

TEACHERS COLLEGE NEW IRB RULE EXPEDITED REVIEW CHECKLIST

INTRODUCTION

Researchers can use this checklist to determine whether their Human Research can be reviewed using the expedited procedure and ensure their protocol is complete prior to submission for Teachers College, Institutional Review Board (IRB) consideration.

Each expedited protocol is reviewed on a case-by-case basis. IRB reviewers will determine, based on the actual submission, if a protocol is exempt, expedited, or full review. Following these guides does not guarantee a protocol will be approved or that a researcher will have a flawless review process. It does however, offer some suggestions on how to frame materials for formal IRB review.

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A project requires IRB review if it includes both research and human subjects. The Institutional Review Board (IRB) will make the final determination of whether a study requires review.

EXCLUSION CRITERIA

If the following is true, the research cannot be reviewed using the expedited procedure:

- The research is Department of Defense (DOD)-regulated and involves Prisoners as subjects.

RISK LEVEL

- The research in its current state presents no more than Minimal Risk¹ to subjects, including Minimal Risk of criminal or civil liability, or damage financial standing, employability, insurability, reputation, or be stigmatization related to invasion of privacy and breach of confidentiality.
- One of the following is true:
 - The research does not involve prisoners as subjects.
 - A prisoner representative has reviewed the research and concurs with the minimal risk determination.
- The activity falls into one of these categories below.

EXPEDITED CATEGORIES

(63 FR 60364-60367, NOV 9, 1998)

- Initial or continuing review of research that only involves one or more of the following:
 - (1)(a) Clinical studies of drugs for which an investigational new drug application (IDE) is not required.
 - (1)(b) Clinical studies on medical devices for which an IDE is not required.

¹ Minimal risk is defined by the federal regulations (45 CFR 46) as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

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- (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture² from healthy, non-pregnant adults who weigh at least 110 pounds, where 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.
- (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, where the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and collection may not occur more frequently than 2 times per week.³
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- (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.

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (5) Research involving materials that have been collected for any purpose, or will be collected solely for non-research purposes.
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7)(a) 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.
- (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

² Each access of an indwelling line is one venipuncture.

³ Consider 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.