Helpful Handouts for Submitting a Protocol for Research with Human Subjects

Contents:

Useful Definitions:

IRB: An Institutional Review Board established in accord with and for the purposes of reviewing research involving human subjects which falls under the jurisdiction of the Code of Federal Regulations, specifically 45 CFR 46.

Human subject: A *human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
(45 CFR 46.102 (e)(1))

Research: *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
(45 CFR 46.102 (l))

Useful Links:

UA-Fayetteville's Research Integrity & Compliance Department website:
http://rsic.uark.edu

Streamlyne Instructions:
http://streamlyneinfo.uark.edu/

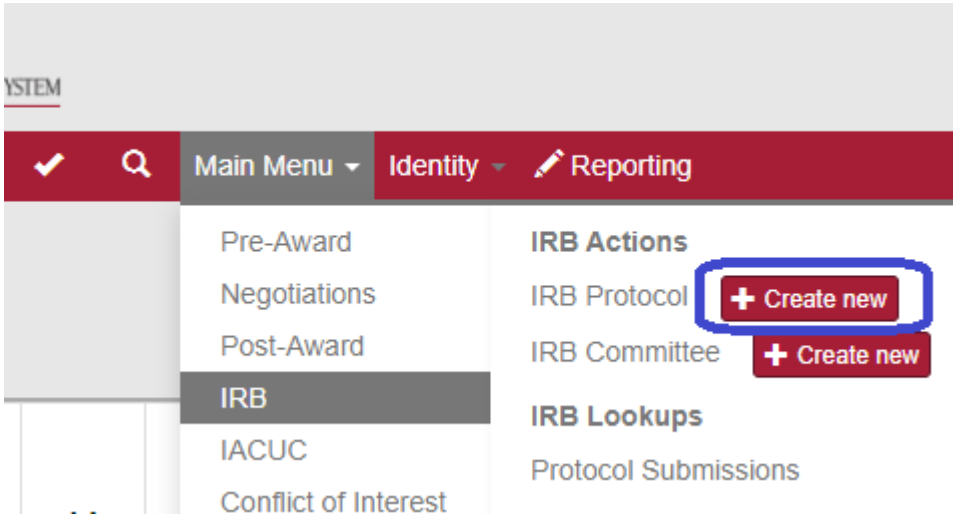
Training in the protection of human subjects:
https://www.citiprogram.org/

IRB Contact information:

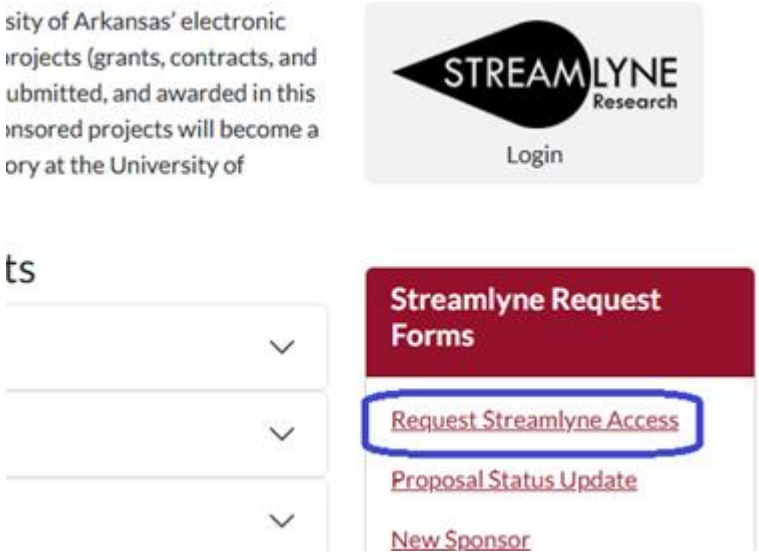
Iroshi (Ro) Windwalker, CIP
Institutional Review Board Coordinator
Research Integrity & Compliance
105 MLKG Building
Fayetteville, AR 72701
Ph. 479.575.2208
Fax 479.575.6527
irb@uark.edu

Creating a New Protocol:

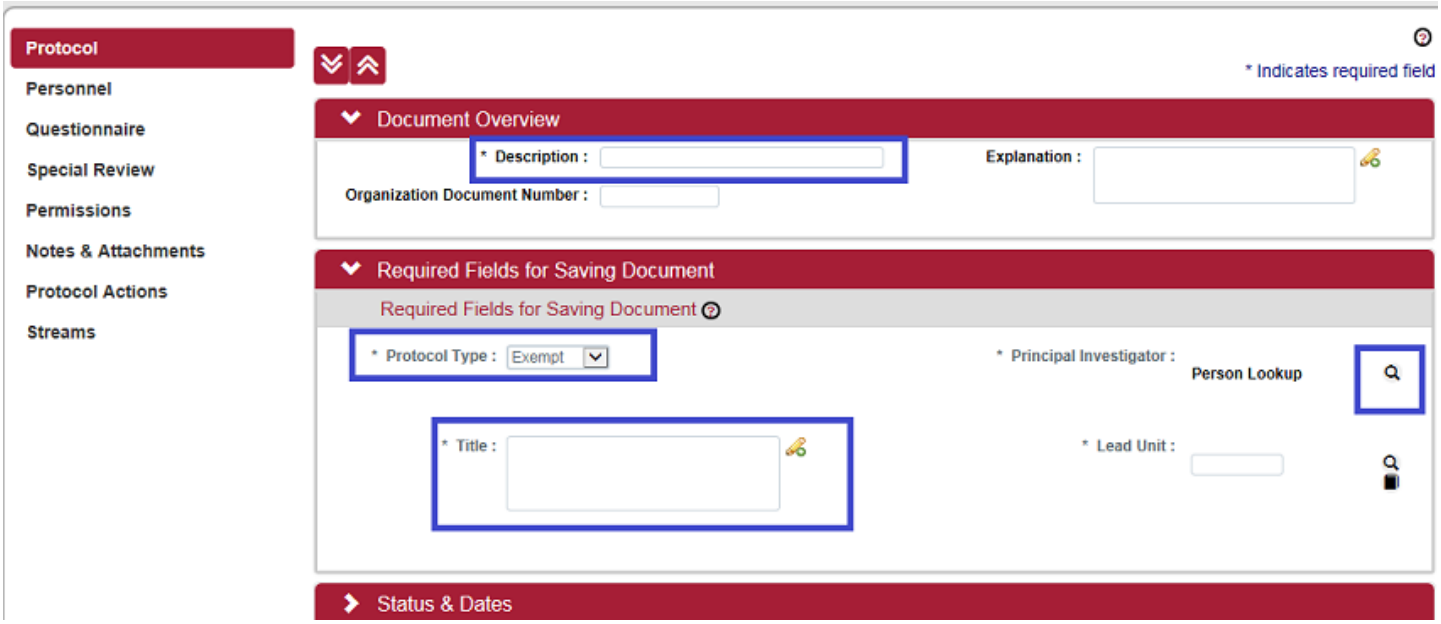
Click on Main Menu -> IRB -> click the **+Create new** button next to the words IRB Protocol:



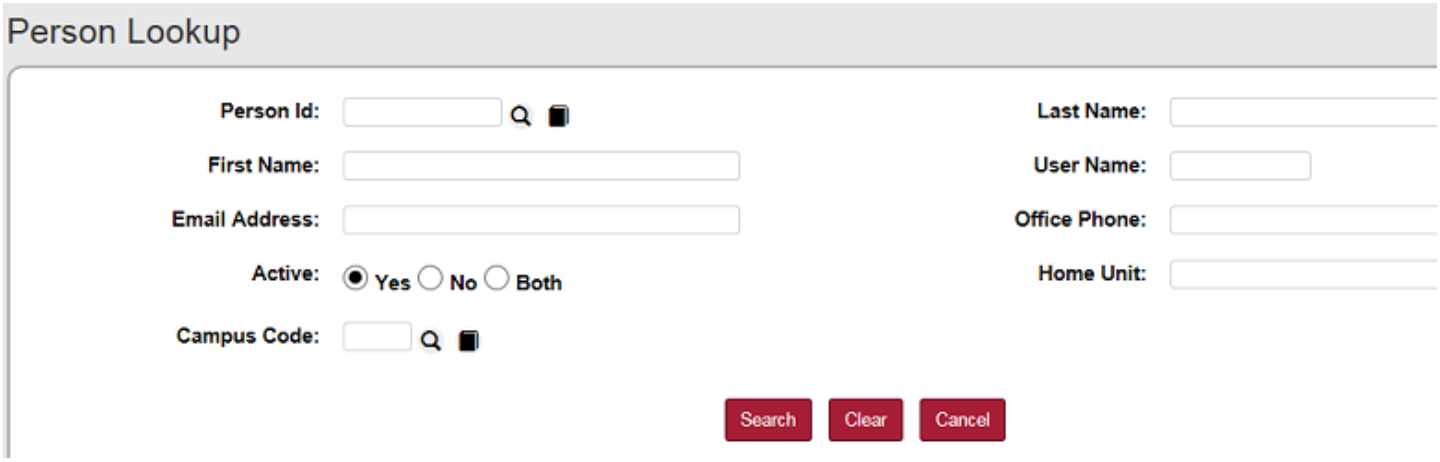
NOTE: If you do not see the +Create new box next to the words IRB Protocol in this menu, then your permissions in the Streamlyne system need to be updated. Please go to the Streamlyne page, at https://osp.uark.edu/streamlyne/ (or https://streamlyneinfo.uark.edu/, which is easier to remember if you're typing it in and not clicking a link), and on the right-hand side, under Streamlyne Request Forms, click the first link, which says "Request Streamlyne Access". Fill out the form, being sure to check the YES radio button which asks if you need access to submit IRB protocols, and click the SUBMIT REQUEST button. An eResearch Administrator will update your permissions at their earliest availability, often the same day, and you will receive an email notification once your access is updated.



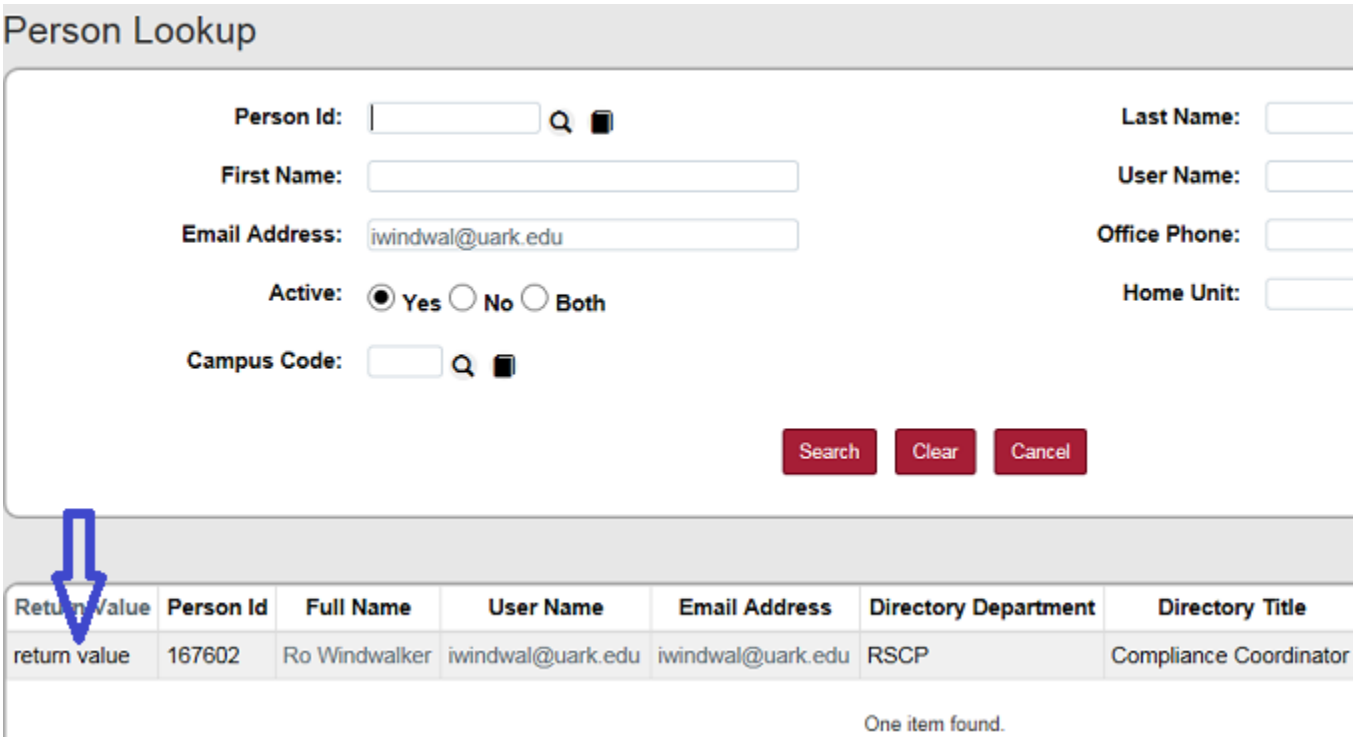
Once you have created a new protocol, you will see the following screen, and the fields with an asterisk * must be filled out.



The person primarily conducting the study should be listed as the Principal Investigator, even if they're a student. To enter the Principal Investigator, click on the magnifying glass next to Person Lookup, which takes you to this search page:

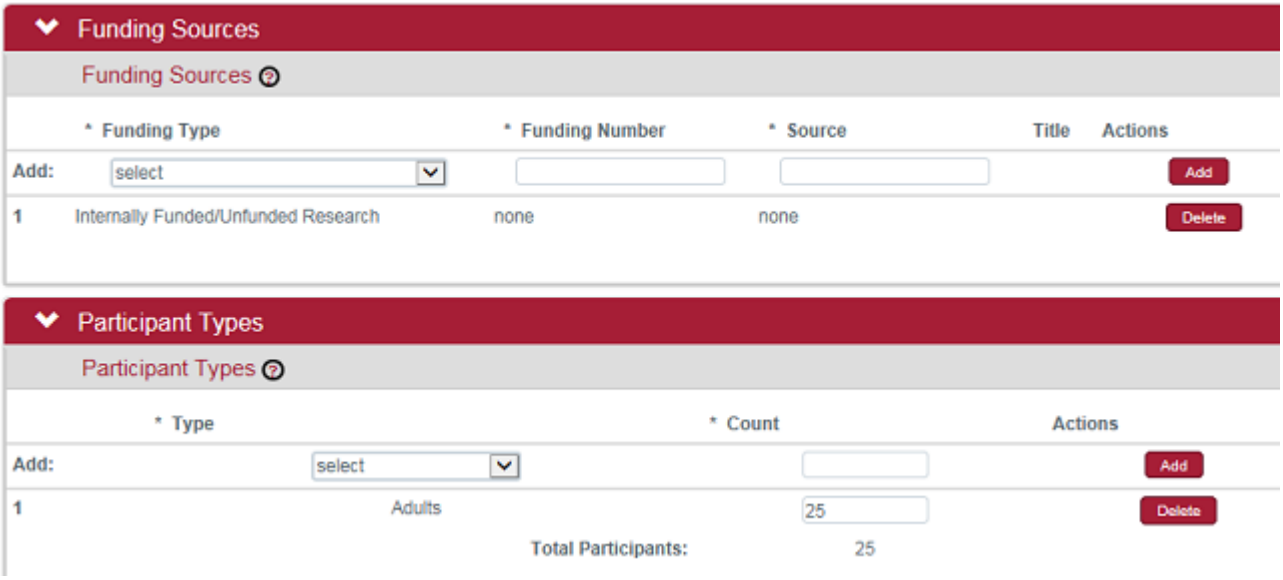


Only fill in ONE field (if multiple fields fill in on their own, then you have auto-fill set on your browser. This will cause you problems in the search, so turn it off. The results of the search will show up UNDERNEATH the red buttons. When you get a result, click on 'Return Value' to return it to your protocol:


Person Lookup
Person Id:
Last Name:
First Name:
User Name:
Email Address:
iwindwal@uark.edu
Office Phone:
Active:
Yes
No
Both
Home Unit:
Campus Code:
Search
Clear
Cancel

Return Value
Person Id
Full Name
User Name
Email Address
Directory Department
Directory Title
return value
167602
Ro Windwalker
iwindwal@uark.edu
iwindwal@uark.edu
RSCP
Compliance Coordinator
One item found.

The other items on the Protocol tab that must be filled in are Funding Source and Participant Types:

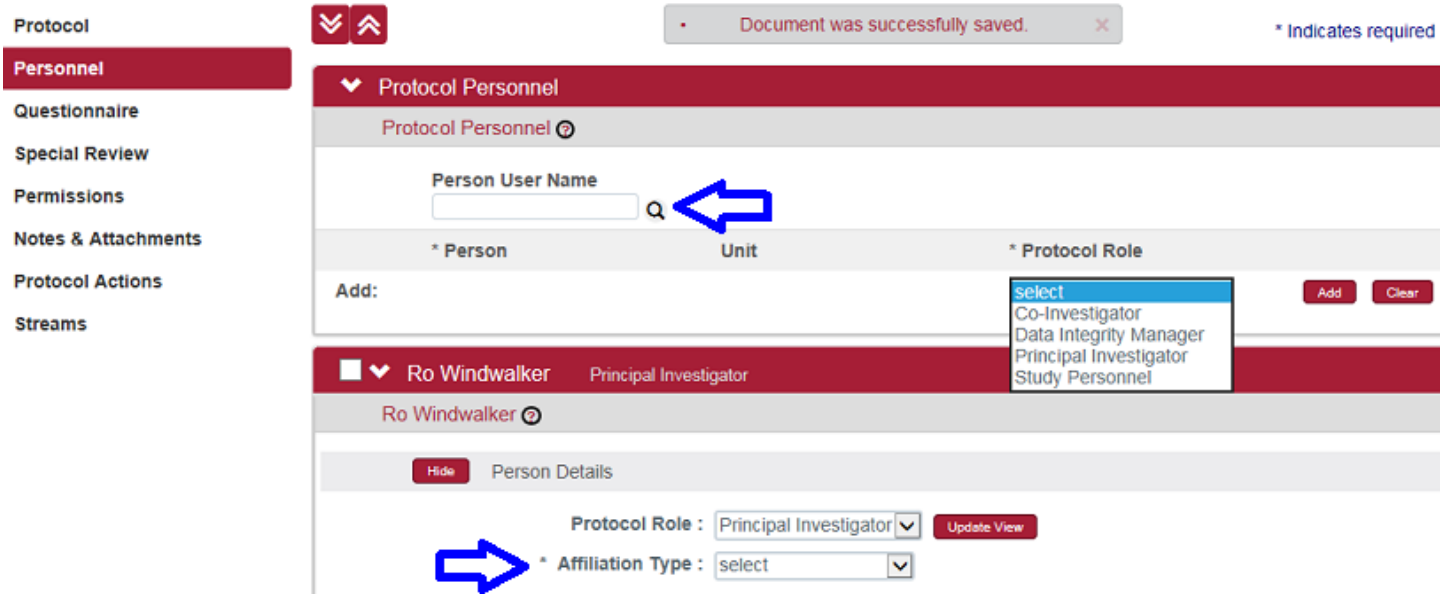


If you have funding through OSP (Office of Sponsored Programs), you will choose “Externally Funded”, which will link you to the grants side of Streamlyne and allow you match up grant proposals with the IRB protocol. If you do not have funding, or you have departmental funding or funding that did not go through the OSP department, then you will choose “Internally Funded/Unfunded” and fill in the text boxes of Funding Number and Source. If you have no funding, you can put N/A in both of those boxes. **Don’t forget to click ADD** at the end of the row, or the information will not save into your protocol.

Choose the type of participant you have, the **MAXIMUM NUMBER** of participants that you might possibly enroll, and again, click add at the end of the row. You can have multiple types of participants, for instance, if you are surveying both students on campus and adults off campus, you will add both UA Students and Adults into your Participant Types.

Completing the Personnel Tab:

Even if you are the only investigator in the study, you still have something that needs to be updated on the Personnel Tab.

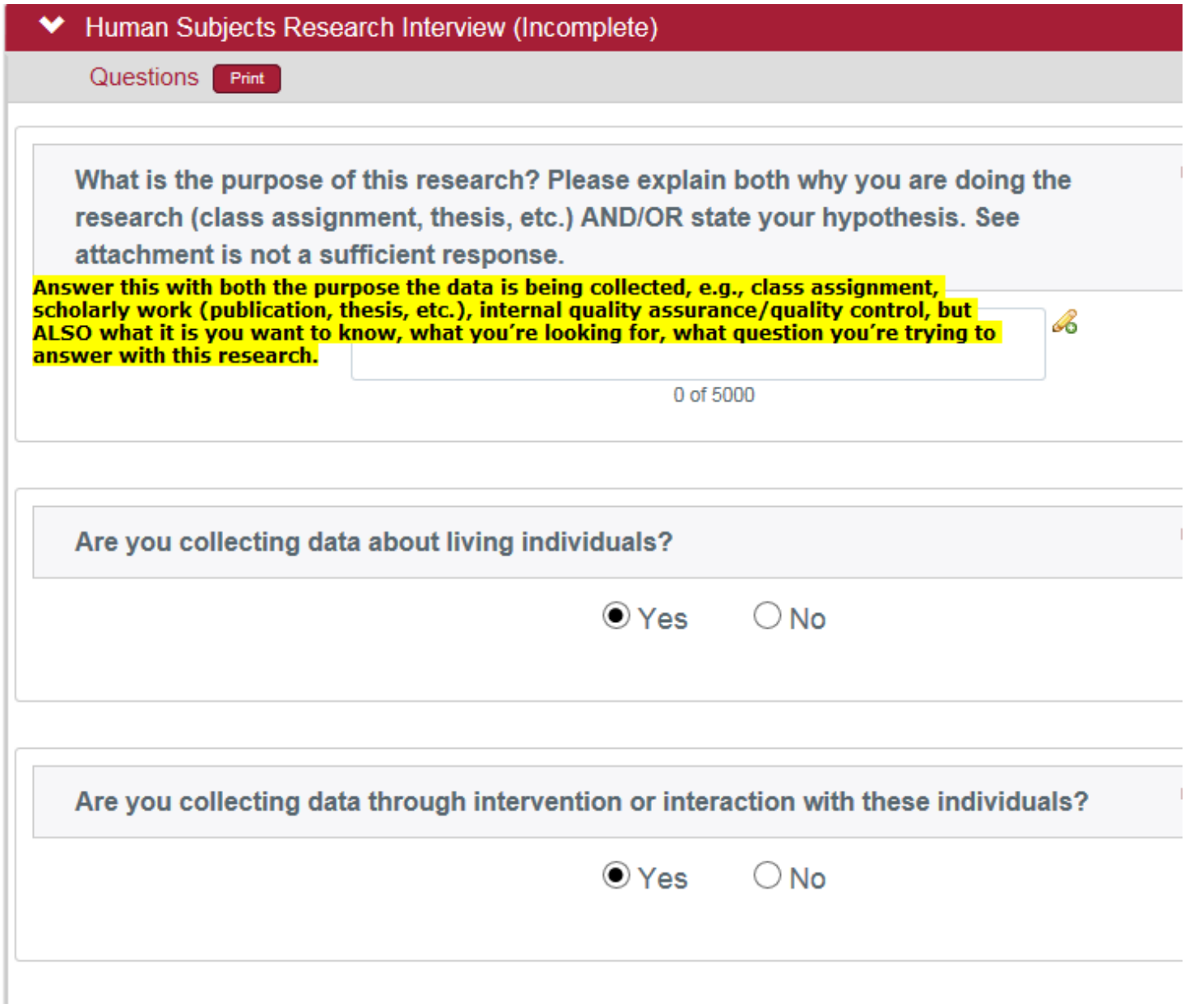


First, click on the red bar with your/the investigator's name, then click on the Show button for Person Details. Fill in the Affiliation Type. If you are a Student Investigator, then another investigator must be listed with the Affiliation Type of Supervisor.

To add more study personnel, click on the magnifying glass next to the Person User Name. This will take you back to the Person Lookup page, which works exactly the same way it did when you were entering the Principal Investigator. Choose the Protocol Role, and click Add, then click on the red bar with their name and add their Affiliation Type as well.

If you are collaborating with investigators who are not affiliated with UA, you will not be able to add them into the study personnel on the Personnel tab, as Streamlyne will only have personnel who are in Workday in the UAF, UADA, and UALR systems. Unaffiliated investigators can be added in a Note in the Notes & Attachments tab (their name and contact information will be needed.)

Completing the Questionnaire Tab for Most Protocols:



First you need to tell us WHOM you are asking to participate. If you're working with students in a 5th grade class at Springdale Elementary, for example, you will have marked "Children" as your Participant Type, but this is where you tell us WHICH children you're working with. If you want to interview CEOs of a particular type of company, then your Participant Type would have been Adult, but tell us WHICH adults you want to interview/survey/do research on. If you're just surveying random adults down on Dickson Street or on the internet, you would check No.

Beyond the basic Participant Types (children, UofA Students, adults, etc.) named elsewhere in this application, do you have a target population (particular group of people) you want to recruit? Some examples might be students in a particular class, members of a particular group or network, people in a specific age range (whether adult or minor), children in a particular school or class, etc.

(●) Yes ( ) No

Describe your target population.

0 of 2500

How are you recruiting participants? Are you standing in a public place asking people to take a survey, sending out introductory emails, posting an ad or blurb on a website or social media, posting a flyer in a public location, etc.? **Please note that all recruitment materials will need to be uploaded in the Notes and Attachments section.

0 of 4000

This is where you tell us WHAT you're doing. If you're conducting a survey, doing interviews, having participants come into a lab and run tests, or measuring how long they can do a set of jumping jacks: detail exactly what you're asking them to do in the Procedures. If you are collecting data ABOUT people, then explain what data you're collecting and what you're doing with it.

Provide a brief description of the procedures involving the participants.

0 of 5000

How long are the procedures likely to take? Include duration and frequency.

I don't need to know that you expect to be working on this for four months. How much of your participant's time are you taking up?

0 of 4000

How will information be given to people to get their informed consent to participate in this research? Answers should include specific methods (e.g., verbal consent, information handout, online consent form, full consent form requiring signature documentation.) **Please note that consent materials -- from a script for verbal consent to full consent forms that require participant signature -- must be uploaded in the Notes and Attachments section.

0 of 2000

Does data collection rely on a scheduled event, such as a convention or specific date?

(•) Yes ( ) No

Provide the date or date range, and the name of the event.

0 of 1000

Tell us how you're collecting, storing, and securing your data:

How will your data be collected? Include all that apply: online, on paper/in person, audio and/or video recordings. **Please note that all data collection materials will need to be uploaded in the Notes and Attachments section. This includes: surveys, questionnaires, interview questions or anything that is given to or asked of a participant.

Please include whether you are collecting identifying information or only anonymous data here.

0 of 2000

How will your data be stored? Include all that apply: electronically, on paper, audio and/or video recordings.

If you are collecting identifying information, such as consent forms, but removing identifiers from the data when you store it, please clarify that here or in the Data Security question below.

0 of 2500

How will that data be kept secure?

0 of 2000

Minimal Risk is defined as risks of harm not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Will participants be exposed to more than minimal risk? Include in your consideration the potential of mental risks if asking sensitive questions, or legal or reputational risks in case of breach of confidentiality.

More Information...

Risks to the participant can include being upset by disturbing or personal questions on a survey, or the risk of personal information getting out, even personal opinions (such as whether their boss is horrible) can be a risk of harm to a participant in a simple survey.

(●) Yes ( ) No

Describe the risks in question and any precautions that will be taken to minimize those risks.

More Information...

0 of 2500

Are participants expected to receive any benefits directly due to their participation in this study? (This does not include any compensation being offered.)

More Information...

Benefits refer to anything that accrues to the participant directly from their participation, not that they receive from the investigator as compensation for participating. Receiving test results is a benefit; consider whether participating may be psychologically beneficial.

(●) Yes ( ) No

Describe the benefits participants will or may receive.

More Information...

0 of 1000

Are you offering incentive or compensation for participant's time and effort in this study?

More Information...

(●) Yes ( ) No

Describe the compensation participants will or may receive.

More Information...

Be aware that in order to prevent coercion, when a research protocol offers class credit for participation, there must also be another method for students to receive the same credit for their class if they choose not to participate, and this should be specified both here and in the consent form.

0 of 5000

Will the proposed research involve deception or the withholding of information from participants?

○ Yes ○ No

Will the proposed research necessitate medical clearance from a physician prior to participation?

○ Yes ○ No

Will the proposed research involve gathering biological samples (blood, tissue, etc.)?

○ Yes ○ No

Will the proposed research involve administering of substances or providing food and drink, other than water, to participants?

○ Yes ○ No

Will the proposed research involve physical exercise or conditioning?

○ Yes ○ No

Does the research require review by a non-UofA IRB?

If you are collaborating with a researcher at another institution, be sure to check if they have an IRB that they are required to submit the protocol to. If so, mark Yes at this first question, and it will tell you where to go to tell us what IRB will be reviewing the study.

(●) Yes ( ) No

Please provide on the Protocol tab, Additional information > Other Identifiers section, all pertinent information regarding the submission to the External IRB(s). Please type 'ok' in the text box to verify your understanding.

0 of 2

Does this research require approval from another institution or agency, such as a school or privately owned business?

If you are doing research at a school or private business, you will need to get approval to conduct your research using their facilities before we can approve the protocol.

(●) Yes ( ) No

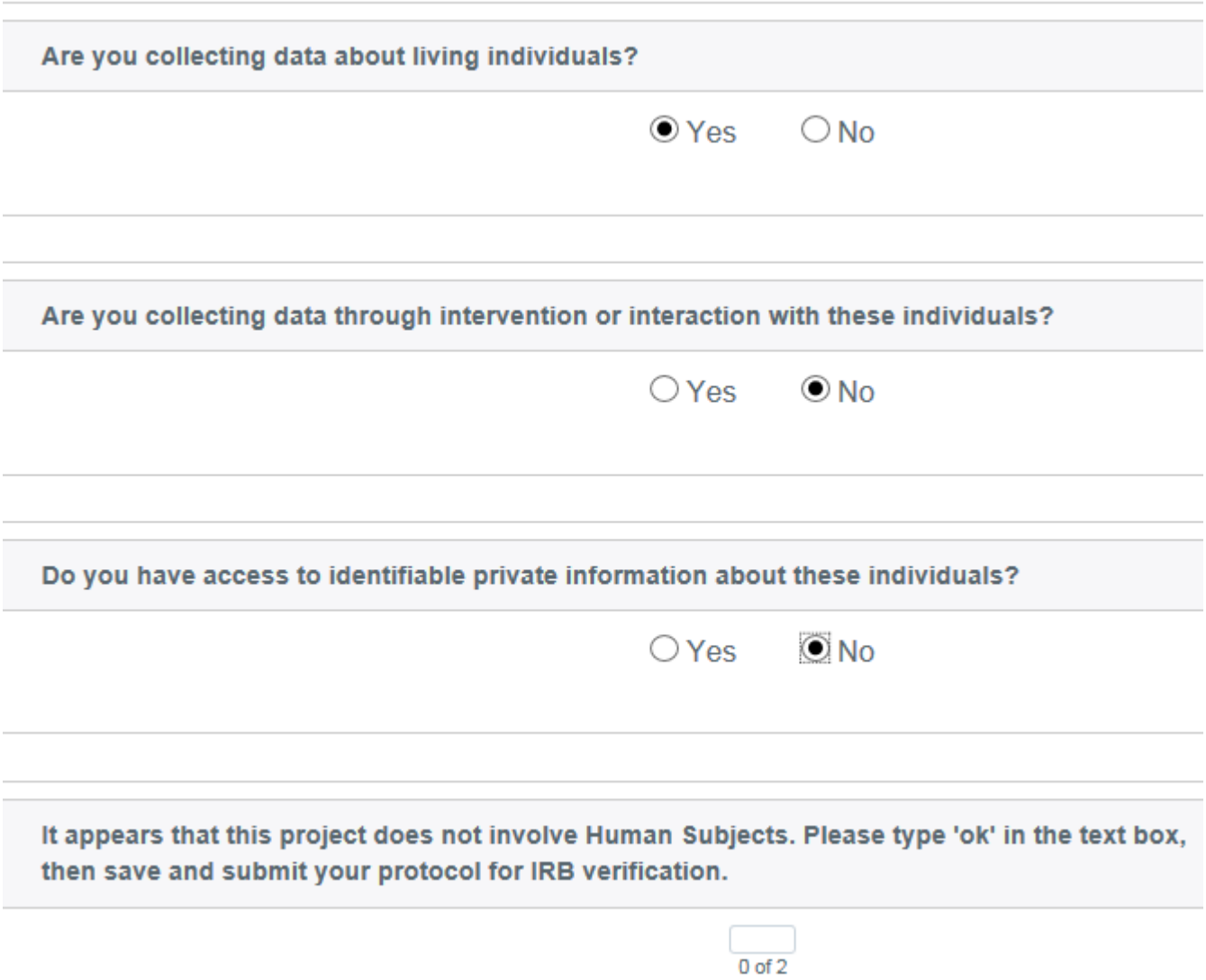
In the Notes and Attachments section, please upload documentation confirming the approval of the agencies or institutions involved. Please type 'ok' to verify your understanding.

0 of 2

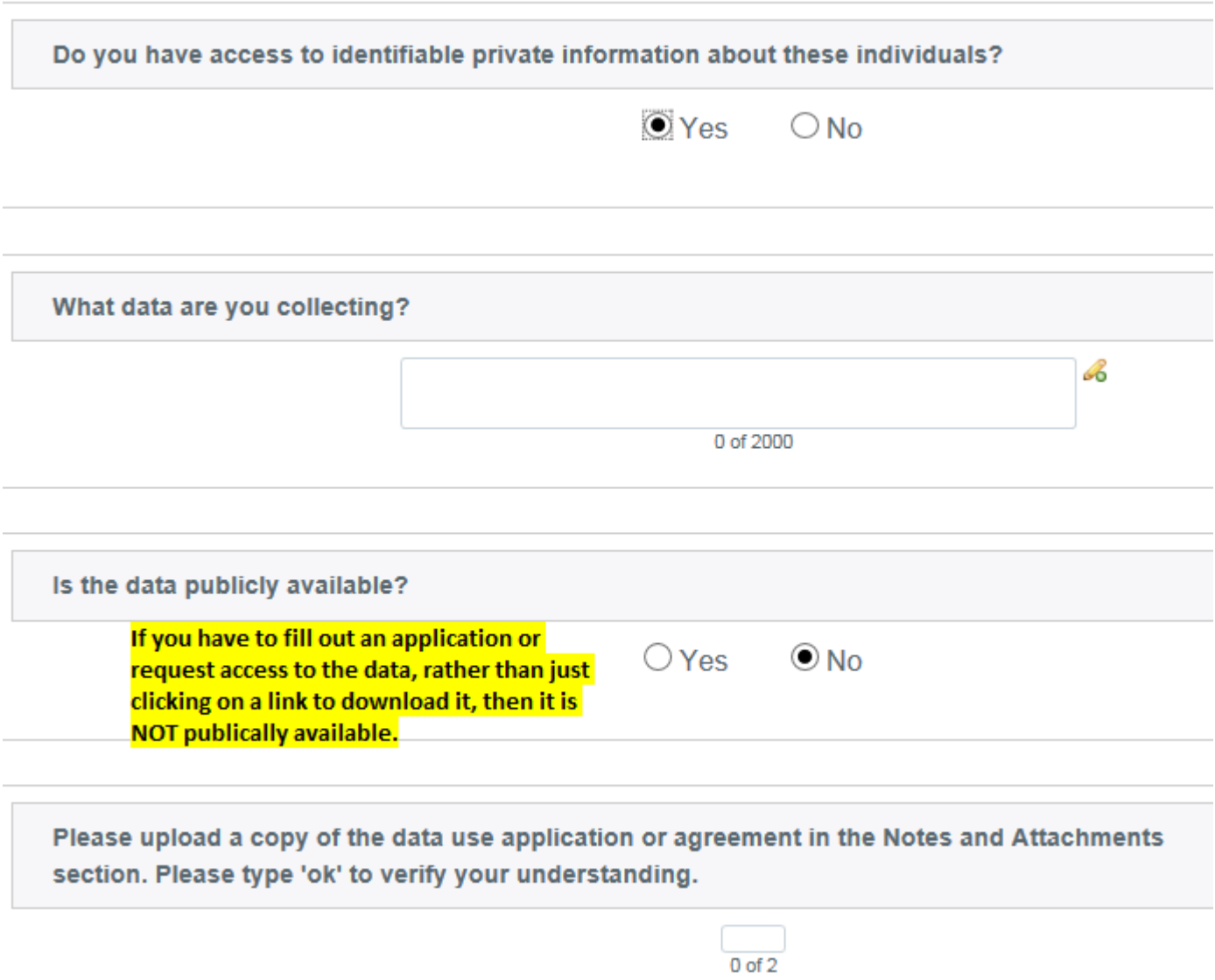
What is the projected start date for this study?

More Information...

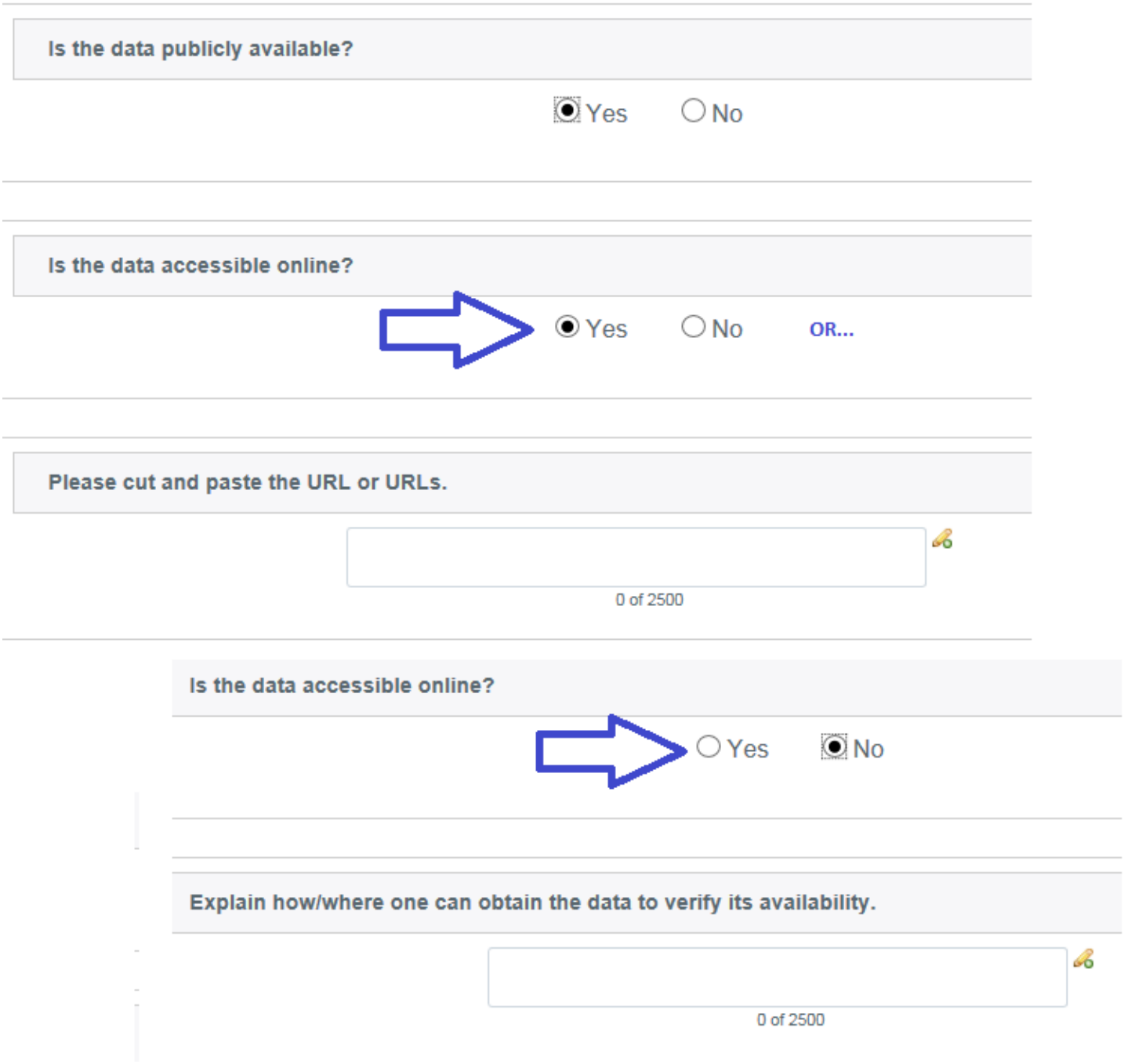
Completing the Questionnaire Tab for Studies with Existing Data:



If you do not have access to private, identifiable information, then you're not doing research with Human Subjects.



If you DO have access to identifiable information, tell us what that data is. If you have to fill out an agreement or application to get that data, we will need to see a copy of that completed application/agreement.

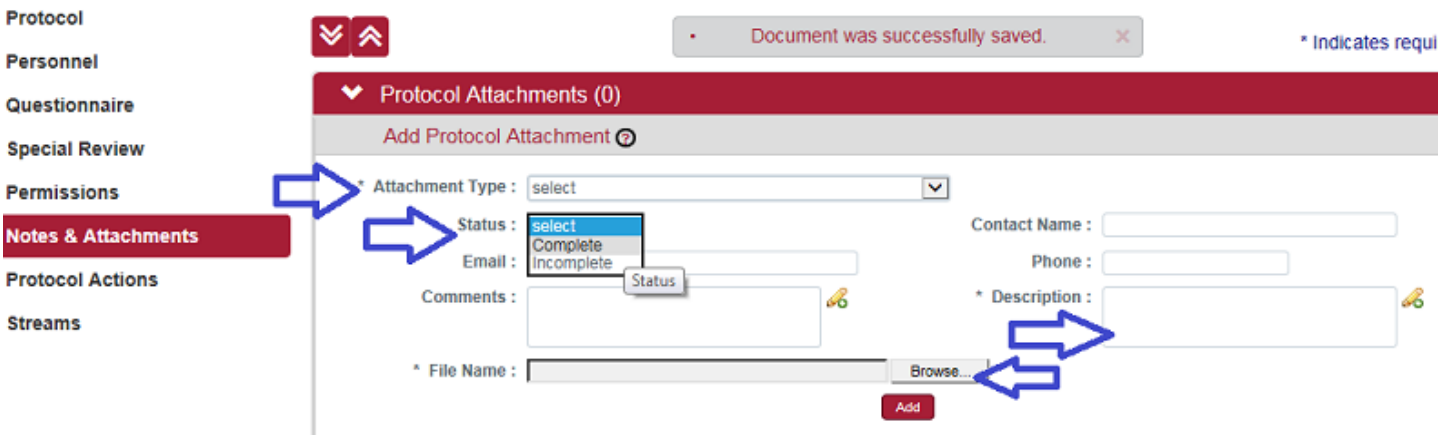


If it IS publically available, we will need to know where you're getting it from, in order to verify that.

Adding Attachments in the Notes & Attachments Tab:

Everything that participants will see as part of the research, from the initial contact for recruitment through any post-participation debriefing, must be uploaded into the Attachments section of the protocol for review. This includes not just actual documents such as consent forms or flyers that will be posted around campus, but also scripts for verbal recruitment such as telephone calls, in-person recruitment, or interview introductions, or text of emails that will be sent out, either as recruitment, or form emails over the course of the study to remind participants of the second phase, ask them to take part in a follow-up interview, etc.

Beyond participant materials, other items that may need to be included in the Attachments are any agreements connected to the research (data use agreements, permission to conduct research at a particular location, etc.) or documentation about any medical devices that may be used in the study.



To upload your attachment, first select the Attachment Type. Your options will be: Adverse Event Summary, Authorization Agreement, Consent Materials, Data Collection Materials, Data Use Agreement/Memorandum of Understanding, Debriefing Materials, Medical Clearance Documentation, Modification Summary, Other Approvals, Protocol, and Recruitment Materials.

PLEASE NOTE that if you choose the wrong Attachment Type, it will NOT affect your review or approval, so don't stress over this. Having said that, a new protocol submission will likely not ever need an adverse event summary or a modification summary; it might possibly need any of the other categories. Also, an Authorization Agreement is a document that is entered into between two institutions when a protocol is covered by more than one IRB, to allow one IRB to review the protocol and the other to accept their review. Generally the researcher would not be the one uploading an authorization agreement; the IRB Coordinator usually uploads the authorization agreement into the attachments of a protocol after it is completed and signed by both institutions.

Of the remaining attachment types that you are more likely to use, but not be sure about:

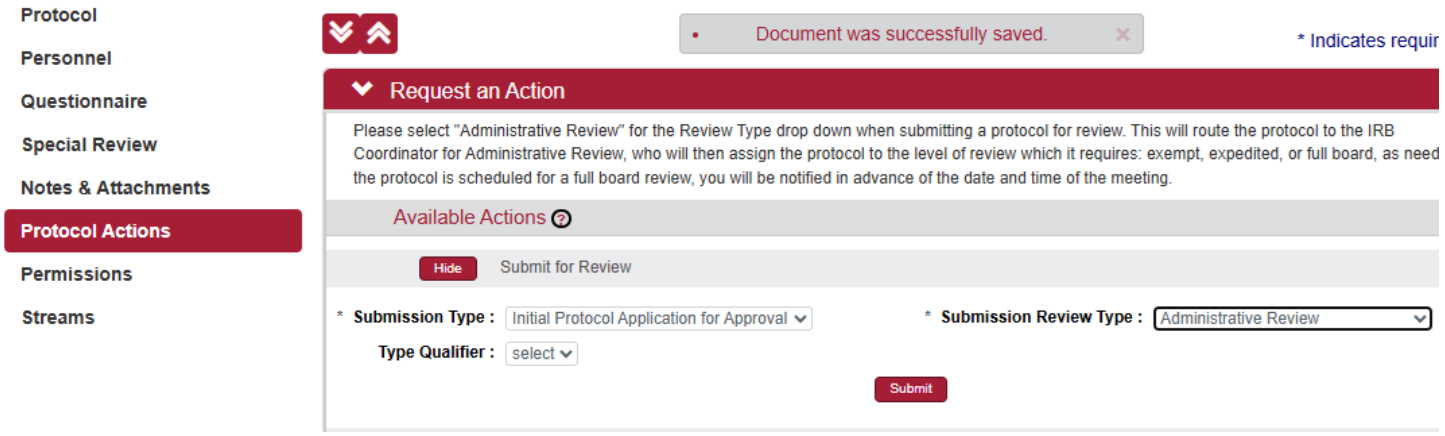
- Consent Materials would include anything involving the consent process, whether that is a verbal script, an informational handout, or the actual consent form requiring signature. (NOTE: You should NOT have signed consent forms at the time of protocol submission, as you should not be contacting participants before protocol approval, but if you do, or if you are submitting an amendment or a renewal, you should NEVER upload signed consent documents into the Streamlyne system.)

- Data Collection Materials are anything by which you are collecting data: this can be the obvious surveys, but it can also be a list of interview questions that you're going to be asking, or a list of data points that you are checking off when observing a classroom. It can also be the list of data points that you are going to be collecting from a medical record or other existing dataset.
- A Data Use Agreement/Memorandum of Understanding is generally only used when you are doing work with an existing dataset, and is a contract whereby you agree with the owner of the dataset for the limit of use.
- Debriefing Materials would be anything that you say or hand out to your participants after they have completed their participation. PLEASE NOTE that not all studies have to have all categories of documents; most protocols do not have debriefing materials, and that is fine.
- Protocol – If you have a separate protocol for your study, this is what it would be submitted as, or a document giving an overview or timeline for the overall research.
- Recruitment Materials: everything that the participant will see/hear/interact with as part of the research up until they have consented to participate, so this will include any scripts, if you are calling or otherwise speaking to them in person, texts of emails to be sent out, social media advertisements, flyers, etc. This also includes screening surveys and any form emails that will be sent out scheduling the first contact.

Once you have chosen the Attachment Type, set the Status of the document to COMPLETE. (You can upload a document as Incomplete, but it will give you an error if you submit the protocol with an Incomplete document in the Attachments.) Enter a description of the document in the Description box to explain what the document is and what it will be used for. You can also enter information in the Comments box, but the information in the Description box is what will show in the list of the Attachments once they are uploaded, without clicking on each file to pull up their details. Then click the Browse button to find the file in your system to upload. Once you have chosen the correct file to upload, click ADD.

This can be repeated as many times as necessary to upload all of the information/documents that are needed for your study.

Submitting the Protocol for Review:



Click the red bar to open the Request an Action section, click SHOW next to Submit for Review, and then just fill out the drop-down boxes (they only have one option each for new protocol submissions), and click the Submit button. It's that easy!

Once a protocol is submitted, it will be routed to any other investigators listed on your protocol to approve the submission, and then it will go to the IRB Coordinator for review.

Co-Investigators and/or Faculty Supervisors can approve the submission by opening it, clicking on Protocol Actions, scrolling to the bottom of the page, and clicking the red Approve button.

INFORMED CONSENT

Title: Title of your study

Researcher(s):
Ronald A. Researcher
Don. A. Advisor, Ph.D., Faculty Advisor
University of Arkansas
College of Everything Important
Department of All the Good Stuff
100 Important Building
Fayetteville, AR 72701-1201
479-575-0000

Compliance Contact:
Ro Windwalker, CIP
Compliance Coordinator
Research Integrity & Compliance
University of Arkansas
105 MLKG Building
Fayetteville, AR 72701-1201
479-575-2208
irb@uark.edu

Description: The present study is an action research project designed to investigate what effects explicit instruction may have in increasing vocabulary achievement in a second grade classroom. Explicit instruction incorporates direct teaching strategies to specifically address an academic issue. At the beginning of the study your child's vocabulary achievement will be assessed using a teacher created assessment. Explicit vocabulary instruction will be taught for 30 minutes a day, four days a week, for nine weeks. Observational records will be recorded daily on the progress of the students. Following the intervention your child's vocabulary achievement will be assessed again using the teacher created assessment. This will be done in order to determine what effects explicit instruction may have had on vocabulary achievement.

Risks and Benefits: There are no risks, other than those associated with regular classroom instruction, anticipated with this project. The potential benefits include improving your child's time spent on task during instruction and increase his/her academic achievement.

Voluntary Participation: Your child will participate in all classroom activities during this research project. However, the decision to allow your child's grades and scores to be used in recording and analyzing data for this project is completely voluntary.

Confidentiality: Your child's scores and grades will remain confidential to the extent allowed by law and University policy. To ensure confidentiality a code will be established by randomly assigning a number to each participant. All scores and grades for data analysis will be recorded using this code. The code as well as all data collected during the study will be stored in a secure place and will be accessible only to the researcher. Neither your child nor his/her scores or grades will be personally identified. The code will be destroyed at the conclusion of the study.

Right to Withdraw: If you choose to allow your child's scores to be used now, but at any time and for any reason change your mind, you may withdraw your consent. In that case your child's scores and grades would not be recorded in the project data. There would be no negative consequences for this decision.

Informed Consent: I, _____, have read the description of this study.
(please print your name)
I understand the purpose of the project, the procedures to be used, the potential risks and benefits, how confidentiality will be established and maintained, as well as the option to withdraw. I have read and discussed this project with my child _____.
(please print your child's name)

My signature below indicates that I and my child freely agree for his/her scores and grades to be recorded and analyzed as a participant in this project.

_____ _____ _____
Parent/Guardian Child/Participant Date

University of Arkansas
Parent or Legal Guardian Permission for Child to Participate in a Research Study
*****Title of Research Project*****

You are being asked to give permission for your child to participate in a research study. Before you give permission for your child to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what your child is being asked to do.

Investigators

My name is **your name**. I am graduate student in the ** Program or course of Study** University of Arkansas. My advisor is Dr. **Name and title of advisor**.

Purpose of the Research

This research study is designed to find **research question**.

The data from this research will be used to **what you are doing with the data**.

Procedures

If you allow your child to participate in this study, he/she will be asked to complete a survey that will include **describe study**. It will also include questions about **explanation of questions**.

Your child's participation will take approximately **how long will it take and where the research will take place**.

Your child will be asked to assent to participate in this research. He/she can refuse to participate without penalty or can stop participation at any time just by telling the investigator that he/she wants to stop.

Potential Risks or Discomforts

Risks.

Potential Benefits of the Research

Benefits.

Confidentiality and Data Storage

Your child's name will only be collected on this permission form and will not be connected to his/her survey in any way. In addition, your child's teacher and school district will be kept confidential to the extent allowed by law and University policy.

Location of completed surveys and who will have access to them.

Participation and Withdrawal

Participation in this research study is voluntary. You may refuse to allow your child to participate without penalty to you or your child. If you decide to allow your child to participate, you are free to stop his/her participation without penalty by just telling the investigator. In addition, your child may stop participating by telling the investigator that he/she wants to stop.

You cannot withdraw from the study after data collection has been completed since your name is not linked to the data.

Questions about the Research

If you have any questions about the research, please ask them now. If you have questions later, you may contact **Advisor's and researcher's email and/or phone number**.

This research project has been reviewed and approved by the Institutional Review Board for the Protection of Human Subjects at The University Arkansas. If you have any questions or concerns about your child's rights as a research subject, you may contact the University's Compliance Coordinator at (479) 575-2208 or irb@uark.edu.

***Parent or Legal Guardian Permission*:**

I have read the information provided above. I agree to let my child participate in this research study. I also understand my child's assent to participate in this study will be sought. Please return one copy of this consent form and keep one copy for your records.

_____
Name of Child (please print)

_____ _____
Signature of Parent/Legal Guardian Date

***Child's Permission*:**

I have discussed this study with my parent or guardian and agree to participate in the study.

_____
Signature of Participant

Title of Research Project
Consent to Participate in a Research Study
Principal Researcher: Principal Researcher's Name
Faculty Advisor: Faculty Advisor's Name

INVITATION TO PARTICIPATE
You are invited to participate in a research study about XXX. You are being asked to participate in this study because you XXX.

WHAT YOU SHOULD KNOW ABOUT THE RESEARCH STUDY

Who is the Principal Researcher?
Principal Researcher's name and contact information
Who is the Faculty Advisor?
Faculty Advisor's name and contact information (delete the FA row if not applicable/not a student protocol)

What is the purpose of this research study?
The purpose of this study is XXX.

Who will participate in this study?
Number of expected participants, who they are, age range, etc.

What am I being asked to do?
Your participation will require the following:
XXX

What are the possible risks or discomforts?
List any possible risks. It is permissible to say there are no anticipated risks to participating, if this is the case.

What are the possible benefits of this study?
This questions asks for benefits to the participant, not just the knowledge gained by the study. It is permissible to say there are no anticipated benefits to the participant, if this is the case. Do not list monetary compensation or extra credit; these should be listed in the Compensation paragraph – this section should only listed benefits that might accrue to the participant directly as a result of their participation

How long will the study last?
Make clear to your participant how long their participation will take, whether a 15-minute survey, or three one-hour meetings spread out over a month, etc.

Will I receive compensation for my time and inconvenience if I choose to participate in this study?
Yes/No (if yes, then explain/describe)

Will I have to pay for anything?
This will generally say, No, there will be no cost associated with your participation

What are the options if I do not want to be in the study?
If you do not want to be in this study, you may refuse to participate. Also, you may refuse to participate at any time during the study. Your job, your grade, your relationship with the University, etc. (only include applicable points; for example, if the researcher is not the participant's teacher and has no access to their grades, or

participants are not students, there is no reason to mention grades in this section) will not be affected in any way if you refuse to participate.

How will my confidentiality be protected?
All information will be kept confidential to the extent allowed by law and University policy. Add whatever steps are being taken to ensure confidentiality, whether data will be anonymous, records will be locked in a secure area, etc.

By signing this consent form, you give permission for the Arkansas Department of Health, the Office of Human Subjects Protection, the UA IRB, and any other UA oversight offices to verify clinical trial procedures and/or data. No identifying information will be reported at any future presentation or published in any future publication.

Will I know the results of the study?
At the conclusion of the study you will have the right to request feedback about the results. You may contact the faculty advisor, Name and contact information, or Principal Researcher, Name and contact information. You will receive a copy of this form for your files.

What do I do if I have questions about the research study?
You have the right to contact the Principal Researcher or Faculty Advisor as listed below for any concerns that you may have.

Principal Researcher's name and contact information

Faculty Advisor's name and contact information

You may also contact the University of Arkansas Research Integrity & Compliance office listed below if you have questions about your rights as a participant, or to discuss any concerns about, or problems with the research.

Ro Windwalker, CIP
Institutional Review Board Coordinator
Research Integrity & Compliance
University of Arkansas
105 MLKG Building
Fayetteville, AR 72701-1201
479-575-2208
irb@uark.edu

I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I understand the purpose of the study as well as the potential benefits and risks that are involved. I understand that participation is voluntary. I understand that significant new findings developed during this research will be shared with the participant. I understand that no rights have been waived by signing the consent form. I have been given a copy of the consent form.

_____

Participant Signature Date

Office for Protection from Research Risks

TIPS ON INFORMED CONSENT

The process of obtaining informed consent must comply with the requirements of **45 CFR 46.116.** The documentation of informed consent must comply with **45 CFR 46.117.** The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.

- **Describe the overall experience that will be encountered**. Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.

- **Describe the benefits that subjects may reasonably expect to encounter**. There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.

- **Describe any alternatives to participating in the research project**. For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.

- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence**. For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g.,subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.

- **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[j]), an explanation must be given of whatever voluntary compensation and treatment will be provided**. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.

- **The regulations prohibit waiving or appearing to waive any legal rights of subjects**. Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations** (45 CFR 46.116[a][8]). It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.

- Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections 46.116(b), 46.205(a)(2), 46.207(b), 46.208(b), 46.209(d), 46.305(a)(5-6), 46.408(c), and 46.409(b). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

Revised 3/16/93

§46.116 - Informed Consent Checklist - Basic Elements

MIN		A statement that the study involves research
MIN		An explanation of the purposes of the research
MIN		The expected duration of the subject's participation
MIN		A description of the procedures to be followed
		Identification of any procedures which are experimental
MIN		A description of any reasonably foreseeable risks or discomforts to the subject
MIN		A description of any benefits to the subject or to others which may reasonably be expected from the research
		A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
		A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
		For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
MIN		An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
MIN		A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
		One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

For anonymous studies for which consent cannot be waived, the minimum elements of consent are marked as "**MIN**" in the list above.

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

Both boxes of C must be checked, or all four boxes of D:	
	C: 1.The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
	C: 2.The research could not practicably be carried out without the waiver or alteration.
OR	
	D: 1. The research involves no more than minimal risk to the subjects;
	D: 2.The waiver or alteration will not adversely affect the rights and welfare of the subjects;
	D: 3.The research could not practicably be carried out without the waiver or alteration; and
	D: 4.Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.	
b. Except as provided in paragraph (c) of this section, the consent form may be either of the following:	
WRITTEN	1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
DONE ORALLY	2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:	
WAIVER of require. for signed form	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.