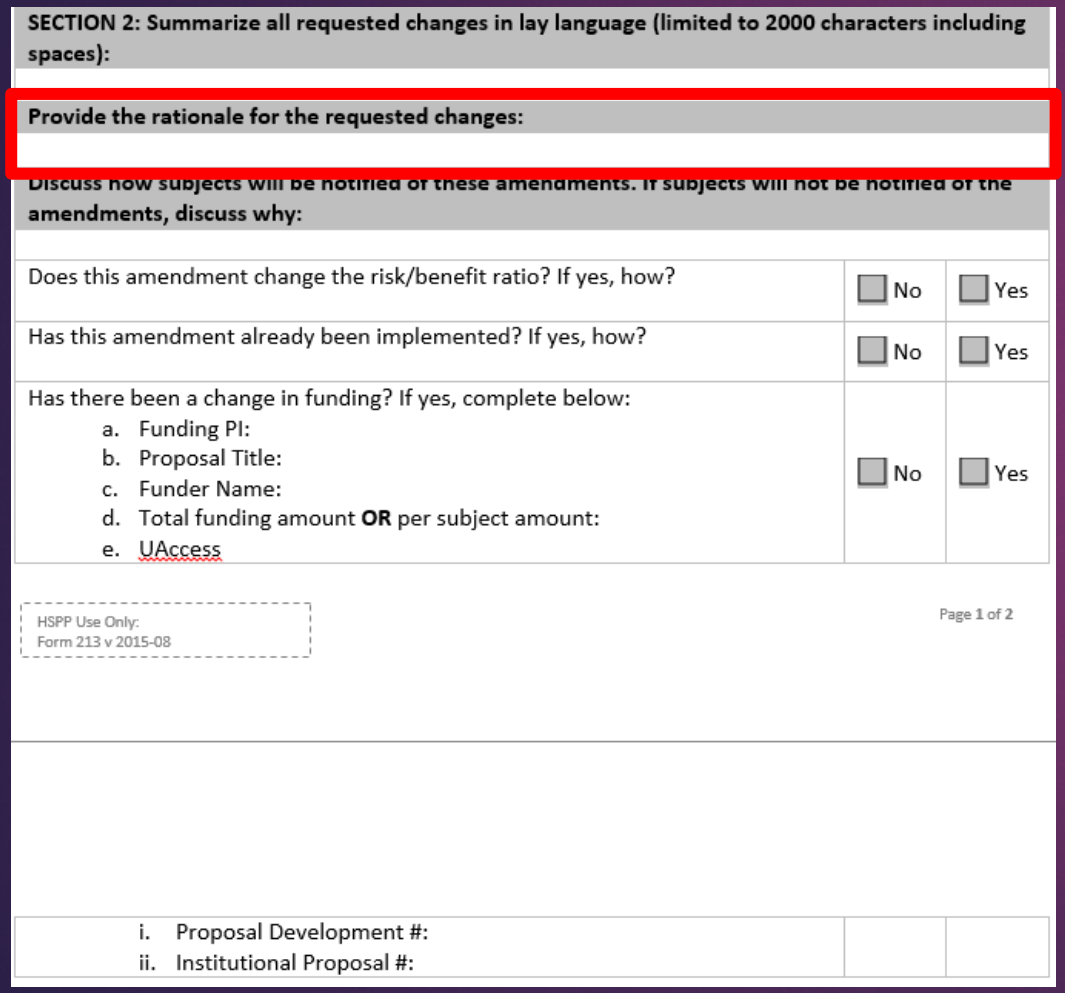
Section 2:

This is where you describe the changes.

Summarize all requested changes in lay language:
For this, we are looking for text surrounding the exact changes you are making. All changes or additions to the protocol must be mentioned here. You must keep this section limited to 2000 characters (including spaces).

Example text: "We will add an 8 ml blood draw to our protocol. Please see the attached blood collection sheet."

F213 continued…



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Provide the rationale for the requested changes:		
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes

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Page 1 of 2

i. Proposal Development #: ii. Institutional Proposal #:		

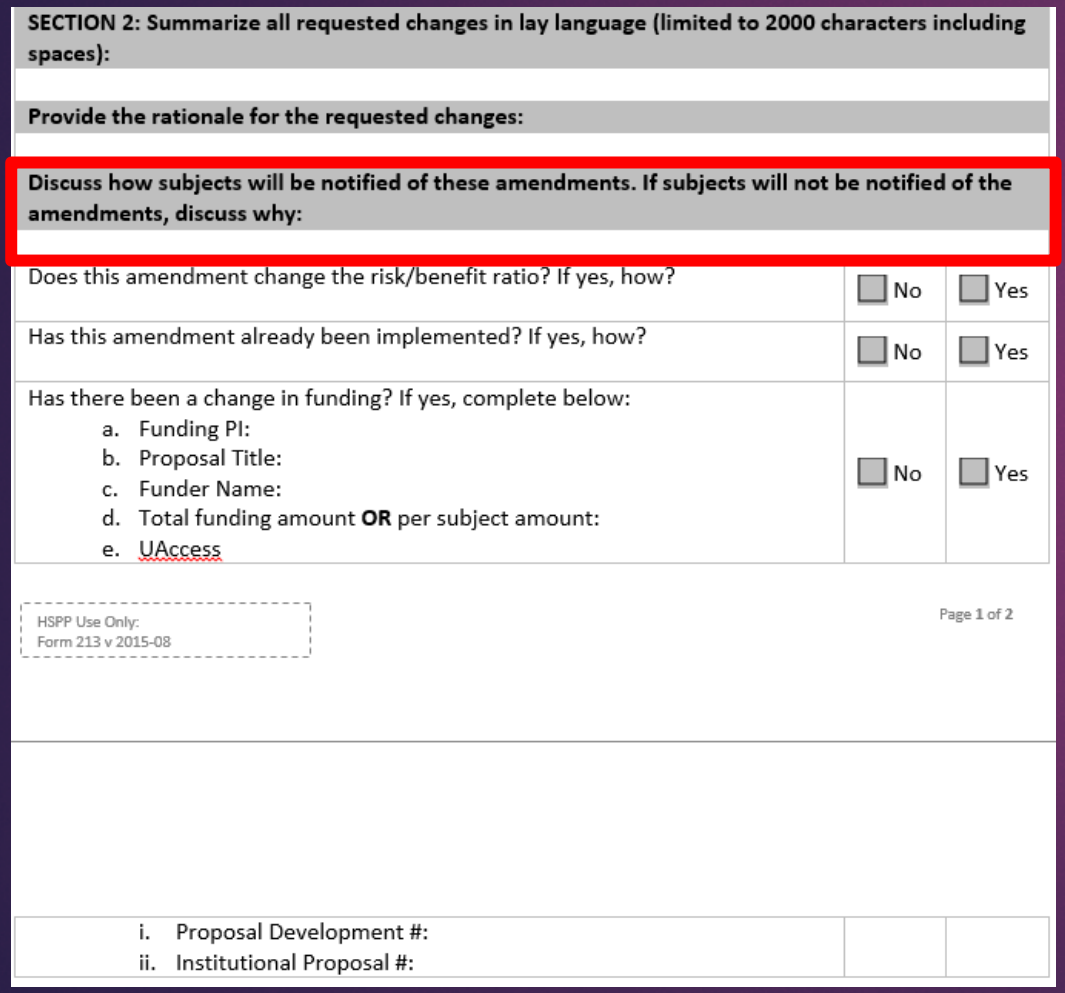
Section 2:

Provide the rationale for the requested changes:

For this, we are looking for your reasoning on <u>why</u> you are making this change.

Example text: "We are adding a blood draw in order to run genetic testing, to support our original hypothesis. "

F213 continued…



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Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes

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Page 1 of 2

i. Proposal Development #: ii. Institutional Proposal #:		

Section 2:

Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

This is the most missed question. For this, please explain if your currently enrolled subjects will be notified of the change you are making. Most of the time, the answer is "no", but you still need to explain why the answer is "no."

Example text: "Addition of the blood draw will not be completed on currently enrolled subjects. Therefore, only new subjects will be notified."

F213 continued…

SECTION 2: Summarize all requested changes in lay language (limited to 2000 characters including spaces):		
Provide the rationale for the requested changes:		
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes

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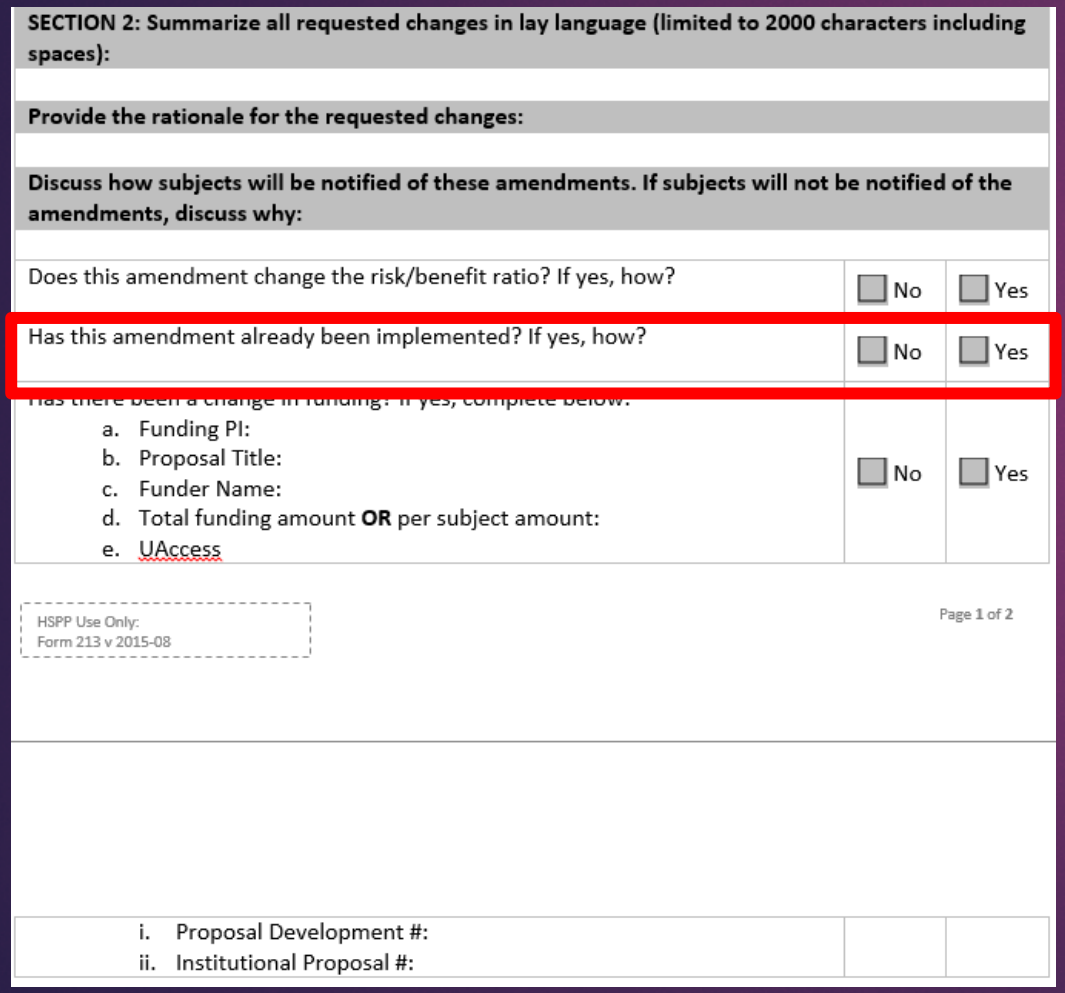
i. Proposal Development #: ii. Institutional Proposal #:		

Section 2:

Does this amendment change the risk/benefit ratio? If yes, how?:

Is the amendment you are requesting increasing overall risks to subjects? If yes, explain how.

F213 continued…



SECTION 2: Summarize all requested changes in lay language (limited to 2000 characters including spaces):		
Provide the rationale for the requested changes:		
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes

HSPP Use Only:
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Page 1 of 2

i. Proposal Development #: ii. Institutional Proposal #:		

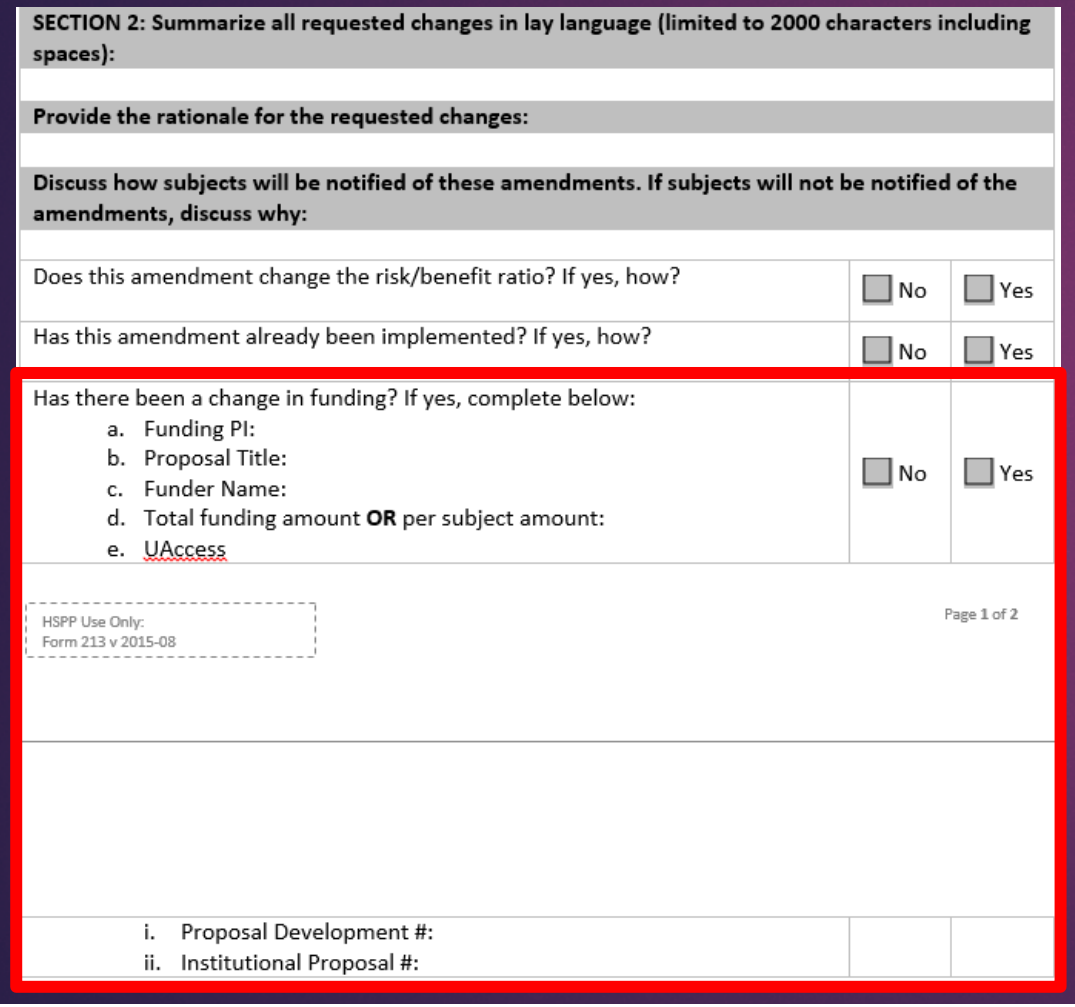
Section 2:

Has this amendment already been implemented? If yes, how?

Has the requested amendment already implemented?

If yes, there better be a really good reason for eliminating immediate hazard or risk to subjects! Otherwise, this is non-compliance!

F213 continued…



SECTION 2: Summarize all requested changes in lay language (limited to 2000 characters including spaces):		
Provide the rationale for the requested changes:		
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:		
Does this amendment change the risk/benefit ratio? If yes, how?	☐ No	☐ Yes
Has this amendment already been implemented? If yes, how?	☐ No	☐ Yes
Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess	☐ No	☐ Yes
HSPP Use Only: Form 213 v 2015-08	Page 1 of 2	
i. Proposal Development #: ii. Institutional Proposal #:		

Section 2:

Has there been a change in funding? If yes, complete below:

If there is a change in the funding, sub-questions a-e **must** be answered.

If you are adding funding, we will need a cover-to-cover copy of the grant application.

F213 continued…

SECTION 3: 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.)	
Document Name	**Version Date**
1.	**1.**

Department Head or Designee Approval	
I have reviewed these changes and determined that all departmental requirements are met. The investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

Section 3:

List of Attachments:

Every attachment that is sent in with the submission must be listed in this section. This allows us to keep track of documents and ensure correct approval letters.

F213 continued…

SECTION 3: 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.)	
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1.	**1.**

Department Head or Designee Approval	
I have reviewed these changes and determined that all departmental requirements are met. The investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

Signatures are required!

F213 continued…

SECTION 3: 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.)	
Document Name	**Version Date**
1.	**1.**

Department Head or Designee Approval	
I have reviewed these changes and determined that all departmental requirements are met. The investigator has adequate resources to conduct the Human Research.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

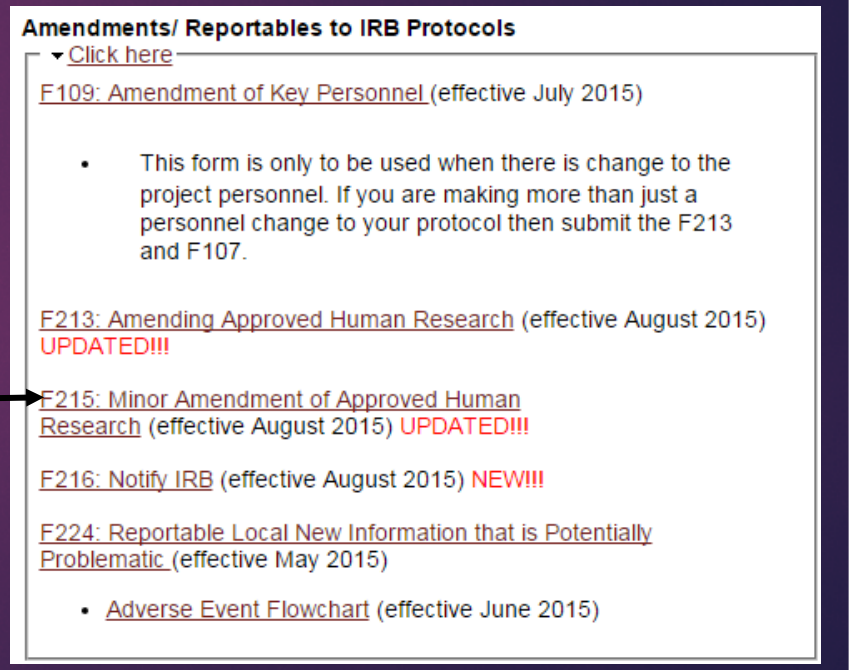
Any document that is affected by the amendment, must be submitted for review. All changes made to the document must be highlighted in order for the IRB to see what has changed.

F215

This form is used to make "**minor**" changes to your project.

This document can only be used to make the following changes:

- Typographical, format, and grammatical changes to previously IRB-approved documents
- Updates to contact information (not for PI changes)
- New recruitment tools using IRB approved language
- Translations to documents where the English version is IRB approved
- Addition of new Funding Source
- Adding site authorization for research site



How do I fill out the F215?

Use to request a minor amendment to previously approved research	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Summarize the amendment:
Provide the rationale for the amendment:
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess- - Provide one of the following below: i. Proposal Development #:	☐ No	☐ Yes

Section 1:

Summarize the amendment:

Tell us exactly what amendments you are making.

F215 continued…

Use to request a minor amendment to previously approved research	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Summarize the amendment:
Provide the rationale for the amendment:
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess- - Provide one of the following below: i. Proposal Development #:	☐ No	☐ Yes

Section 1:

Provide the rationale for the amendment:

Tell us why you are requesting to make those amendments.

F215 continued…

Use to request a minor amendment to previously approved research	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Summarize the amendment:
Provide the rationale for the amendment:
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

Has there been a change in funding? If yes, complete below: a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess- - Provide one of the following below: i. Proposal Development #:	☐ No	☐ Yes

Section 1:

Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why.

"N/A" will <u>not</u> be accepted by the chair.

F215 continued…

Use to request a minor amendment to previously approved research	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA NetID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Summarize the amendment:
Provide the rationale for the amendment:
Discuss how subjects will be notified of these amendments. If subjects will not be notified of the amendments, discuss why:

Has there been a change in funding? If yes, complete below:	☐ No	☐ Yes
a. Funding PI: b. Proposal Title: c. Funder Name: d. Total funding amount **OR** per subject amount: e. UAccess- - Provide one of the following below: i. Proposal Development #:		

Section 1:

Has there been a change in funding? If yes, complete below:

If there is a change in the funding, sub-questions a-e **must** be answered.

If you are adding funding, we will need a cover-to-cover copy of the grant application.

F215 continued…

SECTION 2: 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.)	
Document Name	**Version Date**
1.	**1.**

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

Section 2:

List of Attachments:

Every attachment that is sent in with the submission must be listed in this section. This allows us to keep track of documents and ensure correct approval letters.

F215 continued…

SECTION 2: 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.)	
Document Name	**Version Date**
1.	**1.**

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

PI signature is required!

F215 continued…

SECTION 2: 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.)	
Document Name	**Version Date**
1.	**1.**

Investigator Acknowledgement	
I agree to conduct this Human Research in accordance with all applicable HSPP rules and regulations.	
Investigator signature	Date

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the amendment (highlight all changes made)

Any document that is affected by the amendment, must be submitted for review. All changes made to the document must be highlighted in order for the IRB to see what has changed.

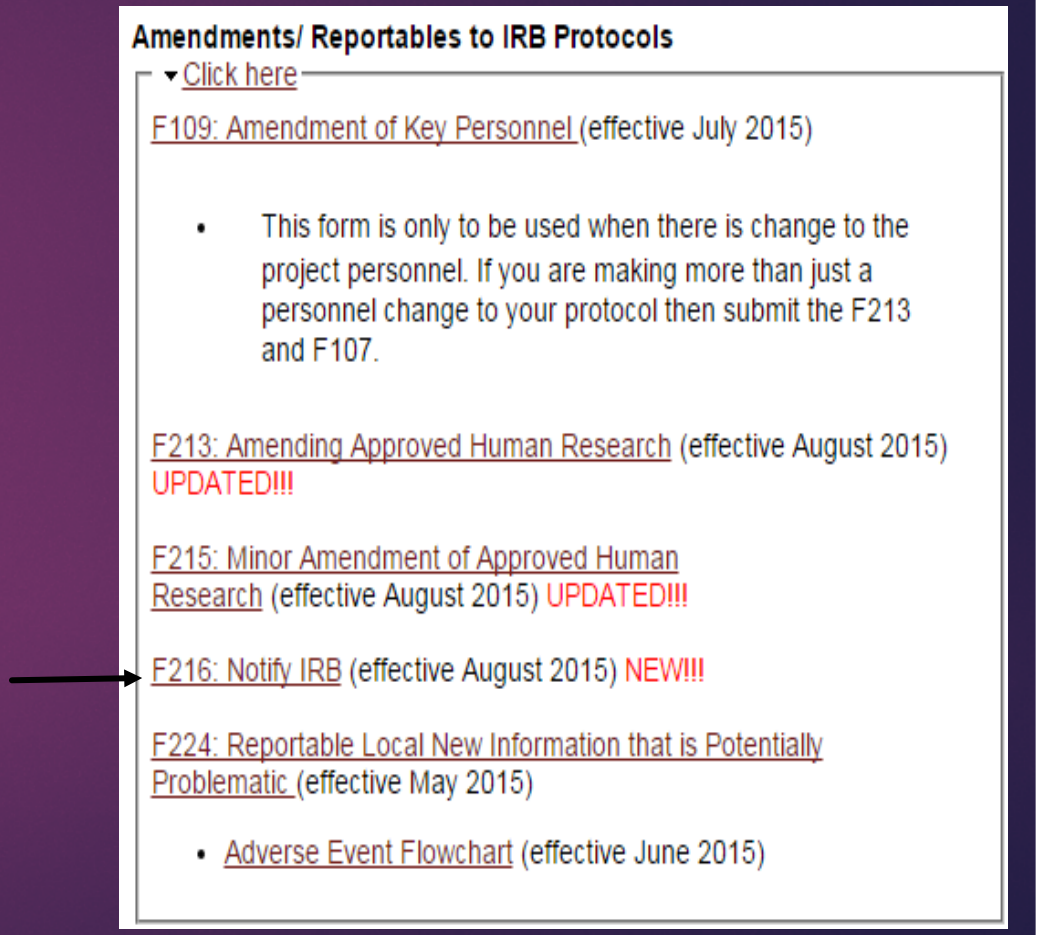
F216

This form is used to notify the IRB of very specific items(see below).

Please note: the IRB is not "approving" these items, but rather "acknowledging" them.

Items this form can be used for:

- Updated Investigational Brochure that do not change the risk of the project or informed consent
- Updated Site Authorization for a new period of approval
- Updated Sponsor Protocol with no local changes, with no consent changes
- DSMB updates that do not increase risk
- Site Monitor Reports that do not increase risk



How do I fill out the F216?

SECTION 1: Project Information	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 2: Summarize the items and rational for the acknowledgement:

SECTION 3: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These items will NOT be listed in the approval letter. The HSPP will respond to the submission email with the acknowledgement.)	
Document Name	**Version Date**
1.	**1.**

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the acknowledgement (highlight all changes made)

Section 2:

Summarize the items and rationale for the acknowledgement:

Tell us exactly what you want the IRB to acknowledge. Make sure that the acknowledgment fits into the mandatory criteria.

F216 continued…

SECTION 1: Project Information	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 2: Summarize the items and rational for the acknowledgement:

SECTION 3: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These items will NOT be listed in the approval letter. The HSPP will respond to the submission email with the acknowledgement.)	
Document Name	**Version Date**
1.	**1.**

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the acknowledgement (highlight all changes made)

Section 3:

List of Attachments:

Every attachment that is sent in with the submission must be listed in this section. This allows us to keep track of documents and ensure correct approval letters.

F216 continued…

SECTION 1: Project Information	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 2: Summarize the items and rational for the acknowledgement:

SECTION 3: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These items will NOT be listed in the approval letter. The HSPP will respond to the submission email with the acknowledgement.)

Document Name	Version Date
1.	1.

See HSPP website for submission requirements

- Provide 1 copy of all documents affected by the acknowledgement (highlight all changes made)

Section 3:

Any document that you wish to be "acknowledged" must be submitted with the F216 submission.

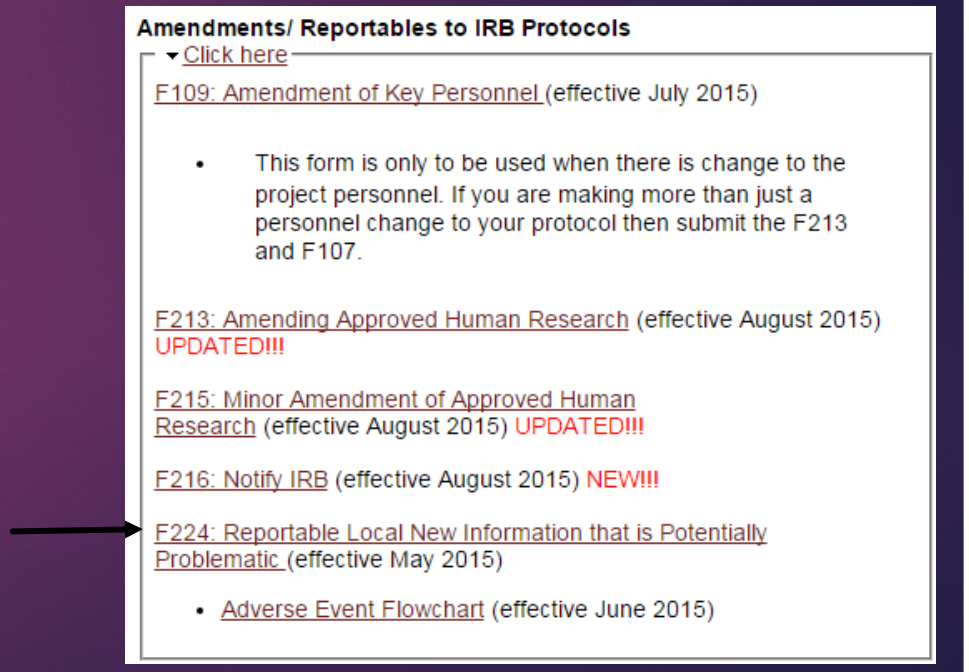
F224

This form is used to notify the IRB of a reportable item.

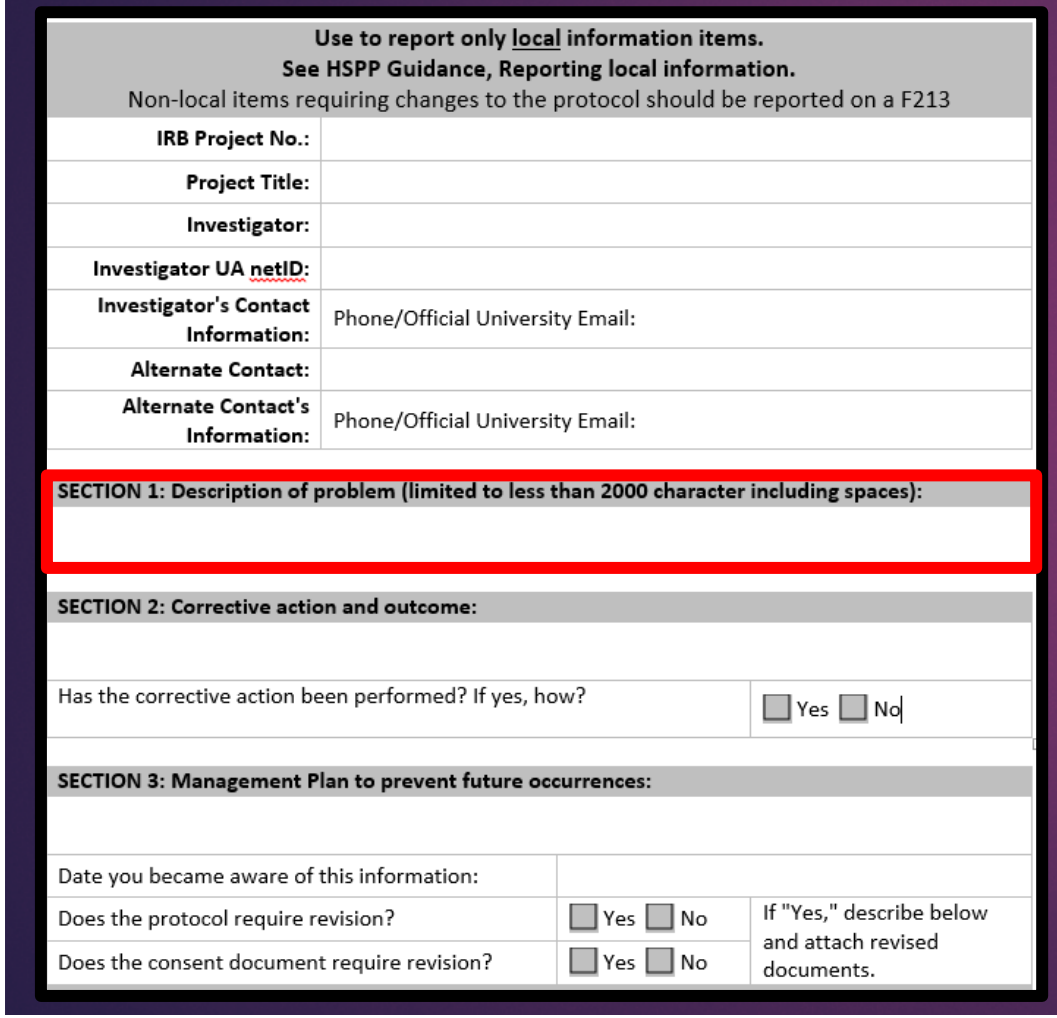
Not all events constitute a reportable item! See our guidance to determine if the IRB needs to be notified of the event:

http://orcr.arizona.edu/sites/orcr.arizona.edu/files/Reporting%20local%20information.pdf

Key dates:
*Most items can be reported within 10 days
*Changes to eliminate risk reported in 5 days
*Unanticipated problems that involve a death must be reported within 24 hours



How do I fill out the F224?



Use to report only local information items.
See HSPP Guidance, Reporting local information.
Non-local items requiring changes to the protocol should be reported on a F213

IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA netID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Description of problem (limited to less than 2000 character including spaces):

SECTION 2: Corrective action and outcome:

Has the corrective action been performed? If yes, how?	☐ Yes ☐ No

SECTION 3: Management Plan to prevent future occurrences:

Date you became aware of this information:		
Does the protocol require revision?	☐ Yes ☐ No	If "Yes," describe below and attach revised documents.
Does the consent document require revision?	☐ Yes ☐ No	

Section 1:

Description of the problem:

Describe to us the reportable item.

Typical language includes:

"Our IRB approved limit to enroll was 25 subjects. We inadvertently enrolled 30 subjects."

F224 continued…

Use to report only local information items. See HSPP Guidance, Reporting local information. Non-local items requiring changes to the protocol should be reported on a F213	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA netID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Description of problem (limited to less than 2000 character including spaces):

SECTION 2: Corrective action and outcome:	
Has the corrective action been performed? If yes, how?	☐ Yes ☐ No

SECTION 3: Management Plan to prevent future occurrences:		
Date you became aware of this information:		
Does the protocol require revision?	☐ Yes ☐ No	If "Yes," describe below and attach revised documents.
Does the consent document require revision?	☐ Yes ☐ No	

Section 2:

Corrective action and outcome:

Describe to us what steps you are taking/have taken to correct the issue so that it doesn't occur again.

Typical language includes:

"We will make sure to always be cognizant of our IRB protocol. We also wish to increase enrollment and to be able to still use the data obtained from the over-enrolled subjects. "

F224 continued…

Use to report only local information items. See HSPP Guidance, Reporting local information. Non-local items requiring changes to the protocol should be reported on a F213	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA netID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Description of problem (limited to less than 2000 character including spaces):

SECTION 2: Corrective action and outcome:	
Has the corrective action been performed? If yes, how?	☐ Yes ☐ No

SECTION 3: Management Plan to prevent future occurrences:		
Date you became aware of this information:		
Does the protocol require revision?	☐ Yes ☐ No	If "Yes," describe below and attach revised documents.
Does the consent document require revision?	☐ Yes ☐ No	

Section 2:

Has the corrective action been performed? If yes, how?:

Please explain if you have implemented your correction action.

Example text:
"We are requesting to increase enrollment to 100 subjects on this F224 "

F224 continued…

Use to report only local information items. See HSPP Guidance, Reporting local information. Non-local items requiring changes to the protocol should be reported on a F213	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA netID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Description of problem (limited to less than 2000 character including spaces):

SECTION 2: Corrective action and outcome:	
Has the corrective action been performed? If yes, how?	☐ Yes ☐ No

SECTION 3: Management Plan to prevent future occurrences:

Date you became aware of this information:		
Does the protocol require revision?	☐ Yes ☐ No	If "Yes," describe below and attach revised documents.
Does the consent document require revision?	☐ Yes ☐ No	

Section 3:

Management Plan to prevent future occurrences:

Please explain the management plan you have put into place to avoid this same issue occurring again.

Example text:
"We have created a "checklist" that includes our key IRB approved elements. This document will be reviewed weekly to ensure we remain in compliance."

F224 continued…

Use to report only local information items. See HSPP Guidance, Reporting local information. Non-local items requiring changes to the protocol should be reported on a F213	
IRB Project No.:	
Project Title:	
Investigator:	
Investigator UA netID:	
Investigator's Contact Information:	Phone/Official University Email:
Alternate Contact:	
Alternate Contact's Information:	Phone/Official University Email:

SECTION 1: Description of problem (limited to less than 2000 character including spaces):

SECTION 2: Corrective action and outcome:	
Has the corrective action been performed? If yes, how?	☐ Yes ☐ No

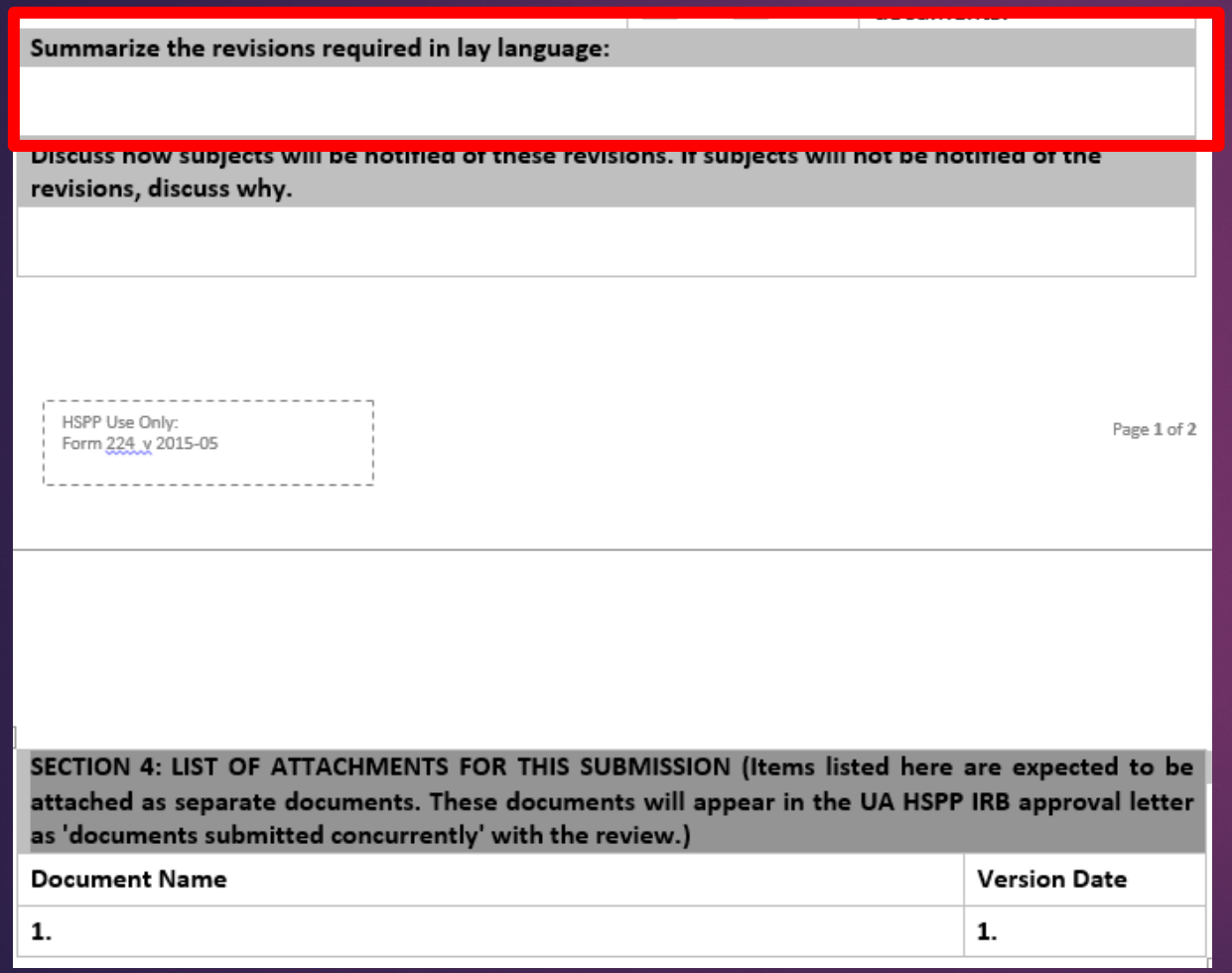
SECTION 3: Management Plan to prevent future occurrences:		
Date you became aware of this information:		
Does the protocol require revision?	☐ Yes ☐ No	If "Yes," describe below and attach revised documents.
Does the consent document require revision?	☐ Yes ☐ No	

Section 3:

The following are a series of questions, please answer each accordingly.

Please note: If you fail to notify us within the required timeframe, you must explain the reasoning behind the delay.

F224 continued…



Summarize the revisions required in lay language:

Discuss how subjects will be notified of these revisions. If subjects will not be notified of the revisions, discuss why.

HSPP Use Only:
Form 224_v 2015-05

Page 1 of 2

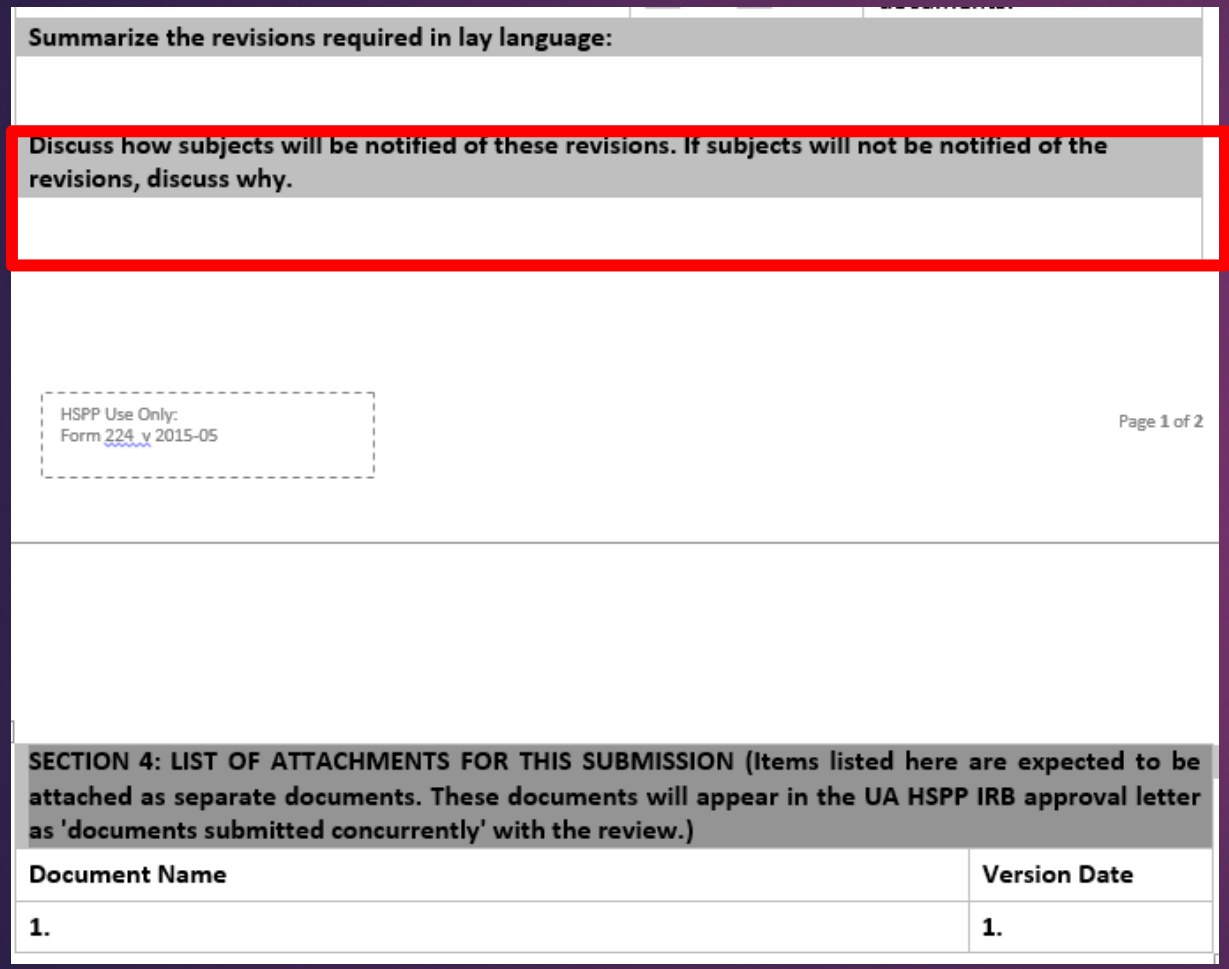
SECTION 4: LIST OF ATTACHMENTS FOR THIS SUBMISSION (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)	
Document Name	**Version Date**
1.	1.

Section 3:

Summarize the revisions required in lay language:

This section only applies if you are requesting an amendment. If you are not requesting an amendment, a simple “I am not requesting an amendment” statement would fit nicely. Otherwise, explain your amendment!

F224 continued…



Summarize the revisions required in lay language:

Discuss how subjects will be notified of these revisions. If subjects will not be notified of the revisions, discuss why.

HSPP Use Only:
Form 224 v 2015-05

Page 1 of 2

SECTION 4: 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.)

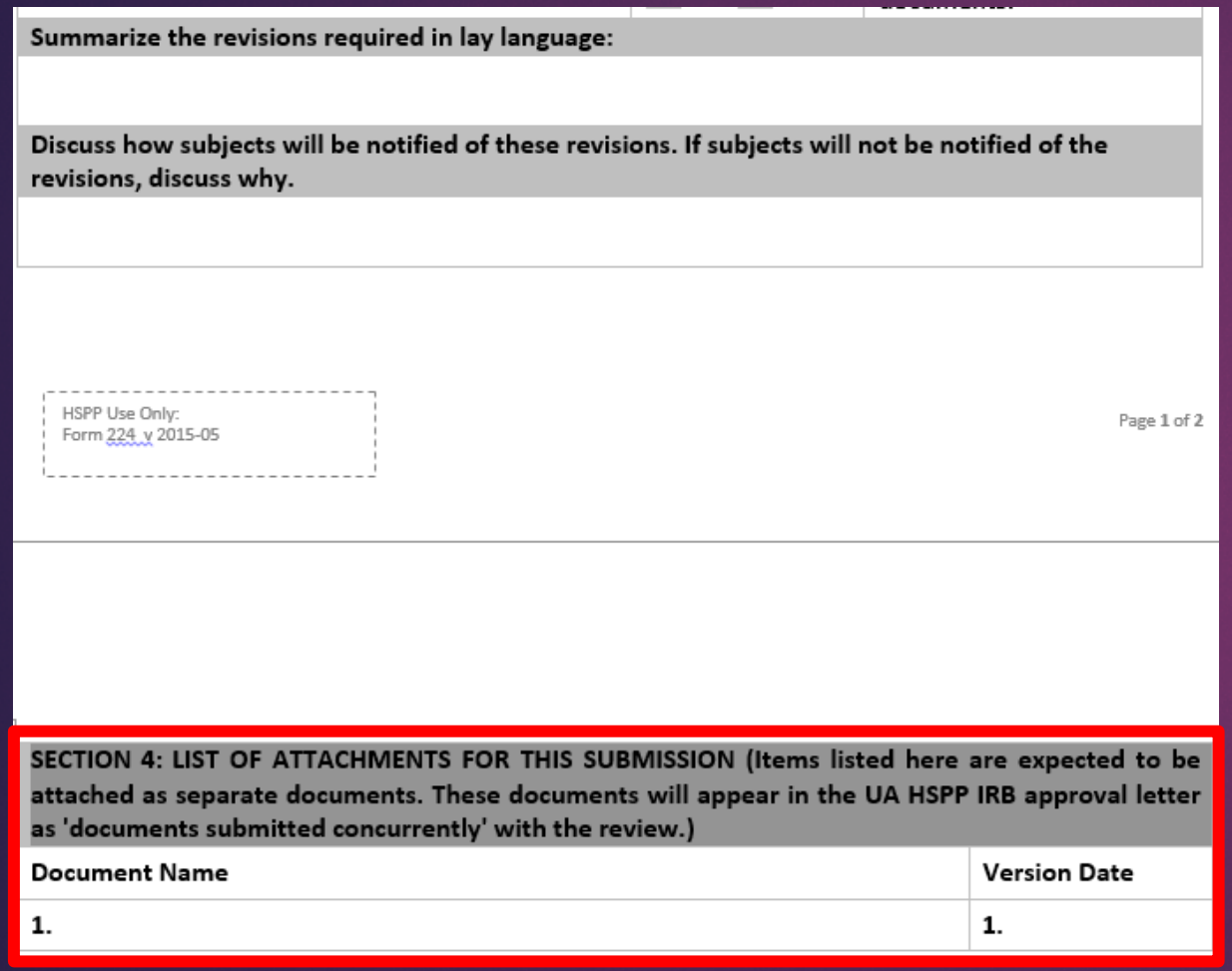
Document Name	Version Date
1.	1.

Section 3:

Discuss how subjects will be notified of these revisions. If subjects will not be notified of the revisions, discuss why:

This section only applies if you are notifying subjects. If you are not notifying subjects, a simple "I am not notifying subjects because…" statement would fit nicely. Otherwise, explain how subjects will be notified of the changes.

F224 continued...



Summarize the revisions required in lay language:
Discuss how subjects will be notified of these revisions. If subjects will not be notified of the revisions, discuss why.

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SECTION 4: 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.)	
Document Name	**Version Date**
1.	**1.**

Section 4:

List of Attachments:

Every attachment that is sent in with the submission must be listed in this section. This allows us to keep track of documents and ensure correct approval letters.

Documents you are amending should be included on this list and sent in with your submission!

F224 continued...

Department Head or Designee Approval	
I am aware of the reportable information and management plan. The investigator has the necessary resources to implement the proposed management plan.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
The above information is a true and accurate statement of the reportable information.	
Investigator signature	Date

See HSPP website for submission requirements.

- Provide 1 copy of all documents affected by the reportable item (highlight all changes made)

Signatures are required!

F224 continued…

Department Head or Designee Approval	
I am aware of the reportable information and management plan. The investigator has the necessary resources to implement the proposed management plan.	
Departmental Chair or Supervisor Signature	Date
Investigator Acknowledgement	
The above information is a true and accurate statement of the reportable information.	
Investigator signature	Date

See HSPP website for submission requirements.

- Provide 1 copy of all documents affected by the reportable item (highlight all changes made)

Any document that is affected by the reportable item (including documents that have been amended) must be submitted.

When do I submit the amendment?

Before you wish to implement the amendment!

Reminder: An amendment cannot be implemented prior to IRB approval, unless it is done to mitigate immediate risk to the subject.

Where do I submit the amendment?

- Please submit the amendment 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”.