Appendix 2.7.1.4.1.2 EXPEDITED REVIEW GUIDELINES

Fontbonne IRB Expedited Review Guidelines

Proposals for Research with Human Participants may be expedited and not subject to full review procedures when what is being proposed does not expose participants to risk either to their persons or to their privacy.

The same materials must be submitted for an expedited review as for a full review. The only difference is the length of time required for the review and the number of IRB members who will review the proposal.

Examples of expedited review procedures include:

1. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants’ behavior and the research will not involve stress to subjects.

2. Recording of data from participants 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays, microwaves).

3. Voice recording made for research purposes such as investigations of speech defects.

4. Moderate exercise by healthy volunteers.

5. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

6. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth, and permanent teeth, if patient care indicates a need for extraction.

7. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

8. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older and who are not pregnant.

9. Collection of both supra- and subgingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

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