How to Determine if Your Study Requires Full Board, Expedited, or Exempt Review

To determine whether your research project should be reviewed by the full IRB or is eligible for exempt or expedited review, use the following checklist:

NOTE: The SMU Institutional Review Board (IRB) makes the final decision of the review category of your research. If the application is made to an inappropriate category, it will delay the review process, thus delaying the start and completion of your research. Please follow directions carefully.

(1) <u>Full IRB Review</u>. Does your research project:

_____receive support from non-university sources that require full IRB approval?

_____involve the likelihood of risk or substantial stress or discomfort to the subject?

_____involve personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher?

_____involve sensitive aspects of a subject's behavior that could reasonably place a subject at risk of criminal or civil liability or be damaging to a subject's financial standing or employability?

_____involve sensitive aspects of a subject's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol?

_____involve health care procedures that are not conducted for the primary benefit of the subject?

_____include diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice?

_____involve deception or procedures that are not known to the subject (e.g., the subject will not be fully informed)?

_____involve special populations (e.g., children, prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent)?

_____involve greater than minimal (i.e., moderate, high) risk to subjects?

_____involve collection of blood samples or other body fluids in any amount?

<u>If you checked any of the descriptors in (1) above your research project must be submitted to the full IRB for review and receive full IRB approval before you commence your research. If you checked no descriptors in (1), go to (2) below.</u>

(2) <u>Expedited Review</u>. Does your research project:

_____involve only minimal risk?

_____involve recording data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice?

_____involve analysis of voice recordings made for research purposes?

_____involve moderate exercise by healthy volunteers?

_____involve the collection or study of existing data, documents, records or specimens?

_____involve research on individual or group behavior, or characteristics of individuals, without manipulation of a subject's behavior and in a manner that does not cause stress to subjects.

<u>If you checked any of the descriptors in (2) above and no descriptors from category (1), your research project meets the criteria for Expedited Review, and must be submitted to and receive approval from your departmental IRB designate before you commence your research. If you checked no descriptors in (1) or (2), go to (3) below.</u>

(3) <u>Exempt Review</u>. If you checked none of the descriptors in 1 or 2 above, your research is eligible for Exempt Review. Examples of research eligible for Exempt Review include:

_____investigations of commonly accepted educational practices in established or commonly accepted settings.

_____analysis of information from educational tests that will be recorded in such a manner that subjects cannot be identified.

_____surveys or interviews in which responses will be recorded in such a manner that a subject cannot be identified directly or through identifiers linked to a subject.

_____observations of public behavior.

_____collection or study of publicly available existing data, documents, records or specimens.

_____collection or study of existing data, documents, records or specimens in which information will be recorded in such a manner that a subject cannot be identified directly or through identifiers linked to a subject.

_____research or demonstration project conducted by or subject to approval of the U. S. Department of Health and Human Services for the purpose of studying procedures, benefits, changes, and payments of entitlement programs.

<u>OUTCOMES of IRB review include (1) full approval; (2) full approval with minor corrections or clarifications; (3) Reconsideration after the investigator responds to identified concerns; or (4) Disapproval for reasons specified in writing to the investigator.</u>