

## Categories of IRB Review and Approval

Once a Principal Investigator (PI) submits an IRB protocol, the IRB staff screen the submission for completeness and to make sure it meets the definition for both 'Human subjects' and 'Research' (see Decision Tree #1). PIs will be notified by phone or e-mail if a submission is missing documentation or necessary signatures. The staff will also verify the PI's initial determination for exempt, expedited or full board review, and initiate the appropriate review process. Any questions concerning the appropriate review level, applicability of the definition of human participants and/or the definition of research, jurisdiction of IRB, or otherwise relating to necessity of review are directed to the IRB Chair.

### *Exempt Procedures*

Exempt research must be minimal risk. As defined in the federal regulations, "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 (45 CFR 46.102(i)). Only the IRB Chair, IRB member, or IRB staff (acting as a designee of the Chair), may determine if a protocol is granted exempt status under the eight categories described in 45 CFR 46.101(b). In most cases, an IRB staff member reviews the protocol application to determine if a project qualifies for exemption, this review is minimal. If the research meets the criteria for 'limited review', then the reviewer will contact the PI to resolve any questions or concerns, or to require edits or revisions, with regards to informed consent process and/or privacy and confidentiality safeguards. Once these are addressed adequate, the protocol will be determined exempt from further review. If the research does not qualify for exemption, the IRB staff may determine that the research qualifies for expedited review or, after consultation with the IRB Chair or an IRB Member, full-board review, but may not deny the project. The PI will be notified via email if expedited or full board review is required, be given the reasons why it is required, and be asked to submit any required materials.

Although the regulations do not require informed consent for exempt research, the IRB encourages that informed consent be obtained as this is good practice and ethically sound. It helps ensure that prospective participants are informed of the research and have an opportunity to decide for themselves whether or not to participate. A Project Summary Statement containing all the information included in a Consent Form without a signature may be used in place of a signed Consent Form. If the study qualifies for exempt status, the IRB staff will notify the PI via the standard exempt determination letter. A list of exempt determinations is provided to the IRB for review and approval by the IRB at each meeting. Any member can request to review the entire IRB file for an exempt study.

For administrative purposes of maintaining the IRB database and files, the IRB staff may contact the PIs of exempt studies biannually to determine if the study is still active.

## ***Exemption Categories***

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices, instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods that are **not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction**. This includes most research on regular and special education
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **if at least one of the following criteria is met:** (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **(b)** Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or **(c)** Identifiable information is recorded and there is risk of harm if results are disclosed but the IRB conducts a **limited review** and determines exemption after adequate safeguards are put in place.
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: **(a)** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **(b)** Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or **(c)** Identifiable information is recorded and there is risk of harm if results are disclosed but the IRB conducts a **limited review** and determines exemption after adequate safeguards are put in place.
  - (i) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (a) The identifiable private information or identifiable biospecimens are publicly available; (b) Information, which may include information about

biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**(Categories 7 and 8 will not be applied at NYUAD)**

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § \_\_.111(a)(8).
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § \_\_.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § \_\_.117; (iii) An IRB conducts a limited IRB review and makes the determination required by § \_\_.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research

results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Per 45 CFR 46.101(i), the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. Also, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observe.

## ***Expedited Procedures***

Expedited research must be no more than minimal risk. Only the IRB Chair, IRB member, or IRB staff (acting as a designee of the Chair) may determine if a protocol is granted expedited status under seven of the nine categories as published in the federal register as 45 CFR 46.110 and 21 CFR 56.110.

One of the following three determinations in regard to the protocol and consent forms:

- **APPROVED:** IRB approval indicates that the IRB reviewer(s) has concluded that the research and consent forms meet the federal criteria for approval.
- **MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL:** The IRB reviewer(s) withhold approval pending submission of revisions/additional information.
- **FULL REVIEW REQUIRED:** The IRB reviewer(s) may determine that the protocol requires full review by the IRB at a convened meeting.

The Chair or his/her designee may not disapprove any research reviewed using the expedited procedure. Expedited reviews can be conducted by an assigned IRB member or staff (designated by the IRB Chair), the protocol application and all of the material required for submission go through desk review. This involves: (1) a review of the protocol to determine if there is missing information or information that requires further clarification, (2) that the research is minimal risk, (3) that if identification of the participants and/or their responses reasonably place them at risk of criminal or civil liability or could be damaging to the participants' financial standing, employability, insurability, or reputation, or be stigmatizing there are reasonable and appropriate protections that will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal (4) a review of the consent form to see if it contains the required elements set forth by relevant federal and local regulations and University policy, (5) a review of the recruitment procedures, (6) approval category, (7) if applicable, permissible categories and required findings for vulnerable populations and/or waivers or alterations of the consent process, and (8) a recommendation regarding one of the three determinations described above.

The Reviewer may contact the PI directly to discuss questions or concerns. If the Reviewer determines the protocol is approved, the PI will be notified via the standard expedited approval letter detailing the expedited approval category(s) and expiration date of protocol. Continuing reviews are no longer a requirement for minimal risk research, though the IRB retains the right to require continuation reviews for certain projects (e.g., those which may present some risks justifying follow up). At the close a project, the PI will be asked to complete a closure form updating the IRB on progress made. While a project is being run, it may be subject to audit.

A list of studies approved via the expedited mechanism is provided to the IRB at each meeting, any member can request to review the entire IRB file for an expedited study.

## ***Expedited Categories***

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. (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
  - b. from other adults and children [\[2\]](#), 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.
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 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.
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.
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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)
8. 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; (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.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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.

### ***Full Board Procedures (IRB and REC)***

At NYUAD, the Full Board meets in two capacities:

1. The 'IRB': For Social & behavioral research that is more than minimal risk or does not qualify for either exempt or expedited status, the full board follows NYUAD IRB procedures as informed by US Code of Federal Regulations, local laws and institutional policies.
2. The 'REC' (or the Research Ethics Committee): For Abu Dhabi-based biomedical research or studies involving collection or storage of human tissue samples, the full board follows Abu Dhabi Department of Health (DOH) policy along with NYUAD IRB procedures.

There is an overlap in membership between the IRB and REC and the differences are few and procedural (For more information on this, please refer to [Standard Operating Procedures and FWA](#)).

Prior to the meeting, the IRB staff, in consultation with the Chair, reviews the protocol to determine if it does in fact require the full Board and whether it qualifies for IRB or REC review. A primary review is conducted by an IRB staff member and it covers the following: (1) A review of the protocol to determine if there is missing information or information that requires further clarification, (2) A general assessment of the risks involved and potential for mediating those risks (3) A review of the consent form to see if it contains the required elements set forth by relevant federal and local regulations and University policy, (4) A review of the recruitment procedures, informing the full IRB of any discrepancies between the detailed protocol and the summary application materials. The protocol along with the primary review feedback are reviewed in depth by the IRB members at the convened meeting. Discussion and voting will follow. IRB members are expected to be familiar with all items on the agenda and contribute toward the discussion of each item. The determinations of the convened board are noted in the minutes.

The Board can make one of the following four determinations in regard to the protocol and consent forms:

- APPROVED: IRB approval indicates that the Board has concluded that the research and consent forms meet the federal criteria for approval.
- MODIFICATIONS REQUIRED IN ORDER TO SECURE APPROVAL: A vote for amendments required indicates the IRB has given the meeting Chair the authority to approve the minor revisions. The IRB withholds approval pending submission of minor revisions/additional information.
- DEFERRED: The IRB withholds approval pending submission of major revisions / additional information. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. Once the revisions have been made by the PI and submitted to the IRB, the revised protocol is added to the next IRB meeting agenda for review.
- DISAPPROVED: Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval.

If the full board determines the protocol is approved, the IRB staff will notify the PI via the standard full board approval letter. Approval is valid through the expiration date noted in the approval letter and during this time the study can be subject to audit. If a PI wishes to renew approval of a full board study, then a continuation request form must be completed and submitted well before the expiry date, as this may require review by the full board. When a protocol receives final approval, the IRB staff assigns the start of the approval period as the date of the convened IRB meeting. If a protocol was determined to require amendments to secure approval and the PI completes the revisions, the approval period starts from the meeting date of the convened IRB at which the protocol was initially reviewed.

If the full board determined the protocol requires modifications to secure approval, the IRB staff prepares a draft determination letter based upon the IRB's discussion at the meeting and shares this with the Chair and members. Once the letter is finalized, it is shared with the PI. The PI responds to revisions requested by the IRB in writing and sends the response to the IRB. PIs are encouraged to submit a point by point response to the IRB's initial determination letter to facilitate review. The PI must submit one copy of the protocol and/or consent form with the revisions highlighted and one copy of the protocol "clean," without revisions highlighted to expedite review of the revisions. Under both IRB and REC procedures, if the revisions are straightforward and minor, the full board can assign a subcommittee or designees (made up of staff and/or members) to review revisions and issue approval once the revisions are satisfactory. Subcommittees/designees can also be assigned to review minor amendments and continuation requests of minimal risk protocols or where there is no change to risk. Any revisions that involve controverted issues or may pose an increase in risk are sent back to the full board.

If the full board determines that a protocol must be deferred, the IRB staff will prepare a draft determination letter based upon the IRB's discussion at the meeting. The letter lists the reasons for the deferral and includes a description of the revisions or clarifications requested. The draft letter is reviewed according to the same procedures described above and sent to the PI. The PI responds to revisions requested by the IRB in writing and sends the response to the IRB. PIs are encouraged to submit a point by point response to the IRB's initial determination letter to facilitate review and to meet with IRB staff to discuss revisions. The PI must submit one clean copy of the protocol and/or consent form and 1 copy of the protocol and/or consent form with the revisions highlighted. The protocol is then added to the agenda for the next scheduled IRB meeting. When a protocol that was initially deferred receives final approval, the IRB staff assigns the start of the approval period as the date of the meeting the protocol was approved or required modifications to secure approval.

If the full board determined the protocol must be disapproved, the IRB prepares a draft determination letter based upon the IRB's discussion at the meeting. The draft letter is reviewed and approved in the same manner as described above. The letter is sent to the PI via email. If A copy of the disapproval determination letter is also sent to the IO, and the PI's Department Head, Sponsored Program Services (if applicable), and other University offices, as necessary.