**UNIVERSITY OF CINCINNATI**

**INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES (IRB-S)**

**PROTOCOL**

**INSTRUCTIONS and TEMPLATE FOR NEW RESEARCH SUBMISSIONS**

***NOTE:*** *A list of items to be included in the IRB-S submission packet and additional considerations for Action Research, Ethnographic Research, Prisoner Research and Secondary Data Analysis are given on the IRB's website (*[*www.researchcompliance.uc.edu/irb*](http://www.researchcompliance.uc.edu/irb)*, Social/Behavioral Submission Packet, Guidelines for Submitting New Social/Behavioral Studies.*

*FEDERAL REGULATIONS (45CFR46.111) require that the IRB determines all of the following are satisfied before research may be approved.*

*1. Risks to subjects are minimized:*

*(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and*

*(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.*

*2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.*

*3. Selection of subjects is equitable.*

*4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative (unless specifically waived by the IRB).*

*5. Informed consent will be appropriately documented (unless specifically waived by the IRB).*

*6. When appropriate [that is, when the research exposes subjects to greater than minimal risk], the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.*

*7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

*8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.*

*PROTOCOL TEMPLATE*

*The protocol must contain a complete description of the research being done.*

* *USE THIS TEMPLATE.*
	+ *Delete this top (gray) portion of the template and BEGIN WITH THE TITLE.*
	+ *Omit all gray text below but keep all black text.*
	+ *Insert information under every section. Lists or bullet points are acceptable. Do NOT omit any sections. If the section does not apply to your study, put "not applicable."*
	+ *Do NOT use bold font within the text; bold may ONLY be used for section headings and during the revision process. Use italics, underline or all capitals if emphasis is needed.*
	+ *This template uses Arial 12-point font. Use the same font for your own text.*
* *Do NOT repeat blocks of text in various sections. That just increases the likelihood that revisions will be made in one place but not in others. Only give information that is specific to the section.*
* *Note the recommended lengths of each section. The information needs to be clear and complete but does not need to be lengthy.*
* *Identify each attachment clearly. Use the same name for the attachments in the protocol text as on the attachment itself.*
* *NUMBER the pages of the protocol (page x of y) and include the VERSION DATE (when you wrote or revised it). Number the pages of attachments separately, with their version dates.*
* *PROOFREAD your protocol and attachments to be sure they are consistent with each other.*

*If you do not follow this template your submission WILL BE RETURNED to you UNREVIEWED.*

**TITLE:**

*The title must be the same on the Research Review Submission Form (RRSF), Conflict of Interest (COI) forms and protocol. It also should be the same on the informed consent document (ICD), unless the protocol explains a compelling reason to use a different title.*

**1. PURPOSE of the research project AND GENERAL INFORMATION:**

1. PURPOSE

*Explain the purpose of your research project. This section will probably be a sentence to a short paragraph in length.*

The purpose of this research study is to…..

1. BACKGROUND

1) Prior research

*Summarize prior research relating to this topic (brief literature review). Explain what is already known and what research has been done in this field previously by you or others. This section may be a paragraph to no more than three pages in length.*

*List references in Section 5 References. If there are many references, select the primary ones so the list is no more than one page long.)*

2) Significance

*Explain the scientific or scholarly significance of your research (how your project will add to the general body of knowledge in your discipline). Include any indirect benefit to society as a whole or to others who did not participate in the study. This section will probably be a paragraph or two in length.*

1. FUNDING

1) Sponsor's name and type

*Identify the source of funding for your research (the “sponsor”) and type (federal, state, non-profit foundation, faculty grant, etc.). This section will probably be a sentence to a short paragraph in length.*

2) Sponsor's role

*Explain how much involvement the sponsor will have in conduct or oversight (monitoring) of your study. This section will probably be a sentence to a short paragraph in length.*

3) Location of funds

*Explain where the funds will be held (i.e., in a UC department or external to UC). This section will probably be a sentence to a short paragraph in length.*

4) Status of funding

*Explain whether the funding has already been approved or is still in the application stage. This section will probably be a sentence to a short paragraph in length.*

*NOTE: if your study is supported by a federal grant, ONE copy of the grant application must be submitted to the IRB along with your research proposal.*

*NOTE: if your study is industry-sponsored (by a for-profit company) and the funding is held outside of the University of Cincinnati (in a private practice group or company), a fee for IRB review will be assessed. If the study is not industry-funded or is federally funded or the funding is held within UC (in a department account or UC internal grant), there will be no fee for IRB review.*

1. FACILITIES

*Explain where the research will be done. Identify the kind of facilities needed for study-related activities (e.g., classroom, office, lab, participant's choice of interview location, internet, Blackboard, etc.). Explain what you have done (or what you will do) to make sure you have access to the necessary facilities. This section will probably be a sentence to a short paragraph in length.*

*NOTE: if the research will be done at a non-UC location such as a school classroom, a company or a community agency, a letter of support from the site should be attached to the submission packet and listed in Section 6 Additional Documentation to document that you have access to the study site to recruit, obtain research data, etc. This is not the same thing as a consent document. The site support letter may be as informal as a brief email agreeing you may come, but it needs to include the name of the person giving permission and their position in regard to the site. (Example: Mary Smith, HR Director)*

1. DURATION OF STUDY

*Explain how long it will take to complete the entire research project. Mention any special time constraint, such as needing to start by a certain date or needing to be completed by a certain date. For research with several phases or complex design it might be appropriate to use a bullet list or a chart to show the time flow. This section will probably be a sentence to a short paragraph or one chart/list in length.*

*NOTE: the time spent by research team members should be explained in Section 1.f below. The time spent by an individual participant should be explained in Section 3 Research Activities.*

1. RESEARCH TEAM

1) Research team and time commitment

*Use the chart below to identify the members of the research team by job title/responsibility (not by name), including PI (yourself) and Faculty Advisor (if you are a student). Explain how much time the various members of the research team will need to spend on research-related activities. Add rows if necessary.*

*NOTE: all research team members must be listed on the RRSF, submit a signed COI form and complete the CITI training.*

|  |  |
| --- | --- |
| Job Title / Responsibility | Time Commitment |
|  |  |
|  |  |
|  |  |
|  |  |

2) Training team members in research ethics

*Explain training you and your research team have received in research ethics. It is helpful but not required to attach CITI completion certificates or a printout of the individual's CITI Main Menu screen showing the list of courses passed. This section will probably be a sentence to a short paragraph in length.*

*Instructions for CITI training are given on the IRB's website (*[*www.researchcompliance.uc.edu/irb*](http://www.researchcompliance.uc.edu/irb)*, Protecting Human Subjects,* [*Demonstrating Knowledge (CITI Training) Instructions*](http://www.researchcompliance.uc.edu/irb/IRB/Demonstrating%20Knowledge-Instructions%20_4-30-09_.pdf)*.*

*NOTE: if some members of your research team are from the community (NOT affiliated with UC or some other university), it is possible for you to train them in research ethics without using the CITI program. Contact the IRB office for more information if you are interested in this option (**claudia.norman@uc.edu* *or 558-5784).*

3) Training team members in research activities

(a) Training

*Explain your plans for training your research team in their responsibilities in this research project. How much supervision of research team members will you do before allowing them to do their work unsupervised? This section will probably be paragraph or two in length.*

(b) Verification

*Explain how you will ensure that you and your research team members are following the correct procedures and using the IRB-approved form versions. This section will probably be paragraph or two in length.*

**2. PARTICIPANTS:**

*DO NOT INCLUDE RESEARCH-RELATED ACTIVITIES IN THIS SECTION. Only include details about your participants and how you will recruit them an obtain their consent. Research activities and data collection should be described in Section 3 Research Activities.*

a. RECRUITMENT

*This section should explain how you will get an individual’s attention, how a person will find out that there is a research study they might consider, how you will invite them to learn more. Do NOT include obtaining consent in this section; explain the consent process in Section 2.b Consent Process below.*

1) Number of participants

(a) Minimum and maximum number of participants

*State the approximate number of participants you plan to enroll. Give the lowest number that will allow data analysis and the maximum number that might agree to participate. If the research involves secondary analysis of existing data, give the estimated number of records that will be used. This section will probably be a sentence to a short paragraph in length.*

(b) Rationale

*Explain why you chose the number of participants stated above. If a power analysis was done, explain it here. This section will probably be a sentence to a short paragraph in length.*

2) Inclusion and exclusion criteria

*Explain criteria you will use to decide who is or is not eligible to participate in your study. For example, must participants be in a certain college course, or be employed in a certain occupation, or live in a certain neighborhood, or be a particular age, sex or ethnic group? Explain why you have selected these criteria. This section will probably be a sentence to a short paragraph in length.*

3) Vulnerable participants

*Some potential participants might be vulnerable to undue influence in the recruitment process, or might be legally unable to make their own choice regarding participation. Such “vulnerable” populations might include, but are not limited to,*

* *minors (under age 18)*
* *prisoners*
* *pregnant women (because the research might impact the fetus)*
* *cognitively impaired*
* *subordinates of the researcher (your own students or employees)*
* *limited educational status (because they might not be able to read the consent form)*
* *economically disadvantaged*
* *non-English speaking (because they might not understand what is being asked of them)*

*NOTE: for some (but not all) vulnerable groups the IRB must document that certain things were considered. Attach any appropriate, completed checklist(s) and list them in Section 6 Additional Documentation.*

* *Research involving CHILDREN:* [*http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Children.doc*](http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Children.doc)
* *Research involving participants who are COGNITIVELY IMPAIRED:* [*http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Cognitive%20Imp.doc*](http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Cognitive%20Imp.doc)
* *Research involving PRISONERS:* [*http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20-%20Prisoners%208-1-07.doc*](http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20-%20Prisoners%208-1-07.doc)
* *Research that targets PREGNANT WOMEN, FETUSES or NEWBORNS:* [*http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Pregnant-Fetus-Neonate.doc*](http://www.researchcompliance.uc.edu/irb/coi%20and%20checklists/CHECKLIST%20FOR%20PIs%20080107%20-%20Pregnant-Fetus-Neonate.doc)

*For more information about “vulnerable” participants, go to* [*www.researchcompliance.uc.edu/irb*](http://www.researchcompliance.uc.edu/irb)*, look under Regulations and Rules and click Regulatory Links, click Office of Human Research Protections, look under Special Issues and click the topic you want to select.*

(a) Vulnerability

*Identify any group(s) you will be recruiting for your research study who might be vulnerable to pressure or undue influence to get them to agree to be in your study (any group listed above or any other group you think might be vulnerable). This section will probably be a sentence to a short paragraph in length.*

(b) Rationale

*Explain why you need to recruit from this vulnerable population. Convenience is NOT a good reason. This section will probably be a paragraph or two in length.*

(c) Confirmation

*Explain how you will confirm that a young adult is or is not 18 years old, or that a person is or is not cognitively impaired or that he/she is or is not educationally limited. This section will probably be a sentence to a short paragraph in length.*

4) Risks and discomforts from participating

(a) Type and level of risk or discomfort

*Using the chart below, list any risks or discomforts participants may experience because of being in your study. Be sure to consider more than physical risks, such as emotional discomforts (such as embarrassment or frustration), legal risks (such as being sued or being arrested), social risks (such as being rejected by family or community), economic risk (such as being fired), etc. Add rows if necessary.*

*Also indicate the anticipated level of risk or discomfort (minimal, greater than minimal, or high) for each risk/discomfort listed. The federal definition for minimal risk is "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45CFR46.102).*

|  |  |
| --- | --- |
| Risk or Discomfort | Level |
|  |  |
|  |  |
|  |  |
|  |  |

*If a participant's vulnerable status will impact the kind or level of risk or discomfort, also include that information in this section.*

(b) Safety monitoring plan

*If any risk or discomfort is greater than minimal, federal regulations require that a safety monitoring plan be developed for the study to keep track of the kind and amount of adverse experiences that occur. Explain how you will monitor the safety of your research participants. This section will probably be a sentence to a short paragraph in length.*

(c) Reporting

(1) Notification of PI

*Explain how you will be made aware if a participant experiences a risk or discomfort because of being in your research. This section will probably be a sentence to a short paragraph in length.*

(2) Notification of IRB

*Explain how the IRB will be made aware if a participant experiences a risk or discomfort because of being in your research. This section will probably be a sentence to a short paragraph in length.*

(3) Other notification

*List any other entities that will need to be made aware if a participant experiences a risk or discomfort, and explain how they will be notified. This section will probably be a sentence to a short paragraph in length.*

(4) Available resources

*Explain the resources needed to respond to the risks or discomforts mentioned above, and how you will ensure that the resources are made available to participants who need them. For example, will a counselor be available on-site if a participant becomes upset while being interviewed? This section will probably be a sentence to a short paragraph in length.*

5) Direct benefits to the participant

*List any benefits an individual may experience because of participating in the research activities. (For example, will participants in your study receive extra tutoring or receive personalized fitness training?) If there is NO direct personal benefit to the participant, state it clearly. Much of the research reviewed by IRB-S has no direct personal benefit to the participant. This section will probably be a sentence to a short paragraph in length.*

*NOTE: Receiving a recruitment incentive or being paid for time and effort is NOT considered a personal benefit from the research activities themselves. Helping you complete your degree requirements is NOT a personal benefit for the participant.*

6) Recruitment activities

(a) Recruitment materials

*Recruitment must be done in language understandable to the participant or representative. ALL RECRUITMENT MATERIALS including scripts of announcements or phone recruitment and examples of flyers, posters, invitation letters, etc. MUST be reviewed by the IRB. Attach samples and list them here.*

List:

(b) Personnel

*Explain which research team member(s) will do the recruiting.*

*NOTE: if a person simply provides information and directs questions to the research, he/she is NOT considered key personnel (research team member). However, if the person acts "on behalf of the researcher" by answering questions and screening volunteers for eligibility, that person must be listed as key personnel on the RRSF and meet documentation and training requirements. This section will probably be a sentence to a short paragraph in length.*

(c) Recruitment activities

*Describe what will be done by the person(s) identified in (b) above using the materials identified in (a) above. “They will invite” is not detailed enough. Where and when will recruitment take place? (Examples: (i) the PI will post flyers in Dyer Hall, (ii) a research team member will read the recruitment script to the class at the end of the period, (iii) the instructor will send the recruitment email to class members via Blackboard.)*

*Be aware that some information is personal and should not be made public out of common courtesy, and some should be protected to avoid identity theft or out of other considerations (for example, if there is a sign-up sheet, personal information such as social security number or phone number should not be requested on it). This section will probably be a sentence to a short paragraph in length.*

(d) Participant response

*Explain how someone will let the appropriate person know that they are interested in participating in the research study. Be sure to take into account whether or not there is a need for privacy during the recruitment process to protect the reputation or safety of the potential participant (e.g., sexual orientation, HIV status, illegal activity, or violence research). This section will probably be a sentence to a short paragraph in length.*

b. CONSENT PROCESS

1) Presenting information to potential participants

* *Information that is given to participants and representatives must be in language that is understandable to them. If participants will not speak English, explain how the information will be presented in language understandable to them.*
* *Describe in detail how full information about your study will be explained to potential participants. For example, will the course instructor leave the room before the consent process begins? Will the consent explanation be done individually or will it be done to all students or focus group members at the same time? Will the ICD be sent to an interested person by email?*
* *Give enough detail that a research team member could read it and know what they should do.*

*This section will probably be a sentence to a short paragraph in length.*

*NOTE: there must be a compelling reason to justify not obtaining the participant's consent. If consent will not be obtained, clearly explain the rationale in this section, attach the Waiver of Consent Process form and list the waiver form in Section 6 Additional Documentation.*

[*http://www.researchcompliance.uc.edu/irb/Medical%20Forms/Consent\_Waiver\_and\_Alteration\_07-24-2006.pdf*](http://www.researchcompliance.uc.edu/irb/Medical%20Forms/Consent_Waiver_and_Alteration_07-24-2006.pdf)

2) Answering questions from potential participants

*Participants (or representatives) must have sufficient opportunity to consider whether or not to participate and have their questions answered. Explain how potential participants will obtain answers to their questions about the study. This is a particularly important issue if the consent presentation is not done in an individualized, face-to-face setting or if participants do not speak -English. This section will probably be a sentence to a short paragraph in length.*

3) Indicating consent

*Explain how participants will indicate their willingness to take part in your research. For example, is the participant asked to sign an ICD, or does submission of their completed questionnaire indicate their consent? This section will probably be a sentence to a short paragraph in length.*

*NOTE: in general, if signature on the ICD could be obtained, then it should be obtained. There must be a compelling reason to justify not obtaining the participant's signature. If consent signature will not be obtained, clearly explain the rationale in this section, attach the Waiver of Consent Signature form and list the waiver form in Section 6 Additional Documentation.*

[*http://www.researchcompliance.uc.edu/irb/Medical%20Forms/Consent\_Waiver\_of\_Documentation\_07-24-2006.pdf*](http://www.researchcompliance.uc.edu/irb/Medical%20Forms/Consent_Waiver_of_Documentation_07-24-2006.pdf)

4) Legally authorized representative (LAR) for minors or cognitively impaired participants

*If any of your participants will be unable to give legal consent for themselves (minors or cognitively impaired), explain the legally authorized representative (LAR) from whom you will obtain permission for the person’s participation (parent, guardian, etc.). This section will probably be a sentence to a short paragraph in length.*

5) Verification of LAR for cognitively impaired participants

*If your participants are cognitively impaired, explain how you will verify their LAR's guardianship before accepting the LAR’s permission (e.g., a durable power of attorney or court order). This section will probably be a sentence to a short paragraph in length.*

6) Avoiding coercion

*Explain what steps you have built into your consent process to make sure an individual does not feel any pressure or coercion to agree to participate. For example, some PI arrange for someone with no authority over the participants to handle recruitment and consenting; some arrange for signed ICDs be collected and held by someone else until after grades have been posted, so non-participation cannot affect grades; some have everyone hand in a consent document even if it is not signed so no one in the group knows who did or did not give consent. Just telling them they do not have to participate is not enough. This section will probably be a sentence to a short paragraph in length.*

7) Recruitment incentives

*Describe any gifts, coupons, extra credit, etc. that are offered to encourage individuals to agree to participate in your study, including the amount. (Do NOT include reimbursement for money participants had to pay (such as parking) or payment for time and effort (some dollar amount per hour) in this section; those payments should be explained in Section 3 Research Activities.)*

*Explain why you chose that incentive. Explain when the incentive will be given to the participant. (Usually an incentive is given at the beginning of participation, or else is pro-rated based on the amount of participation.) Recruitment incentives need to be appropriate for your participants, fairly distributed to all potential participants, and not coercive. This section will probably be a sentence to a short paragraph in length.*

*NOTE: lotteries or drawings for prizes are NOT permitted by the IRB-S.*

c. CONSENT DOCUMENTS (ICDs)

* *Attach a sample of each kind of ICD used in your study and list them here.*
* *Number the pages (page x of y) of each ICD and include the VERSION DATE (when you wrote or revised it).*
* *Write the ICD according to the consent templates posted on the IRB's website (*[*www.researchcompliance.uc.edu/irb*](http://www.researchcompliance.uc.edu/irb)*, Social/Behavioral Submission Packet, Informed Consent. If there is a compelling reason for not using the posted templates it must be explained in this section.*

List:

**3. RESEARCH-RELATED ACTIVITY:**

*THIS WILL BE THE MAIN PORTION OF YOUR SUBMISSION. Be very clear and detailed. If someone had to help you with your study, they should be able to use this section to know what to do. SUGGESTION: have a friend or family member who does not know anything about what you are doing read this section. If he/she gets confused, you need to refine your explanation.*

a. SECONDARY ANALYSIS of an EXISTING DATASET

* *The entire dataset must already be in existence before you submit your proposal to the IRB for it to be considered “existing data”. If the data are in the process of being collected and will be given to you after IRB approval, describe your research under Section 3.c below.*
* *See the list of individual identifiers in Section 3.c below when writing this section.*

*NOTE: ANONYMOUS means no one (not even you) knows which data are from which participant. CONFIDENTIAL means you will not reveal the participant’s identity or which data are his/hers.*

1) Person or entity that holds the dataset

*This section will probably be a sentence to a short paragraph in length.*

2) General description of the data, including when and how the data were obtained

*This section will probably be a sentence to a short paragraph in length.*

3) List of the fields (or description of the kinds of information) that will be used from the dataset, with specific mention of any individually identifying data

*This section will probably be a sentence, short paragraph or single list in length.*

4) Explanation why individually identifying data are needed for your study, how confidentiality of individually identifiable data will be assured, and how soon identifiers will be purged from the dataset

*This section will probably be a sentence to a short paragraph in length.*

5) Explanation of how the dataset (or portion of the dataset) will be obtained from the current holder

*This section will probably be a sentence to a short paragraph in length.*

b. REVIEW OF RECORDS that were collected for NON-RESEARCH PURPOSES

* *"Non-research purposes" includes class assignments, quiz scores, medical records, etc.*
* *See the list of individual identifiers in Section 3.c below when writing this section.*
* *If you need a waiver of HIPAA authorization (for medical information) or if you need to consider FERPA protections (for educational information), include that explanation in this section.*

*NOTE: ANONYMOUS means no one (not even you) knows which data are from which participant. CONFIDENTIAL means you will not reveal the participant’s identity or which data are his/hers.*

1) Person or entity that holds the records

*This section will probably be a sentence to a short paragraph in length.*

2) General description of the kind of records, including when and how the records were obtained

*This section will probably be a sentence to a short paragraph in length.*

3) Specific description of the information (i.e., data fields) that will be used from the records, with specific mention of any individually identifying information

*This section will probably be a sentence, short paragraph or single list in length.*

4) Explanation why individually identifying information is needed for your study, and how soon identifiers will be purged from the research records

*This section will probably be a sentence to a short paragraph in length.*

5) Explanation of how the records (or excerpts from the records) will be obtained from the current holder

*This section will probably be a sentence to a short paragraph in length.*

c. RESEARCH ACTIVITIES

1) Privacy of participation

*Sensitive research topics or unequal power dynamics might cause risk to a participant simply by being in (or refusing to be in) a study. Minimal risk research of non-sensitive topics might not need to hide an individual’s participation. Explain whether or not it will be necessary to keep the fact of an individual's participation private. If needed, explain how privacy of participation will be protected. For example, will appointment times and room location be arranged so individuals do not see each other when coming or going? Or will participants be able to select a location for their interview where they can control the privacy? This section will probably be a sentence to a short paragraph in length.*

*Do NOT include confidentiality of research data in this section; explain data confidentiality in the next section below.*

2) Confidentiality of data

*In most cases, the identity of the participant who provided specific research data should be kept confidential (for example, questionnaires might show a study ID number instead of a name and the master list of names and ID numbers will be stored separately from the completed surveys). Sensitive research topics or unequal power dynamics might cause risk to a participant if it becomes known which responses or test results were theirs. Additionally, some research data is personal and should not be made public out of common courtesy, and some should be protected to avoid identity theft or out of other considerations. On the other hand, in some situations a participant might want his/her identity to be revealed and linked to his/her response.*

* *If you need to collect identifiable data or audio or video recordings, explain why this is necessary in light of the purpose of your study. (See the list of identifiers below.)*
* *Explain how confidentiality will be protected. If confidentiality will NOT be protected, explain why not. If data are collected by electronic means such as email or internet, provide information about how the data are secure (protected from hackers).*
* *Explain how long you will keep identifiers with the data or how soon identifiers will be deleted (e.g., after the data have been entered into a spreadsheet or database, or after the final set of follow-up questionnaires has been obtained, or after the findings have been written, etc.).*

*This section will probably be a paragraph or two in length.*

*NOTE: ANONYMOUS means no one (not even you) knows which data are from which participant. CONFIDENTIAL means you will not reveal the participant’s identity or which data are his/hers.*

*IDENTIFIERS*

*1. Names*

*2. Geographic subdivisions smaller than state, including street address, county, precinct, ZIP code, equivalent geocodes*

*3. All elements of dates (except year) related to the individual*

*4. Telephone numbers*

*5. Fax numbers*

*6. Electronic mail addresses*

*7. Social Security numbers*

*8. Medical record numbers*

*9. Health plan beneficiary numbers*

*10. Account numbers*

*11. Certificate/license numbers*

*12. Vehicle identifiers and serial numbers (includes license plate)*

*13. Device identifiers and serial numbers*

*14. Web Universal Locaters (URL’s)*

*15. Internet Protocol (IP) address numbers*

*16. Biometric identifiers, including finger and voiceprints*

*17. Full-face photographic image and any comparable images; and*

*18. Any other unique identifying number, characteristic, or code*

3) Research-related activities

*THIS SECTION IS THE “MEAT” OF MOST RESEARCH PROPOSALS.*

(a) Participant cohorts

*If there are two or more cohorts of participants, describe how individuals are assigned to the different groups. This section will probably be a sentence to a short paragraph in length.*

(b) Activities and duration

* *Explain what participants will do in your project, one step at a time.*
	+ *Explain in detail the types of data being collected (such as personal opinions, test grades, task performance, etc.) and the methods being used (such as survey, focus group, computer monitoring, etc.).* *Be very clear and detailed.*
	+ *Identify what participants will do in any phases or stages to your study (e.g., pre-test/post-test, or pilot/main data collection, etc.)*
	+ *Explain whether or not all participants have to take part in every activity. For example, if an individual does not want to be audio-taped or video-taped, can they still participate?*
	+ *Explain what will be done with the data already collected from an individual who quits part-way through the study.*
	+ *Also explain how long it will take a participant to do each activity.*
* *Explain any alternative activities that are offered for non-participants (such as reading silently instead of completing a survey, etc.). In many cases the alternative is simply not to participate.*
* *The duration of any phases or stages of your study and your research team activities were described in Section 1 Purpose and General Information above. They do NOT need to be repeated here.*
* *Recruitment and consenting activities were explained in Section 2 Participants above. Do NOT repeat them here.*
* *Explain the difference between activities done by any different groups or cohorts of participants (such as control versus intervention groups).*
* *Clearly identify any non-research activities that are required, for which consent will be sought to use the activities for research purposes also. For example, perhaps all students are required to do all homework assignments and a class presentation, but grades from the homework and presentation will be used as research data after quarter grades are posted only from students who gave written consent.*
* *Be consistent with the names you use for your data collection tools. If something is called a survey in one place, do not call it a questionnaire later. If a questionnaire is administered orally, do not call it a questionnaire in one place and an interview later. Be sure to use the same names in this section and on the list in Data collection tools below.*
* *Be consistent with the names you use for your consent documents. Refer to the IRB's website for correct names of the various kinds of consent documents. Be sure to use the same names in this section and on the list of consents in Section 2.b above.*

*This section may be a paragraph to many pages in length, depending on the complexity of the study design.*

(c) Data collection tools

* *Attach a sample of each spreadsheet, questionnaire, interview guide, observation guide or other data collection tool mentioned above. This helps the IRB-S to confirm the completeness of your described research activities. Be sure to clearly label each item with the title used for it in your description of research activities above.*
* *It is OK to photocopy copyrighted materials for this purpose because they will never be used for data collection by the IRB-S. If you submit original copyrighted data collection tools, however, and would like to have them back after review is complete, please include that request with your materials.*
* *List the attached tools in this section. Citations for copyrighted data collection tools may be included here also.*

List:

(d) Payments to participants: reimbursement of expenses or payment for time and effort

*Describe any payments your participants will receive for their participation in your study (such as reimbursement for parking or other expenses, or payment for their time and effort, etc.). Explain why you chose that amount and method of payment. Explain when payment will be given to the participant. Payment must be appropriate for your participants, fair to all participants, and not coercive. This section will probably be a sentence to a short paragraph in length.*

**4. DATA ANALYSIS:**

* *Describe the data analysis method you will use. Explain why you selected this method.*
* *Mention how you will report your findings (e.g. in aggregate form, or individually but with only a study ID number, etc.).*

*This section will probably be a sentence to a short paragraph in length.*

**5. REFERENCES:**

*List references that were mentioned in Section 1.b Background. If there are many references, select the primary ones so the list of references is no more than one page long.*

List:

**6. ADDITIONAL DOCUMENTATION:**

* *Attach any other documentation that may assist IRB reviewers or may be required for your research, and list the items here (e.g., IRB approval notification from another IRB, or a site support letter, or a special form from the dataset holder that the IRB Chair must sign, etc.). Be sure each item is mentioned in the appropriate part of Section 1, 2, 3 or 4 above so the reviewers understand why it has been provided.*
* *Clearly label each attachment. Use the same name for the attachments in the protocol as on the attachment itself.*
* *Number the pages of each attachment separately (page x of y), with their version dates.*
* *Many research submissions have no additional documents.*

List: