جامعة نيويورك ابوظبي

NYU ABU DHABI

EXPEDITED REVIEW REQUEST FOR NEW PROTOCOLS

Instructions

Some categories of human subjects research that do not qualify for exemption qualify for expedited review. A project is eligible for expedited review if:

- ⇒ the project passes certain initial eligibility tests, and
- ⇒ all of the project's human subjects research falls within one or more of the expedited review categories defined by government regulations
- ⇒ This checklist will help you determine whether your project may qualify for expedited review.
- ⇒ The application for expedited review is the same as for full-board review, but the application is reviewed by one or two IRB members, rather than by the entire board.
- ⇒ *If you think your project qualifies, submit this checklist,* ***and an original and one (1) copy*** *of the* Application for Review by the IRB.
- ⇒ If you are unsure about any of the decisions required by the checklist, please get in touch with the IRB at 02-628-4313, email: IRBnyuad@nyu.edu.

PROJECT TITLE:
PRINCIPAL INVESTIGATOR OR FACULTY SPONSOR:
STUDENT INVESTIGATOR

ELIGIBILITY TESTS

TEST I: PRELIMINARY QUESTIONS

Yes	No	Does your project involve . . .
◯	◯	A. Clinical studies of medical devices, procedures, treatments, or drugs?
◯	◯	B. pregnant women, fetuses, neonates, or human in vitro fertilization?
◯	◯	C. prisoners?
◯	◯	D. Deception
If you answered YES to any of A through C, your project is <u>not</u> eligible for expedited review by the IRB and will require full board review. If you answered YES to D, further assessment is needed.		

TEST II: MINIMAL RISK

Does any part of your project present more than minimal risk to human subjects?

Minimal risk means that 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.

◯ Yes ◯ No

If you answered . . .

NO …..… Your project passes Test II.

YES …… Your project fails Test II, and is not eligible for expedited review. Complete an application for full board review.

TEST III: IDENTIFIABILITY RISKS & PROTECTIONS

(a) Could identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing?

◯ Yes ◯ No

(b) Will reasonable and appropriate protections be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?

◯ Yes ◯ No

If you answered . . .

NO to (a) **OR**
YES to (b) Your project passes Test III. See Expedited Review Categories Below.

YES to (a) AND
NO to (b) Your project fails Test III, and is not eligible for expedited review. Complete an application for full board review.

EXPEDITED REVIEW CATEGORIES

Consider each category to determine whether any part of your project falls into that category.

CATEGORY 1

[This category encompasses some clinical studies of drugs and medical devices, and is not applicable to the NYUAD IRB.

CATEGORY 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant 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

(b) from 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. 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.

☐ Check if any part of your project falls within Category 2.

CATEGORY 3

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring 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 gumbase 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.

☐ Check if any part of your project falls within Category 3.

CATEGORY 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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.

☐ Check if any part of your project falls within Category 4.

CATEGORY 5
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for **non-research purposes** (such as medical treatment or diagnosis).
☐ Check if any part of your project falls within Category 5.

CATEGORY 6
Collection of data from voice, video, digital, or image recordings **made for research purposes**.
☐ Check if any part of your project falls within Category 6.

CATEGORY 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.
☐ Check if any part of your project falls within Category 7.

QUALIFICATION FOR EXPEDITED REVIEW

Does **all** of the human subjects research in your project fall into one or more of the expedited review categories?

◯ YES Cat.# s	Your project may be eligible for expedited review. Complete an Application for Review (see Application Forms on the IRB website). Submit this checklist with your application.
◯ NO	Your project requires full-board review. Complete an Application for Review. Do not attach this checklist.

For IRB Use

Assigned HS #

◯ Submit to expedited reviewer(s)

◯ Not eligible for expedited review – submit to full board.

Reason(s):