1. Policy Statement

The UREC generally conducts two types of review: expedited or full review. The Chair makes the final determination of the type of review the protocol will undergo, prior to assignment to reviewers. Although the application form instructs the proponent to categorize his or her protocol, this is mainly to facilitate documentation by the Secretariat and for the proponent to exercise self-reflection of the risk level of his or her protocol.

An expedited review is conducted by at least two (2) members of the UREC designated by the UREC Chair. In an expedited process, the assigned reviewers exercise all the authorities of the UREC except that the reviewers may not disapprove the research. A research activity may be disapproved only after full review in a UREC meeting.

1.1 Criteria to qualify for expedited review

The research protocol submission is eligible for expedited review if both of the following criteria apply to the study:

- The research activities present no more than minimal risk to human participants, where minimal risk is defined as the probability and magnitude of physical and psychological harm that is normally encountered in daily life, or in the performance of routine medical, dental, or psychological examination of healthy persons. Protocols that are greater than minimal risk would require a full review (refer to SOP 4.3).
- The research involves one or more of the activities listed in the categories of research enumerated in section 1.2 of this SOP

1.1.1 Categories of research that qualify for expedited review

Inclusion in this list does not automatically indicate that the study is minimal risk, but rather that the study is eligible for the expedited review process. The categories listed here apply regardless of age of participants, unless noted. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of whether expedited or full review is conducted.

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

(a) Research on drugs for which the national drug registration authority (i.e. Food and Drug Administration or FDA) has approved the drug for distribution or

marketing or (ii) the filing and submission of applications as indicated in FDA Circular 2014-009 is not required. (However, research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product should undergo full review.)

(b) Research on medical devices which have been cleared/approved for marketing by the FDA and the Bureau of Health Devices and Technology (BHDT) and the medical device is being used in accordance with its cleared/approved labeling. (However, FDA requires researchers to comply with ISO 14155:2011 for medical device investigations.)

Category 2: Collection of blood samples by finger stick, heel stick, ear stick or venipuncture:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds: 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 participants, 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.

Category 3: Prospective collection of biological specimens for research purposes by non-invasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- 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;
- Placenta removal at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- 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;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization

Category 4: Collection of data through non-invasive procedures routinely employed in clinical practice, not involving general anesthesia or sedation, and excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must have been cleared/approved for marketing and use. Examples include:

- 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 participant or an invasion of the participant's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(Studies intended to evaluate the safety and effectiveness of medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Refer to FDA and ISO 14155:2011 for additional guidance.)

Category 5: Research involving materials (existing data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis) (However, if these sources are publicly available or if the information is recorded in such a manner that participants cannot be identified, the study may be exempt for review; refer to SOP 4.1 on Exclusions and Exemptions).

Category 6: Collection of data from voice, video, digital, and/or image recordings

Category 7: Researches 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) employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (However, refer to SOP 4.1 on Exclusions and Exemptions for possible exemptions of such studies from review).

1.2 Ethical basis for recommendations and decision-making in an expedited review

The UREC bases its recommendations and decisions on national and international standards for ethics in research involving human participants. Mainly, the AdMUREC

standards are based on the 2011 National Ethical Guidelines for Health Research, the 2011 WHO Standards and Operational Guidance for Ethics Review, applicable provisions of the U.S. Federal Policy for the Protection of Human Subjects or the "Common Rule" (note that the AdMU has Federalwide Assurance from the U.S. Dept of Health and Human Services Office for Human Research Protections), and the 1979 Belmont Report.

UREC recommendations and decision-making involve the following key considerations (refer to the Protocol Assessment Form for more details):

- Scientific design and conduct of the study [scientific justification and soundness of methods; qualifications of research personnel; adequacy of resources]
- Risks and potential benefits [minimization of and measures to mitigate potential harms; balance of potential benefits of the research vis-à-vis the risks; probable adverse events and protocols to address]
- Selection of study population and recruitment of research participants [justification of sample characteristics; fair and equitable distribution of potential benefits and potential risks of participation in the selection of participants]
- Inducements, financial benefits, and financial costs [just reimbursement or compensation of costs to participation, without undue coercion or influence]
- Protection of research participants' privacy and confidentiality
- Informed consent process [assurance of voluntary consent with full information about the research; appropriate consent considerations and measures for persons unable to provide informed consent]
- Community considerations [community participation; respect for community traditions; community benefits vis-à-vis harms]

2. Objectives and Scope of the Activities in SOP 4.2

The guidelines and procedures indicated in this section ensure that the evaluation of studies classified under expedited review demonstrates due diligence and compliance with national and international standards in the protection of human participants. The procedures are intended to maximize efficiency without sacrificing standards and quality of review.

2.1 This SOP applies to initial and post-approval (i.e. continuing review; protocol amendment) protocol submissions which have been classified for expedited review.

2.2 This SOP applies to independently-conducted student research projects such as theses, dissertations, honors/capstone/ internship projects and the like (also refer to SOP 4.4 on Review of Class-Based Student Research). Student applications include a signed endorsement and acceptance of overall responsibility by a faculty supervisor.

2.2.1 If the independent student research project undergoes a technical review process (e.g. a formal departmental defense) then the application for ethics clearance takes place after the defense to help ensure that the research is technically sound and that the protocol under ethics review would not still be undergoing significant changes.

2.2.2 The student and faculty supervisor should be mindful of the time period generally necessary for UREC review (for expedited, 2-4 weeks from submission; for full review, 4-6 weeks from submission) and schedule their research activities accordingly.

3. Workflow of Expedited Review Process and Persons Responsible

WORKFLOW OF EXPEDITED REVIEW (refer to SOP 2 for preliminary steps)	**RESPONSIBILITY**	**WORKING DAYS**
Step 1: Send ethics clearance application and protocol package to the assigned reviewers together with Protocol Assessment Form (PAF) • application may be for initial review, continuing review, or protocol amendment	UREO OA	(within 13 working days from receipt of complete protocol; see SOP 2)
Step 2: Review the protocol and submit accomplished PAF to UREO	UREC reviewers UREO OA	up to 10 days from confirmation of reviewer assignment

WORKFLOW OF EXPEDITED REVIEW (refer to SOP 2 for preliminary steps)	RESPONSIBILITY	WORKING DAYS
Step 3: Send UREC communication to PI (if approved, or minor/major revisions), or include protocol in agenda of UREC plenary meeting (if recommendation is disapproval)	UREC Chair *(to approve and sign communications)* UREO Director *(to note and sign communications)* UREO OA *(to draft communications)*	0-5 days from submission of review
Step 4: [If applicable] Respond to reviewers' recommendations for minor or major modifications and submit revised application	Principal Investigator	5-10 days from receipt of UREC communication
Step 5: Revert to Steps 1 - 3	UREO OA UREC reviewers	communication sent to PI - up to 10 days from reviewers' receipt of resubmission
Step 6: Document and file all submissions, recommendations, and decision for the protocol	UREO OA	
Step 7: Report protocol and decision at UREC plenary meeting	UREC Chair	

4. Description of Procedures

4.1 Send ethics clearance application and protocol package to the final assigned reviewers together with Protocol Assessment Form (PAF)

At least two reviewers are invited by the UREC Chair to review the protocol (refer to SOP 2 on Management of Initial Submissions): one (1) of the reviewers must be in the same or allied discipline as the principal investigator, or have disciplinal familiarity with the topic of the research; the other reviewer is from a different discipline for a balance of perspectives.

Once the assigned reviewers signify their agreement to review the protocol, the UREO OA sends the full protocol package and the Protocol Assessment Form to the reviewers. Unless the reviewers request a printed copy, a digital zipped file of the protocol submission is emailed to the reviewers. The zipped folder and files are appropriately labeled with the AdMUREC ID number (refer to SOP 2 on Management of Initial Submissions).

4.2 Review the protocol and submit accomplished PAF to UREO Secretariat

The reviewers evaluate the protocol and relevant materials (i.e. instruments, informed consent forms, etc.) and complete the PAF.

The reviewers may confer or communicate with each other via email, or face-to-face. The UREO email address is cc'd in all email communications, and only one email thread is devoted to communications about a particular protocol. This facilitates tracking and monitoring of protocol assignments, reviews, recommendations, and attachments. The email communications / email thread is saved in pdf format and included in the protocol file.

If an independent consultant was assigned to review or comment or clarify aspects of the protocol, the reviewers obtain a copy of the consultant's report from the UREO and considers this in their evaluation. The reviewers complete and submit their PAFs only after the consultant's report has been considered.

The PAFs are submitted to the UREO OA on or before the due date indicated in the invitation to review the protocol (i.e. up to 10 working days from the acceptance of the assignment).

4.3 Send UREC communication to PI (refer to SOP 6.2 on Communicating Decisions) or include protocol in agenda of UREC plenary meeting

If the decision is to approve the protocol, an ethics clearance letter is sent to the Principal Investigator.

If there are recommended major or minor modifications, the notification letter with consolidated reviewer recommendations, comments, and questions is sent to the Principal Investigator.

If the recommendation is disapproval, the protocol is included in the agenda of the next

plenary UREC meeting where the reviewers present their findings and the UREC deliberates on decision (quorum and votes required). Disapprovals cannot proceed from an expedited review.

If the protocol is disapproved after the UREC plenary deliberation, a notification of the UREC decision is sent to the PI with the justification for the disapproval.

In all UREC communications, the draft letter is prepared by the UREO OA based on the consolidated comments on the reviewers' PAFs; the UREC reviewers and the UREC Chair reviews the draft letter and finalizes it. The UREC Chair signs it and the UREO Director notes and signs the letter.

The relevant action in this step is done no more than 5 working days after receiving the complete recommendations of all reviewers.

4.4 [If applicable] Respond to reviewers' recommendations for minor or major modifications and submit revised application

The PI is given 5-10 working days to respond to the recommendations (due date depends on the complexity of the modifications). The resubmission of modified documents and the response to questions and comments is sent to the UREO OA.

If the PI is unable to submit his/her response within 10 working days, the UREO OA will request a letter from the PI that explains the failure to submit a response and may request an extension. This letter must be signed by the adviser (if applicable). If the PI does not submit this letter within 10 working days, the protocol is considered to have been withdrawn and there will be no more forthcoming work on it.

Responses from the PI may be accepted only up to a maximum of two months after the notification letter is sent by the UREO OA to the PI. If the PI still wishes to pursue ethics clearance for his/her project after this period, he/she will have to resubmit the protocol; this will be considered a new submission. When possible, this resubmission will be assigned to the same two reviewers.

4.5 Revert to steps 1 – 3

The UREO OA receives the protocol resubmission and accompanying files, which are labeled and filed according to the protocol ID number. The resubmission is entered into

the UREC database. The recorded protocol resubmission is forwarded to the same initial reviewers.

The reviewers evaluate the resubmitted protocol, revised attachments, etc. If further modifications are recommended, or if the protocol is approved, the appropriate communication is sent to the PI. If the recommendation is to disapprove, the protocol is included in the agenda for the next plenary meeting.

If a second iteration of the process is required (i.e., approval is still not obtained and modifications are needed even after the resubmission), the UREC Chair may decide to have a meeting with the applicant to facilitate the communication of recommendations and the revision process.

4.6 Record and file all submissions, recommendations, and decision for the protocol

When a final disposition on the protocol has been issued, the UREO OA records this in the database and files all pertinent documents for the protocol in digital and hard copies of folders. (Refer to SOP 7.1 on Managing Protocol Files.)

4.7 Report protocol and decision at UREC plenary meeting

The UREO Chair includes the protocol and its final disposition in the report / update of protocols submitted and reviewed at the next UREC plenary meeting.

5. Forms

AdMUREC Form 1 - Application Form for Initial Ethics Clearance: Expedited or Full Review

AdMUREC Form 3 - Protocol Assessment Form

Template of letter requesting minor / major modifications

Template of ethics approval letter

Informed Consent Form Template

6. History of the SOP

Version No.	Date	Authors	Main Change
01	2017 Jan 30	Liane P Alampay (LPA)	
02	2017 May 26	LPA	In accord with PHREB

			recommendations: ▪ Inclusion of statement that the Chair makes final determination on type of review the protocol will undergo (p.1)
03	2022 May 11	Ronald Allan L. Cruz, Nico A. Canoy, Eduardo Valdez, Joseph Johnson, Alfred Pawlik	A section has been added that requires proponents who are unable to respond to reviewers' comments to explain their failure to respond and sets a maximum of two months to respond, after which any submission from the proponent on the same protocol will be considered a new submission.