Exempt from Review Guideline

Purpose

To describe the process of review of protocols that qualify for exempted from review.

Scope

This SOP applies to exemption for review of protocols that do not need to undergo either full or expedited review as decided upon by the Chair of the IEC.

Responsibility

It is the responsibility of the Chair to assess whether a study protocol may be exempted from review of the IEC.

Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Receive the submitted documents and forward to the Chair immediately for initial Review	Secretariat
Step 2	Review and determine per criteria that the protocol is exempt from IEC review within 5 days	Chair
Step 3	Prepare a letter of exemption to the PI indicating the protocol is exempted from IEC review	Secretariat
Step 4	Keep copies of all related documents and compiles them in their respective protocol Files	Secretariat
Step 5	Update the IEC database	Secretariat

Description of Detailed Procedures

For research proponents or principal investigators (PI) who have protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., systematic review and meta-analysis protocols) and require an IEC letter of exempt from review (e.g., for documentation purposes), they may apply for exempt for review by submitting a cover letter and a copy of the protocol.

If the proponent or PI is unsure whether his/her protocol does not involve more than minimal risks/harms or can be exempt from review or does not fall under the above criterion, s/he may submit a cover letter and submit documents following the Protocol Checklist (FORM 2A-V2-2019) as guide. The application documents received from the PI are checked for completeness by the secretariat using the Protocol Checklist. After checking the documents are complete, the Secretariat signs a copy of the Application Form (FORM 2B-V1-2012) to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

The Secretariat receives the submitted documents and forwards them to the Chair immediately for initial review.

The Chair reviews and determines per criteria that the protocol is exempt from IEC review within 5 days.

For the proponent's or PI's guidance and in compliance to the National Ethical Guidelines for Health and Health- Related Research 2017 (NEGHHRR 2017), the DLSMHSI-IEC considers the following Exempt from Review criteria:

- Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., systematic review and meta-analysis protocols) shall be exempted from ethical review.

- Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the REC for exemption from review:

    - Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

    - Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

        - There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

- The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

- Protocols that involve the use of publicly available data or information.)

The IEC Secretariat prepares a letter of exemption (FORM 4I-V2-2019) to the proponent or PI indicating the protocol is exempted from IEC review.

The IEC Secretariat keeps copies of all related documents and compiles them in their respective protocol files.