Institutional Review Board – Human Subjects
Proposal Approval Checklist

This checklist when completed provides a record of the decision-making process when a researcher submits a Request for IRB Approval of Research Involving Human Subjects. Please complete the checklist for all applications and retain the original checklist with accompanying comments, if any, for the official records of IRB actions. A copy of each checklist should be forwarded with the quarterly summary reports of approval/revision recommendations to the University's Human Subjects Administrator. This new process will help us evaluate our process of approval and review.

Title of proposal: _____
Researcher _____ Date reviewed _____

Criteria for IRB Approval of Research

- ☐ Risks to participants are minimized by using procedures consistent with sound research design.

- ☐ Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably be expected to result.

- ☐ Selection of participants is equitable considering the purposes of the research, the research context, and any special-groups participation.

- ☐ Informed consent will be obtained as required in 45 CFR 46.116.
  - *Statement that the study involves research*
  - *Explanation of the purpose (Y/N), duration (y/n) & procedures (Y/N) of the research*
  - *description of risks (Y/N), benefits (Y/N), alternative procedures (Y/N)*
  - *extent to which confidentiality is maintained (Y/N)*
  - *if more than minimal risk, compensation, medical treatment (Y/N)*
  - *whom to contact (Y/N)*
  - *participation is voluntary (Y/N)*

    When appropriate:
  - *Additional risks are unforeseen (Y/N/NA)*
  - *Anticipated circumstances which may warrant termination of participation (Y/N/NA)*
  - *Any additional costs (Y/N/NA)*
  - *Consequences for subject's withdrawal; orderly termination (Y/N/NA)*
  - *Significant new findings will be provided to subject (Y/N/NA)*
  - *Approximate number of subjects (Y/N/NA)*

- ☐ Informed consent is appropriately documented as required in 45 CFR 46.117.
  - *Signed written consent form (Y/N)*
  - *Short form of consent doc presented orally (Y/N/NA)*

- *May waive consent if: (Y/N/NA)*

☐ An adequate research plan is provided for monitoring data collection.

☐ A clear process to protect the privacy of participants and the confidentiality of data is provided.

☐ Adequate safeguards are in place to protect the rights and welfare of vulnerable populations included in this research.

Assessment of Risks and Benefits

☐ This research is determined to place participants at *minimal risk* (as defined in 45 CFR 46.102), and risks are not unreasonable in relation to the anticipated benefits.
Miminal risks: not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine… psychological examination (45 CFR 46.102)

☐ This research is determined to place participants at *greater than minimal risk* and must provide precautions, safeguards, or alternative approaches to protocols to reduce the probability of harm or to limit its severity or duration.

☐ The researcher is competent in the planned area of research.

☐ The researcher does not have dual roles that might produce a conflict of interest.

☐ The intent of the proposed research is to yield useful data that will benefit the research participants and/or similar groups in the future.

IRB Review Determination

☐ The proposed project is exempt from IRB review because it meets the requirements in one of the six exempt categories as determined by Federal regulations (45 CFR 46.101).

☐ The proposed research or change in approved research qualifies for **expedited review** as defined in university policies and Federal regulations.

☐ The proposed research or change in approved research must have a **full board review** and must receive approval by a majority of the voting members of the IRB board.

☐ Another certified IRB-HS has approved this protocol. IRB name _____ and date of approval _____. (Please attach the approval form.)

If not a full board review, signature(s) of Chair and/or area reviewer is/are required.

______________________________ ________________
Signature Date

______________________________ ________________
Signature Date