



CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH
INSTITUTIONAL REVIEW BOARD
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IRB APPLICATION

PART III – EXPEDITED REVIEW

Study Title: _____

Principal Investigator: _____

Complete this form if requesting expedited review for revisions, continuing review or other future actions.

	<p>Research activities that present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure</p> <p>NOTE: If participants include prison inmates, pregnant women or fetuses, the study will not be eligible for expedited review.</p> <p><i>Check off the relevant section (s):</i></p>
	<p>1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p>(a) Research on drugs for which an investigational new drug application is not required.</p> <p>(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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/approved labeling.</p>
	<p>(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p>(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</p> <p>(b) from other adults and children², 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. For these subjects, 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.</p>

	(3) Prospective collection of biological specimens for research purposes by noninvasive means.
	(4) 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 cleared/approved for marketing.
	(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
	(7) Research on 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 research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.