

**INSTITUTIONAL REVIEW BOARD for RESEARCH**

**RESEARCH PROTOCOL REVIEW FORM**

For information or help completing this form, contact: THE OFFICE OF HUMAN SUBJECTS RESEARCH (OHSR), e-mail: [humansubjects@Faulkner.edu](mailto:humansubjects@Faulkner.edu) Web Address: <http://www.Faulkner.edu/research/>



*For OHSR Office Use Only*

DATE RECEIVED IN OHSR: \_\_\_\_\_ by \_\_\_\_\_

PROTOCOL # ASSIGNED: \_\_\_\_\_

DATE OF OHSR CONTENT REVIEW: \_\_\_\_\_ by \_\_\_\_\_

DATE ASSIGNED IRB REVIEW: \_\_\_\_\_ by \_\_\_\_\_

DATE OF IRB REVIEW: \_\_\_\_\_ by \_\_\_\_\_

DATE OF IRB APPROVAL: \_\_\_\_\_ by \_\_\_\_\_

DATE OF REVIEW BY DEAN: \_\_\_\_\_ by \_\_\_\_\_

DATE OF REVIEW BY ACADEMIC VP: \_\_\_\_\_ by \_\_\_\_\_

**RESEARCH PROTOCOL REVIEW FORM CHECKLIST**

GENERAL INSTRUCTIONS:

Research protocols must be typed and submitted according to the approved format. The forms are available from the Office of Human Subjects Research (OHSR) or from the [OHSR web pages](#). The forms are designed to be using a personal computer. The forms and all supporting materials must be submitted in the appropriate number of copies. Information should be provided in a concise and succinct language accessible to a layperson. All items must receive a response. All questionnaires and surveys to be used in the project must be attached, as must all informed consent documents. In cases where it is appropriate to waive formal consent, an Information Letter, dated and signed by the investigator, should be included.

For research subject to full review and approval, the investigator should submit an original and copies for each IRB member. For an Exempt review, only the original protocol must be submitted. The investigator is urged to contact the OHSR for assistance in determining the most likely type of review required. All protocols submitted for full review must be received by the last business day or the month prior to the IRB meeting at which the protocol will be reviewed. The IRB currently meets on the second Wednesday of each month.

All protocols must include the following items:

- \_\_\_ 1. Research Protocol Review Form (All signatures included and all sections completed)
- \_\_\_ 2. Consent Form or Information Letter (examples are found on the OHSR website)
- \_\_\_ 3. Appendix A "Reference List"
- \_\_\_ 4. Appendix B if flyers, advertisements, generalized announcements or scripts are used to recruit participants.
- \_\_\_ 5. Appendix C if data collection sheets, surveys, tests, or other recording instruments will be used for data collection. Be sure to mark each of the data collection instruments as they are identified in section # 13, part c.
- \_\_\_ 6. Appendix D if a debriefing form will be used.
- \_\_\_ 7. If research is being conducted at sites other than Faulkner University or in cooperation with other entities, a letter from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of IRB approval from each entity is required prior to initiating the project.
- \_\_\_ 8. Written evidence of acceptance by the host country if research is conducted outside the United States.

Abbreviated Project Title: \_\_\_\_\_

**RESEARCH PROTOCOL REVIEW FORM**

1. PROJECT TITLE: \_\_\_\_\_

2. REVIEW TYPE<sup>a</sup>:     Full Board     Expedited     Exempt

3. PROPOSED DATES OF STUDY: From: \_\_\_\_\_ To: \_\_\_\_\_

4. PRINCIPAL INVESTIGATOR: \_\_\_\_\_

POSITION/TITLE: \_\_\_\_\_

DEPARTMENT: \_\_\_\_\_

PHONE: \_\_\_\_\_ FAX: \_\_\_\_\_ E-MAIL: \_\_\_\_\_

ADDRESS FOR CORRESPONDENCE: \_\_\_\_\_

5. FUNDING SUPPORT:

A. FUNDING SOURCE:     Not Applicable/Required     Internal     External (External Agency)

B. FUNDING STATUS:     Not Applicable     Approved     Pending     Received

6. GENERAL RESEARCH PROJECT CHARACTERISTICS<sup>b</sup>

A. Research Content Area:

1. Please check all descriptors that best apply to this proposed research project.

- |  |  |
|--|--|
| <input type="checkbox"/> Anthropology              | <input type="checkbox"/> History               |
| <input type="checkbox"/> Anthropometry             | <input type="checkbox"/> Journalism            |
| <input type="checkbox"/> Biological Sciences       | <input type="checkbox"/> Medical Physiology    |
| <input type="checkbox"/> Behavioral Sciences       | <input type="checkbox"/> Physical Sciences     |
| <input type="checkbox"/> Chemical Sciences         | <input type="checkbox"/> Political Science/Law |
| <input type="checkbox"/> Counseling/Family Science | <input type="checkbox"/> Psychology            |
| <input type="checkbox"/> Education                 | <input type="checkbox"/> Sociology             |
| <input type="checkbox"/> English                   | <input type="checkbox"/> Other (Please list:)  |

2. Please list 3 or 4 keywords to identify this research project: \_\_\_\_\_

B. Research Methodology: Please check all descriptors that best apply to the research methodology.

1. Data collection will be:     Prospective     Retrospective     Both

2. Data will be recorded so that participants can be directly or indirectly identified:     Yes     No

3. Data collection will involve the use of:

- |   |   |
|---|---|
| <input type="checkbox"/> Educational Tests (cognitive, diagnostic, aptitude, achievement) | <input type="checkbox"/> Interview/Observation                            |
| <input type="checkbox"/> Surveys/Questionnaires   | <input type="checkbox"/> Audiotaping and/or Videotaping                   |
| <input type="checkbox"/> Private Records/Files  | <input type="checkbox"/> Physical / Physiologic Measurements or Specimens |
| <input type="checkbox"/> Historical/Archival Records                                      |   |

Abbreviated Project Title: \_\_\_\_\_

C. Participant Information: Please check all descriptors that apply to the participant population.

1. Gender:  Males  Females

2. Vulnerable Populations

Adolescents

Mentally Challenged

Children

Physically Challenged

Economically Challenged

Pregnant Women

Elderly

Prisoners

3. Do you plan to recruit Faulkner University Students?  Yes  No

4. Do you plan to compensate your participants?  Yes  No

D. Risks to Participants

Please identify all risks that may reasonably be expected as a result of participating in this research.

Breach of Confidentiality

Psychological

Coercion

Social

Deception

None

Physical

Other (please list) \_\_\_\_\_

Abbreviated Project Title: \_\_\_\_\_

7. PROJECT ASSURANCES<sup>c</sup>

PROJECT TITLE: \_\_\_\_\_

A. PRINCIPAL INVESTIGATOR'S ASSURANCE

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Faulkner University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Faulkner University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Faulkner policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
  - a. Conducting the project by qualified personnel according to the approved protocol
  - b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Human Subjects Research (except in an emergency, if necessary to safeguard the well-being of human subjects)
  - c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
  - d. Promptly reporting significant adverse events and/or effects to the Office of Human Subjects Research in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise OHSR, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Faulkner University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Human Subjects Research before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Faulkner University IRB.
8. I will prepare and submit a final report upon completion of this research project.

Principal Investigator (Please Print): \_\_\_\_\_

Principal Investigator's: \_\_\_\_\_ Date: \_\_\_\_\_

Signature

B. FACULTY SPONSOR'S ASSURANCE

1. By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
2. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
3. I agree to meet with the investigator on a regular basis to monitor study progress.
4. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
5. I assure that the investigator will promptly report significant adverse events and/or effects to the OHSR in writing within 5 working days of the occurrence.
6. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the OHSR by letter of such arrangements.
7. I have read the protocol submitted for this project for content, clarity, and methodology.

Faculty Sponsor (Please Print): \_\_\_\_\_

Faculty Sponsor's: \_\_\_\_\_ Date: \_\_\_\_\_

Signature

C. DEPARTMENT HEAD'S ASSURANCE

By my signature as department head, I certify that every member of my department involved with the conduct of this research project will abide by all Faulkner University policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants.

Department Head (Please Print): \_\_\_\_\_

Department Head's: \_\_\_\_\_ Date: \_\_\_\_\_

Signature

Abbreviated Project Title: \_\_\_\_\_

8. PROJECT ABSTRACT<sup>d</sup>: Prepare an abstract (400-word maximum) that includes: I.) A summary of relevant research findings leading to this research proposal; II.) A concise purpose statement; III.) A brief description of the methodology; IV.) Expected and/or possible outcomes, and V.) A statement regarding the potential significance of this research project. Please cite relevant sources and include a "Reference List" as Appendix A.

9. PURPOSE & SIGNIFICANCE<sup>e</sup>.

A. Clearly state all of the objectives, goals, or aims of this project.

B. How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)

10. KEY PERSONNEL INVOLVED WITH DATA COLLECTION<sup>f</sup>. Identify each individual involved with the conduct of this project and describe his or her roles and responsibilities related to this project. Be as specific as possible. (Copy format as needed to list all key personnel)

Individual: \_\_\_\_\_

Title: \_\_\_\_\_ Department/Affiliation: \_\_\_\_\_

Roles / Responsibilities: \_\_\_\_\_

Individual: \_\_\_\_\_

Title: \_\_\_\_\_ Department/Affiliation: \_\_\_\_\_

Roles / Responsibilities: \_\_\_\_\_

11. LOCATION OF RESEARCH<sup>g</sup>. List all locations where data collection will take place. Be as specific as possible. \_\_\_\_\_

12. PARTICIPANTS<sup>h</sup>

A. Describe the participant population you have chosen for this project.<sup>i</sup> \_\_\_\_\_

\_\_\_\_\_

What is the minimum number of participants you need to validate the study? \_\_\_\_\_

What is the maximum number of participants you will include in the study? \_\_\_\_\_

Abbreviated Project Title: \_\_\_\_\_

- B. Describe the criteria established for participant selection.<sup>j</sup> (If the participants can be classified as a “vulnerable” population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals.)

\_\_\_\_\_  
\_\_\_\_\_

- C. Describe all procedures you will use to recruit participants.<sup>k</sup> Please include a copy of all flyers, advertisements, and scripts and label as Appendix B.

\_\_\_\_\_  
\_\_\_\_\_

What is the maximum number of potential participants you plan to recruit? \_\_\_\_\_

- D. Describe how you will determine group assignments<sup>l</sup> (e.g., random assignment, independent characteristics, etc.).

\_\_\_\_\_  
\_\_\_\_\_

- E. Describe the type and amount and method of compensation for participants.<sup>m</sup>

\_\_\_\_\_  
\_\_\_\_\_

13. PROJECT DESIGN & METHODS.<sup>n</sup> Describe the procedures you will plan to use in order to address the aims of this study. (NOTE: Use language that would be understandable to a layperson. Without a complete description of all procedures, the Faulkner University IRB will not be able to review protocol.)

- A. Project overview. (Briefly describe the scientific design.)

\_\_\_\_\_  
\_\_\_\_\_

- B. Describe all procedures and methods used to address the purpose.

\_\_\_\_\_  
\_\_\_\_\_

- C. List all instruments used in data collection.<sup>o</sup> (e.g., surveys, questionnaires, educational tests, data collection sheets, outline of interviews, scripts, audio and/or video methods etc.) Please include a copy of all data collection instruments that will be used in this project and label as Appendix C.

\_\_\_\_\_  
\_\_\_\_\_

Abbreviated Project Title: \_\_\_\_\_

D. Data Analysis<sup>p</sup>: Explain how the data will be analyzed.

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14. RISKS & DISCOMFORTS<sup>q</sup>: List and describe all of the reasonable risks that participants might encounter if they decide to participate in this research. If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use and label as Appendix D.

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15. PRECAUTIONS.<sup>r</sup> Describe all precautions you have taken to eliminate or reduce risks that were listed in #14.

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16. BENEFITS.<sup>s</sup>

A. List all realistic benefits participants can expect by participating in this study.

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B. List all realistic benefits for the general population that may be generated from this study.

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17. PROTECTION OF DATA.<sup>t</sup>

A. Will data be collected as anonymous? \_\_\_ Yes \_\_\_ No If "YES", go to part "g".

B. Will data be collected as confidential? \_\_\_ Yes \_\_\_ No

C. If data is collected as confidential, how will the participants' data be coded or linked to identifying information?

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D. Justify your need to code participants' data or link the data with identifying information.

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Abbreviated Project Title: \_\_\_\_\_

E. Where will code lists be stored?

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F. Will data collected as "confidential" be recorded and analyzed as "anonymous"? \_\_\_ Yes \_\_\_ No

G. Describe how the data will be stored (e.g., hard copy, audio cassette, electronic data, etc.), where the data will be stored, and how the location where data is stored will be secured in your absence.

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H. Who will have access to participants' data?

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I. When is the latest date that the data will be retained?

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J. How will the data be destroyed? (NOTE: Data recorded and analyzed as "anonymous" may be retained indefinitely.)

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## **Definitions and Instructions for Submissions**

### **Exempt Projects**

For purposes of definition, "Exempt" means only that the proposed project does not require review by a member of the Board or by the full IRB. **However, faculty members who are anticipating the need for University resources and/or release time must apply for Level 2 review by the University IRB, as explained in the Faulkner University Institutional Review Board for Research Policy.**

Faculty may request approval of their research under IRB Exempt guidelines; however, only research filed with and approved by the IRB or under IRB procedure will be sanctioned by Faulkner University. Research involving human subjects not approved by the IRB or under IRB procedures may be challenged if used as part of a student's undergraduate coursework or graduate thesis or dissertation. Faculty may be subject to disciplinary action for non-compliance with the University's policy regarding research with human subjects.

Certain categories of research have been designated by DHHS as exempt from review (see 45 CFR 46.101). Exempt procedures apply only to those research activities eligible for such review under specific parts of the regulations, unless the research is covered by other subparts of the regulations. If the protocol is approved as "Exempt," the investigator will be notified, in writing. If the Exempt status is not approved, the investigator will be notified that the activity requires clarifications, revisions, or additional copies before review by the full IRB.

*Note: The Exempt Review process generally is not appropriate for research involving "vulnerable" or "special" subject populations.*

### **Instructions for Submitting an Exempt Protocol – Level 1 Review:**

- **Deadline:** Materials to be reviewed for Level 1 Review must be received by the Chair of the IRB Committee by 5:00 p.m. (CST) on the first business day of any month. Protocols will be reviewed in order according to the day and hour of receipt in the OHSR. Materials will be with the reviewers a minimum of seven (7) days, but may be retained longer for a final determination and return to the researcher.
- Documents must be typewritten and materials stapled into one set with original signatures in the following order:
  - Investigator's Request for IRB Exemption
  - Protocol for the Use of Human Subjects in Research
  - Informed Consent Form(s) or Information Letter
  - Attachments (Samples of tests, task outlines, authorizations, etc.)

### **At Risk and Minimum Risk Projects**

At Risk projects are those projects where the proposed activities pose a reasonable possibility of physical, psychological or social risk to subjects which exceeds the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals.

Minimum Risk projects are those projects where the probability and magnitude of harm is that normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals.

**Instructions for Submitting an At Risk and Minimum Risk Project and/or those Projects in which University Resources / Release Time are Requested – Level 2 Review:**

- Deadline: Deadline: Materials to be reviewed under Level 2 Review must be received by the Chair of the IRB Committee by 5:00 p.m. on the first business day of any month. Protocols will be reviewed in order according to the day and hour of receipt in the OHSR. Materials will be with the reviewers a minimum of seven (7) days, but may be retained longer for a final determination and return to the researcher.
  
- Documents must be typewritten and materials stapled into seven (7) complete sets, with each set containing the following order of documents:
  - Protocol for the Use of Human Subjects in Research
  - Informed Consent Form(s) or Information Letter
  - Attachments (Samples of tests, task outlines, authorizations, etc.)

**The Principal Investigator**

The Principal Investigator designs the research study,

- writes the protocol,
- submits the protocol to the IRB, and
- complies with IRB decisions and stipulations.

The Principal Investigator also

- is responsible for the conduct of the protocol, including rigorous adherence to sound scientific and ethical principles,
- submits all required information/forms to the IRB for continuing review, and
- reports promptly to the IRB any unanticipated events involving risk(s) to participants or others, or serious harm to participants.

Finally, the Principal Investigator

- submits to the IRB proposed amendments to previously proposed research,
- complies with all requirements of the Food and Drug Administration when using investigational drugs, biologics or other regulated test articles, and
- reports to the IRB any serious and/or continuing non-compliance with 45 CFR 46 or the determination of the IRB

**Institutional Review Board**

The primary responsibilities of the IRB are to:

- protect human subjects who participate in research which Faulkner faculty, staff, and students direct, supervise, or conduct,
- aid investigators in meeting the requirements of federal and state agencies as they relate to the use of human subjects in research projects, and
- determine that adequate provisions for the protection of human subjects are provided and that legally effective, informed consent will be obtained in a manner and method which meets the requirements of 45 CFR 46.116 and 46.117, and in the case of special or vulnerable populations, the appropriate section of 45 CFR 46.

The IRB will:

- review all research involving human subjects, and all other activities which even in part involve such research if the research is sponsored by Faulkner University, or the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects,
- non-public information to identify or contact human research subjects or prospective subjects,
- report to the institutional officials and the Office for Human Research Protections any serious or continuing noncompliance by investigators for IRB requirements and any suspension or termination of an investigator's IRB approval, and

Abbreviated Project Title: \_\_\_\_\_

- report promptly to institutional officials any information received concerning injuries to human subjects, unanticipated problems involving risks to subjects or others as well as changes in research activities which are reviewed and approved by the IRB.

<sup>a</sup> All proposed research involving human subjects must be reviewed by the IRB in one of 3 categories: "EXEMPT" from DHHS policy, "EXPEDITED", or requiring a "FULL BOARD REVIEW".

Investigators should not make an independent determination about whether or not their research is technically exempt from DHHS policy; however, investigators may request a review category. [Refer to the Department of Health & Human Service's definitions for research that is "EXEMPT" from DHHS policies (45 CFR 46 101.b) and research that may be reviewed as "EXPEDITED" (45 CFR 46 110).]

Research that may be technically "EXEMPT" from DHHS policy should still be reviewed by at least one member of the IRB. Any research that does not meet exempt status as outlined by the DHHS must be reviewed in the expedited category or by the full IRB prior to initiating the project.

For questions, e-mail Dr. Marci Johns at [mjohns@faulkner.edu](mailto:mjohns@faulkner.edu) and /or Dr. Joel Farrell at [jfarrell@faulkner.edu](mailto:jfarrell@faulkner.edu).

<sup>b</sup> Please complete each of the sections (A,B,C & D) as accurately as possible. Information in this section helps the OHSR and IRB to provide for an appropriate review of this protocol. For example, information from this section will help the OHSR and IRB to review this packet for completeness, determine the appropriate review category and to assign appropriate primary and secondary reviewers.

<sup>c</sup> Be sure to read each of the assurances listed prior to signing this form. The assurances provide for the legal and ethical conduct of research involving the use of human subjects. Please Note: All signatures are required before your protocol can be assigned for review.

<sup>d</sup> Your abstract should include a concise summary of your intended research. Briefly explain the background of this project so that we will understand why it is important to perform this research project. Next, include information on the purpose, the participant group, methods and procedures, expected outcomes and the potential impact of the project. The IRB committee will be reviewing this section with these key questions in mind:

Are there adequate preliminary data to justify the proposed research?

How do you intend to address your research aims?

How will the results contribute to the existing knowledge?

<sup>e</sup> Provide a brief statement of the purpose of the research project. Where appropriate, the statement should include the hypothesis to be tested. Also provide a brief statement regarding how the study results will be disseminated. Information provided in this section will help the IRB to determine why the research is being conducted and the investigator's research intent. The IRB committee will be reviewing this section with these key questions in mind:

Are the aims clearly specified?

What will be learned from the proposed study?

What do the researchers plan to do with the study results after the data has been collected and analyzed?

<sup>f</sup> Describe all of the research activities that will be assigned to each member of your research team (e.g., participant recruitment, conducting the informed consent process, data collection, data analysis, etc.). The IRB committee will be reviewing this section with these key questions in mind:

Are the individuals performing the procedures appropriately trained?

Are the roles and responsibilities assigned to each investigator appropriate for completing the research project?

<sup>g</sup> Include all locations where data will be collected and analyzed. If specific sites cannot be identified or are not presently known, please provide a general description of the types of locations or facilities that may be used to complete the data collection and analysis.

<sup>h</sup> Include a complete description of the population targeted for inclusion in this project. The IRB committee will be reviewing this section with these key questions in mind:

Who will be recruited for participation in the proposed study?

Is the choice of participants appropriate for the questions being asked?

Will the results of this study benefit the population you intend to include as participants?

<sup>i</sup> Investigators should have strong rationale for the sample size they have chosen. For example, investigators of experimental studies should have power calculations to support the proposed sample size.

The issue of sample size in experimental research is critical for determining the risk versus benefits of conducting the study. For example, a study may be otherwise well designed; yet, lack the power to detect significance, if indeed, significance were to

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exist. In this situation, the risk of participation may likely outweigh the proposed benefits simply because benefits that may indeed exist cannot be determined by studying such a small cohort.

Qualitative researchers may not be as concerned with sample size issues. In the case of qualitative research where sample size is not a concern, please provide the minimum number of participants you need in order to adequately address the research questions.

Also, please identify the maximum number of participants that you will include in the data collection process, given the time and resources devoted to this project.

<sup>j</sup> Please detail all of the inclusion and exclusion criteria. The IRB committee will be reviewing this section with these key questions in mind:

Are the inclusion and exclusion criteria clearly specified and appropriate?

If women, minorities, or children are included or excluded, is this justified?

Is participant selection equitable? In other words, will the participants, who bear the burden of the research risk, share in the generalizable benefits generated from the study?

Can the generalizable benefits be extrapolated to other groups? If so, why aren't participants from other groups included in the study?

<sup>k</sup> The IRB committee will be reviewing this section with these key questions in mind:

Are the methods for recruiting potential subjects well defined?

Are the location and timing of the recruitment process acceptable?

Is the individual performing the recruiting appropriate for the process?

Are all recruitment materials submitted and appropriate?

Are there acceptable measures for screening potential participants before recruitment?

<sup>l</sup> The IRB committee will be reviewing this section with this key question in mind:

Is the group assignment procedure clearly defined and appropriate for answering the research question(s)?

Is the group assignment procedure equitable for all participants?

The IRB recognizes that for some research projects participants are not assigned to groups. In these instances please state that participants will not be assigned to different groups.

<sup>m</sup> Compensation is different from a benefit. Compensation is some form of payment for time and effort and is not something unique to participating in the study. A benefit is something unique that can be derived from participating in a study.

The IRB committee will be reviewing this section with these key questions in mind:

Is the amount and type of compensation or reimbursement reasonable for the population?

Are there adequate provisions to avoid out-of-pocket expenses by the research participants, or is there sufficient justification to allow participants to pay?

If children or adolescents are involved, who receives the compensation and is this appropriate?

<sup>n</sup> Use a level of detail that would be similar to what would be used when submitting an article for publication in a peer-reviewed journal. Please define terms and explain concepts that might be confusing to reviewers who are not experts in this area. The IRB committee will be reviewing this section with these key questions in mind:

Are the details and rationale of the research procedures accurately described and acceptable?

Do the procedures and methodology specifically address the aims of the proposed research?

Are there any alternative methods for obtaining the research information that may pose less risk to the participants than the proposed procedures?

Are there alternative methods by which participants could obtain benefits similar to those received by participating in this research? If so, how will the participants be made aware of the alternative procedures?

<sup>o</sup> The IRB committee will be reviewing this section with these key questions in mind:

Are all instruments used in the data collection process included in the review packet?

Are all instruments used in the data collection process complete?

Are all instruments used in the data collection process appropriate for addressing the purpose of the proposed research?

<sup>p</sup> The IRB committee will be reviewing this section with this key question in mind:

Are the plans for data and statistical analysis defined and justified?

<sup>q</sup> The IRB committee will be reviewing this section with these key questions in mind:

Are the risks and discomforts adequately identified, evaluated and described?

If applicable, what are the unique risks that may be incurred by vulnerable populations?

Are the potential risks and discomforts minimized?

Is there adequate justification for the use of deception if this technique is part of the research protocol?

Abbreviated Project Title: \_\_\_\_\_

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<sup>r</sup> The IRB committee will be reviewing this section with these key questions in mind:  
Are the precautions to prevent or minimize risks and discomforts adequately identified and described?  
Are the precautions adequate for preventing or minimizing the risks and discomforts?  
Are there any other reasonable precautions that the researchers should employ to assure the safety of participants and maximize the risk / benefit ratio?

<sup>s</sup> Remember, compensation is not necessarily a benefit!

The IRB committee will be reviewing this section with these key questions in mind:

Are the benefits adequately identified, evaluated and described?

If applicable, what are the unique benefits that vulnerable populations may receive by participating in this research?

Do the potential benefits "outweigh" the potential risks and discomforts?

Do all participants receive the same benefits? For example, if the study requires the use of a control group, will participants assigned to the control group receive the same benefit as the treatment group?

<sup>t</sup> The IRB committee will be reviewing this section with these key questions in mind:

Are there adequate provisions to protect the privacy and assure the confidentiality of the research participants?

Are there adequate plans to store and code data?

Is the use of identifiers or links to identifiers necessary, and how is this information protected?