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PRE-APPROVED STUDY PROTOCOL APPLICATION

All Pre-approved Study Protocols (PASPs) are to be maintained and controlled by the Principal Investigator/Faculty Supervisor. The Principal Investigator/Faculty Supervisor is responsible for the current and approved versions.

PASPs are reviewed and approved with a Full Board Review as an independent application separate from a study protocol submission.

Once the PASP has been reviewed and approved, investigators can refer to the PASP within a study protocol application, referring to the IRB Approval # for the PASP, and indicating any specific modifications to the PASP for the current study.

Continuation review of PASPs will be conducted every 3 years, unless substantial changes are made to the PASP, in which case a Modification should be submitted.

Title of PASP:

☑ I acknowledge that as the principal investigator/faculty supervisor I am responsible for updating this PASP and notifying the IRB office through a modification request form if any of the procedures as outlined above change or require revision.

A. PURPOSE

This PASP describes the xxxxxx (provide a short description of what the PASP is for – procedure, equipment, method, etc)

B. PROCEDURES/STUDY PROTOCOL

Bullet format is fine – outline the basic procedures and protocol for this method

C. EQUIPMENT (if relevant)

Include manufacturer, make, model information for any technical equipment utilized in this PASP.

D. TRAINING OF INVESTIGATORS (If relevant)

What personnel are involved in the protocol/method and what training/instruction have they received? If not the PI, what supervision is provided?

E. DESCRIPTION TO STUDY PARTICIPANTS (if relevant)

Describe how participants will be instructed, how procedure will be described to them **(note: any language to participants included in the approved PASP application, must be included verbatim in consenting and/or recruitment documents. This applied to Risks, Safeguards and Benefits also.)**

F. RISKS

TO PARTICIPANTS

TO RESEARCHERS

G. SAFEGUARDS/SAFETY PROCEDURES

FOR PARTICIPANTS

FOR RESEARCHERS

H. BENEFITS (if relevant)

FOR PARTICIPANTS

I. REFERENCES (if relevant)