

DILLARD UNIVERSITY INSTITUTIONAL REVIEW BOARD
Request for Expedited or Chart Review

Principle Investigator:	
Title of Project:	

Research projects that present no more than minimal risk to human subjects **AND** involve only procedures listed in one or more of the categories outlined below may be reviewed by the IRB through the expedited review procedure.

Minimal risk is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i); 21 CFR 50.3(k); and 21 CFR 56.102(j)].

Categories Eligible for Expedited Review
(Please select all that apply to this project)

1. Clinical studies involving drugs and medical devices only when condition (a) or (b) is met:
 - (a) Research on drugs for which an investigational new drug application is not required.
 - OR**
 - (b) Research on medical devices for which (i) an investigational device exemption application is not required or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared and or approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:
 - (a) Healthy, nonpregnant adults who weight at least 110 pounds. The amount of blood drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week
 - OR**
 - (b) Other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount drawn may not exceed the lesser of 50 mL or 3 mL per Kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Note: Children is defined by the DHHS regulations as “persons who have not attained the legal age for consent for treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402(a)]

3. Research involving materials (data, documents, records, or specimens) that:
 - (a) have already been collected for some other purpose
 - OR**
 - (b) will be collected for non-research purposes (e.g. medical treatment or diagnosis)

4. Research on:
- (a) Individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)
 - OR**
 - (b) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
5. Continuing review of research previously approved by the convened IRB as follows:
- (a) Where, (i) the research is permanently closed to the enrollment of new subjects, and (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects
 - OR**
 - (b) Where no subjects have been enrolled and no additional risks have been identified
 - OR**
 - (c) Where the remaining research activities are limited to data analysis
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Continuing review of research, not conducted under an investigational drug application or investigational device exemption, where categories 2 through 8 do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
8. Prospective collection of biological specimens for research purposes by non-invasive means

Note: Examples include but are not limited to: hair and nail clippings in a non-disfiguring manner; deciduous teeth at the time of exfoliation or during routine extraction; permanent teeth during routine extraction; excreta and external secretions; placenta at delivery; amniotic fluid at the time of rupture, sputum; mucosal and skin cells by scraping, swab, or washing; uncannulated saliva collected either in an unstimulated fashion or by chewing gumbase or wax or the application of dilute citric acid to the tongue.

9. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be clear/approved for marketing.

Note: Examples include but are not limited to: Physical sensors applied either to the surface of the body or at a distance and do not involve significant amounts of energy into the subjects or an invasion of privacy; weighing or testing sensory acuity; magnetic resonance imaging (MRI); EKG, EEG, thermography, Doppler blood flow, echocardiography, or ultrasound; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate.

IRB Number: _____

****Studies intended to evaluate the safety and effectiveness of medical devices are generally not eligible for expedited review***

Signature of Principle Investigator

Date

Section II

Additional Material

Please attach the following materials to this application:

- Form IRB-A, Dillard University IRB Application for Initial Review
- Informed consent document (if applicable)
- Assent document for children (if applicable)
- Conflict of Interest Forms for all investigators
- Human subjects protection training certificate
- Any recruitment notices or advertisements
- Any survey instruments, researcher-created instruments, psychological tests, interview forms, or scripts to be used in the research
- Investigator's qualifications (CV or biosketch)
- Research proposal/protocol (Minimum 10 pages)

Section III

FOR IRB USE ONLY

- Research approved by Expedited Review (Category _____)
- Expedited Review Not Allowed *(See Comments Below)*

Comments:

Signature of IRB Chairperson

Date