**IRB Application from Checkbox (12-2017)**

Every researcher must complete this entire application form and a complete submission

must include all relevant attachments (see attachment list). Signature of the PI and faculty

advisors (for student researchers) are required in two locations: request for approval of

human participant research and PI assurance form. Incomplete applications will be returned.

REQUEST FOR APPROVAL OF HUMAN PARTICIPANT RESEARCH The IRB protocol

is the formal design of plan for the proposed experiment or research activity. A protocol

is a document that describes the parameters of a research experiment in detail. The protocol

includes a description of the research design or methodology to be employed, the eligibility

requirements for prospective subjects and controls, the treatment regimen(s), and the proposed

methods of analysis that will be performed on the collected data. The information provided

must be descriptive enough to facilitate the understanding of a review without leaving

too many unanswered questions. However please be as brief as possible.

Name

Phone

Email

Project Title

Date Planned to Begin Research (anticipated)

Date the Collection of Data is to End (anticipated)

Principal Investigator (s)

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| |  | | --- | | \*Status: | | |  | | --- | | Rivier Faculty/Staff | | Rivier Doctoral Student | | Rivier Graduate Student | | Rivier Undergraduate Student | | Student (Non-Rivier) | | Researcher (Non-Rivier) | | Other | | |

Department:

Faculty Advisor (if student researcher):

Faculty Advisor Email (if student researcher):

Anticipate funding source (Specify Funding. If grant funded provide the following: Source and Grant #):

Type of Project:

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| --- |
| Faculty research |
| Faculty supervised student research |
| Non-Rivier affiliated research |
| Research proposing to use Rivier participants that has been approved by another IRB (include a copy of IRB letter of approval from other institution as attachment in the next item)  If Research has been approved by another IRB please upload letter of approval.  Summary: Briefly summarize (approximately 1-2 pages) the purpose of the research and planned use of human participants in terms understandable to a lay person.  PARTICIPANTS: a) How many participants will be involved in this research?  PARTICIPANTS: b) List specific eligibility requirements for participants (or describe screening procedures) including those criteria that would exclude otherwise acceptable participants. For example, if your study uses only male or female participants explain why.  PARTICIPANTS: c) How will participants be recruited? (Include as an attachment at the end of the application any flyers, announcements, etc. that will be used to recruit participants).  PARTICIPANTS: d) Is there a formal relationship between the researcher and participant (i.e., teacher/student, superintendent/principal/teacher, employer/employee, etc.) that might lead to the perception of coercion? If so, identify options to participation.  PARTICIPANTS: e) Does your study focus specifically on any of the following vulnerable populations? If so, please check the appropriate box(es):  Minors  Prisoners  Pregnant women  Persons with disabilities  Educationally or economically disadvantaged  Other  Research Methods   |  | | --- | | Interview, focus group or non-anonymous questionnaire | | Anonymous questionnaire | | Observation of public behavior | | Analysis of de-indentified data collected elsewhere | | Other, please specific | |
| RESEARCH METHODS: a) Please describe the procedure to be followed in your research (what participants will do) and the interaction between the researcher and the participants. Include if appropriate a description of the ways in which different subjects or groups of participants will receive different treatment. |
| RESEARCH METHODS: b) How many times will you meet/interact with participants? |
|  |

RESEARCH METHODS: c) How much total time will be required of each participant?

RESEARCH METHODS: d) Where are the performance sites for this research? (i.e., where will it take place?)

RESEARCH METHODS: e) If you are conducting surveys, include a copy of the survey instrument as an attachment at the end of the application. If you are conducting individual interviews or focus groups, including ethnographies or oral histories, attach a list of interview questions. If the interview format isn’t yet specified or you are conducting unstructured interviews, attach a list of specific topics to be discussed.

RESEARCH METHODS: f) Do you or any other investigators associated with the project described in this application have or appear to have any actual or potential conflicts of interest with respect to this research?

Yes

No

INFORMED CONSENT: a) What categories of consent documentation will you be obtaining from your participants? Check all that apply:

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| --- |
| Written Participant Consent |
| Written Parental Consent |
| Participant Assent |
| Oral Consent |
| Click Consent for an online survey with minimal risk |
| Unsigned Consent (for use with anonymous questionnaires) |
| I will not be documenting consent  INFORMED CONSENT: If you are not obtaining written consent, you will need a waiver from the IRB. If this is the case please specify which type of alternative consent you are obtaining and why you are utilizing this type of consent (e.g., participant is under the age of 7, this is a phone interview, there are literacy issues, having a consent document could pose some risk to participants) or why you are foregoing consent (anonymous survey without risk).  COLLECTION/RETENTION OF INFORMATION: a) Describe the method(s) of recording participant responses (e.g., audiotape, videotape, written notes, survey, etc.) you will be using.  COLLECTION/RETENTION OF INFORMATION: b) Where and for how long will these materials be stored? Please describe the precautions being taken to ensure the security and safety of materials.  COLLECTION/RETENTION OF INFORMATION: c) When/How will they be disposed of when the research is completed?  COLLECTION/RETENTION OF INFORMATION: d) Will the recordings of participant responses be coded for subsequent analysis?  COLLECTION/RETENTION OF INFORMATION: e) Where and for how long will the coded data be stored? Please describe the precautions being taken to ensure the security and safety of the materials.    CONFIDENTIALITY: a) What assurances will be given to participants about the information collected?   |  | | --- | | Anonymity is assured (data cannot be linked to participant identity) | | Confidentiality is assured (names and identifying information are protected, i.e. stored separately from data) | | Neither anonymity or confidentiality is assured |   CONFIDENTIALITY: b) If you checked that information is Confidential describe the methods that will be taken to provide confidentiality.  CONFIDENTIALITY: c) IF you checked that neither Anonymity or Confidentiality is assured explain 1) why confidentiality is not assured and 2) measures taken to assure participants understand how their information will be used. Describe and include as an attachment at the end of this application any written or permission releases that will be requested from participants.  RISKS: a) Could participating in this study cause participants physical harm? If so what steps will be taken to protect them?  RISKS: b) Could participating in this study cause participants to feel uncomfortable or distressed? If so, what steps will be taken to protect them?  RISKS: c) Are there any other risks associated with participation in this study? Measures being taken to mitigate these additional risks?  RISKS: d) Are any of the risks associated with participation in this study (e.g., physical, psychological, financial, social, legal, etc.,) greater than what participants would encounter in their normal day to day lives?  BENEFITS: a) Please briefly describe the potential benefits for the researcher.  BENEFITS: b) Please describe the potential for guaranteed benefits for the participants, EXCLUDING cash or in-kind payments.  BENEFITS: c) What are the potential benefits to society from this research?  BENEFITS: d) What are the intended uses of the data?  BENEFITS vs RISKS: Do the benefits of this study outweigh the risks? Please briefly explain why.  CO-INVESTIGATORS, COOPERATING DEPARTMENTS,  COOPERATING INSTITUTIONS: If you are working with/conducting your research at another institution or organization, include a letter of cooperation from that institution. IF the cooperating institution is a primary data collection site, the RIVIER IRB will need a letter of approval from that institution's IRB.  **Please check all the documents below that apply to your research. Then copy the documents into one file and upload them in the next item.**   |  | | --- | | Written Consent/Assent form(s) (see separate link on IRB website for checklist, templates, and samples) | | Recruitment letter, poster, ad | | Subject instructions | | Tests/Surveys/Questionnaires | | Interview guides | | Debriefing materials | | Other institutional approval letters | | Human Subject Certificate (Required) |   **Please upload your signed Assurance of Principal Investigator (provided**  **below) and Faculty Advisor Form here.**   |  | | --- | | \***Planning for Date Research is to begin:** *Check one box.* | | |  | | --- | | I have a specific date I need to start my research | | There is no specific date I need to start my research | | Upon IRB approval | | |
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