Peace Corps Master's International Institutional Review Board (IRB) Manual

Created by: Colleen C. Naughton

Date: 12/19/2013

Foreword

Dear USF Peace Corp's Master's International Students,

This manual has been put together to help guide you through the sometimes over complicated and stressful, Institutional Review Board (IRB) process. My name is Colleen Naughton and I served in Mali, West Africa as a PC MI from 2009-2012 and extended my service and education for my doctorate at USF as well. I have been IRB certified since 2009 for a public health course I took while I was on campus the year before Peace Corps and have since taken the refresher course twice. I have submitted two IRBs for both my thesis (on handwashing) and dissertation (on Shea Butter) research.

Hopefully this guide helps break down the process in ten steps and is detailed without being too cumbersome. Though the IRB process may seem tedious and even pointless at times, remember it is important to protect human subjects based on some horrific cases in history.

If you have any questions and/or suggestions for the manual please do not hesitate to contact me at ccnaughton@gmail.com.

Good luck with the IRB process and your research!

Sincerely,

Colleen Naughton

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Appendices

Step 1: Understanding IRB and how it applies to your research.

First a few basic definitions (see Appendix A for IRB 101 presentation):

1. **IRB**- acronym for the Institution Review Board which is responsible for the review and approval of all *research* involving *human subjects*. The function of the IRB is to protect the rights, welfare, and safety of human subjects. IRB was born out of crimes against humanity in the name of science and research (i.e. Nuremburg, the Monster study, Tuskegee syphilis study, etc.)

2. **Research –** systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3. **Human Subjects-** a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Initially, I was going to entitle this, "Do I need IRB?" but really the answer to this 99% of the time is **YES**. Even if you are unsure, it is better to go through the process and have the USF IRB decide that your research does not constitute human subjects research and give you proof (study number and submission) to include in your thesis and/or journal article. See flowchart (page 2).

The risks of not doing IRB:

1. Not being able to use the field data you collected (surveys and any measurements in the field).

2. ***Delayed or missed graduation*** (having to do a different thesis, course work masters, extending stay in Peace Corps to complete IRB coursework and wait for approval and (re)collect data).

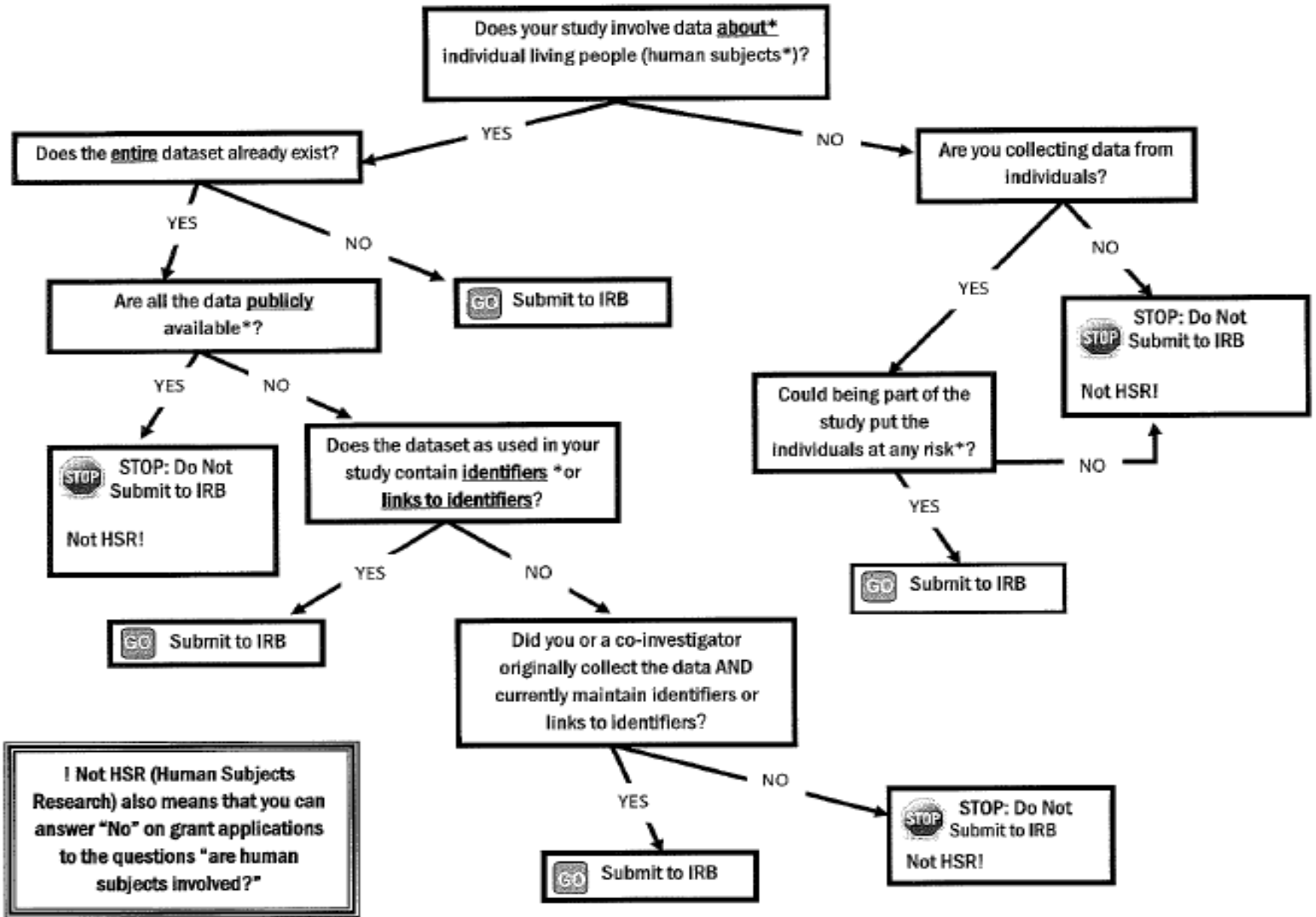
3. Disappointing your advisers and University.

4. Unneeded stress. Peace Corps and research are stressful enough; no need to add this to it and make it ten times worse.

Now that you may be significantly scared/motivated. **RELAX.** Yes, this process is time consuming and detailed but just breath and take it one step at a time. You made it through engineering classes like aquatic chemistry or physical and chemical principles, you can do this!

However, ***DO NOT put it off, START EARLY.*** Yes, if you are doing this from the field, your precious internet time is valuable but this is time sensitive especially if you are trying to get your research done before your Close of Service (COS). Your study needs to be approved by the department and the review board that may undergo revisions. Allow at least **2 months or more**!

USF IRB Guidance Regarding When to Submit Applications



Step 2: USF-IRB educational requirements (online courses through CITI)

Now that you understand more of what IRB is and why you need it. It is time to start the process and learn even more about IRB. You must complete the online coursework through CITI (Collaborative Institutional Training Initiative). This will take ***at least 2-3 hours*** and mostly involves reading/skimming materials and texts and answering multiple choice questions.

***NOTE:* They will have a lot of attachments to the original documents like the Belmont report which you do not need to read thoroughly unless you want to. There should be enough information from the text online to answer the questions.

1. Please choose one of CITI courses listed below to complete at https://www.citiprogram.org (see more detailed instructions on the next page).

- Biomedical Investigators and Key Personnel
- Social/Behavioral Investigators and Key Personnel*
- IRB Member
- Spanish Language Biomedical Modules
- VA Human Subjects Protection and Good Clinical Practices

*You only need to take one of these but I have taken all three since my research is interdisciplinary as most of yours will be as well. The one recommended by the help desk is the Social/Behavioral Investigators and Key Personnel but any one of the courses (Basic or Refresher) will count for certification. The full list of courses offered on page 5 where the ones that will satisfy the education requirement have chat bubbles next to them and those that are recommended are highlighted.

There is a Responsible Conduct for Engineers course. You may take this. It is not required but **IT ALONE WILL NOT SATISFY THE IRB EDUCATION REQUIREMENT.

2. Save your certificate of completion (see example on page 6). They may have a link at the end of the course or send you an e-mail but you can always find your certificate by searching your last name at: http://www.research.usf.edu/resource/ETS/eD-MXAA.asp?ClassProgram=IRB

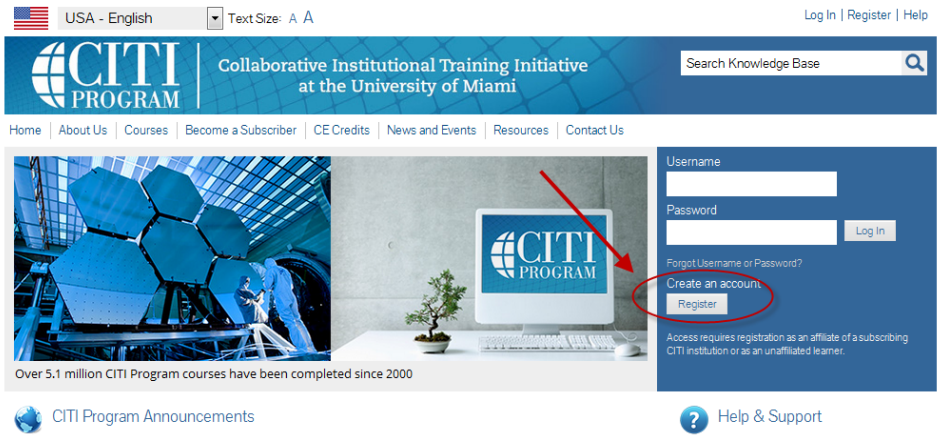
University of South Florida:
Instructions for Completing the
CITI Program Registration Process

Go to www.citiprogram.org and click on "Register Here."

The registration screen will appear.

- Choose "University of South Florida" from the drop down list of available "Participating Institutions."

- (OPTIONAL: for VA Researchers):
  If you are affiliated with the James A. Haley VA, you may choose to also affiliate with the VA by selecting "Tampa, FL-673" from the drop down list associated with "Veterans Affairs."



- If desired, you may elect to request CME/CEU credits from CITI. However, that this is **NOT** funded by USF.
- Select your courses from the list to make them available in your pending queue.
- You will receive an account validation email to the address provided.

After validating your account through email, you will be able to access the Main Menu of your account.

Main Menu: Click on a course name to begin the course. If you don't see the course you need click on **Add a Course or Update Learner Groups** in the 'My Learner Tools for University of South Florida' section.

To see the list of valid courses for IRB certification click on the **View Instruction Page** in the 'My Learner Tools for University of South Florida' section. The courses valid for IRB certification are also listed on the USF page here.

Institutional support for CITI Program contact: USF Research & Innovation, Research Integrity & Compliance
ARC Help Desk (eIRB, eCOI, eIACUC): (813) 974-2880 - E-Mail: rsch-arc@usf.edu
Telephone and email support provided: M-F 8AM – 5PM

CITI Program:
Call 305-243-7970 option 1 or send email to citisupport@med.miami.edu
Telephone support is available M-F 8AM - 5:30PM

CITI Courses Currently Offered by USF DRIC

March 29, 2011

Physical Science Responsible Conduct of Research – Basic Course

Biomedical Responsible Conduct of Research – Basic Course

Buenas Practicas Clinicas – Stage 1

CITI Good Clinical Practice – Basic Course

Biomedical Investigators and Key Personnel – Basic Course*

Biomedical Investigators and Key Personnel – Refresher Course*

Social/Behavioral Investigators and Key Personnel – Basic Course*

Social/Behavioral Investigators and Key Personnel – Refresher Course*

IRB Members – Basic Course*

IRB Members – Refresher Course*

VA Human Subjects Protection and Good Clinical Practices – Basic Course*

VA Human Subjects Protection and Good Clinical Practices – Refresher Course*

Humanities Responsible Conduct of Research – Basic Course

Responsible Conduct of Research for Administrators – Basic Course

Responsible Conduct of Research for Engineers – Basic Course

Social and Behavioral Responsible Conduct of Research – Basic Course

Spanish Language Biomedical Modules Course – Spanish Biomedical*

Working with Animals in Biomedical Research – Refresher Course – Basic Course

Working with Mice in Research Settings – Basic Course

Working with Nonhuman Primates in Research Settings – Basic Course

Working with Rats in Research Settings – Basic Course

Working with the IACUC – Basic Course

(*) Denotes Course Accepted for Human Subjects Protection Education

Certificate of Completion

Colleen Naughton

Has Successfully Completed the Course in

CITI IRB Members

On

Sunday, April 10, 2011

USF
UNIVERSITY OF
SOUTH FLORIDA

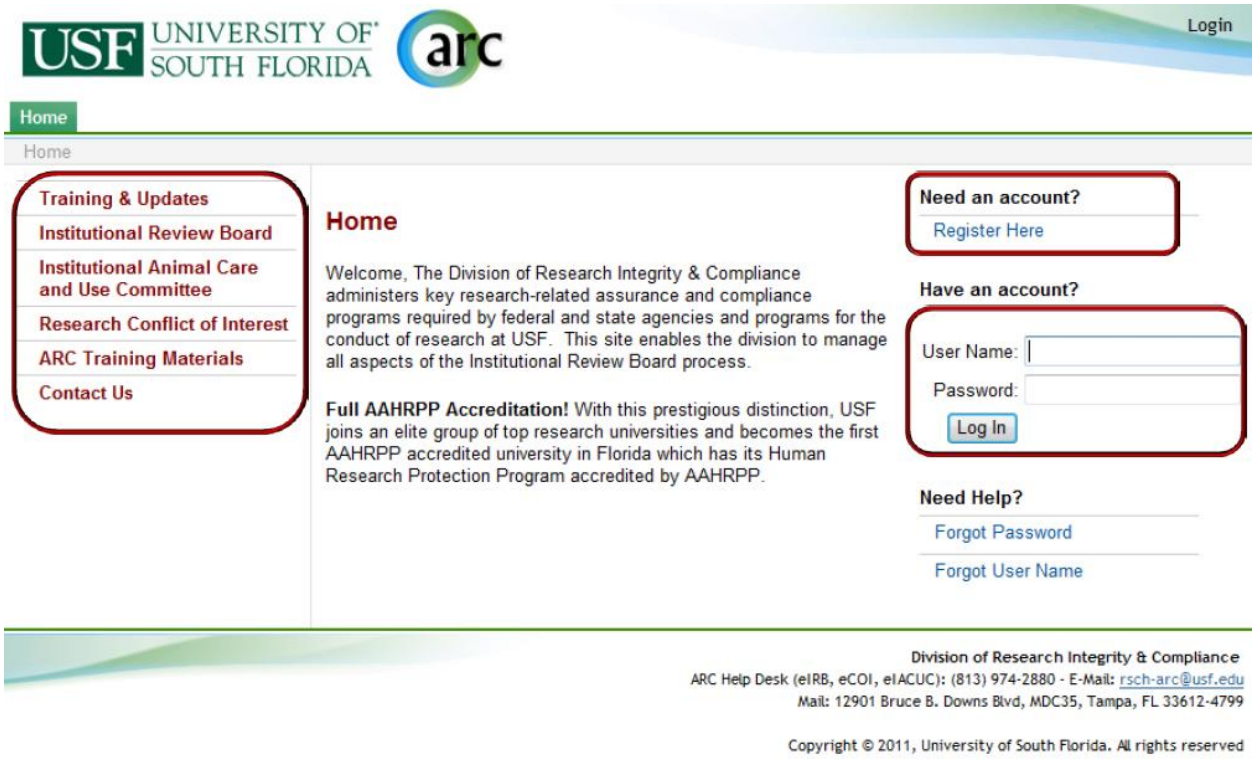
1/31/2012 8:01:23 AM

Step 3: Submitting a study (eIRB/USF arc)

Now that you have completed the CITI online course, it will take 24-48 hours and then you can create an eIRB/USF arc account at https://arc.research.usf.edu/prod.

- It will have you fill out a basic registration form with your name, e-mail address, phone number, department, etc.
- Then your username and password will be e-mailed to you.

For more detailed registration instructions and if you forget your password see the eIRB study team manual in Appendix B.

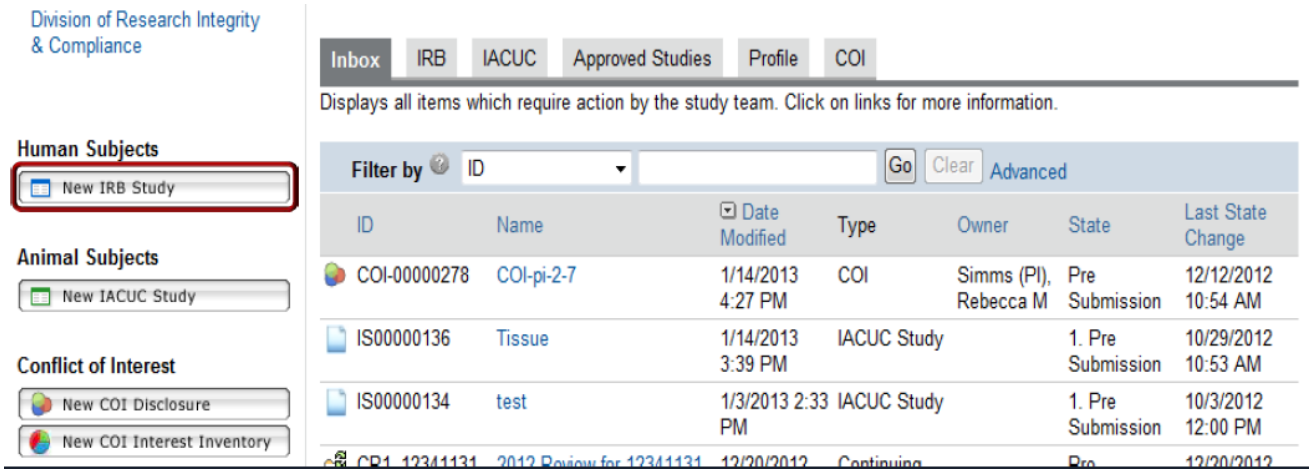


Step 4: Creating your research study

Now you are finally ready to submit your research study for approval from USF IRB or an official rejection that it does not constitute human subjects research. This section will not include every section of the online, SmartForm but some key tips and trouble areas. Page 6-14 of Appendix B have more detailed instructions in case you have questions. Appendix C includes an example IRB print out for Naughton's research on Shea butter.

Create a New Study

Now you can start filling out the online form ("SmartForm") for your study which will require you to log into your eIRB/arc account that you created in Step 3. This will be on the left hand side of your screen as seen in the figure.

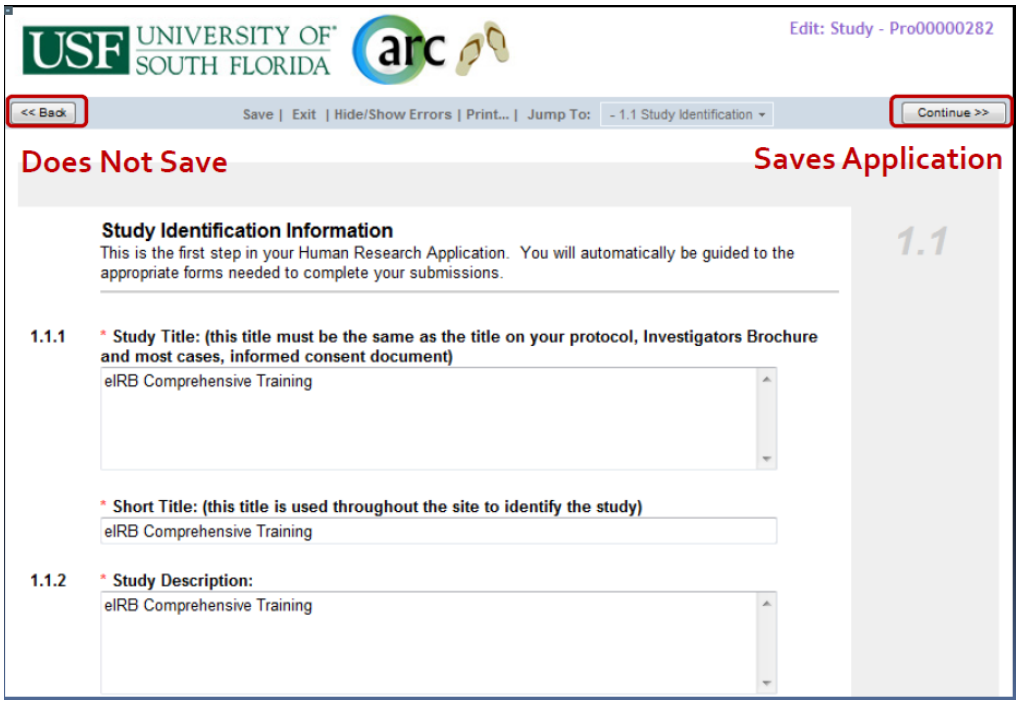


I would not recommend trying to create your study all in one sitting. This may take up to 8 hours or more depending how in-depth your study is and there are lots of boxes to fill out. You will get fatigued, so set aside several days and take breaks.

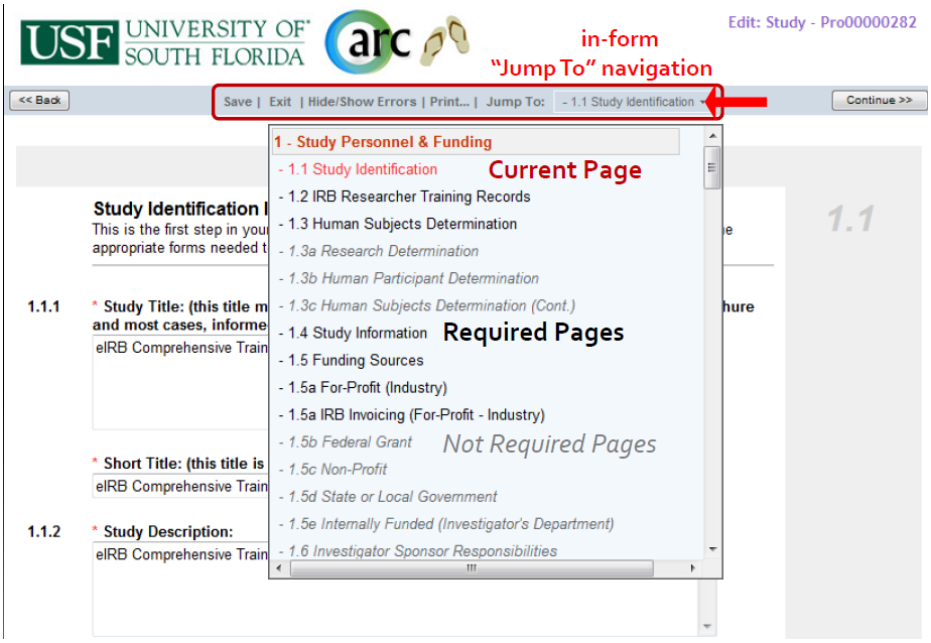
***TIP:** A lot of it you can copy and paste from your existing literature review and quarterly reports. Have these open on your computer. No need to retype everything. Many of the questions are repetitive as well.

Smart Form Navigation

Here are some notes on the smart form navigation. Do not push back (in the form or in your internet browser) and expect that it has saved your information. ***Save frequently and often especially with the internet connections in the developing world!***



There is nice "Jump to" navigation in case you have text you want to copy and paste in another section or want to change something or just see how much more you have left.



Study Team: Role Selection
A note on 1.1.5 Principle investigator/Student Investigator, 1.1.6 Study Coordinator, and Co-Investigators/Faculty Advisors. I had a revision on this and this is the correct way:

1.1.5 * Principal Investigator / Student Investigator:
Colleen Naughton

You are listed automatically as a Study Coordinator. If there is someone else on the study that will assist with the IRB process, they should be listed as a Study Coordinator and/or Secondary Study Coordinator.

1.1.6 Study Coordinator / Primary Regulatory Specialist:
Colleen Naughton

1.1.6a Secondary Study Coordinator / Regulatory Specialist:

The PI does not need to be listed as a Co-Investigator or Key Personnel.

1.1.7 * Are there any Co-Investigators/Faculty Advisors involved in this study? *If you are a student, you must list your Faculty Advisor as a Co-Investigator.*

(•) Yes ( ) No

If yes, please add Co-Investigators:

Last Name	First Name	Organization	Profile
Mihelcic	James	Civil and Environmental Engineering	00001715

Here are some definitions of the roles in case they are unclear:

A ***PI*** creates and edits applications, responds to requested revisions, submits/withdraws applications

Study Coordinator (s) creates and edits applications, responds to requested revisions, submits/withdraws applications

- Cannot submit the study until the PI has submitted it initially
- Can now have up to 2 coordinators on a study

Co- Investigator(s) create and edit applications, respond to requested revisions

- Cannot submit or withdraw

Key Personnel have view only access

You will need to upload your CV/resume as well as anyone else on the study team. They all have to be IRB certified and have certifications that are current.

***TIP:** If you plan on involving other volunteers in your data collection, they will either have had to go through the certification that you had OR you can say that the surveys are existing data that you are using that is being collected for Peace Corps (section 6.4 Retrospective Chart/Record Review).

IRB Researcher Training Records

The following information is taken from your currently approved training records on your researcher profile.

1.2.1

Principal Investigator: Rebecca Simms
CV/Biosketch: dsfasdf(0.01)
Certification Renewal Deadline: 9/28/2012

1.2.2 **Study Team Certification and CV/Biosketch:**

First Name	Last Name	Dept	Certification Date	Certification Renewal Deadline	Account Profile.showIRBCertStatus ()	CV
Daniel	Duvette	ONCOLOGY			Certification not current	Test CV for Study Team Member (0.01)
Norma	Arnot	IMMUNOLOGY			Certification not current	Someones CV(0.01)
Jin	Kim (Co-Investigator)	GASTROENTEROLOGY	7/30/2009	7/30/2011	Certification current	
Carmen	Alverado (Study Coord.)	GASTROENTEROLOGY	12/1/2010	12/1/2011	Certification current	YOUR CV HERE (0.02)

Uploading Documents
There are a number of documents that IRB requests. An example of some of these documents are included in Appendix D. Make sure that all the names of the files as they appear on the SmartForm have the version number and date as below:

1.8c.3 **Please upload any relevant documentation include documentation of approval from the host country.**

Name	Version
NAUGHTON_international_support_v1_6_24_13	0.01

Also all documents should have the version number, date and eIRB number as a footer of the document such as: Version 1, 3.1.12, eIRB# 13497

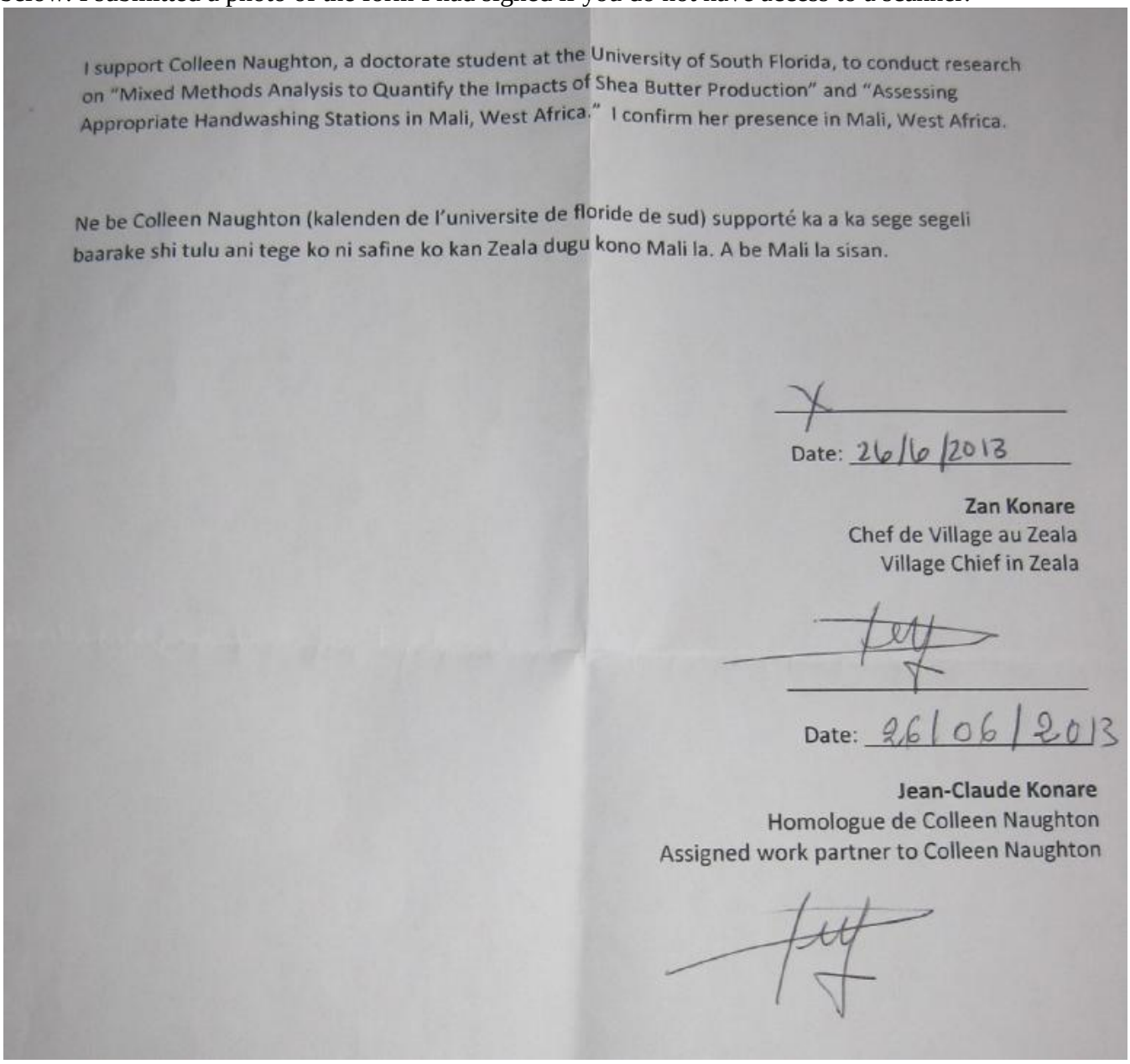
A reviewer may ask you to put this in the header of surveys:
Version 2
Version date: 7/18/2013
SheaButter_verbal_intro_v2_7_18_13.doc
Handwashing Station Research Introduction

These things will save you time in back and forth with revisions.

Sections were you may have to upload documents:
1.8c.3 Approval from host country
2.1.3 Study Protocol
3.4.1 Interview-Focus Groups
3.5.1 Surveys and Questionnaires
6.4.5 Data capture sheet
Section 7: Informed consent

International Study (Section 1.8)

Most of you will need an international study consent form. This is not as intimidating as it sounds. It can be a simple statement (in English and national language) signed by two of the following: village chief, the mayor, and your work partner/service organization. See example below. I submitted a photo of the form I had signed if you do not have access to a scanner.



I support Colleen Naughton, a doctorate student at the University of South Florida, to conduct research on "Mixed Methods Analysis to Quantify the Impacts of Shea Butter Production" and "Assessing Appropriate Handwashing Stations in Mali, West Africa." I confirm her presence in Mali, West Africa.

Ne be Colleen Naughton (kalenden de l'universite de floride de sud) supporté ka a ka sege segeli baarake shi tulu ani tege ko ni safine ko kan Zeala dugu kono Mali la. A be Mali la sisan.

Date: 26/6/2013

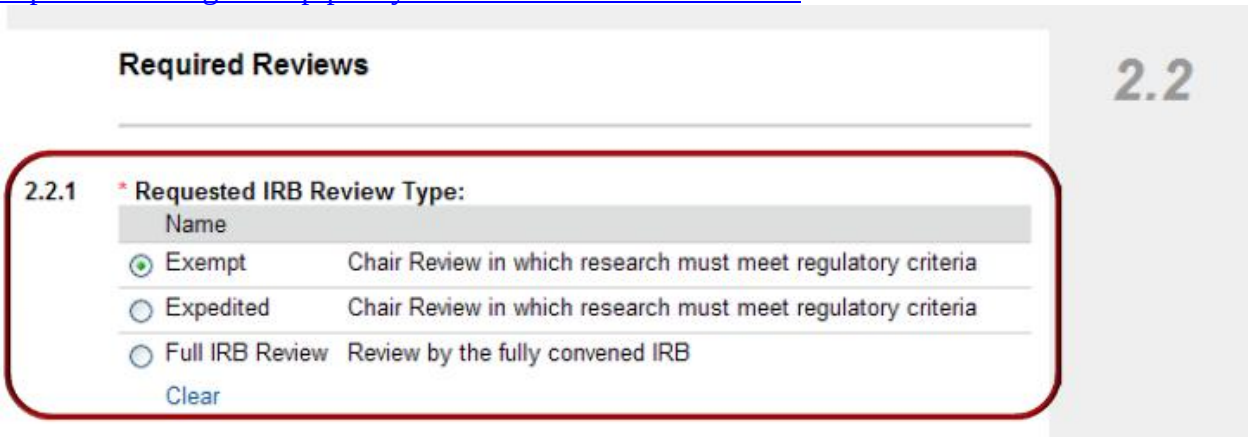
Zan Konare
Chef de Village au Zeala
Village Chief in Zeala

Date: 26/06/2013

Jean-Claude Konare
Homologue de Colleen Naughton
Assigned work partner to Colleen Naughton

Review Types (2.2.1)
There are three main review types for an IRB: Exempt, expedited and full board. Exempt requires the least amount of approval time and paperwork, followed by expedited and then full board. Some basic definitions of these three review types are provided below from pages 21- 24 of Appendix A. ***Most of the Master's International research will fall either into exempt or expedited***. You will need to specify the type on your online application on 2.2.1.

There are decision charts on the different exempt status on the following website: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html.



1. Exempt (HRPP Policy #303)
Minimal risk research, which is reviewed by the Chairperson or Designee. Study approval for five years and then automatically closed.

Examples:
- –Anonymous Surveys
- –Data that is "already on the shelf"
  - •Recorded in a de-identified fashion (See next slide for 18 HIPAA Identifiers)
  - •Cannot be "coded" (Identifying information such as name, date of birth, telephone number, geographical location, etc. must be replaced with a number , letter symbol etc and a key to decipher the code exists, enabling linkage of the identifying information)
- –Research comparing standard practice methodology in an educational setting
  - •No radically new instructional strategy or use of random assignment of subjects
  - •Common practice in elementary, secondary, or post-secondary settings

2. **Expedited (HRPP Policy #204)**
Minimal risk research, which is reviewed by the Chairperson or Designee. Study approval for one year. Continuing review application must be submitted to continue study activities.
Examples:
- –Surveys that include identifiable information

–Interviews

–Analysis of data collected (or that will be collected) for non-research purposes

–Secondary data analysis

–Video or audio recordings

–Focus Groups

3. Full Board

Reviewed by fully convened Board. Study approval for one year. Continuing review application must be submitted to continue study activities.

Examples:

–Greater than minimal risk research

–Studies involving prisoners or data about prisoners

–Novel therapeutic interventions

–Other vulnerable populations

–Collecting information that could place the participant at risk of civil or criminal liability or may cause other societal harms (stigma, ostracism, excommunication, etc.)

Informed Consent (Section 7)

The next major hurdle of IRB is Informed Consent. If you are doing any sort of surveys or research with subjects, you may need to be asked to have respondents sign a form of consent or you may have to at least give a verbal statement explaining the research purpose and objectives. You can try to have this waived if your study is minimal risk (expedited review type). I would recommend this! The following was taken from pages 25-28 of Appendix A.

Informed consent is central to the protection of human subjects. It is both a process and a procedure

–The process is the exchange of information that takes place between the prospective subject, and the investigator and study staff, before, during and sometimes after the study

–The procedure includes the shaping and signing of an informed consent document

–There are also times the IRB can waive consent

IC is founded on the principle of Respect for Persons

•Requires that individuals be treated as autonomous agents, and that the rights and welfare of persons with diminished autonomy be appropriately protected

•Respect for persons requires that prospective research subjects "be given the opportunity to choose what shall or shall not happen to them" and thus necessitates adequate standards for informed consent

•Per 45CFR46.166 (a), the list of required elements includes:

–A statement that the study involves research, an explanation of the purposes, the expected duration, a description of the procedures, and identification of any experimental procedures

–A description of foreseeable risks/benefits

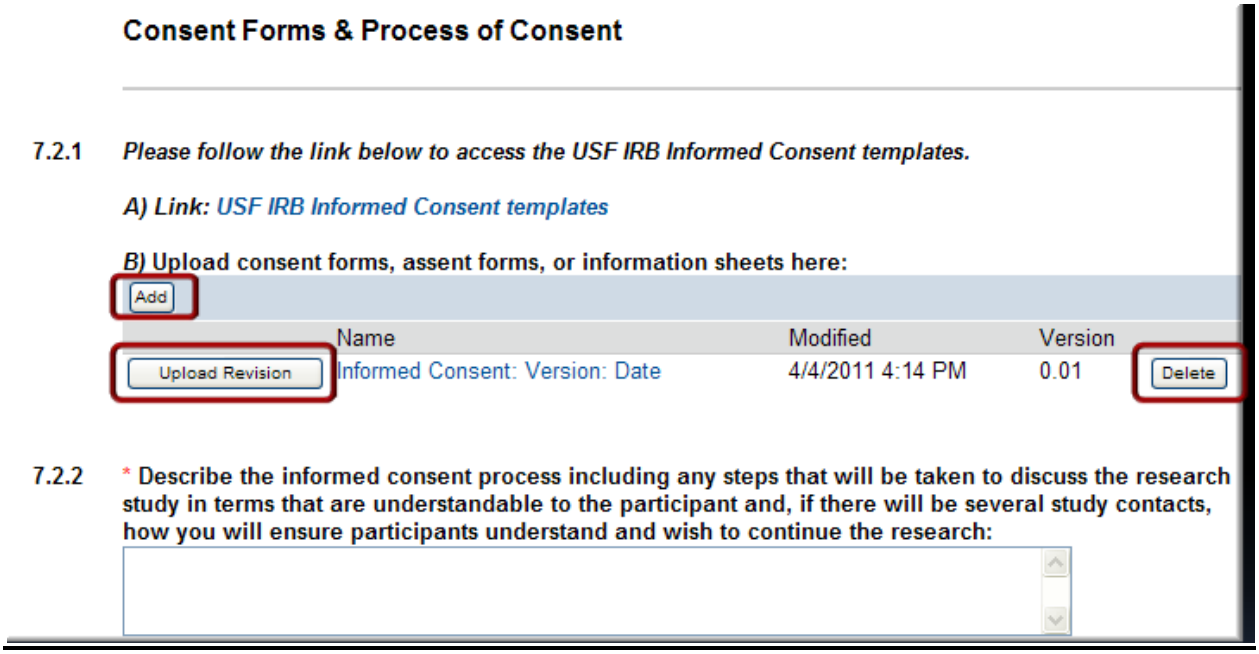
–Disclosure of appropriate alternatives or courses of treatment, if any, that might be advantageous to the participant
–A statement on the extent to which confidentiality will be maintained
–Discussion of compensation
–Contact information for questions about research subject rights
–A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the subject is free to withdraw at any time
–Contact information for the IRB in the event research staff could not be reached and in the event the participant wishes to talk to someone other than the research staff

The IRB has developed several templates to ensure that informed consent documents include all of the required elements - https://arc.research.usf.edu/Prod

–Click on "Institutional Review Board" on left side of page and select "Consent Form Templates"

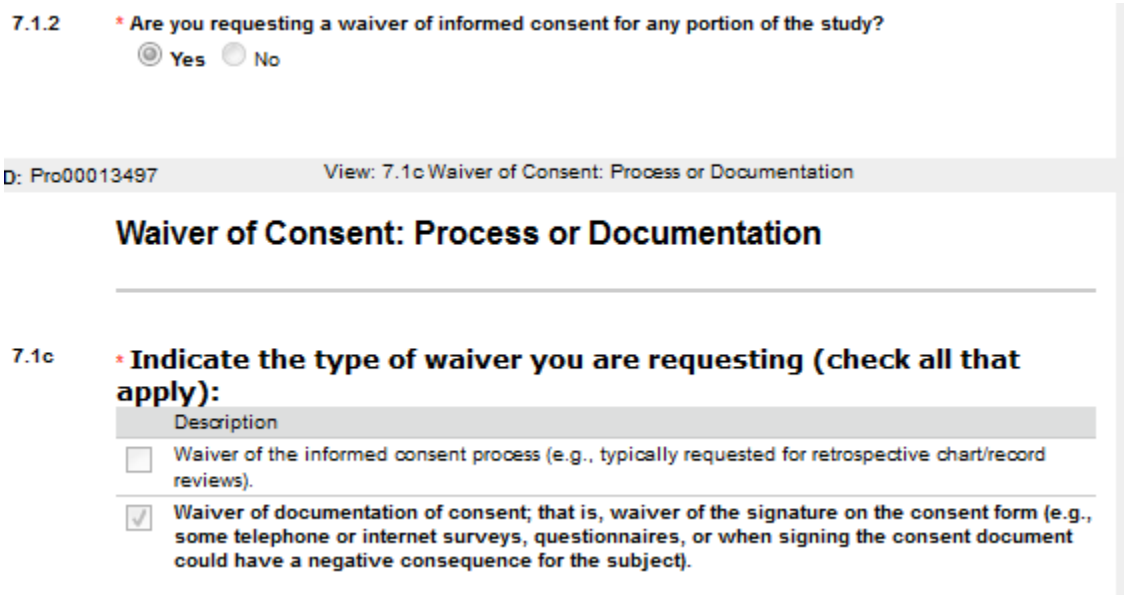
•There are also Tip Sheets located on the IRB website at: http://www.research.usf.edu/dric/hrpp/resources.asp#tip

Informed consent is located in section 7 of the SmartForm application.



Waiver of Informed Consent

Many times in the developing world it would be cumbersome and intrusive to ask respondents to sign forms especially if most of the population is illiterate. Under section 7.1.2 and 7.1c, you can request a waiver of the documentation of consent (see below).



7.1.2 * Are you requesting a waiver of informed consent for any portion of the study?

(●) Yes ( ) No

D: Pro00013497 View: 7.1c Waiver of Consent: Process or Documentation

Waiver of Consent: Process or Documentation

7.1c * **Indicate the type of waiver you are requesting (check all that apply):**

	Description
☐	Waiver of the informed consent process (e.g., typically requested for retrospective chart/record reviews).
☑	**Waiver of documentation of consent; that is, waiver of the signature on the consent form (e.g., some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject).**

Below is the verbal introduction that was uploaded for the example Shea butter study in place of signed forms. This was also translated into the local language (not included in example).

Mixed Methods Analysis to Quantify the Impacts of Shea Butter Production
eIRB # Pro13497
Colleen Naughton
e-mail: ccnaughton@gmail.com
mobile: +223-78455446

Shea Butter Research Introduction

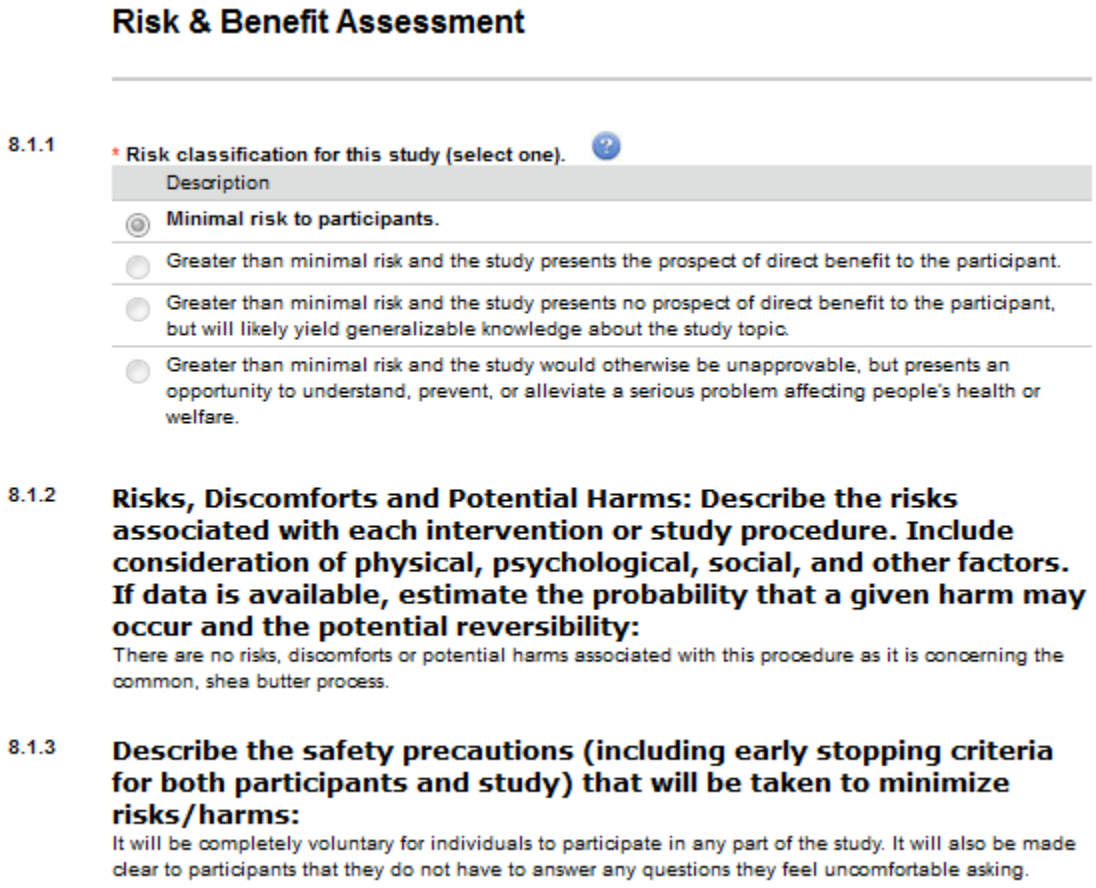
My name is Colleen Naughton and I am a student at University of South Florida and former Peace Corps Volunteer. For my master's thesis I am conducting research on Shea Butter. This is a completely voluntary study. You will not lose any of your benefits if you decide not to participate. All research records can be reviewed by the USF IRB and the Dept. of Health and Human Services. If you have any questions about the research or your rights as a research subject you can contact the IRB at 813-974-5638.

Specifically, my research concerns the human and embodied material energies involved in the shea butter production process. I will be observing all aspects of the process from collection of nuts to making the butter and recording the amount of time it takes in each step as well as weighing shea nuts, butter, and firewood. I will be collecting GPS coordinates of Shea Butter trees as well so that I may map them. I will also be conducting ethnographic interviews and surveys to determine the importance of shea butter to Bamanaw women and their families during the rainy season.

Local Language (Bambara) Translation:

Minimal Risk (Section 8)

If at all possible, and in most cases in the Master's International research anyways, you will want to specify your study as minimal risk unless you would like to go through the Full Board process and have to obtain signed informed consent. Here is an example from the Shea Butter study.



Risk & Benefit Assessment

8.1.1 * **Risk classification for this study (select one).**

	Description
◉	**Minimal risk to participants.**
○	Greater than minimal risk and the study presents the prospect of direct benefit to the participant.
○	Greater than minimal risk and the study presents no prospect of direct benefit to the participant, but will likely yield generalizable knowledge about the study topic.
○	Greater than minimal risk and the study would otherwise be unapprovable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting people's health or welfare.

8.1.2 **Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention or study procedure. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility:**

There are no risks, discomforts or potential harms associated with this procedure as it is concerning the common, shea butter process.

8.1.3 **Describe the safety precautions (including early stopping criteria for both participants and study) that will be taken to minimize risks/harms:**

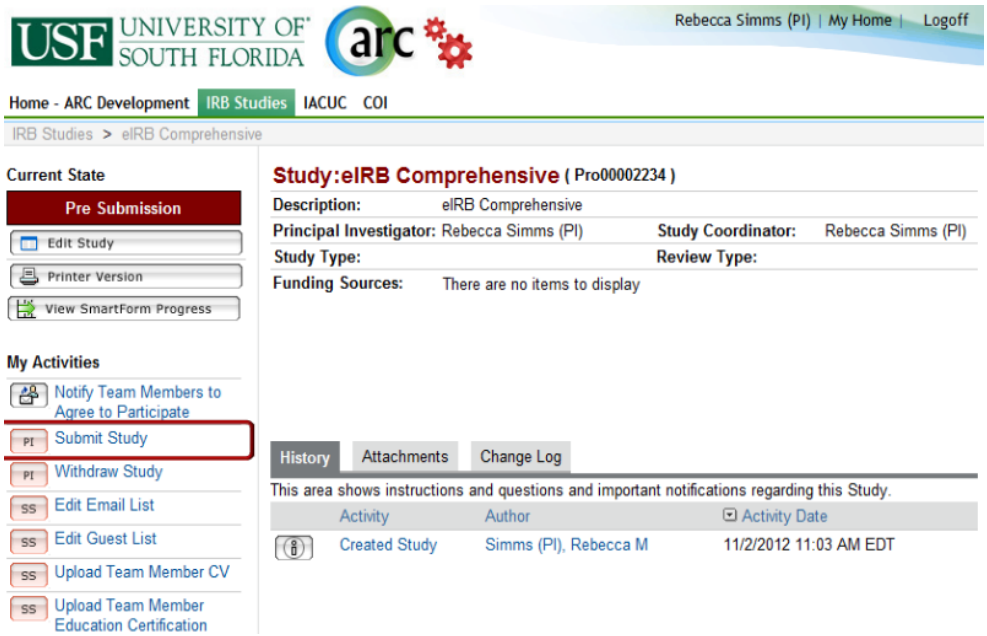
It will be completely voluntary for individuals to participate in any part of the study. It will also be made clear to participants that they do not have to answer any questions they feel uncomfortable asking.

Step 5: Submitting your research study

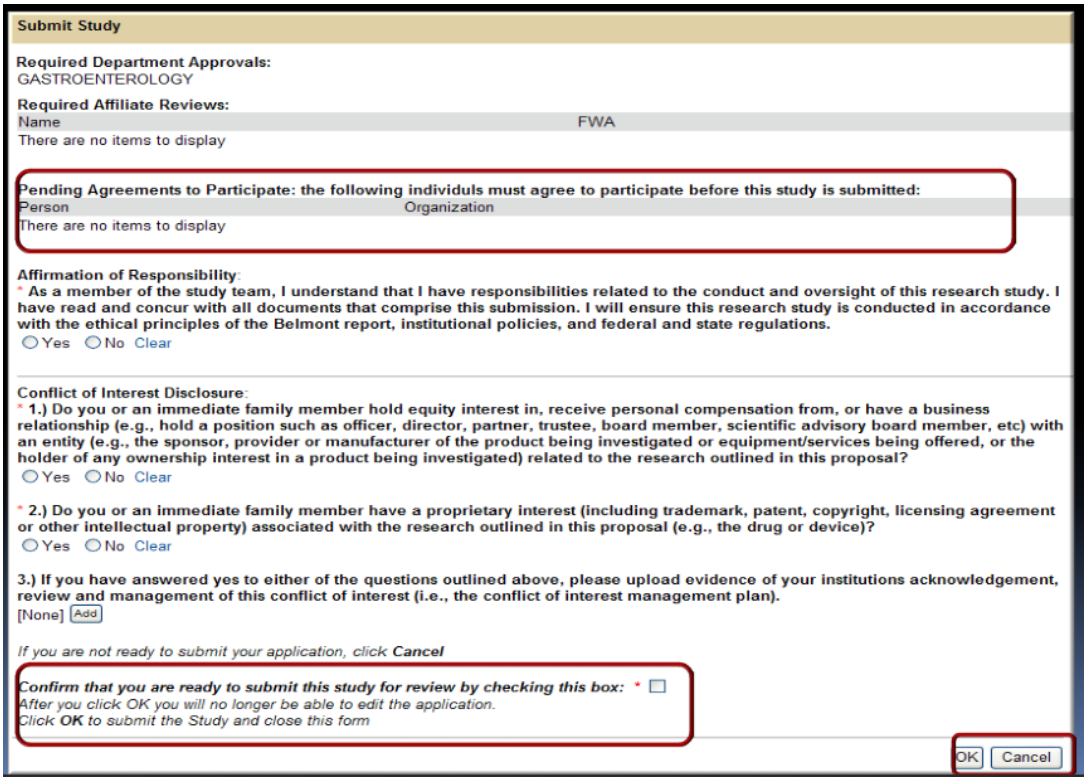
Now that you have completed all the SmartForm and looked over it for any errors (this is a good idea that will save you time later than with going back and forth with reviewers), it is time to submit the study. This is not as easy as just ONE button push. Make sure your study is submitted correctly or you may waste time waiting for a response when you have not completed all the necessary tasks.

1. Pre-submission: You must first notify all participants of your study (usually just Dr. Mihelcic). He must agree to participate in your study before submission. He will be sent an e-mail through arc but also send him an e-mail to watch for this. You can not submit your study without this approval.

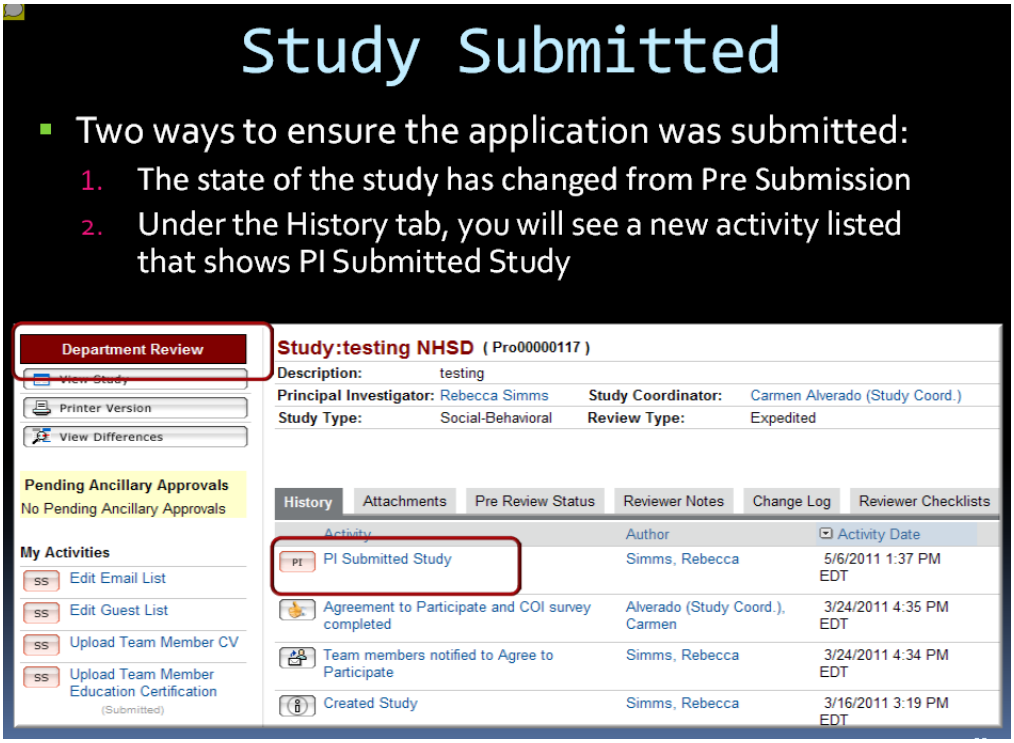
2. Submit the study



This screen will then show up. Make sure to check the box at the bottom and confirm that you are ready to submit this study for review. Click OK.

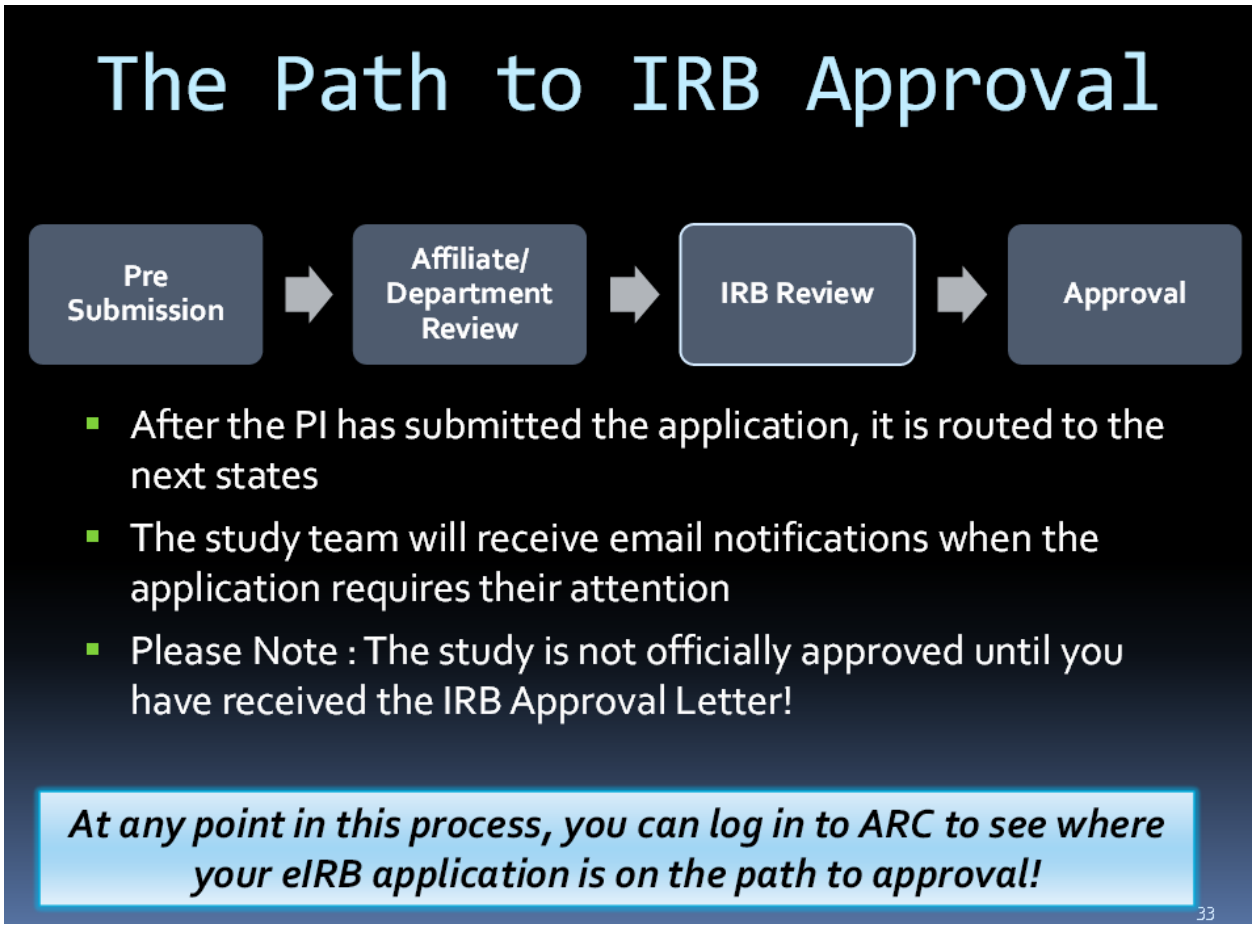


3. Double check your study has been submitted:



Below is an important flow chart and notes on what happens to your IRB once it has been submitted.

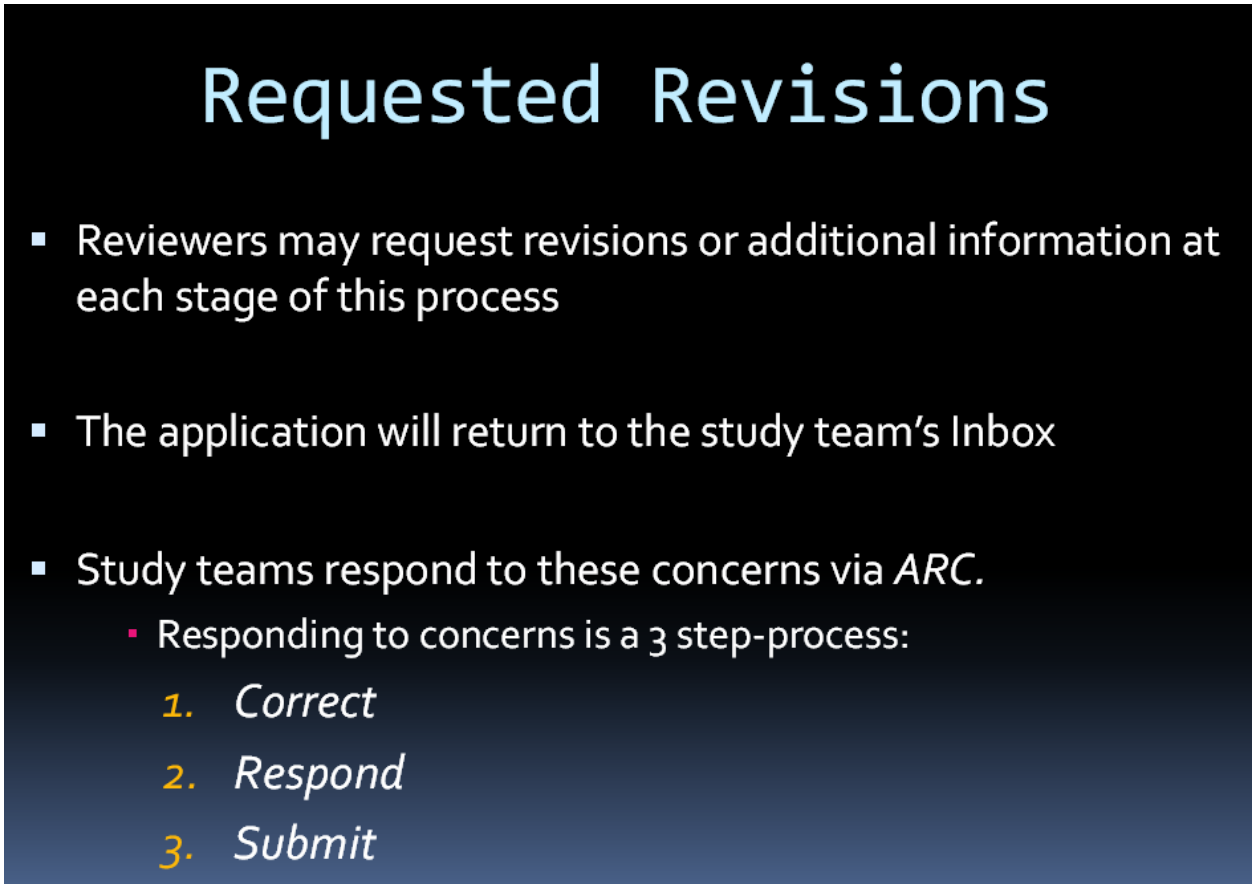
****IMPORTANT**:** If you find your study is still under department approval after two weeks or more, contact the department contact listed. There have been incidents where the person in the department designated for this task has changed or missed the e-mail in their inbox. You should see your study move from Department review to IRB review quickly.



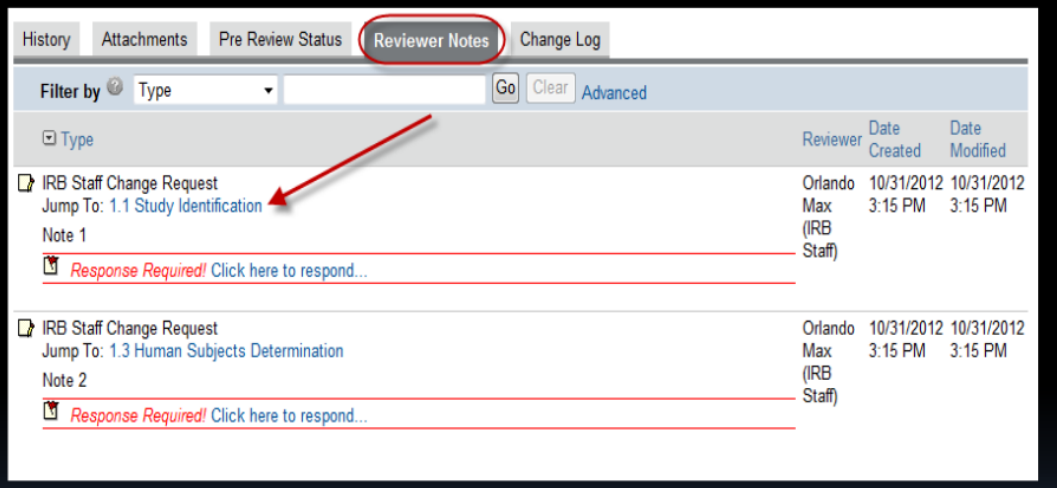
Step 6: Revising your research study

Hopefully after submitting your study it will be magically approved and you can proceed to step 7 but, unfortunately, this usually is not the case and you may have some minor revisions to address.

The following slides from the eIRB explain the process well. It is important to note that you not only need to correct the areas that need to be revised but include what you changed in a note to the reviewers.

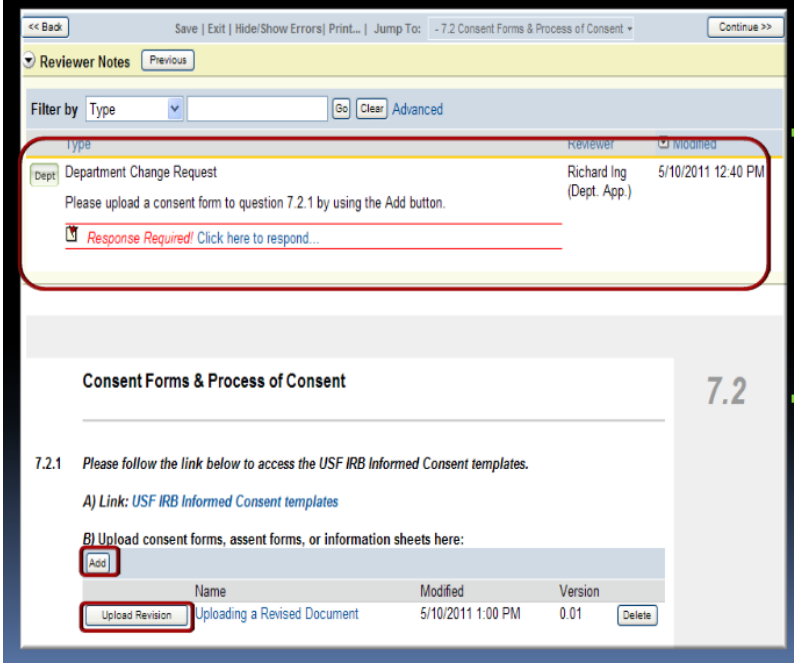


Requested Revisions



- Click the **Reviewer Notes** tab in the study workspace to see all the notes that were added
- Click the **Jump To** link to take you to the page of the application where the requested change needs to be made

Requested Revisions



STEP ONE:

- Read the Requested Change placed on the page of the question.
- Complete the request on the application.
  - *If a revised document needs to be uploaded, use the Upload Revision button.*

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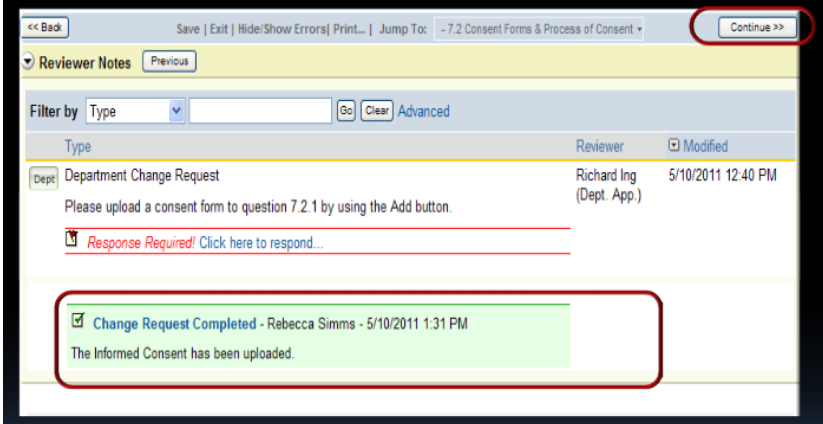
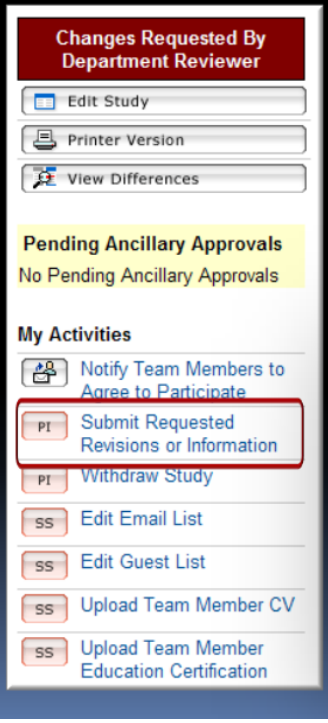
Requested Revisions

STEP TWO:



- Respond to the Reviewer Note!
  - *Your response will turn green*
- Some changes may add new pages with questions that need to be answered.
  - *Click Continue through the rest of the application*

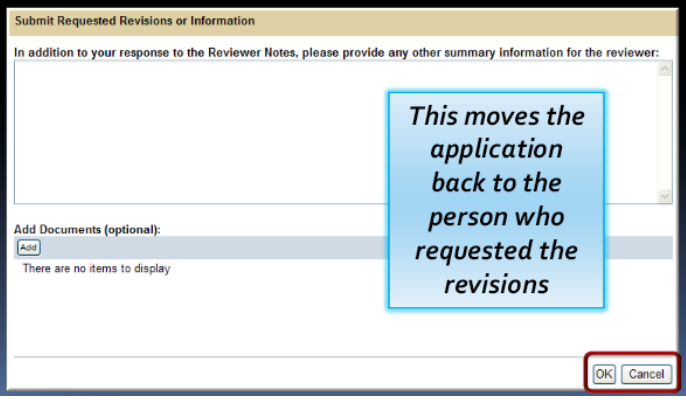
Requested Revisions



STEP THREE:

- Once all changes have been made, Save and Exit the application.
  - *You will return back to the Study Workspace.*
- Under My Activities, click on:

  Submit Requested Revisions or Information,
- Then click 'Ok' in the resulting dialog box.



This moves the application back to the person who requested the revisions

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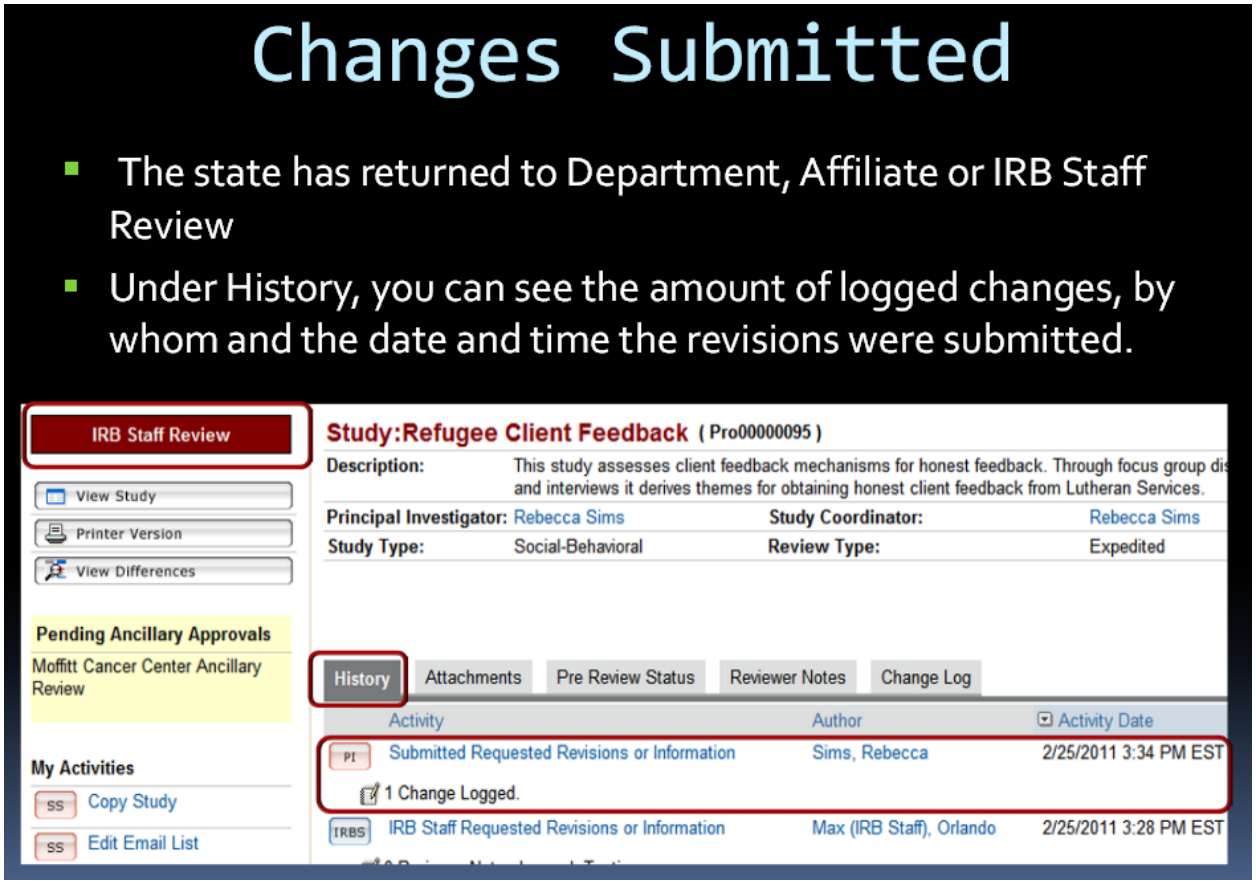
Just as with submitting your study, don't forget to submit your revisions. Before you do this make sure you have completely answered all the reviewers' comments. It will take more time if you need to go through two rounds of revisions.

***TIP:** You can always ask the reviewers questions through the inbox function on arc. They are usually quick to respond. They also usually have a phone number listed if you have enough credit on your phone/Skype to call them and need a quicker response.



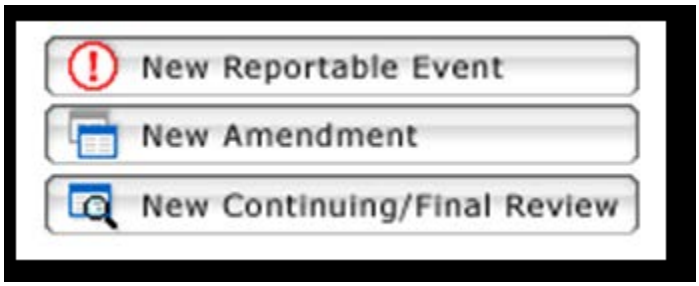
Step 7: Study approved, time for research!

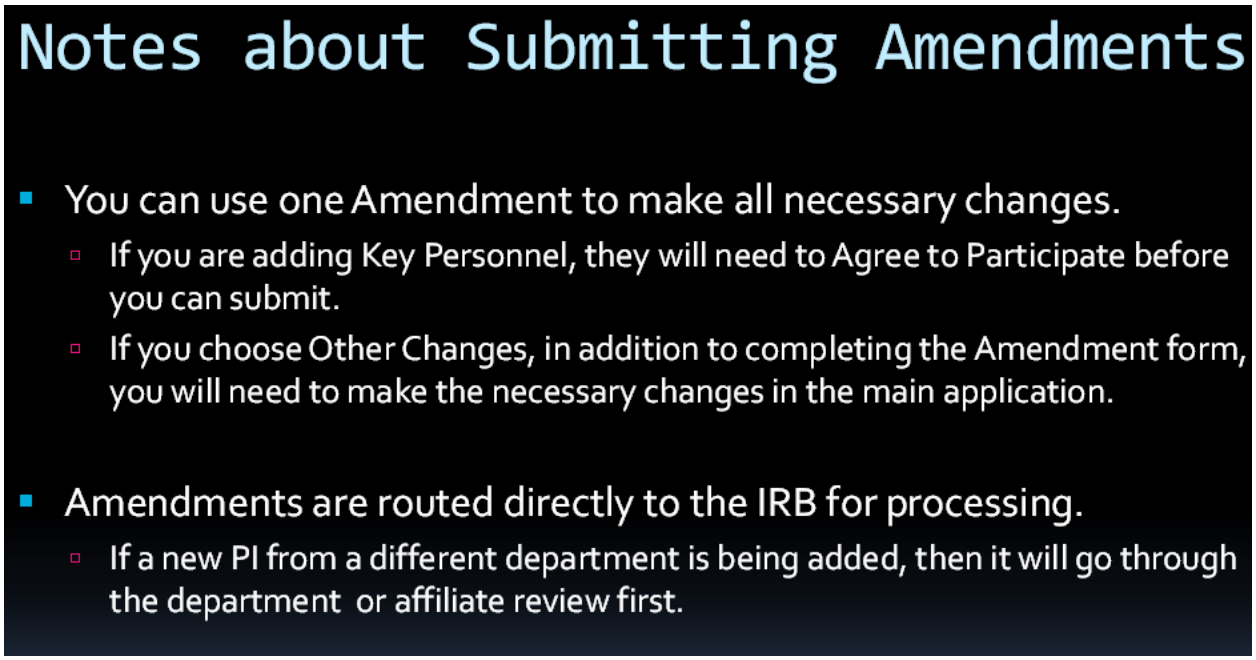
So, how will you know your study is approved? You will receive an e-mail but if you somehow miss that in your clogged inbox you may also look it up through arc. Only now, not during the submission process, may you begin data collection and administering surveys.

Step 8: Updating (amending) a study

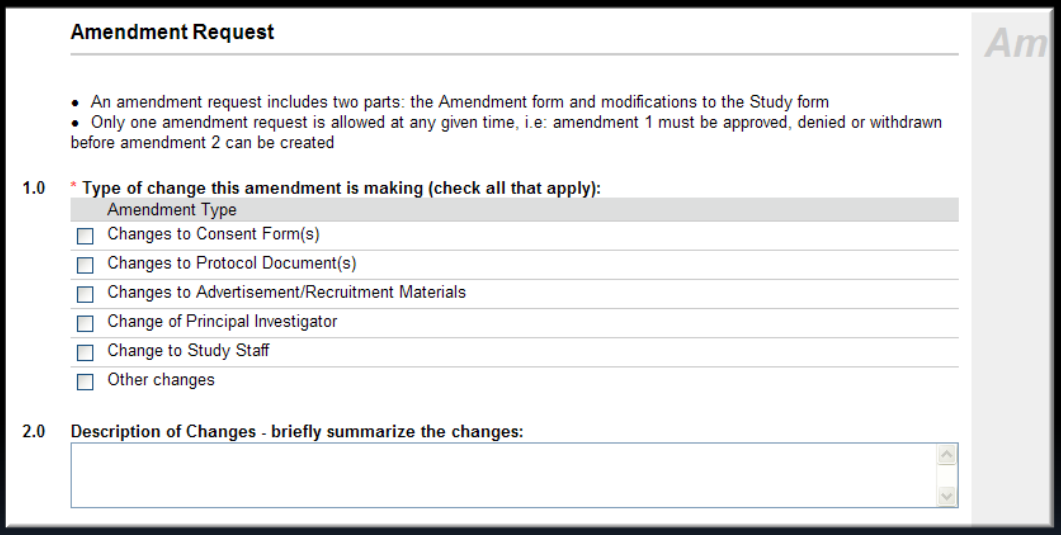
If for some reason you add to your study such as a new survey question or additional survey or other field measurements, you will need to submit an amendment to your study for approval which is usually processed relatively quickly.

Under study subprojects, click on "New Amendment."





Select Changes



Amendment Request

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created

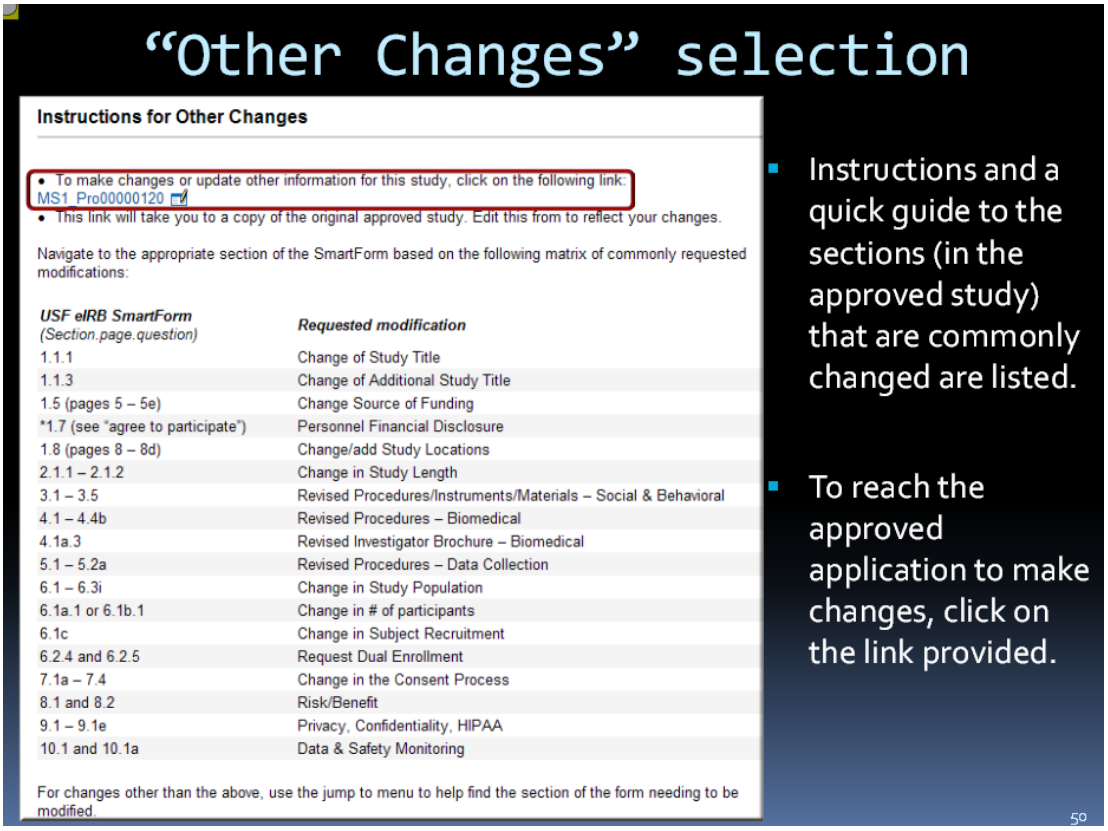
1.0 * **Type of change this amendment is making (check all that apply):**

Amendment Type
☐ Changes to Consent Form(s)
☐ Changes to Protocol Document(s)
☐ Changes to Advertisement/Recruitment Materials
☐ Change of Principal Investigator
☐ Change to Study Staff
☐ Other changes

2.0 **Description of Changes - briefly summarize the changes:**

- The first page of the Amendment will ask the types of changes you are making and for brief description.

"Other Changes" selection



Instructions for Other Changes

- To make changes or update other information for this study, click on the following link: MS1_Pro00000120
- This link will take you to a copy of the original approved study. Edit this from to reflect your changes.

Navigate to the appropriate section of the SmartForm based on the following matrix of commonly requested modifications:

USF eIRB SmartForm (Section.page.question)	*Requested modification*
1.1.1	Change of Study Title
1.1.3	Change of Additional Study Title
1.5 (pages 5 – 5e)	Change Source of Funding
*1.7 (see "agree to participate")	Personnel Financial Disclosure
1.8 (pages 8 – 8d)	Change/add Study Locations
2.1.1 – 2.1.2	Change in Study Length
3.1 – 3.5	Revised Procedures/Instruments/Materials – Social & Behavioral
4.1 – 4.4b	Revised Procedures – Biomedical
4.1a.3	Revised Investigator Brochure – Biomedical
5.1 – 5.2a	Revised Procedures – Data Collection
6.1 – 6.3i	Change in Study Population
6.1a.1 or 6.1b.1	Change in # of participants
6.1c	Change in Subject Recruitment
6.2.4 and 6.2.5	Request Dual Enrollment
7.1a – 7.4	Change in the Consent Process
8.1 and 8.2	Risk/Benefit
9.1 – 9.1e	Privacy, Confidentiality, HIPAA
10.1 and 10.1a	Data & Safety Monitoring

For changes other than the above, use the jump to menu to help find the section of the form needing to be modified.

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- Instructions and a quick guide to the sections (in the approved study) that are commonly changed are listed.
- To reach the approved application to make changes, click on the link provided.

Submitting the Amendment

After you click Finish, you will exit the form and will be directed to the Amendment Workspace.

If you added study team members, use the Notify Team Member to Agree to Participate activity.

After all agreements are received, use the Submit Amendment activity.

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Step 9: Incorporating IRB study details in thesis and publications

You must include in your thesis and journal article submissions your IRB number. This is usually done in the methods sections as follows:

"The research methods described below were first considered exempt by the Institutional Review Board (IRB) of the University of South Florida under IRB# Pro00004487 since monitoring of the handwashing stations was not considered human subjects research. However, when the thesis author added PPI® questionnaires to her research methods, a revised study (IRB# Pro00013532) was submitted and approved on July 2, 2013. See Appendix A for all IRB documentation in this study."

Step 10: Updating your IRB education requirements (every 2 years)

Your certification doesn't last forever. You will need to take a refresher online course every two years. Don't miss the deadline and lose all your work and studies in the CITI and arc systems!

You should receive an e-mail such as this about 60-90 days before you must renew:

Colleen Naughton,

This is an automatically generated email reminder from the Collaborative Institutional Training Initiative website. (Please do not reply to this email.)

Your current CITI Program training will expire 04/10/13. Now, your organization has additional course requirements for you to complete. To re-enter the website (www.citiprogram.org), you will need your username (cnaughto) and password (click here to receive your account password by email).

1. Name on Completion Report: Colleen Naughton
2. Affiliated Institution: University of South Florida
3. Grade Book and Group Curriculum: Human Research, IRB Members - will expire
4. Expiration date: 04/10/13
5. Completion Report Number: 5402699

For more information regarding this email reminder, click here to access our knowledge base site.

CITI Program
University of Miami – Miller School of Medicine
www.citiprogram.org

Appendix A- IRB 101 Presentation

IRB 101
Social & Behavioral Research

What is an IRB?

- IRB is an acronym for Institutional Review Board
- The IRB is responsible for the review and approval of all research involving human subjects
  - Scientific validity
  - Ethical review
- Function of the IRB: Protecting the rights, welfare and safety of human subjects through
  - review
  - approval
  - continuing oversight

IRB Jurisdiction

Jurisdiction of the IRB -All research activities involving human subjects

Per Federal Regulations:

- Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

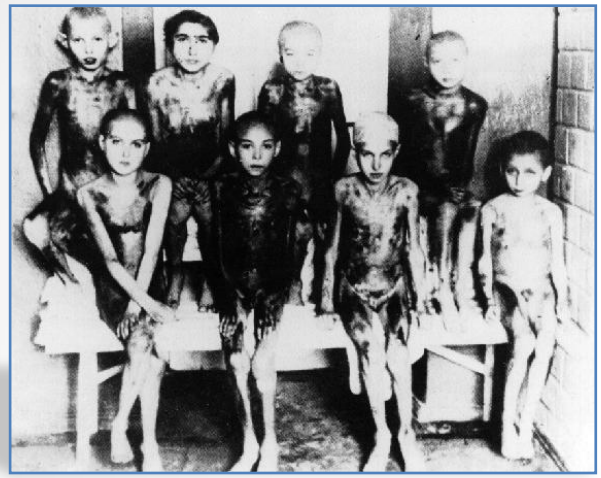
- A Human Subject is defined as a living individual *about whom* an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information

For a project to include human subjects research under the purview of the USF IRB, both of the definitions outlined above must be met.

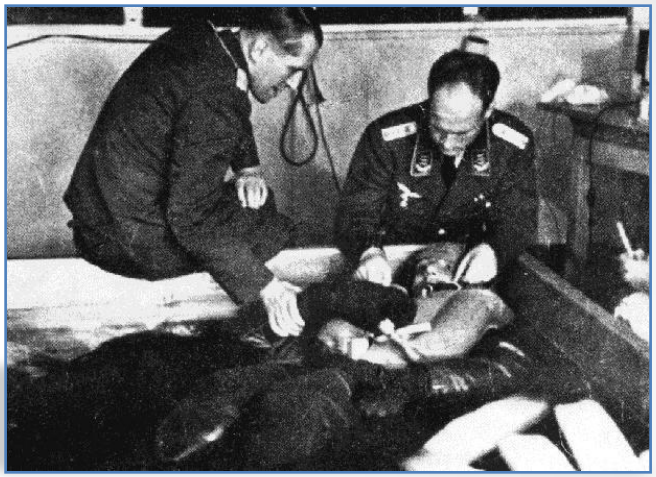
Why Were IRBs Formed?

The birth of the Institutional Review Board resulted from an unfortunate history of crimes against humanity in the name of science and research.

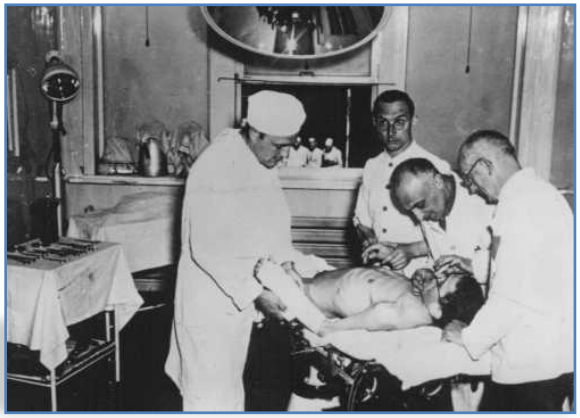
Nuremburg Photographs



Children of Auschwitz exposed to medical experiments during the Nazi regime



Cold Water experiments



Medical personnel experiment on a prisoner at the Buchenwald concentration camp.

Nuremburg Trials: 1946 - 1947

- Trials at Nuremburg – series of military tribunals in response to WWII atrocities in the concentration camps
  - "Researchers" conducted cruel experiments on children & adults held in the camps with no informed consent

- Many defendants argued that the experiments were morally justified
  - Participants were going to die anyway
  - Sacrifice would provide scientific knowledge benefiting many

- 15 of the 25 defendants (20 MDs) were found guilty and 7 were sentenced to death

Nuremburg Code: 1947

- As a direct result of the Nazi medical experiment atrocities committed during World War II that were revealed at the Nuremberg Trials, the Nuremburg Code was developed as part of the judgment.

- Makes clear that
  - The welfare and rights of human subjects must be protected
  - The research conducted must be sound and beneficial
  - The freedom of human subjects to participate or not is inviolable

Monster Study: 1939

- Termed the “Monster Study” by peers of the PI, Wendell Johnson from University of Iowa
- 22 orphaned children selected for this study on stuttering. Some who actually stuttered and some who did not.
- The investigators provided positive feedback to some of the subjects and negative feedback to others, depending upon whether they were included in the control or experimental group
- Many of the children with normal speech patterns suffered negative psychological effects, and some developed lifetime speech problems

Willowbrook State School: 1963-1966

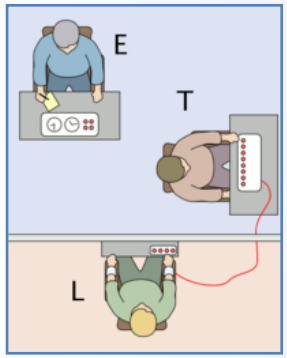
- Designed to gain an understanding of the natural history of infectious hepatitis and to test the effects of gamma globulin in preventing or ameliorating the disease

- Children subjects were deliberately infected with the hepatitis virus
  - Early subjects were fed extracts of stools from infected individuals and later subjects received injections of more purified virus preparations
  - Only children whose parents gave permission to participate in the research were admitted

- Investigators stated that the vast majority acquired hepatitis while at Willowbrook, and it would be better for them to be infected under carefully controlled research conditions

Milgram Experiments: 1960s

- Measured the willingness of subjects to obey an authority figure who instructed them to complete a task that conflicted with their conscience
  - Subject (T) instructed by the researcher (E) to give what subject believes are painful shocks to the learner-actor (L) when an incorrect answer is given
  - Subjects believed actual shocks were being given for incorrect responses



- Many subjects realized they were capable of committing acts of extreme violence against others

- Ethical questions raised due to the associated extreme emotional stress and insight into personal flaws inflicted upon the subjects

http://en.wikipedia.org/wiki/File:Milgram_Experiment_v2.png

The Tearoom Study: 1965-1970

- Conducted by Laud Humphreys, a Ph.D. student studying stereotypical beliefs about men who committed impersonal sexual acts with one another in public restrooms.
- He gained the trust of individuals by posing as a voyeur and lookout.
- He secretly followed some men and recorded license numbers of their vehicles.
- A year later, Humphreys showed up at their private homes disguised and claiming to be a health service interviewer. He asked questions about their sexual orientation, marital status, race, job and other personal information.

The Tearoom Study, cont.

- The report had enough detail that the identities of some participants were obvious to them and their families.

- Issues:
  - Subjects were never consented
  - Invasion of privacy
  - Failure to protect against deductive disclosure of identity
  - Deception was used with no debriefing
  - There was a risk of societal harm and risk of civil or criminal liability (many of the men were married and these at the time, arrests for this behavior in public was more prevalent)

Tuskegee Syphilis Study: 1932 – 1972

- US Public Health Service Sponsored: “The Study of Untreated Syphilis in Negro Male”

- Subjects were disadvantaged, rural African-American men, several who were already infected and some who were not
  - Provided with free medical exams, free meals, and burial insurance, but were not told about their disease

- Infected men were denied treatment, although penicillin was accepted treatment in 1943, and PCN was available for syphilis treatment in 1952

Outcomes

- Tuskegee Lead to the **National Research Act of 1974**, requiring regulatory protection for human subjects

- The National Research Act also created the **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**
  - This commission wrote the "**Belmont Report**" in 1979, which is the cornerstone statement of ethical principles for treatment of research subjects

- In 1981 the DHHS & FDA published convergent regulations that were based on the Belmont Principles

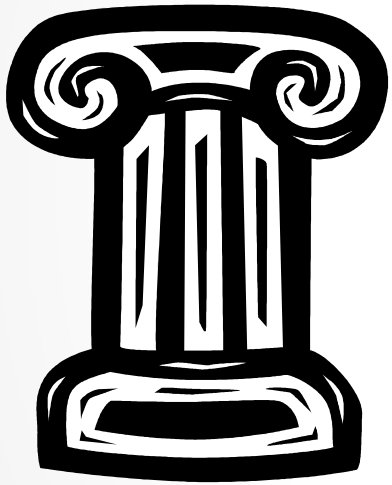
- In 1991, after 10 years of negotiation, 17 federal departments and agencies agreed to adopt the basic human subjects protections. This is referred to as the "**Common Rule**"

The Belmont Report: 1979

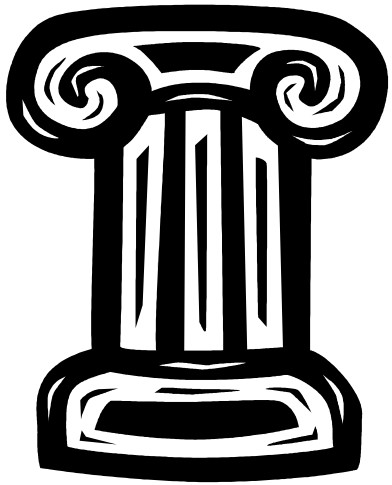
- Issued April 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Made necessary due to a long history of various questions, concerns, difficulties and problems that arose in medical experimentation and other forms of research efforts involving the enrollment of human subjects
- Distinguished between medical practice (treatment) and research
- Established the responsibility of the investigator to submit research activity for review by an Institutional Review Board

The Three Pillars of Belmont

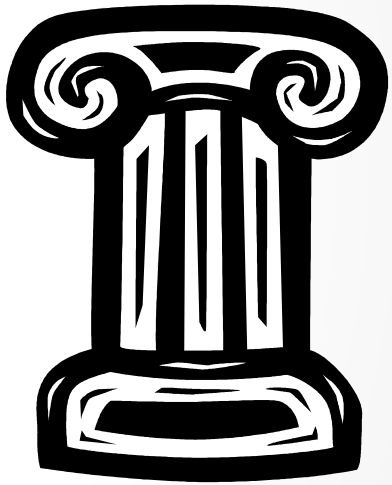
Respect for Persons



Beneficence



Justice



Respect for Persons

- The freedom and capacity of subjects must be protected
- Each subject is an autonomous agent, capable of making their own decisions, and not to be used as a means to an end
- Special measures must be taken to protect the rights and welfare of persons with diminished autonomy
- Informed consent is central to protecting the autonomy of human subjects

Beneficence

- Researchers have the obligation to secure the well-being of subjects
- Possible benefits must be maximized and possible harms must be minimized

Justice

- Researchers question who receives the benefits of research and who bears its burdens

- There must be fairness in the distribution of the risks and benefits of the research

The Havasupai: 2010

- As part of a partnership with the tribe, Arizona State University (ASU) collected specimens for diabetes research in 1989.
- Researchers then used the samples, without complete consent, for unrelated studies on schizophrenia, migration and inbreeding- all taboo topics for the tribe
- In 2004, the Havasupai Tribe filed a lawsuit against Arizona Board of Regents and ASU researchers
- A settlement was reached in 2010:
  - $700,000
  - Medical care & educational services
  - Return of known remaining specimens

http://www.nytimes.com/2010/04/22/us/22dna.html

Review Types

Exempt (HRPP Policy #303)

Minimal risk research, which is reviewed by the Chairperson or Designee. Study approval for five years and then automatically closed.

Examples:

- Anonymous Surveys
- Data that is “already on the shelf”
  - Recorded in a de-identified fashion (See next slide for 18 HIPAA Identifiers)
  - Cannot be “coded” (Identifying information that has been replaced with a number , letter symbol etc and a key to decipher the code exists, enabling linkage of the identifying information)
- Research comparing standard practice methodology in an educational setting
  - No radically new instructional strategy or use of random assignment of subjects
  - Common practice in elementary, secondary, or post-secondary settings

18 HIPAA Identifiers

These identifiers must be removed for a study to be considered de-identified:

1. Name
2. All geographical subdivisions smaller than a state (street address, city, county, precinct). Note: Zip codes or the equivalent must be removed, but the first three digits of the zip code is not considered a "direct identifier" if geographical unit formed by combining all zip codes with the same three digits contain more than 20,000 individuals)
3. All elements of dates except year, for dates directly related to an individual, e.g., date of birth, admission date, discharge date, date of death. For individuals who are 90 years or older, all elements of date, including year, is considered a "direct identifier." Note: if such ages and elements are aggregated into a single category of "age 90 or older" then it is not considered to be a direct identifier.
4. Telephone numbers
5. Facsimile numbers
6. Electronic mail addresses
7. Social Security numbers
8. Medical Records numbers, prescription numbers
9. Health Plan numbers
10. Account Numbers
11. Certificate/license numbers
12. Vehicle identification/serial numbers/license plate numbers
13. Device identifiers/serial numbers
14. Universal Resource Locators (URLs) for Web sites
15. Internet Protocol (IP) Address
16. Biometric Identifiers, e.g. fingerprints, voice prints
17. Full face or comparable photographic images
18. Any other unique number, characteristic, or code that could be used to identify the individual . (If you abstract any unique identifiers, please specify)

Review Types, cont.

Expedited (HRPP Policy #204)

Minimal risk research, which is reviewed by the Chairperson or Designee. Study approval for one year. Continuing review application must be submitted to continue study activities.

Examples:

- Surveys that include identifiable information
- Interviews
- Analysis of data collected (or that will be collected) for non-research purposes
- Secondary data analysis
- Video or audio recordings
- Focus Groups

Review Types, cont.

Full Board

Reviewed by fully convened Board. Study approval for one year. Continuing review application must be submitted to continue study activities.

Examples:

- Greater than minimal risk research
- Studies involving prisoners or data about prisoners
- Novel therapeutic interventions
- Other vulnerable populations
- Collecting information that could place the participant at risk of civil or criminal liability or may cause other societal harms (stigma, ostracism, excommunication, etc.)

What Is Informed Consent?

(HRPP Policy #601)

- Informed consent is central to the protection of human subjects. It is both a process and a procedure
  - The process is the exchange of information that takes place between the prospective subject, and the investigator and study staff, before, during and sometimes after the study
  - The procedure includes the shaping and signing of an informed consent document
  - There are also times the IRB can waive consent

Informed Consent & Belmont

- IC is founded on the principle of Respect for Persons
- Requires that individuals be treated as autonomous agents, and that the rights and welfare of persons with diminished autonomy be appropriately protected
- Respect for persons requires that prospective research subjects “be given the opportunity to choose what shall or shall not happen to them” and thus necessitates adequate standards for informed consent

Required Elements of the ICD

- Per 45CFR46.166(a), the list of required elements includes:
  - A statement that the study involves research, an explanation of the purposes, the expected duration, a description of the procedures, and identification of any experimental procedures
  - A description of foreseeable risks/benefits
  - Disclosure of appropriate alternatives or courses of treatment, if any, that might be advantageous to the participant
  - A statement on the extent to which confidentiality will be maintained
  - Discussion of compensation
  - Contact information for questions about research subject rights
  - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the subject is free to withdraw at any time
  - Contact information for the IRB in the event research staff could not be reached and in the event the participant wishes to talk to someone other than the research staff

Informed Consent Templates & Tip Sheets

- The IRB has developed several templates to ensure that informed consent documents include all of the required elements - https://arc.research.usf.edu/Prod
  - Click on “Institutional Review Board” on left side of page and select “Consent Form Templates”

- There are also Tip Sheets located on the IRB website at:

  http://www.research.usf.edu/dric/hrpp/resources.asp#tip

What to Expect during Review

- Once your study has been fully submitted through eIRB, a Research Compliance Administrator (RCA) will review the application
  - He/she will contact you if there are questions or necessary revisions needed

- The study will be reviewed per its "category"
  - Exempt & Expedited review studies are reviewed by the Chair and/or Designee (Most Social & Behavioral fall into these categories)
  - Full-board studies are reviewed at the convened meetings
    - 3 Biomedical/1 Social & Behavioral per month

Important to Consider With IRB Review of New Studies

Although the USF IRB has a competitive turnaround time, completing all of the required steps can involve multiple parties (PI, all study staff, Dept. approver, RCA, Chairperson, IRB Reviewer and full committee). It is recommended that you allow 30-45 days for an Expedited or Exempt review and *at least* 60 days for a Full Board review.

Useful Links and Resources

IRB Policies and Procedures:
http://www.research.usf.edu/dric/hrpp/policy-procedure.asp

ARC (Online submission system) Help Desk Contact:
RSCH-arc@usf.edu or 813-974-2880

ARC Home Page: https://ARC.research.usf.edu/prod/ (ARC training materials can be found in the menu on the left side of the page)

IRB (HRPP) Web Site:
http://www.research.usf.edu/dric/hrpp/default.asp

CITI Education: https://www.citiprogram.org/

Questions?

Appendix B- eIRB Study Team Manual

eIRB Study Team Manual

This guide serves to aid the study team become familiar with the basic functions of the eIRB module of the ARC system.

Table of Contents

Welcome to ARC

Our on-line *ARC* system streamlines the process of submitting, approving, tracking, and managing eIRB eCOI, and eIACUC applications.

ARC is available via Internet connection 24 hours a day, 7 days a week.

The *ARC* HelpDesk is available during regular business hours at (813) 974-2880 and by email at RSCH-arc@usf.edu.

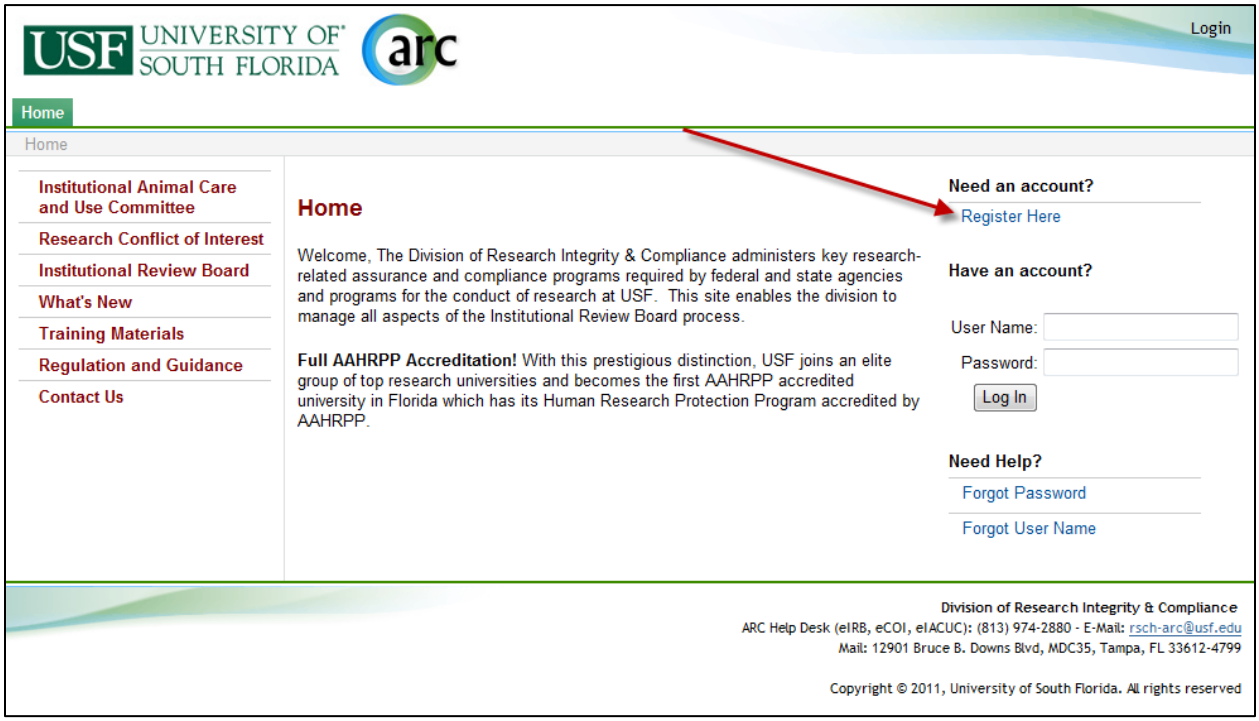
Accounts

In order to create and submit applications in ARC, you will first need to obtain an account by submitting a new user registration request.

New Account Registration

To open your new *ARC* account:

1. Go to the *ARC* Web Site: https://ARC.research.usf.edu/prod/
2. Click **Register Here** on the right hand side of the page.

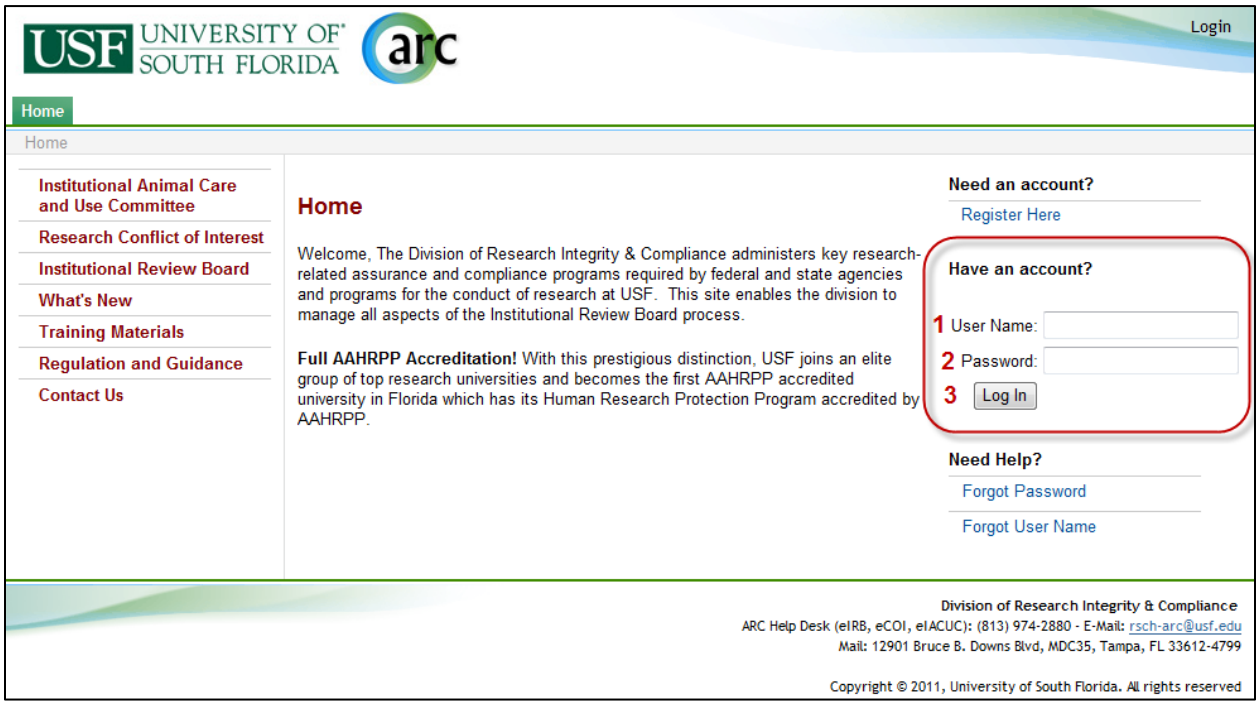


3. Complete the required fields (*) and provide your USF Net ID, Employee ID, and USF or affiliate email address.
4. Select all relevant roles, such as Study Staff, PI, Department Approver, etc.
5. Click **Register.**

6. Within two business days your new account will be activated and you will receive an e-mail containing your account information (i.e., User Name & Temporary Password).

Log In

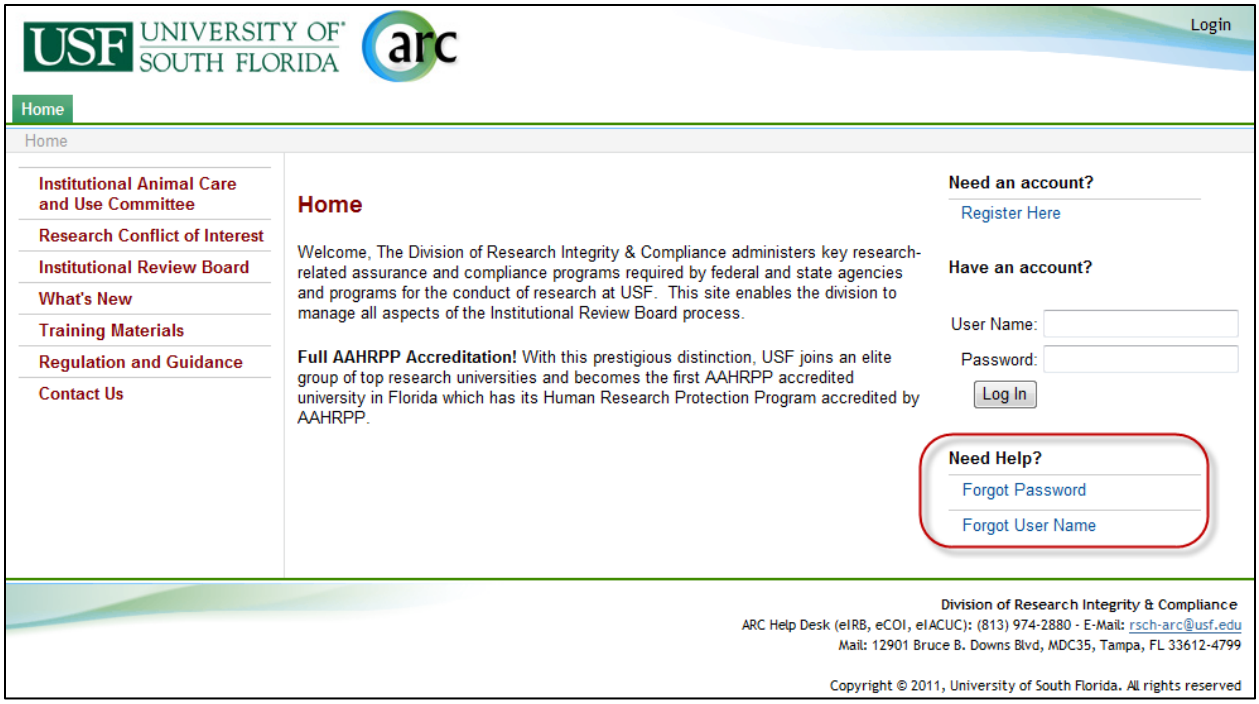
1. Type your **User Name** in the login section on the right side of the *ARC* screen.
2. Type in your **Password.**
3. Click **Log In**.



Forgot Your User Name or Password?

If you ever forget your account credentials, you can have them emailed to you on the ARC Home page.

1. The **Forgot Password** and **Forgot User Name** options are available under **Need Help?.**

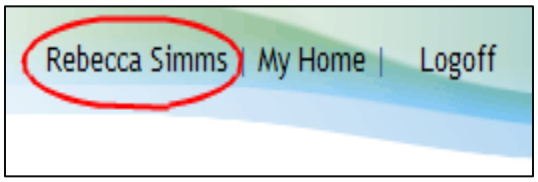


1. If you select **Forgot user name?**, you will be prompted to confirm your email address. Once confirmed, your user name will be emailed to you.
2. If you select **Forgot password?**, you will be prompted to confirm your user name and email address. Once confirmed, a new temporary password will be emailed to you. Upon log in, you will be required to change your password.

If you have forgotten both your user name and your password, select **Forgot user name?** first as it only requires your primary email address. After receiving your username, you can select **Forgot password?**.

Account Changes

It is important to keep your account information current. To make changes to your account, click your name in the upper right hand corner of your screen to open your account properties.



Then make the necessary changes and click **Apply**. **Note** - For changes to your department affiliation and assigned roles, you will need to contact the helpdesk.

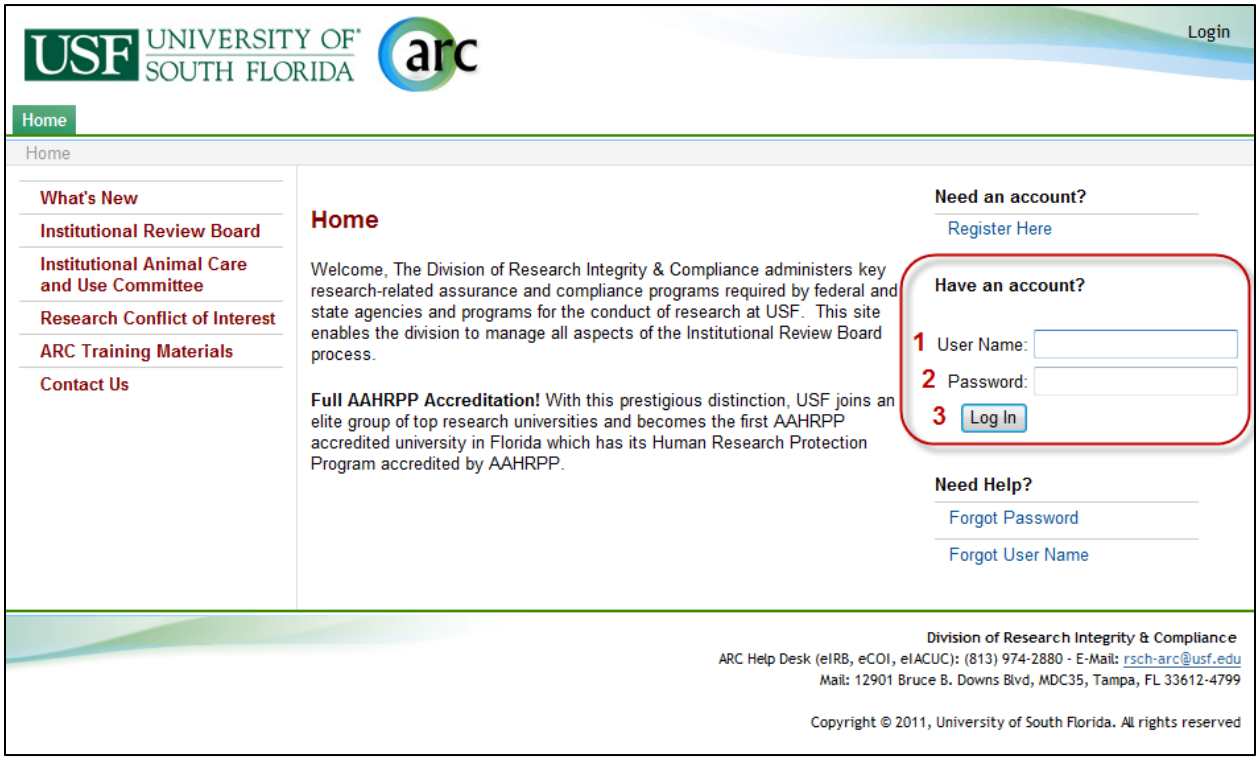
To change your password, click on your name (as described above). On your Account page, click the **Account** tab. Type in your old password, your new password, and your new password again in their respective boxes. Click **Apply**.

After receiving your username and a temporary password, you can log in to the ARC system.

Navigation

Log In

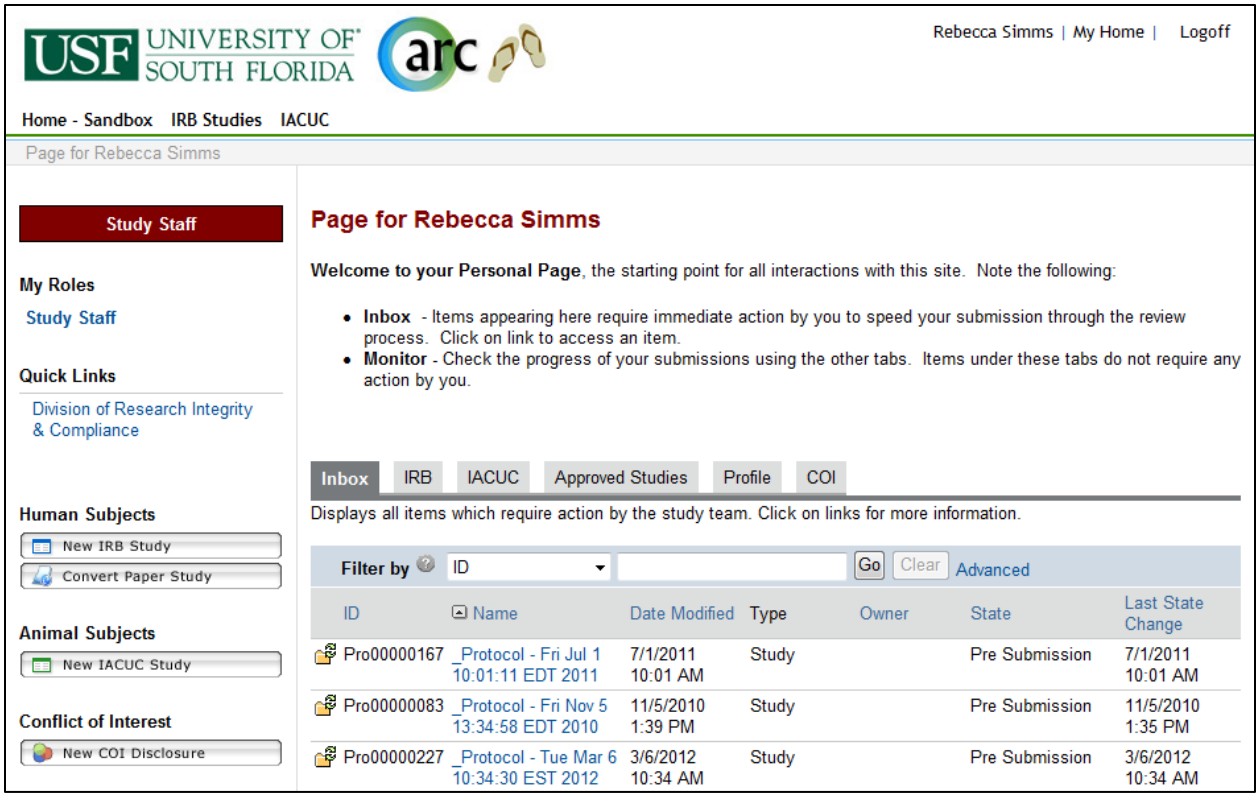
1. Type your **User Name** in the login section on the right side of the *ARC* screen.
2. Type in your **Password.**
3. Click **Log In**.



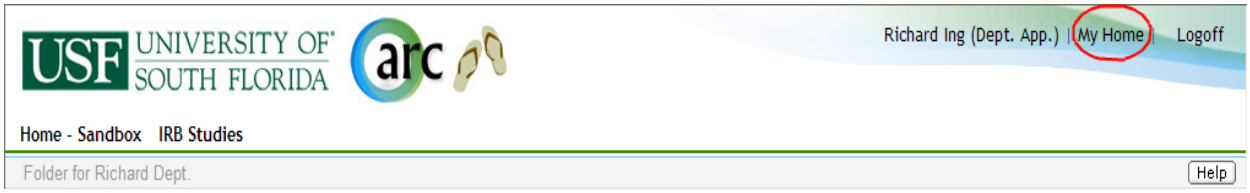
My Home Folder

After logging in, the screen displays your **Folder** which is like a personal home page.

Here you will be able to view and manage those studies relevant to your **Role**.



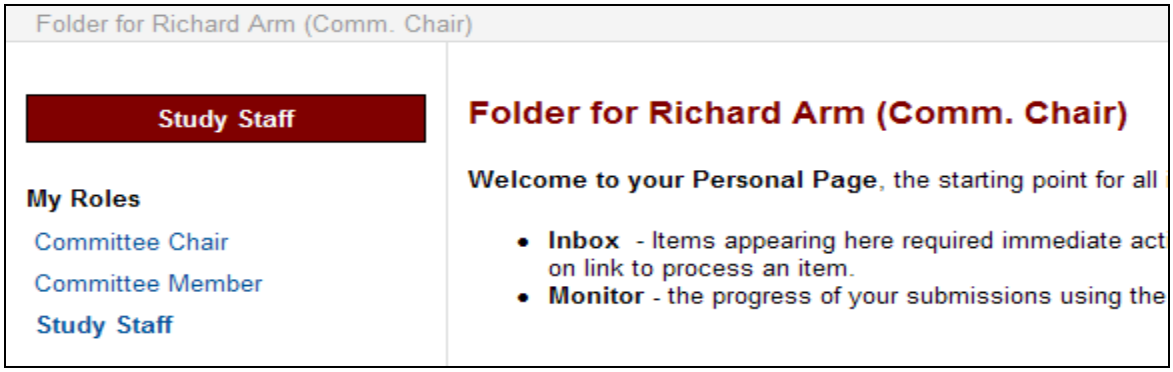
When you are in other sections of the *ARC* system, you can easily get back to your homepage by clicking the link to **My Home**.



Roles

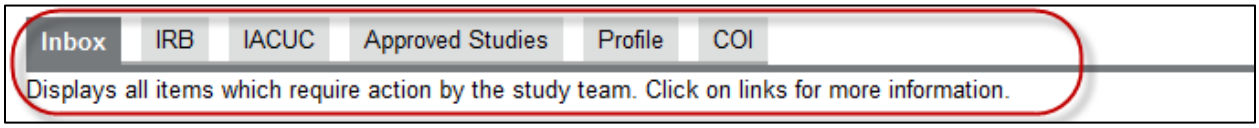
A person can have multiple **Roles** in *ARC* such as Principal Investigator (PI), Co-Investigator, Study Coordinator, Department Approver, IRB Committee member, etc. Different Roles provide access to different applications, information, and activities. A person with the PI role will also have the role capabilities of Co-Investigator, Study Coordinator and Study Staff.

Your current **Role** will be displayed in the red banner at the top of the column on the left side of your Folder. Your current role will be **Bold** in the listing of your available Roles If you have more than one role, each time you log in, be sure that the correct role is selected. If the desired role is not selected, click on the role you need.



Navigation Tabs

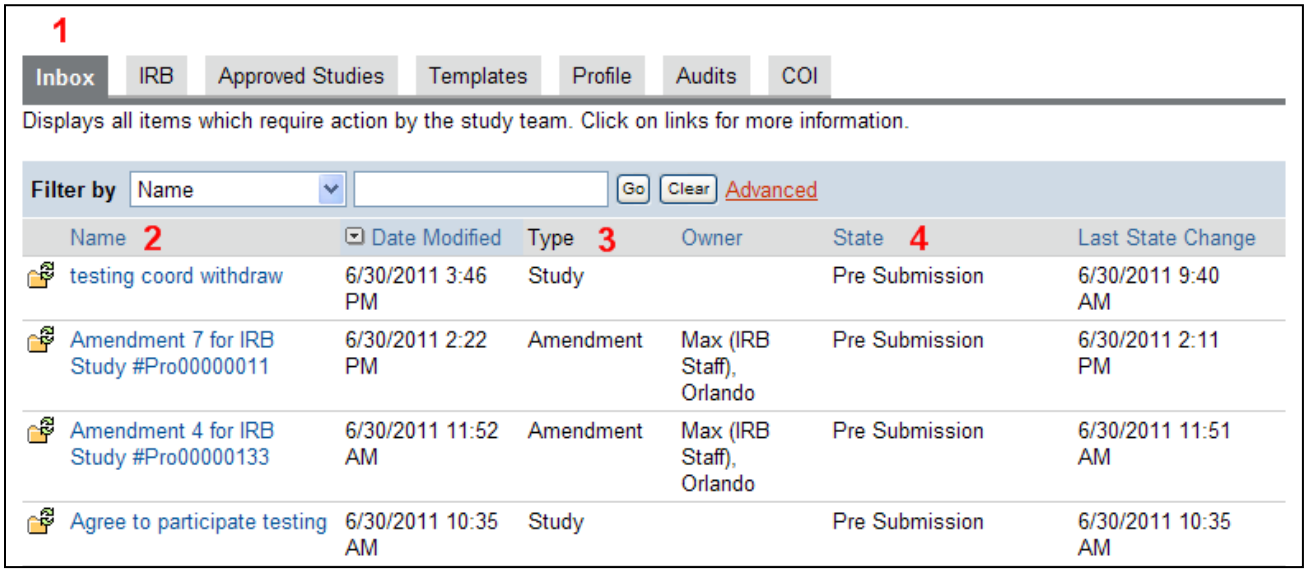
The central area of your Folder (My Home) provides a row of navigation tabs.



Inbox Tab

Inbox lists all applications (studies, amendments, continuing reviews, and reportable events) that require action by you or other staff on your study team in your current Role.

Below is an example of your **Inbox**:



Key to the **Inbox** page:

1. The **Inbox** tab. Displays all applications requiring attention by the study team.

2. **Name** column. Displays the name of applications in your Inbox. Clicking the name will bring up that application's workspace.
3. **Type** column. Displays the type of application (Study, amendment, etc.)
4. **State** column. Displays where the application is in the IRB process.

Once you have completed the required activities, the application is moved electronically from one respective Inbox to the next according to whose attention it requires.

If an application is not in your Inbox, it's someone else's turn to work on it. **If an item is in your Inbox, it still requires your attention.**

IRB, Approved Studies, and COI Tabs

The **IRB** tab lists all applications with which you are associated regardless of the state. In the **IRB** tab, you can monitor the **State** of all of your applications. You can view applications under the IRB tab by clicking the application Name.

The **Approved Studies** tab lists all of your studies that have been approved by the IRB.

The **COI** tab lists all of your conflict of interest applications.

Application Workspace

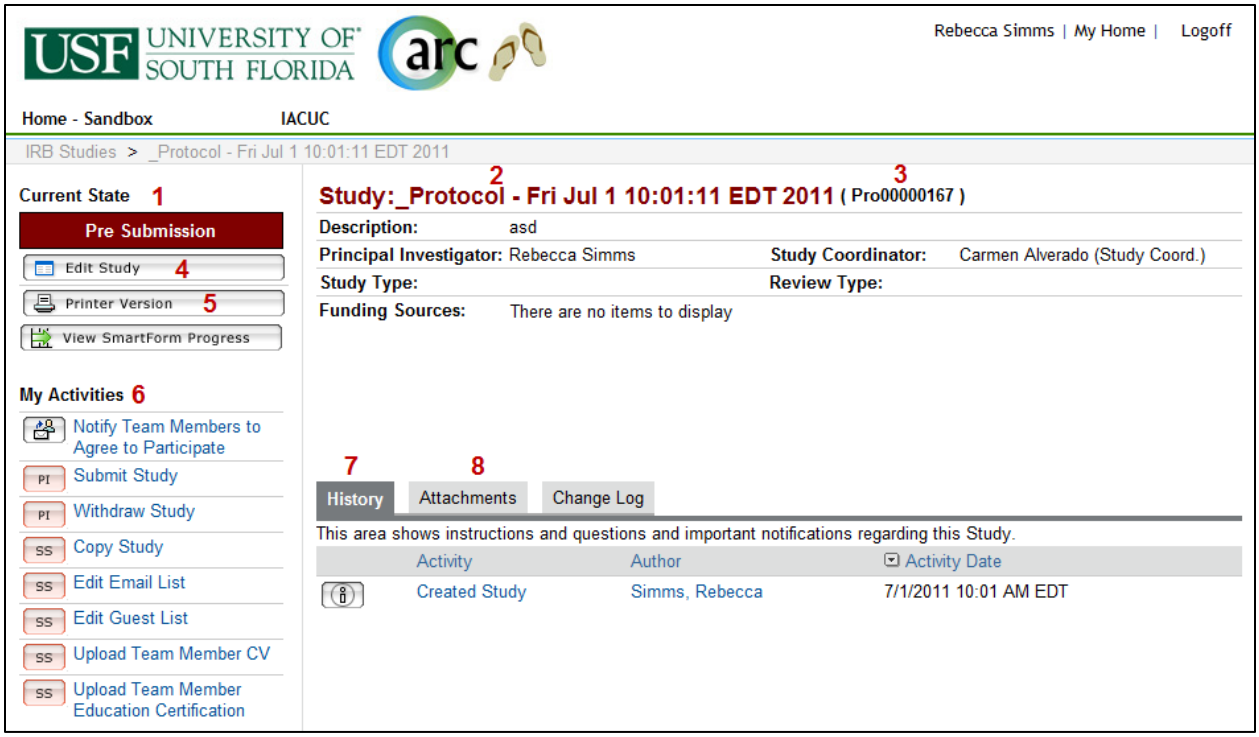
Work on an application begins in the application **Workspace** which is like a home page for the application. Open an application Workspace by clicking on its **Name** in your **Inbox**.

The application Workspace provides:

- information about the application
- links to specific sections and documents related to the application
- buttons to initiate **Activities** and move the application to the next step in the IRB process (these buttons are only available to you when the application is in your Inbox)
- history of all activities performed on the application

After a study has been approved, tabs for Adverse Events, Amendments, and Continuing Reviews are displayed next to the History tab in the study workspace.

Below is an example of a study Workspace screen:

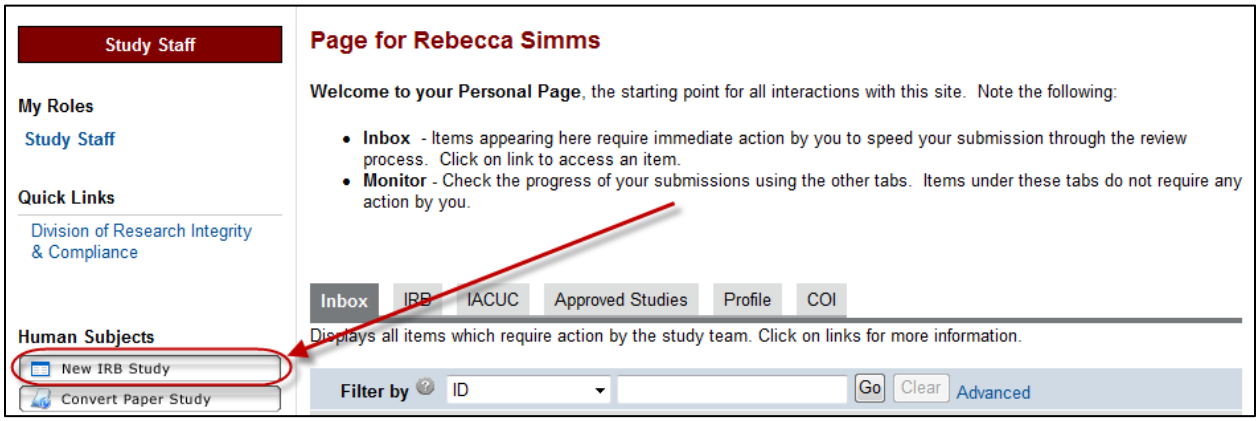


Key to the study **Workspace** screen:

1. **Current State** indicates the stage in the IRB review process for this study. This changes as Activities are completed.
2. The summary panel displays information about this study. The information changes when a study becomes active.
3. IRB Study Number (also referred to as the Pro #).
4. **Edit Study** button opens the application SmartForm for editing (while the study is in your study team's Inbox only). When the application is not in your Inbox, the button is **View Study** and will provide read-only access.
5. **Printer Version** button opens all of the relevant SmartForm screens in one easy-to-print window.
6. The left column lists actions and **Activities** that can be performed on the study in its **Current State**. The list will vary depending on the Current State and role. The legend on each button indicates which Role (i.e., PI only or any study team member) can perform this activity. Click the button/link to open the Activity screen.
7. The **History** tab lists chronologically all actions that have been performed on the study. Click the Activity name in the listed History to view details.
8. The **Attachments** tab lists all documents that have been uploaded for this application. Successive versions are archived automatically so that you have access to the most currently approved versions, i.e., protocol, informed consent, advertisement, etc.

Create a New Study

In the role of Study Staff, you can create a new study (Initial Application) by clicking the **New Study** button in the column on the left side of your homepage.



The IRB Study Number is assigned automatically the first time you save the study (or after you complete the first page of the application and click **Continue**).

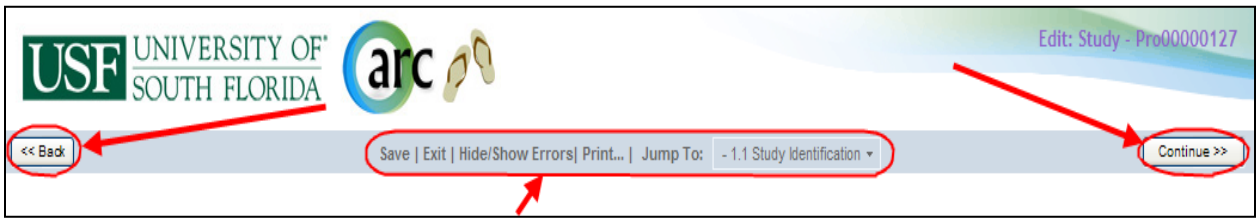
Working with Smart Forms

All applications in *eIRB* use SmartForms which present only those questions that are relevant to your study. It is important that you respond to each question displayed on the SmartForms.

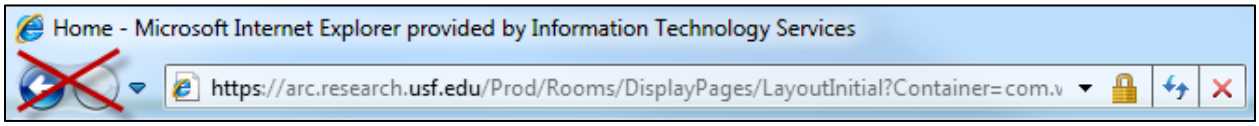
Required fields are marked with a red asterisk *.

You can answer text questions by typing directly into the text box or by pasting in text from other documents. **Add** function allows you to attach relevant documents or select your answer from a pre-populated list depending on the question.

Navigation controls are located in the navigation bar at the top and bottom of each page. Use the **Continue** and **Back** buttons to move to the next or last-viewed screen.



Use the SmartForm navigation controls instead of the controls in the browser bar (e.g., Internet Explorer, Firefox, Chrome, Safari, Opera).



Save your application by clicking **Save** or **Continue**.

> **WARNING:** The **Back** button does not save changes. After you enter or edit data on a screen, click **Save** before going **Back**!

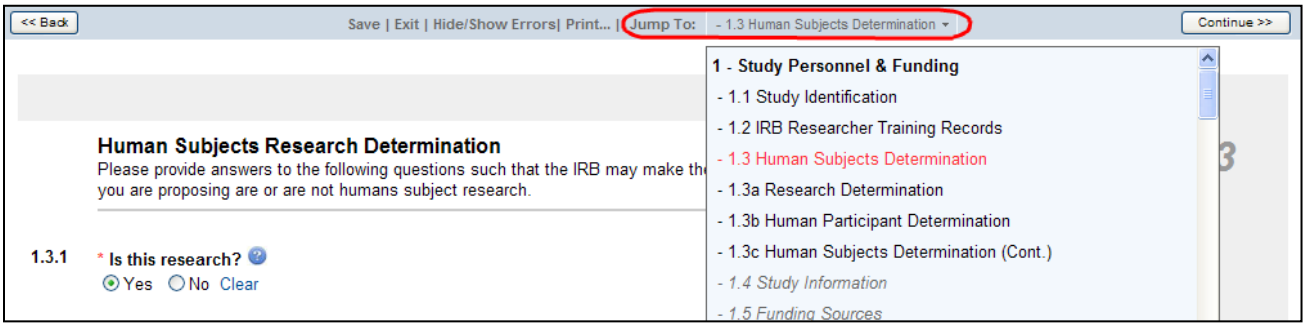
Use **Exit** to close the application and return to that application's Workspace.

> **WARNING:** Always **Save** before exiting!

Each section and question is numbered for easy navigation and reference. Numbering is consistent through all SmartForm applications; however, remember that only the relevant questions for each specific study are displayed.

Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To** drop-down menu. The title of the displayed page will be red. Items not relevant to this study will appear gray in the Jump To menu.

> **WARNING:** After you enter or edit data on a screen, click **Save** before using **Jump To**! The Jump To menu does not save.

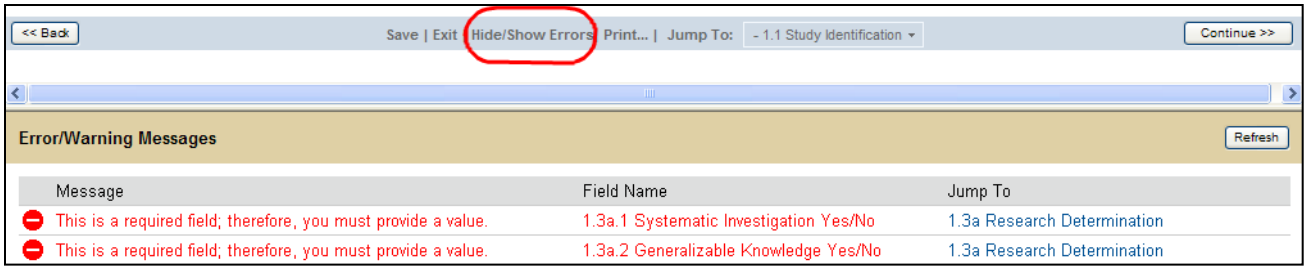


Attaching Documents

Attach documents, such as the protocol and consent forms, by using the **Add** button associated with the relevant question in the SmartForm. Before attaching a document, be sure you have named it using an accurate description (Example - Informed Consent-Spanish-Study000000342).

Hide/Show Errors

Within a SmartForm, use this tool to gauge your progress with the application. In the menu bar, click **Hide/Show Errors** to list the required fields that need to be completed.



Click the link again to hide Error/Warning Messages.

Completion and Submission: A Two-Part Process

1. **Complete the application**: The PI and Study Staff create and complete the application. The application remains in your Inbox.
2. **Submit the application**: The PI submits the completed application. Submission moves the application from your Inbox to the next State.

Part 1 – Complete the Application

When an application is created, it starts out in the Pre-Submission State. In this State, all Study Team members can work on the application, attach documents, and save changes.

To prepare a completed application for submission to the IRB:

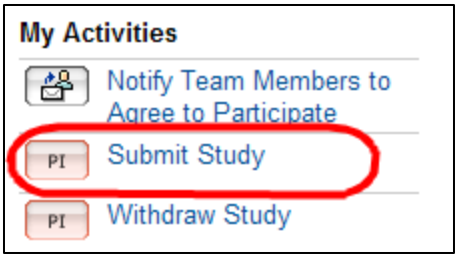
1. In the study Workspace under My Activities, click **Notify Team Members to Agree to Participate (1)**. Click **OK** to send notice to team members.

2. When they receive the notice, all Study Staff must agree to participate and must respond to the Conflict of Interest questions.

Part 2 – Submit the Application

Only the Principal Investigator for the study can submit the initial study. After the initial application is submitted, the study coordinator or secondary coordinator/regulatory specialist can submit additional applications (requested revisions, amendments, reportable events, and continuing reviews.)

1. To submit the initial study to the IRB, the PI will open the application Workspace and click **Submit Study** under My Activities.



2. *ARC* will run a final validation check on the entire application before submission. If there are any required fields that have been left blank or staff who have not agreed to participate, they will be indicated and your application will not be submitted. The application must be error-free before it can be submitted.
3. After the application has been submitted, it moves from the Pre-Submission State to the next State. Once submitted, it cannot be edited (unless changes are requested by a reviewer and it is returned to the Study Team Inbox).
4. After submission, required Department or Affiliate reviews are conducted *before* the study is routed to the IRB for review.

IRB Review and Approval

Progress Notifications

eIRB automatically sends e-mail notifications to the study team when significant events occur in the review process. Be sure to keep your e-mail address current in the *ARC* system! To change your e-mail address, see Account Changes on page 5.

The Study team will receive e-mail notifications at the following times:

- Requests for information and changes to the application.
- Official actions from the IRB (i.e., when the application is scheduled for a board meeting, once an application is approved/disapproved, etc.)
- When studies are due for Continuing Review

You can also check the progress of your application at any time by checking the **History** log.

History Log

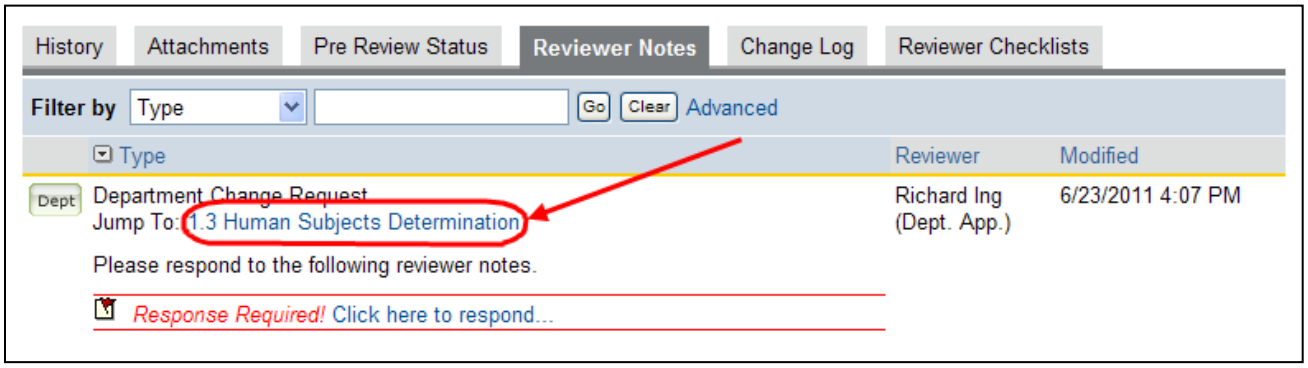
The **History** tab in the study Workspace displays the permanent history log of all actions that have been performed on the study. It lists chronologically those actions which you have permission to view.

Click an Activity name in the History log to view its details.

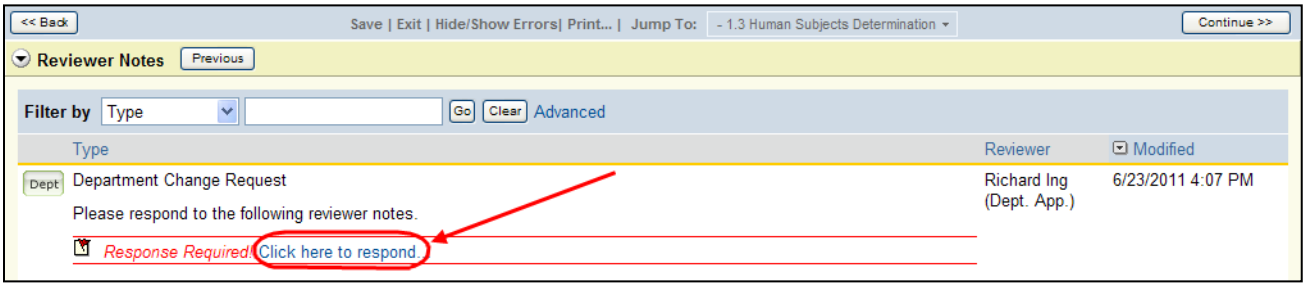
When an application is approved, *ARC* creates a **Project Snapshot** that is a permanent archive of the project and all its documents. Snapshots are stored in the history log and can be accessed there.

Respond to Requests for Revisions or Information

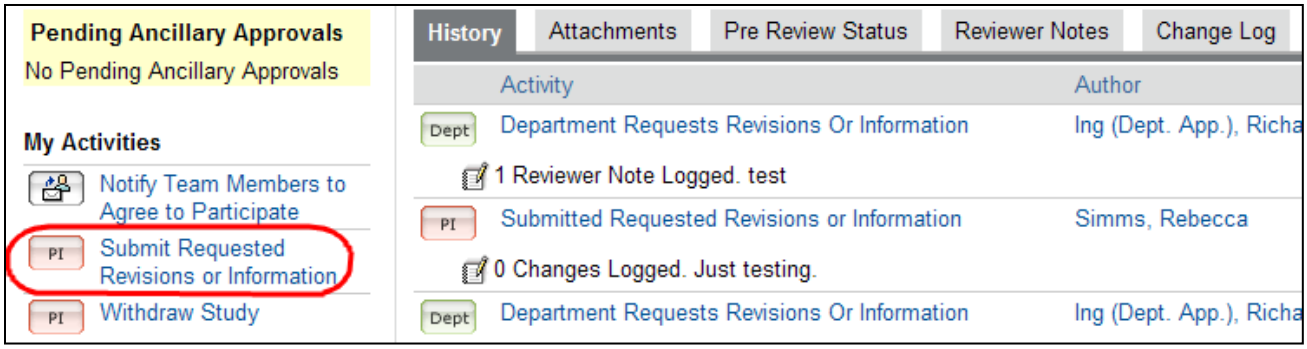
1. In your Folder **Inbox**, click the study Name to open the application workspace.
2. Under the **Reviewer Notes** tab, you will find all notes that have been added to the study. Each note provides a **Jump To** link that will take you to the page where the requested change needs to be made.



3. Respond to each change requested.



4. Be sure to **Save** before you **Exit** the SmartForm.
5. When the Study Staff have completed all of the requests in the application workspace, click the **Submit Requested Revisions or Information** and complete the submission, attaching any requested documents.



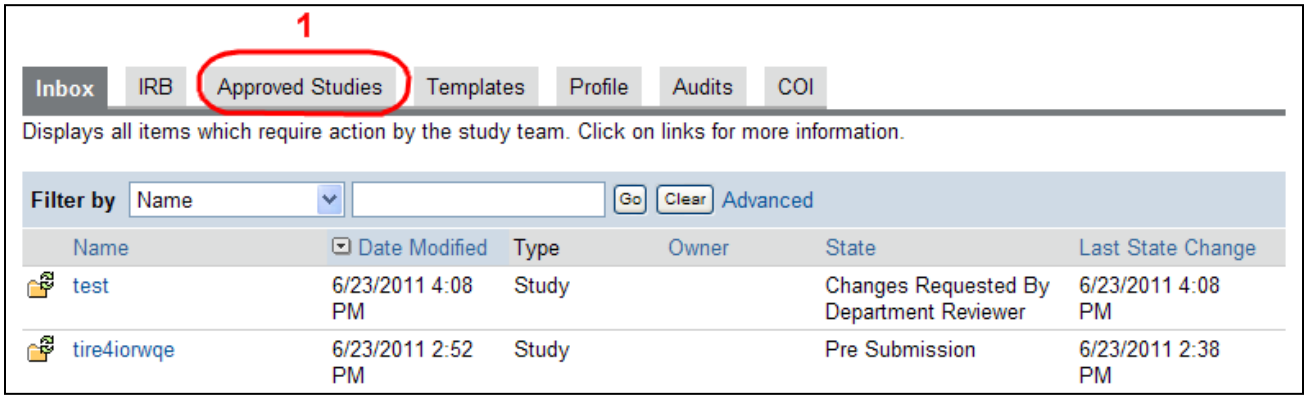
After you have submitted your response, the application will no longer be displayed in your Inbox because it has moved to the reviewer for further review. However, it will be listed under the **IRB** tab in your Folder (My Home), where you can view a read-only copy.

Approval Letter

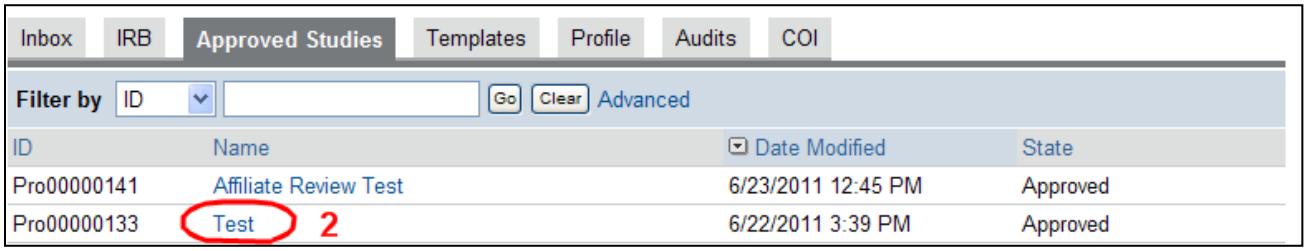
When the IRB has approved your study, you will receive an e-mail notification of approval. The approval letter will also be available in the study Workspace.

To view the approval letter in *eIRB*:

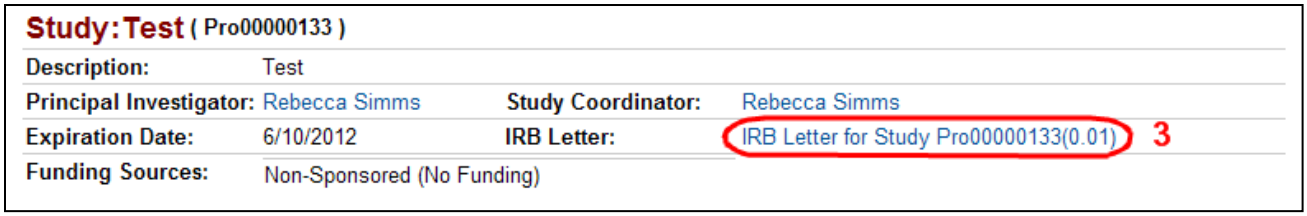
1. In your Folder (My Home), click the **Approved Studies** tab.



2. In the Approved Studies folder click the study name.



3. In the study workspace, the summary panel will now display a link to view the Letter of Approval. Click on **file next to IRB letter** (**3**).

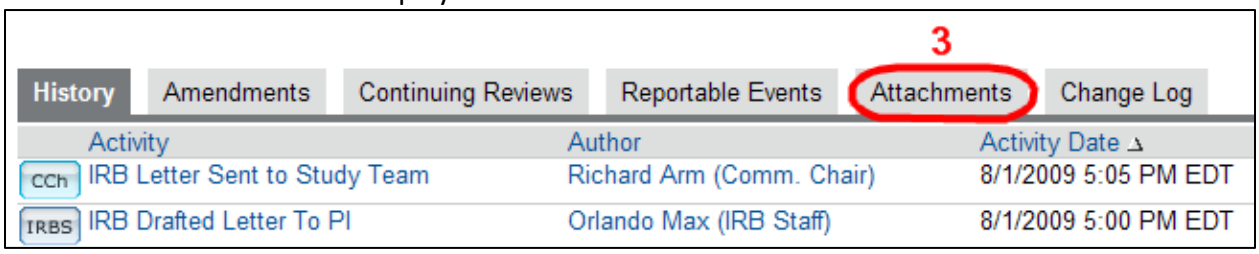


Attachments and Informed Consent Documents

All attachments to the study application, including the approved consent forms, can be viewed in the study Workspace under the **Attachments** tab.

After IRB approval, all attachment to the approved study can be viewed by following these steps:

1. In your Folder (My Home), click the **Approved Studies** tab (see illustration **1** above).
2. In the Approved Studies folder click the study name (see **2** above).
3. In the study workspace, click the **Attachments** tab (see **3** below). A list of all attachments will be displayed.



- The Approved Consent Forms section will list all of the consent forms approved for use in the consent process. These documents will be read-only pdf files.
- The remainder of this screen displays each question in the SmartForm that prompts for a document to be uploaded. This includes unstamped consent forms in MS Word format should there be a future need to make changes. Scroll down to quickly locate any attachment to the application.

Creating Reportable Events, Amendments, & Continuing Reviews

After a study has IRB approval, you can create a study sub-project: a new reportable event, amendment, or continuing review application.

In the study Workspace, click the relevant activity button and then complete the SmartForm application that is displayed.

Workspaces for study sub-projects are similar to the study Workspace.

After a reportable event, amendment, or continuing review has been created and saved, it can be accessed in your Inbox until you submit it.

After it has been submitted, it will be routed to the IRB, and can be viewed in the study Workspace under the respective tab (Amendments, Continuing Reviews, Reportable Events).

If a previous amendment for this study is pending IRB approval, the New Amendment button will not be displayed (until after the previous amendment is approved).

If you have submitted a Continuing Review (CR) that is now pending review and you need to amend the study, you will need to either:

- wait until the CR is processed
  or
- withdraw the CR and submit the Amendment (and then re-submit the CR after the Amendment is approved).

New Terms

- Modification Request = **Amendment**
- Progress Report = **Continuing Review**
- Determination = **Not Human Subjects Research**
- Information Reports and Adverse Events = **Reportable Events**

Appendix C- Naughton Example Shea Butter IRB

Date: Thursday, December 19, 2013 3:36:20 PM

Print Close

ID: Pro00013497 View: 1.1 - Study Identification Information

Study Identification Information

1.1

You must complete all of the required questions on this page to create your Human Research Application. As you continue through the application, you will automatically be guided to the appropriate pages needed to complete your submission.

1.1.1 * **Study Title** ***(this title must be the same as the title on your protocol, Investigators Brochure and most cases, informed consent document)*****:**
Mixed Methods Analysis to Quantify the Impacts of Shea Butter Production on the Livelihoods of Sub-Saharan, African Women Producers

* **Short Title** ***(this title is used throughout the site to identify the study)*****:**
Mixed Methods Analysis to Quantify the Impacts of Shea Butter Production

1.1.2 * **Brief Study Description:**
This research project will employ a mixed methods approach to quantify the impact of the Shea Butter Production process on the livelihoods of sub-Saharan, African Women producers. Mixed methods will include a human and embodied energy analysis of the traditional and ameliorated shea butter processes, mapping of the Shea Butter belt using Geographic Information Systems (GIS), weighing of shea nuts and fire wood to quantify carbon black emissions emitted from shea butter production, and ethnographic methods to better understand the significance of Shea butter in the livelihoods of Malian women and their families in the hungry season.

1.1.3 **Grant or Other Title** ***(Optional)*****:**

1.1.4 **Provide a brief rationale for your additional study title and indicate how this will be used:**
This proposed research will help quantify the energy, emissions, and impacts from the Shea Butter process and provide insights into the vital role of Shea butter across Africa and its importance to African women and their families.

1.1.5 * **Principal Investigator / Student Investigator:**
Colleen Naughton

You are listed automatically as a Study Coordinator. If there is someone else on the study that will assist with the IRB process, they should be listed as a Study Coordinator and/or Secondary Study Coordinator.

1.1.6 **Study Coordinator / Primary Regulatory Specialist:**
Colleen Naughton

1.1.6a **Secondary Study Coordinator / Regulatory Specialist:**

The PI does not need to be listed as a Co-Investigator or Key Personnel.

1.1.7 * **Are there any Co-Investigators/Faculty Advisors involved in this study?** ***If you are a student, you must list your Faculty Advisor as a Co-Investigator.***

(•) **Yes** ( ) No

If yes, please add Co-Investigators:

Last Name	First Name	Organization	Profile
Mihelcic	James	Civil and Environmental Engineering	00001715

1.1.8 * **Are there any Key Personnel on this study?** ( ) Yes (•) **No**

If yes, please add Key Personnel/Study Staff:

Name	Organization	Roles on Study	Other Role On Study
There are no items to display			

1.1.9 **Is this study a resubmission of a study previously reviewed and/or approved by the USF IRB?**

( ) Yes (•) **No**

If yes, please provide the Title and USF IRB/Pro Number for the study previously submitted and reviewed and/or approved by the USF IRB.

ID: Pro00013497 View: 1.2 Researcher Training Records

IRB Researcher Training Records

1.2

The following information is taken from the IRB training records on the Researcher Profiles of each study team member.
For more information on completing IRB Educational Requirements, please visit the Human Subjects Education page.

1.2.1

Principal Investigator: Colleen Naughton
CV/Biosketch: NAUGHTON_CV(0.04)
Certification Renewal Deadline: 6/8/2015

Education Status: Certification current

This page displays current training information for the PI and study team.

1.2.2 **Study Team Certification and CV/Biosketch:**

First Name	Last Name	Dept	Certification Date	Certification Renewal Deadline	Education Status	CV
James	Mihelcic	Civil and Environmental Engineering	12/5/2012	12/5/2014	Certification current	James Mihelcic CV(0.02)

**If some study team members are not yet certified, submission and initial review can still proceed; however, current certification of all members is a prerequisite of full IRB approval.*

ID: Pro00013497 View: 1.3 Human Subjects Determination

Human Subjects Research Determination

1.3

Please provide answers to the following questions such that the IRB may make the final determination as to whether or not the activities you are proposing are or are not humans subject research.

1.3.1 * **Is this research?** ***Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.***

(●) **Yes** ( ) No

1.3.2 * **Does this research involve Human Subjects?** ***Human subjects are defined as a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.***

(●) **Yes** ( ) No

ID: Pro00013497 View: 1.5 Study Funding Information

Study Funding Information

1.5

1.5.1 * **Select appropriate funding sources for this study (Check all that apply):**

	Funding Type
☐	Federal Funding (i.e., grant)
☐	For-Profit (Industry)
☐	Non-Profit (Foundations, Voluntary Health Organization, etc.)
☐	State or Local Government
☐	Internally Funded (Investigator's USF Department)
☐	Principal Investigator is the Sponsor (FDA-Regulated Research Only)

Funding Type

☑ **Non-Sponsored (No Funding)**

1.5.2 **USF Proposal or Project ID Number for study (from FAST):**

1.5.3 **Principal Investigator listed on the grant/contract:**

1.5.4 **Please upload the complete grant/funding proposal. This should include the aims and methods sections of the grant:**

Name	Version
There are no items to display	

ID: Pro00013497 View: 1.8 Study Locations

Study Locations

Please indicate the location(s) where your study will be performed.

1.8

1.8.1 **USF Sites (Add all that apply):**

Facility
There are no items to display

If Other USF Sites:

1.8.2 **USF Affiliate Sites (Check all that apply):**

Name	FWA
There are no items to display	

Please note that studies performed at the above listed affiliated sites will be routed to the Affiliate for review and approval prior to review by the USF IRB.

1.8.3 **Non-USF or Non-Affiliate Sites (Check all that apply):** **Are you recruiting at another school or organization?**

Name
There are no items to display

If Other Non-USF or Non-Affiliate Sites:
Mali, West Africa (Villages Zeala and Nci'Bugu about 90 KM North East of the capital Bamako)

1.8.4 * **As the Principal Investigator of this study are you planning to conduct research outside the State of Florida?**

○ Yes ◉ **No**

1.8.5 * **As the Principal Investigator of this study, are you planning to conduct research outside of the United States?**

◉ **Yes** ○ No

1.8.6 * **Are you one site in a group of sites conducting this research (i.e., is this a multi-site study)?**

○ Yes ◉ **No**

ID: Pro00013497 View: 1.8c International Study

International Study

You have indicated your research will be conducted in another country (i.e., outside the United States of America). Please note International laws differ regarding human subjects research.

1.8c

Please note that if the study is federally funded and the host country is receiving funding as part of the research study, they are required to obtain a Federalwide Assurance (FWA). Please contact the IRB office for additional information.

1.8c.1 * **Please indicate the names and number of sites:**
Mali, West Africa- 2 sites (Zeala and Nci'Bugu)

1.8c.2 * **Please provide the IRB assurances that all governmental and institutional procedures of the host country will be followed, including obtaining appropriate IRB oversight in the host country.**
All governmental and institutional procedures of the host country will be followed, including obtaining appropriate IRB oversight in the host country if necessary. The investigator is applying for expedited review or an exemption as this study constitutes minimal risk to human subjects and is collecting data on the Shea Butter process and not specifically on the humans involved.

1.8c.3 **Please upload any relevant documentation include documentation of approval from the host country.**

Name	Version
NAUGHTON_international_support_v1_6_24_13	0.01

1.8c.4 **How will you ensure that the cultural norms of the host country are respected and that the participants will not suffer adverse consequences from participation, such as being subjected to retaliation from local authorities or local community?**
The investigator has gone through intense language and cultural training through the Peace Corps in her 3-year service in the communities identified in these studies. She is well aware of cultural norms and the research does not deal with sensitive or culturally inappropriate topics.

How will documents such as the informed consent form which will be used with the population be translated into a language understandable by the study participants?
The volunteer is fluent in the local language, Bambara. She passed ACTFL exam at the Advanced/high level on April 5, 2012. She has had 174 hours of language training and three years of research and work experience in Mali. She also will work with local language tutors to double check her translation.

If you are providing compensation to the study participants, please explain how the currency will be equivalent to that of the host country. In addition, please include safeguards to protect study participants from being unduly influenced to participate due to the amount of compensation being offered.
No compensation is offered through this study and it is completely voluntary. This will be explained clearly to the participants.

ID: Pro00013497 View: 2.1 Study Summary

Study Summary

2.1

2.1.1 * **State concisely the hypotheses and the associated objectives for your proposed research:**
1. Shea butter plays an ever important role in the lives of the Bamanaw particularly women in the hungry season.
1,1 Determine how Shea butter plays a role in the lives of Bamanaw women and their families during the rainy season months (June-September).
1.2 Determine which family roles and income generating activities are assumed during the rainy season to cope with the lean period.
1.3 Distinguish how Shea butter is used throughout the year.
1.4 Discover the difference among the different women age groups and shea butter production.
1.5 Determine what is used to replace Shea butter when it is finished.
1.6 Ascertain if people at the community level notice a difference in shea trees and their subsequent yield as a result of climate change impacts (decreased rainfall).

2. Improved shea butter processes require higher human and embodied energy inputs but offer future daily energy saving benefits to women that can increase shea butter production.
2.1 To identify and quantify all embodied and human energy inputs of unimproved and improved traditional shea butter processes.
2.2 Analyze human and embodied energy inputs of shea butter processes and compare with economic benefits.
2.3 Quantify the energy contribution of shea butter consumption in rural households in Mali.
2.4 Use research findings to determine economic and social sustainability of shea butter processes.

3. Quantify the carbon black emissions from Shea Butter production.
3.1 Weigh the amount of wood used to roast and boil 1 kg of shea butter by various women in the community.
3.2 Measure the temperature of shea smokers.

4. Quantify the amount of potential shea yield and shea butter producers across sub-saharan Africa.
4.1 Map the suitable area for shea trees (vitellaria paradoxa) in Geographic Information Systems (GIS) using

precipitation, soil use, population, fire, and temperature maps.

2.1.2 * **Briefly provide a rationale and background for this study including, if available, 2 to 3 most recent citations, publications, research papers, etc. For biomedical studies please include relevant information from prior animal and human studies.**

Shea oil contributes significantly to world fat and oil supplies of up to 60% in some countries. (Tano-Debrah et. al, 1995) Processed shea butter and oil has many uses from edible oils, soap, cosmetics, and medicinal purposes. The fruits are also an important source of protein, sugar, calcium, and potassium right at the beginning of the rainy season or “hungry season” when storages of grain are low and energy demand is high for planting crops. (Maranz et al., 2004) Shea trees or vitellaria paradoxa are located in Africa with in a 500-750 kilometers wide area stretching 5000 kilometers from Sudan to Guinea in 18 countries. (Elias et al., 2006) The trees bear fruit harvested between May and July and the nuts (Figure 5) inside have a high oil content (20%-50%) that can be extracted. (Maranz et al., 2004) Shea is also unique since it is completely controlled by women from extraction to commercialization. (Elias et al., 2006) It was estimated in the 1980s that across 13 African countries, 2 million women produce shea butter. (Hyman, 1991) Money from selling shea nuts and/or butter also usually belongs to women to spend as they need (buy clothes, or pay school fees). (Maranz et al., 2004) This can account for over 60% of women’s income in the Sahel. (Akingbala et al., 2007) However, shea processing is extremely labor intensive and arduous process from gathering fruits to kneading to extract the butter. (Maranz et. al, 2004) There is a wealth of literature on the origin, production, use, and gendered qualities of Shea Butter but little on the role of Shea butter in the hungry season of Malian women and their families. The proposed research applies a mixed methods approach that has the potential for applications in many countries outside of Mali as well as the broader field of anthropology studies of gender in West Africa. This research is also important in the ever expanding Shea butter sector as it becomes more of a world commodity.

2.1.3 * **Upload your study protocol here. Please refer to the Protocol Guidelines for additional information regarding the contents of an appropriate protocol.**

Name	Modified	Version
Shea Butter Research Proposal ver.1 3.1.12	6/24/2013 1:44 PM	0.02

ID: Pro00013497 View: 2.2 Required Reviews

Required Reviews

2.2

2.2.1 * **Requested IRB Review Type:** Exempt Categories Expedited Categories

	Name	
○	Exempt	Chair Review in which research must meet regulatory criteria (see Exempt Categories link above)
◉	**Expedited**	**Chair Review in which research must meet regulatory criteria (see Expedited Categories link above)**
○	Full IRB Review	Review by the fully convened IRB

2.2.2 **Required Department Approvals (Select One or More Departments):**

Department Name	Approvers
Civil and Environmental Engineering	Manjriker Gunaratne

Please note that studies performed by USF faculty, students, or staff MUST include a Department. The study will be electronically routed to the above listed USF Department for review and approval prior to submission to the USF IRB.

2.2.3 **Required Affiliate Reviews:**

Name	FWA
There are no items to display	

ID: Pro00013497 View: 2.4 Research Types

Research Types

2.4

2.4.1 * **Research Types:**

Social-Behavioral

2.4.2 * **Does this study involve data collection or analysis? This includes record reviews, surveys, questionnaires, or recordings.**

(•) **Yes** ( ) No

2.4.3 * **Does this study involve specimen collection?**

( ) Yes (•) **No**

ID: Pro00013497 View: 3.1 Methods & Procedures: Social-Behavioral Research

Methods & Procedures: Social-Behavioral Research

3.1

3.1.1 * **Select all Social-Behavioral methods and procedures which apply to this study:**

- [ ] Audio/Visual Recording
- [ ] Behavioral Interventions
- [x] **Behavioral Observations and Experimentation**
- [ ] Population Based Field Study
- [ ] Deception
- [x] **Interview/Focus Groups**
- [ ] Psychophysiological Recording
- [ ] Record, Chart, or Dataset Review
- [ ] Specimen Collection or Analysis
- [x] **Surveys & Questionnaires/Psychometric Testing**
- [ ] Other Social-Behavioral Procedures

3.1.2 * **Identify the type of research design (e.g., correlational, cross-over, qualitative, etc.) to be used in this research:**

Mixed methods (qualitative and quantitative)

3.1.3 * **Concisely describe all of the research procedures that you will use to collect data:**

Quantitative methods will include calculations of the human and mechanical embodied energy inputs into unimproved and improved traditional Shea butter processes. Embodied energy seeks to evaluate products and services by quantifying the total energy consumed during the entire life cycle of a product or service. This includes upstream energy used during the extraction, processing, manufacture, and transportation of materials; “use” energy required to operate and maintain the product or service; and energy associated with “end-of-life” issues. The research methods developed to determine embodied material and human energy by Held et al. (2012) will be applied to the Shea Butter Process in Mali.

The calculation of embodied material energy utilizes economic input-output LCA models which require knowledge of costs and country of origin for materials and/or labor. Material costs and their origins will be determined by asking locals about the machinery they use. Energy used by firewood will also be calculated using basic thermodynamic equations and extrapolated to the all areas in the shea belt to get an idea of the amount of deforestation and air pollution caused by traditional shea butter production. In Held et al.’s (2012) method, transportation energy is also calculated using data from Halpern et al. (2008), Oak Ridge National Laboratories (2010), and carbonfund.org (2010). Human energy is determined using caloric expenditure of an individual from an individual’s gender-specific basal metabolic rate and a physical activity ratio required for a specific activity. Total embodied energy is the sum of material and human energies. Inputs (materials costs, origins, amount of time in different steps of the shea butter process and individuals’ age, etc.) will be collected using participant observation and surveys by the principal investigator in a small, rural Malian village where she served from 2009-2012.

Other quantitative data includes the individual weighing of shea nuts and firewood for each woman in the research site in each stage of the shea butter production process during the shea harvest season from June-October. This will allow for the calculation of the shea butter yield, the average amount of firewood used to produce one kilogram of shea butter, and total amount of shea nuts collected and shea butter produced in the research site disaggregated by each woman. The researcher has weighed shea butter produced in the community during this time period and recorded the amount that is reserved for household use, the amount sold, and what is done with the money for her work for the Peace Corps. Furthermore the researcher has collected GPS coordinates on over one hundred shea trees and recorded their diameters, present of parasites, whether

they have fruited, and if they are suffering from drought.

Qualitative methods will also be employed using anthropological methods in ethnographic interviews, focus groups, and participant observation to explore the cultural implications and importance of shea particularly during the rainy or hungry season as well as the views of locals on the impacts of climate change. Ethnographic interviews are conducted using Spradley's method which includes asking a mixture of questions (description, structural, etc.) that can lead to a deeper understanding of shea to the Bamanan women and also used to develop culturally appropriate surveys in the local language.

3.1.4 * **Clearly indicate which procedures, if any, are new and might involve unforeseen risks to participants:**
Procedures are not new and do not involve unforseen risks to the participants as it solely involves the shea butter process.

3.1.5 **Please indicate the time commitment of the participant (i.e., number of study visits, length of visit, length of participation in months or years, etc).**
Individuals involved in the ethnographic interviews will require three separate one hour sessions. Questionnaires should only take 25 minutes. The remaining methods do not involve an additional time commitment from the participant as the principal investigator will be observing women during their daily routines and not interfering with their work. Participant observation of shea butter production will be a two hour visit for those making the butter. Participant observation of shea nut collection will take several 2 hour sessions. Weighing of shea nuts and wood will take place daily over the course of several months. The observer actually helps the women in her labor as she weights the nuts and adds them to the smoker. Data collection will take place over at least two different summers in 2013 and 2014 for 6-8 week durations.

ID: Pro00013497 View: 3.4 Interview-Focus Groups

Interview-Focus Groups

3.4

3.4.1 **Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.**

Name	Version
Ethnographic Interview/Focus Group Questions ver. 1 6.20.13	0.02

ID: Pro00013497 View: 3.5 - Surveys and Questionnaires

Surveys and Questionnaires

3.5

3.5.1 **Add information regarding all instruments used on this study:**

	Name	Standard Instrument	Upload Instrument	Usage of Instrument
View	Shea Butter Survey	yes	Shea Butter Survey(0.01)	This survey will be given to Shea butter producers over the age of 18 in the villages of Zeala and Nci'Bugu.

3.5.2 * **Could any portion of the questioning be upsetting to the participants?**

○ Yes ◉ **No**

3.5.3 **If yes, please describe the nature of these questions and how you will refer research participants for counseling or other assistance:**
Financial questions about loans and shea butter are commonly discussed amongst women particularly at their microfinance meetings. The principal investigator is a member of one of the microfinance organizations. Women must state that purpose of their loan when taking one out. So though financial questions may seem upsetting from an American point of view this is culturally appropriate in the area of rural Mali where the research is being conducted.

ID: Pro00013497 View: 5.1 Methods & Procedures: Data Collection

Methods & Procedures: Data Collection

5.1

You have indicated your study involves data collection and/or analysis of collected data (e.g. surveys, questionnaires, or recordings) Please answer the following questions. Please be aware that studies can have both retrospective and prospective elements.

5.1.1 * **Will any of the data be collected prospectively (data does not currently exist)?**

(•) **Yes** ( ) No

5.1.2 * **Describe how the data will be collected:**

Data will include ethnographic interviews, focus groups, and surveys of shea butter producers. Ethnographic interviews will be recorded and then transcribed. Answers to surveys will be recorded in note books then coded and recorded in excel. Participant observation of shea butter collection and production will involve recording the amount of time and physical activity level. Shea nuts, butter, and firewood will be weighed throughout the shea butter process. Time data and physical activity level will be observed directly while women collect shea nuts and make shea butter. GPS coordinates of homes and shea trees will be taken using a GPS device. Previous participant observation, GPS coordinates, and weighing of shea nuts, fire wood, and butter have been collected by the researcher for the participant observers work with Peace Corps from 2010-2012 and will be used.

5.1.3 * **Describe how the collected data will be used:**

Ethnographic interviews conducted will be used to create domains and taxonomies of the local language used to describe the shea butter process and answer the research questions. Surveys will be coded and statistically analyzed to answer research questions. Shea nut, firewood, and shea butter weights will be used to calculate the human and material energy and carbon black emissions involved in shea butter production. These results will be used in the author's dissertation and eventual publications in scientific journals.

5.1.4 * **Is this study a retrospective chart/records review (data already exists)?**

(•) **Yes** ( ) No

ID: Pro00013497 View: 6.1 Study Population

Study Population

6.1

6.1.1 **Please check all that apply to describe the study population you are targeting for recruitment:**

	Study Population
☑	**Normal Healthy Adult Subjects**
☐	Children (Minor Subjects are defined as individuals who have not reached legal age to consent to the treatment or procedures in this research; e.g., State of Florida legal age is 18 years)
☐	Cognitively Impaired Individuals
☐	Employees or Students
☐	Prisoner
☐	Adult Patients (Defined as individuals seen in a clinical setting)
☐	Pregnant Women, Human Fetuses or Neonates
☐	Wards of the State
☐	Socially Disadvantaged Persons
☐	Other Adult Subjects

ID: Pro00013497 View: 6.1 Study Population (Cont.)

Study Population (Cont.)

6.1

6.1.2 * **List the inclusion criteria (specify the characteristics that must be met for individuals to be enrolled in your study, such as physical/mental/health status, gender, occupation, or diagnosis):**
Female, of good health, over 18, and a producer or former producer of shea butter.

6.1.3 * **List the exclusion criteria (specify the characteristics that will exclude individuals from your study, such as physical/mental/health status, gender, age, race, occupation, or diagnosis) and justify why these persons will be excluded:**
Individuals that are not in good health and under 18 will be excluded in this study since this would constitute a vulnerable population for the IRB. Males and women that do not or have never produced shea butter will not be included in this study as this is outside of the research scope.

ID: Pro00013497 View: 6.1a Recruitment & Enrollment: Social-Behavioral

Recruitment & Enrollment: Social-Behavioral

6.1a

6.1a.1 * **How many participants will be recruited (Including drop-outs, withdrawals, etc.)?**
200

ID: Pro00013497 View: 6.1c Study Population: Age & Recruitment

Study Population: Age & Recruitment

6.1c

6.1c.1 * **What is the age range of participants?**
18-75

6.1c.2 * **Describe your recruitment procedures including a) how you will identify potential participants, b) the steps for recruitment of participants, and c) who will have responsibility for recruitment:**
a. Potential participants will be identified by the researcher from her former experience and observations serving in the two villages as a Peace Corps volunteer from 2009-2012.

b. First the research will be described at a weekly meeting of the village elders and also at a weekly meeting of the Women's shea cooperative. Next, women identified will be approached individually and the primary investigator will explain the study to them. The principal investigator will then confirm with those individuals after at least 2 days if they would like to participate.

c.The primary investigator will have the responsibility for recruitment.

6.1c.3 **Attach copies of any recruiting materials, e.g., flyers, brochures, advertisements. Please review HRPP Policy 708 for required elements.**

Name	Version
There are no items to display	

6.1c.4 * **Describe how you will ensure the privacy of research subjects given the identification and recruitment procedures you have described above.**
Research subjects names will not be recorded on surveys, observations, or interview transcripts.

6.1c.5 * **How will you provide ample time for subjects to review the information and consider whether or not they wish to participate? Include how long subjects will have between receiving information regarding the study including review of the informed consent document and actually agreeing to participate/signing the informed consent document.**

Subjects will have as much time as they desire to decide if they would like to participate in the study. As most women are illiterate in the village, the study will be described to them verbally. They will usually be given several days to decide to participate in a survey, interview, focus group, shea weighing, or participant observation.

ID: Pro00013497 View: 6.1d Ethnic/Racial Categories

Ethnic and Racial Categories

6.1d

6.1d.1 **Please provide the number of Participants you plan to enroll by Ethnic and Racial Group**
(Note that totals will be calculated when you click 'Save') :

Ethnic Category	Females	Males	Total
Hispanic or Latino			0
Not Hispanic or Latino	200		200
Ethnicity Unknown			0
Ethnic Category: Total of All Participants*			200
Racial Categories	**Females**	**Males**	**Total**
American Indian / Alaskan Native			0
Asian			0
Native Hawaiian / Pacific Island			0
Black or African American	200		200
White			0
Race Unknown			0
Racial Categories: Total of All Participants*			200

I do not plan to collect data related to:

- [x] **Race**
- [ ] Gender
- [x] **Ethnicity**

Please note that your total enrollment estimate of Ethnic Group members must equal your total enrollment estimate of Racial Category members.

ID: Pro00013497 View: 6.2 Enrollment, Compensation, & Costs

Enrollment, Compensation, & Costs

6.2

6.2.1 **Will compensation be offered to participants for their participation in the study?**

- ( ) Yes
- (•) **No**

6.2.1a **If yes, describe the compensation and the payment schedule for participants. Address how payment will be disbursed including dispersal for participants who chose to withdraw from the study:**

Please note: Payment cannot be based on completing the study but rather should be paid in full or pro-rated based on the time volunteered.

6.2.2 * **Describe any costs that participants will incur because of participation (e.g., travel costs, parking fees, purchase of special materials, etc.) that are over and above the costs that would be incurred from standard care or services, were they not in this study. Indicate whether these costs will be reimbursed. In addition, describe any support that may be available to help defray costs to participants:**

No costs will be incurred by participants as most research activities are conducted during their normal activities and are unobtrusive. Ethnographic interviews, focus groups, and surveys will be conducted at night when the women have finished their work for the day and are the least busy.

6.2.3 * **Do you intend to recruit individuals who are actively enrolled in another IRB approved study?**

○ Yes ◉ **No**

ID: Pro00013497 View: 6.3f Normal Healthy Volunteers

Normal, Healthy Volunteers

6.3f

6.3f.1 **Please select all that apply to describe your study population:**

	Description
☑	**Normal, healthy volunteers**
☑	**Elderly persons (>65) not cognitively impaired**

6.3f.2 **Target number of Normal, Healthy Volunteers:**

200

ID: Pro00013497 View: 6.4 Retrospective Chart/Record Review

Retrospective Chart/Record Review

6.4

6.4.1 * **Please provide the source or identify the location of the existing data:**

Source of the existing data is from Peace Corps Mali records for the Shea Butter manual.

6.4.2 * **Describe how you have authority to access these charts/records:**

The principle investigator was a former Peace Corps Volunteer and helped collect this data for the manual.

6.4.3 * **How will you determine which charts/records to review (e.g. by year, by diagnosis, etc.)?**

Data collected by the researcher during her service will be used.

6.4.4 * **Number of charts/records you will review:**

N/A These are not charts. Records constitute a manual.

6.4.5 * **Please attach your data capture sheet (data collection form) or a document that includes the variables you will collect to answer your question(s):**

Name	Version
Shea Data Capture	0.01

Please note that only individuals listed as study team members can have access to/review charts.

ID: Pro00013497 View: 7.1a Informed Consent Determination

Informed Consent Determination

7.1

7.1.1 * **Are you obtaining signed informed consent?**

○ Yes ◉ **No**

7.1.2 * **Are you requesting a waiver of informed consent for any portion of the study?**

◉ **Yes** ○ No

ID: Pro00013497 View: 7.1c Waiver of Consent: Process or Documentation

Waiver of Consent: Process or Documentation

7.1c

7.1c * **Indicate the type of waiver you are requesting (check all that apply):**

	Description
☐	Waiver of the informed consent process (e.g., typically requested for retrospective chart/record reviews).
☑	**Waiver of documentation of consent; that is, waiver of the signature on the consent form (e.g., some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject).**

ID: Pro00013497 View: 7.3 Waiver or Alteration of Informed Consent Documentation

Waiver or Alteration of Informed Consent Documentation

7.3

Federal regulations at **45 CFR 46.117 (c),** permit an IRB to waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

OR

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

7.3.1 * **Explain how the only record linking the subject and the research would be the consent document and the principal risk to the subject(s) would be the potential harm resulting from a breach in confidentiality. Each subject will be asked whether he/she wants documentation linking their information with the research and their wishes will govern.**

The subjects name will not be recorded on any documents and the subject will not be able to be linked to the research.

7.3.2 * **Describe how the research presents no more than minimal risk of harm to the subjects and involves no procedures or activities for which written consent is not normally required outside of the research context.**

The research only asks questions pertaining the shea butter process which does not go beyond average, daily risks and is conducted in a culturally appropriate context by a person integrated in the community and fluent in the local language. Subject participation is completely voluntary and they do not have to answer any questions they do not want to.

7.3.3 **By completing this form, you are requesting the IRB to waive the requirement for the documentation of informed consent (i.e., having participants sign the informed consent form). However, the IRB expects subjects to be informed about the research they will be taking part in. Please upload the script you will be using to inform subjects about the**

research project:

Name	Version
Shea Butter Verbal Description vers. 2 7.18.13	0.03

ID: Pro00013497 View: 8.1 Risk & Benefit Assessment

Risk & Benefit Assessment

8.1

8.1.1 * **Risk classification for this study (select one).**

	Description
◉	**Minimal risk to participants.**
○	Greater than minimal risk and the study presents the prospect of direct benefit to the participant.
○	Greater than minimal risk and the study presents no prospect of direct benefit to the participant, but will likely yield generalizable knowledge about the study topic.
○	Greater than minimal risk and the study would otherwise be unapprovable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting people's health or welfare.

8.1.2 **Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention or study procedure. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility:**

There are no risks, discomforts or potential harms associated with this procedure as it is concerning the common, shea butter process.

8.1.3 **Describe the safety precautions (including early stopping criteria for both participants and study) that will be taken to minimize risks/harms:**

It will be completely voluntary for individuals to participate in any part of the study. It will also be made clear to participants that they do not have to answer any questions they feel uncomfortable asking.

ID: Pro00013497 View: 8.2 Anticipated Risk & Benefits

Anticipated Risk & Benefits

8.2

8.2.1 * **Please describe any potential for direct benefits to participants and to society:**

The participants will be able to have a record of the amount of shea butter they produce, the yield rate, and the amount of fire wood used. They may use this information to improve their harvest for the next year or collect the appropriate amount of firewood earlier in the season during less busy times to be used when roasting shea nuts during the rainy season. The quantification of the human energy involved in shea butter and the associated carbon black emissions has a huge potential benefit across sub-Saharan Africa for development of labor saving and pollution prevention technologies.

8.2.2 * **Alternatives to Participation: Describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study:**

Alternatives to participation are membership in the shea butter cooperative or attendance at a community meeting where results will be discussed.

8.2.3 * **Risk/Benefit Analysis: Describe the risk to benefit relationship of participation in the research (relative to non-participation and/or alternatives).**

There is no greater risk or benefit to either participants or non participants. All parties can benefit by comparison

or attendance at meetings.

ID: Pro00013497 View: 9.1 Privacy & Confidentiality

Privacy & Confidentiality

9.1

9.1.1 * **Will this study record any information which can identify the participants of this study?** Identifiable Information

Yes **No**

9.1.2 * **Will this study record information that, if released, could reasonably place participants at risk of criminal or civil law suits?**

Yes **No**

9.1.3 * **Describe the steps that will be taken to protect the privacy of participants during the conduct of the research.**
No participant names will be recorded in research notebooks. Taped interviews will be kept in a locked bag by the researcher and taken toe the United States whens he returns for storage.

9.1.3a * **Describe how the data (including informed consent documents) will be kept confidential during collection, analysis, and storage. Address both physical and electronic records.**
The principal investigator has applied for a waiver of informed consent documents. Other data is not compromising if discovered as there will not be identifiers and does not contain confidential information. Though the researcher will keep notebooks on her at all times or in her locked suitcase. Her lap top where electronic records are stored has a password to log in.

9.1.3b * **How and where will the data be stored? How long will data be kept (** See Requirements **) and how will it ultimately be destroyed?**
Data will be stored in the researchers locked suitcase and password protected lap top. Data will be kept indefinitely.

9.1.4 * **Do you plan to share confidential data with anyone other than members of your research group?**

Yes **No**

9.1.4a **If Yes, describe with whom you will share the confidential data and under what circumstances this will occur and explain how/whether participants will be informed that this data will be shared:**

9.1.5 * **Will the participants be providing private, indentifiable information about individuals other than themselves (e.g., family, friends)?**

Yes **No**

9.1.5a **If Yes, describe who these other individuals are and how the privacy or confidentiality of these individuals will be protected:**

9.1.6 * **Will you or any study team member review protected health information (PHI) in the course of conducting this research?**

Yes **No**

ID: Pro00013497 View: 10.1 Data Monitoring Plan

Data Monitoring Plan

10.1

10.1.1 * **Describe your plan for ensuring the integrity of the data you collect, including how often you plan to monitor the data:**
Ethnographic interviews will be used to further develop the survey tool to make sure appropriate language is used. Weighing of shea nuts, butter, and firewood will be done with calibrated instruments. Many women of

different ages will be interviewed. The researcher plans to return to the community annually.

Please note: Every research project should include a plan for monitoring the integrity of the data; that is, the data collected must appropriately address the research questions.

ID: Pro00013497 View: SC.0 - Check for Errors

Check for Errors

SC.0

In order to review your Study forms for completeness, please use the Hide/Show Link to check for errors. When all questions are complete, please Continue to the next page.

ID: Pro00013497 View: SC.a Initial Application: Final Page

Initial Application: Final Page

USF Study Completion

SC.a

You have completed your application! This study has been assigned the following identification number:
ID: Pro00013497.

Please click the "Finish" button to finalize and exit this application. Doing so will **NOT** submit the application for review.

To submit this application for review, the Principal Investigator must press the "SUBMIT STUDY" button under the My Activities menu. Please note an application may be prepared by other members of the research team; however, only the Principal Investigator may submit the application to the IRB for review.

All study team members must agree to participate and answer questions related to conflicts of interest prior to submission of the application. Please use the "Notify Team Members to Agree to Participate" button under the My Activities menu.

You may track the ongoing status of this application by logging into the study workspace at any time. Please feel free to contact the USF Human Research Protections Program (HRPP)/IRB with any questions or concerns at 813-974-5638 or use this system to send us an e-mail.

Note that submission of this study for review constitutes agreement to the following Statement of Assurance:

PRINCIPAL INVESTIGATOR'S STATEMENT OF ASSURANCE

This application, which describes my proposed investigation involving human participants, was prepared in accordance with the policies of University of South Florida (USF) and its affiliates for the protection of humans participating in

research.

- I certify that I have read and will conduct this study in accordance with the terms of Ethical Principles set forth in The Belmont Report and the USF Human Research Protection Program (HRPP) Policies and Procedures.
- I understand USF's policies concerning research involving human participants and I agree to:

    a. Obtain the voluntary informed consent of participants (or of participants' legally authorized representatives), in a language that is understandable to them, to the extent required by federal regulations and by the determinations of the IRB.
    b. Report promptly to the IRB any problem that requires reporting (See "List of Problems that Require Prompt Reporting to the IRB") and submit an Information Report within the appropriate reporting period.
    c. Cooperate with the IRB in the timely continuing review of this project (submit IRB progress reports in a manner consistent with USF policies).
    d. Obtain prior approval from the IRB before implementing changes in the approved research protocol or approved informed consent document (submit a Modification Request Form).
    e. Maintain informed consent documents and progress reports as required by institutional and federal policies (for more information, see the Research Integrity and Compliance Web Site at www.research.usf.edu/cs/).
    f. Accept responsibility for the conduct and supervision of this research and protect human participants as required by state and federal law and regulation, and as documented in all applicable Federalwide Assurances.
    g. Ensure that research staff and students have been trained and are qualified to conduct this research and to protect human participants. I agree to provide supervision to research staff and students that will ensure the protection of human participants. I will keep records that prove that these requirements have been met.
    h. Allow site visits for evaluation and monitoring by the FDA, the DHHS, the USF Division of Research Integrity and Compliance, and the USF IRBs.

I attest to conduct the research in accordance with the ethical principles of the Belmont Report, the requirements of the federal regulations, and the policies of the University of South Florida.

Appendix D- Naughton IRB supporting documents

Mixed Methods Analysis to Quantify the Impacts of Shea Butter Production on the Livelihoods of Sub-Saharan, African Women Producers

Introduction. As evident by the title of the 2012 article in Environmental Science & Technology "Fundamental Changes to EPA's Research Enterprise: The Path Forward.", the EPA has been making substantial changes in their research structure centered around the concept of sustainability. EPA's third strategic goal of Sustainable and Healthy Communities (SHC) program is organized around three broad themes: "working with communities to develop sustainability approaches; developing decision analysis, methods, tools, and metrics to support sustainability in communities; and targeting high priority research needs" (Anastas, 2012). Moreover, prior to EPA's Path Forward, in September 2000 a commitment was made by the international community to achieve eight Millennium Development Goals (MDGs) by 2015 to eradicate poverty, hunger, gender inequality, malnutrition, and disease and to provide universal education, empower women, and undertake environmental sustainability.

A portion of EPA's mission states it well that "…the United States plays a leadership role in working with other nations to protect the global environment" which is inextricably tied to improving global health (EPA, 2011). A global perspective and lessons from the developing world can also impact and be beneficial to the United States (Peace Corps, 2011). Thus, the proposed research is a synergy between both the EPA mission, the "path forward" and the MDGs. Based in West Africa and with global applications, this research will focus on the promotion of an innovative method in Shea butter production and Life Cycle Analysis (LCA) that strives to improve livelihoods through better community health, sustainability and gender equality.

Background on Shea. Shea oil contributes significantly to world fat and oil supplies of up to 60% in some countries. (Tano-Debrah et. al, 1995) Processed shea butter and oil has many uses from edible oils, soap, cosmetics, and medicinal purposes. The fruits are also an important source of protein, sugar, calcium, and potassium at the beginning of the rainy season or "hungry season" (Maranz et al., 2004). As shown in Figure 1, shea trees or *vitellaria paradoxa* are located in Africa within a 500-750 kilometers wide area stretching 5,000 kilometers from Sudan to Guinea in 18 countries (Elias et al., 2006). The trees bear fruit harvested between May and July and the nuts inside have a high oil content (20%-50%) that can be extracted. (Maranz et al., 2004)

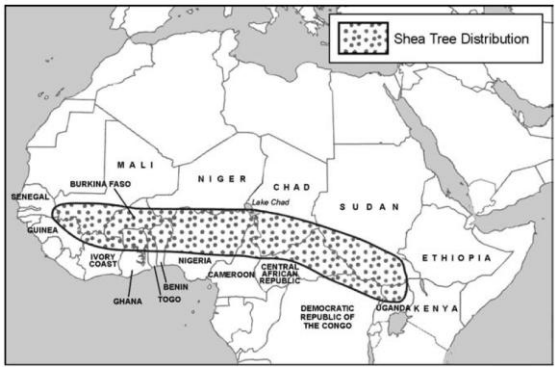


Figure 1: Shea tree distribution (Elias et al., 2007)

The shea butter is extremely labor intensive, including eight steps as shown in Figure 2.

Figure 2: The basic, eight step, Shea butter production process (adapted from Lovett, 2004)

The improved traditional process of boiling instead of roasting nuts (step 3) is being promoted throughout Mali. The goal of this process is to produce better quality butter for consumption and sale. Roasting or smoking of nuts can introduce hydrocarbons, contaminating the nuts and eventual butter product. (Masters, 2010) Also increase of temperature, often the case in smoking/roasting of nuts, can increase the Free Fatty Acid (FFA) content which is used as a quality index for shea butter. (Akingbala et al., 2006; Masters, 2010)

Gender and Shea. Shea is unique since it is completely controlled by women from extraction to commercialization. (Elias et al., 2006) It was estimated in the 1980s that across 13 African countries, 2 million women produce shea butter. (Hyman, 1991) Money from selling shea nuts and/or butter also usually belongs to women to spend as they need (buy clothes, or pay school fees). (Maranz et al., 2004) This can account for over 60% of women's income in the Sahel. (Akingbala et al., 2007) Improvements and research in the shea sector thus have positive implications for women. The importance of gender equality and women's empowerment to development and poverty eradication has been strongly recognized in the MDGs. Despite the fact that women are half of the world's population, they are not half of the world's leadership, employed, advantaged, or educated. Of the one billion poorest people in the world, three fifths are women and girls and of the 960 million people that cannot read, two thirds are women. (UNIFEM, 2011) Development and significant reduction in poverty and disease cannot be achieved without the participation of women.

Shea and Climate Change. The important role of shea trees in the livelihoods of women and their families may be in danger in some areas due to decreased rainfall as an effect of climate change. Through his literature review Maranz cited a 20-40% drop in precipitation for the Sahel region of Africa between the two periods of 1930-1965 vs. 1966-2000. (Maranz, 2009) This translates into an average annual rainfall decrease of over 100 mm that may represent a tipping point for the long-term survival of shea trees. (Maranz, 2009) He states that the "effect of vegetation change therefore represents a loss of livelihood to Sahel peoples" (Maranz, 1183)

Though Shea is under threat from climate change it also is a contributor to climate change since the traditional process heavily relies on firewood to dry harvested nuts and also heat shea kernels before butter extraction. Johnson et al., 2012 indicated that 6.4 kg of wood was used to produce one kg of shea oil resulted in a village wide energy use (population 770) of 117,000 MJ/yr or 7,950 kg/yr of wood. As observed by the researcher, the wood used to dry nuts in the traditional smokers are larger, more mature limbs than those used for cooking so that they may burn throughout the day to dry nuts without the women having to keep feeding the fire when away in their fields. Multiply this amount of energy expended and wood needed in shea production in one small Malian village to the millions of small villages across the 5,000 km shea belt as in figure 1 and you have a large contributor to carbon black only to increase as rising populations tap into the resource in an emerging market. The ameliorated shea butter production method of boiling the shea nuts instead of smoking them investigated in this proposal can reduce this wood usage by up to 75% according to initial data collected by the primary investigator of this proposal.

The proposed research is in line with the memorandum of cooperation between the EPA and the Peace Corps related to testing cook stoves. This is because recent carbon emissions inventories suggest that household emissions from cookstoves of black carbon (with short-lived climate forcing) are estimated to rank second behind CO_2 in regards to climate change, being responsible for 18% of the planet's warming (compared with 40% for CO_2).

Research Questions. The overall goal of this proposed research is to promote innovation that takes into account gender and environmental sustainability to improve livelihoods through the human and embodied energy analysis of Shea butter processes. Below are the research hypothesis and corresponding objectives.

1. Shea butter plays an ever important role in the lives of the Bamanaw particularly women in the hungry season.

    1.1 Determine how Shea butter plays a role in the lives of Bamanaw women and their families during the rainy season months (June-September).

    1.2 Determine which family roles and income generating activities are assumed during the rainy season to cope with the lean period.

    1.3 Distinguish how Shea butter is used throughout the year.

    1.4 Discover the difference among the different women age groups and shea butter production.

    1.5 Determine what is used to replace Shea butter when it is finished.

    1.6 Ascertain if people at the community level notice a difference in shea trees and their subsequent yield as a result of climate change impacts (decreased rainfall).

2. Improved shea butter processes require higher human and embodied energy inputs but offer future daily energy saving benefits to women that can increase shea butter production.

    2.1 To identify and quantify all embodied and human energy inputs of unimproved and improved traditional shea butter processes.

    2.2 Analyze human and embodied energy inputs of shea butter processes and compare with economic benefits.

    2.3 To quantify the energy contribution of shea butter consumption in rural households in Mali.

    2.4 Use research findings to determine economic and social sustainability of shea butter processes.

3. Quantify the carbon black emissions from Shea Butter production.

    3.1 Quantify the amount of wood used to roast and boil 1 kg of shea butter by various women in the community.

    3.2 Measure the temperature of shea smokers.

4. Quantify the amount of potential shea yield and shea butter producers across sub-Saharan Africa.

    4.1 Map the suitable area for shea trees (*vitellaria* paradoxa) in Geographic Information Systems (GIS) using precipitation, soil use, population, fire, and temperature maps.

Methods This proposed research topic will utilize interdisciplinary qualitative and quantitative research methods. Quantitative methods will include calculations of the human and mechanical embodied energy inputs into unimproved and improved traditional Shea butter processes. Embodied energy seeks to evaluate products and services by quantifying the total energy consumed during the entire life cycle of a product or service. This includes upstream energy used during the extraction, processing, manufacture, and transportation of materials; “use”

energy required to operate and maintain the product or service; and energy associated with "end-of-life" issues. The research methods developed to determine embodied material and human energy by Held et al. (2012) will be applied to the Shea Butter Process in Mali.

The calculation of embodied material energy utilizes economic input-output LCA models which require knowledge of costs and country of origin for materials and/or labor. Energy used by firewood will also be calculated using basic thermodynamic equations and extrapolated to the all areas in the shea belt to get an idea of the amount of deforestation and air pollution caused by traditional shea butter production. In Held et al.'s (2012) method, transportation energy is also calculated using data from Halpern et al. (2008), Oak Ridge National Laboratories (2010), and carbonfund.org (2010). Human energy is determined using caloric expenditure of an individual from an individual's gender-specific basal metabolic rate and a physical activity ratio required for a specific activity. Total embodied energy is the sum of material and human energies. Inputs (materials costs, origins, amount of time in different steps of the shea butter process and individuals' age, etc.) will be collected using participant observation and surveys by the principal investigator in a small, rural Malian village she has served in for over two years.

Other quantitative data includes the individual weighing of shea nuts and firewood for each woman in the research site in each stage of the shea butter production process during the shea harvest season from June-October. This will allow for the calculation of the shea butter yield, the average amount of firewood used to produce one kilogram of shea butter, and total amount of shea nuts collected and shea butter produced in the research site disaggregated by the each woman. The researcher has weighed shea butter produced in the community during this time period and recorded the amount that is reserved for household use, the amount sold, and what is done with the money. Furthermore the researcher has collected GPS coordinates on over one hundred shea trees and recorded their diameters, present of parasites, whether they have fruited, and if they are suffering from drought.

Qualitative methods will also be employed using anthropological methods in ethnographic interviews, focus groups, and participant observation to explore the cultural implications and importance of shea particularly during the rainy or hungry season as well as the views of locals on the impacts of climate change. Ethnographic interviews are conducted using Spradley's method which includes asking a mixture of questions (description, structural, etc.) that can lead to a deeper understanding of shea to the Bamanan women and also used to develop culturally appropriate surveys in the local language.

Embodied material and human energy for the different shea butter processes will be compared with qualitative data collected to provide insight into the sustainability of the different Shea butter production methods for the chosen, representative community. This analysis will also be expanded across the shea tree distribution area (figure 1) looking at the material and human energy embodied across sub-Saharan Africa its emissions of carbon black in the context of climate change and adverse effects on human health[1] . Moreover, using this form of Life Cycle analysis on shea butter production will offer another application beyond that of water supply and treatment in the U.S, developing it as a useful tool to measure sustainability in a variety of processes. (Mo et al., 2011).

Expected Results. The results of this study will be compiled into a dissertation for a doctorate in Civil Engineering. The dissertation will consist of three to four chapters, each of which will be submitted to separate scientific journals for publications. The results of shea nut and firewood weights will also be shared in the community in a general meeting as well as a general discussion on the anthropological and carbon black emission results.

Roles of the Study Staff. The study staff consists of the primary investigator, Colleen Naughton, who will conduct all participant observation, ethnographic interviews, focus groups, and weighing of nuts and firewood.

Risk to the Subjects. There is no risk to the human subjects. Questions and observations are focused on the shea butter process. Participation is voluntary in all interviews and focus groups.

Human Subjects Consideration. The primary investigator is requesting that this study be considered exempt and informed consent forms will not need to be signed. A meeting will be held at the weekly, village meetings to explain the research purpose and objectives. Human subjects will be explained the purpose of the study and asked to participate in any of the research methodologies even weighing of shea nuts and firewood.

Data and Safety Monitoring Plan. No actual names will be recorded in observations, surveys, interviews, or focus groups. Only general age ranges will be estimated (as most women in the sites where the interviews are conducted do not know their birthdates) to correspond to surveys and interview and focus group data.

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Ethnographic Interview Questions

Descriptive Questions

1) Grand tour questions

1.1 Typical grand tour

- Could you describe a typical day in village when Shea is not harvested?
- Could you describe a typical day in village when Shea is harvested?

1.2 Specific grand tour questions

- Tell me what you did yesterday from getting up to going to sleep.
- Tell me the last time you made shea butter. When was it? What were the reasons for choosing that day?

1.3 Guided grand tour questions

- Could you show me around the village?
- Could you show me around your concession?
- Could you show me around your garden?

1.4 Task-related grand tour questions

- Could you draw a map of the market on the ground and explain it from your perspective?
- Could you water your garden and explain what you are doing?
- Could you describe a typical day in village when Shea is harvested?

(2) Mini-tour questions

2.1 Typical mini-tour

- Could you describe a typical day in the market?
- Could you describe a typical day in the garden?
- Could you describe a typical meeting with the women's association?

2.2 Specific grand tour questions

- Could you describe to me the last time you were in the market?
- Could you describe to me the last time you were in the garden?
- Could you describe to me the last time you were in the fields?
- Could you describe to me the last time you went to a women's association meeting?

2.3 Guided grand tour questions

- Could you show me around the village?
- Could you show me around your concession?
- Could you show me around your garden?
- Could you show me around your field?

2.4 Task-related grand tour questions

- Could you draw me a map of your garden?
- Could you draw me a map of your field?
- Could you draw me a map of your concession?
- Could you draw me a map of your place in the market?