**Full Board REVIEW submission checklist**

**for Human subjects research**

This checklist is designed to assist DU investigators who are requesting a full board review for their proposed research. Investigators should refer to the checklist items below to ensure that all the submission requirements are fulfilled in order for the IRB to have the necessary documents to review and issue an expedited review approval letter. If any of the items below are not included or addressed in the IRB application, the application will be considered incomplete and will delay the IRB review process.

**PLEASE NOTE: In response to the COVID-19 pandemic,** **all human subjects research protocols submitted to the DU IRB for review will be required to observe all the current COVID-19 restrictions that were implemented by the University of Denver on March 20, 2020. Please incorporate these requirements into your IRB application. If the current COVID-19 restrictions are not observed and implemented, the IRB will not approve the research protocol and will be placed in a database until the restrictions are lifted.**

**Attain Valid Certification in Human Subjects Protection Training**

All investigators must be certified in human subjects protection training to conduct human subjects research. This training must be completed through the online Collaborative Institutional Training Initiative (CITI) Program.

**Note:** As of September 2018, the training requirements for conducting expedited review research changed. If you have successfully completed the CITI training modules for Social, Behavioral, & Educational Research (SBER) within the last four years, those completed modules will be automatically applied to your training profile. You will not be required to complete any additional modules for your expedited project unless your new project involves a different intervention or population group that was not covered under the initial CITI training curriculum.

**Complete the Part I: Human Research Application**

The Part I: Human Research Application serves as the Protocol Narrative for a full board review project. All sections of this application must be completed and clearly addressed in order for the IRB to conduct a thorough review of the proposed project. Please do not complete and post the Protocol Narrative document in addition to the Part I application as part of your IRBNet submission package.

**Attach Appendix Forms (Supplemental Forms)**

Multiple appendix forms, also referred to as supplemental forms, may be required for full board review projects depending on the nature of the research and the potential subject population. Please review the list of appendix forms found in IRBNet under the Forms & Templates section and select all relevant forms that will be a part of the proposed research (e.g., Appendix N: Research Involving the Internet)

**Recruitment Materials**

**Note:** Any materials that will be used to recruit subjects or establish contact with potential referral sources, must be included in the IRB application for review. Examples include recruitment fliers, advertisements, website posting, emails, letters, or scripts used for in-person, telephone or online recruitment purposes. Recruitment templates are provided in the IRBNet Forms & Templates section and on the DU IRB website.

**Attach Informed Consent Documents (Written, Implied or Verbal)**

**Note:** If you will use a method where consent is not appropriate or cannot be obtained in the research, such as utilizing the internet to obtain consent, you must request a waiver through completing Appendix A to request a Waiver of Informed Consent or a Waiver of Written Documentation of Informed Consent. The IRB still requires the use of a consent even if an implied consent (waiver of written documentation) is used in order to provide potential subjects with basic information about the research project.

**Sign the IRBNet package**

**Note:** If a research assistant/coordinator completes an IRB application on behalf of the faculty or staff investigator, the Principal Investigator (PI) is required to electronically sign the package before the application is formally submitted for review. Securing this signature verifies that the PI has reviewed the application and approves the submission as written. **An IRB application that is submitted without a PI signature is considered incomplete and will delay the IRB review process.**

**Note to Students:** All students serving as a Principal Investigator MUST obtain their Faculty Sponsor’s signature to make their IRB application complete. The student investigator cannot sign their package on behalf of their faculty sponsor. Obtaining the Faculty Sponsor signature verifies the application has been reviewed and is ready for IRB review. **A student IRB application that is submitted without the Faculty Sponsor’s signature is considered incomplete and will delay the IRB review process.**

**Submit the Signed IRBNet Package to the DU IRB**

**Note:** To confirm a successful submission, you will receive a confirmation email generated by the IRBNet system when your package has been submitted. The IRB Office will automatically be issued an email confirming a new submission to the IRBNet system. The status of your project will be posted in IRBNet as “pending review” until the final determination letter has been issued.