ADDENDUM A
HSRC APPLICATION CHECKLIST FOR NON-EXEMPT RESEARCH
Academic Year 2021-2022

Carefully read this document and, if necessary, revise your application before submitting materials to the HSRC. Not adhering to this addendum may cause delays in protocol processing and review time.

IMPORTANT TO REMEMBER

➢ The application you submit is <u>the document of record</u>.
➢ Inadvertently omitted details from the application materials cannot be reviewed, and thus, are not approved.
➢ If there are inconsistencies in the application materials, expect delays in the review and processing your submission.
➢ The checklist below is <u>not</u> exhaustive; rather, it provides a list of common issues that delay protocol reviews.

GENERAL REVIEW

☐ Review each question to make sure that you have fully answered it. Some questions may involve multiple answers. Take your time to read the question(s).
☐ Proofread all application materials for correct grammar and spelling, as well as errors of omission. IRB Manager has the same red underscore as MSWord that indicates when a word is misspelled.
☐ Application materials are easy to follow using layman's terms when possible.
☐ Acronyms are referenced only <u>after</u> the name is initially spelled out with the acronym in parentheses.
☐ For more complex studies, a flow chart is attached to illustrate the research process and study procedures.
☐ Information is consistent throughout the HSRC application and supplemental materials.

HSRC APPLICATION

☐ Anticipated start and end dates for the study are reasonable and allow time for the review process. For example, anticipated start date should not precede when the application was submitted.
☐ Characteristics of the research problem and population are clearly described.
☐ Study design is scientifically appropriate to answer the research questions/hypotheses.
☐ Hypotheses are clear and concise; outcome measures well-defined.

NOTE: Your close knowledge of your study can lead to inadvertently omitting details or important clarifications that would help the members of the HSRC, many of whom are not in your field, to understand the study. *After reviewing and revising your application based on this addendum*, the HSRC recommends that you ask a colleague or friend to proofread your application, which you can share in IRBManager by clicking on the '👥Collaborators' icon at the top of the page.

SUPPLEMENTAL MATERIALS

☐ Information on supplemental materials (recruitment, screening documents, questionnaires, etc.) is correct and consistent with the application. For example, the number of study subjects and the inclusion/exclusion criteria should be the same on the application and on the consent form.

☐ Supplemental materials are written in the second person ("you/your"), since they are addressed to participants.

☐ Supplemental materials (flow charts, data collection sheets, interview guides, etc.) attached to the HSRC application are labeled with an appropriate, descriptive file name and referenced, when necessary, in the application. For example:

- File attached to the HSRC application is named "Appendix A – Study flow chart"
- "*The attached flow chart (Appendix A) illustrates each of the study procedures below*."

INFORMED CONSENT

☐ All elements of informed consent are included.

NOTE: It is strongly recommended that you use the informed consent template provided on the HSRC website because all elements are listed there.

☐ Consent is written in second person ("you/your") and at an 8th grade reading level.

☐ Inclusion/exclusion criteria are clear, and consistent with the HSRC application.

☐ All risks and benefits are listed, and consistent with the HSRC application.

☐ Procedures participants will be asked to perform are described chronologically and consistent with the HSRC application.

☐ Expected subject completion time for each procedure listed, and the total study time for the study are included and prominent.