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PCMC IR-EC SOP 9.0: Management of Expedited Review

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9.0 MANAGEMENT OF EXPEDITED REVIEW

9.1 Policy Statement

The IR-EC shall conduct expedited review for protocols that do not entail more than minimal risk and do not involve vulnerability issues.

The initial communication regarding an expedited review shall be released to the researcher within 14 days from receipt of a complete protocol package.

9.2 Purpose of the Activity

To ensure protection of human participants despite the low risk without involving the whole committee.

9.3 Scope

This SOP includes the procedures for the management of expedited review that begins from the determination of IR-EC action/type of review and ends with preparation of protocol folder (SOP Management of Active Files).

9.4 Process Flow/Steps for Management of Expedited Review

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Determination of IR-EC action / Type of Review	Chair/Secretary
2	Assignment of Primary Reviewers	Chair/Secretary
3	Distribution of Pertinent Protocol Documents to Primary Reviewers	IR-EC Secretariat
4	Review of Protocol Documents using Assessment Form	Primary Reviewers
5	Submission of Accomplished Assessment Forms to the Secretariat	Primary Reviewers
6	Review of Assessment Forms for Appropriate Action	Chair/Secretary
7	Notify PI of IR-EC Decision	IR-EC Secretariat
8	Preparation of Report to Full Board	IR-EC Secretariat
9	Preparation of Protocol Folder (SOP Management of Active Files)	IR-EC Secretariat

9.5 Detailed Instructions

9.5.1 Determination of IR-EC action / Type of Review

9.5.1.1 **For initial review**, the Chair/Secretary shall evaluate whether the protocol qualifies for expedited review. A study shall be qualified for expedited review if it presents no more than minimal risk to the subject.

9.5.1.2 Types of Protocols for Expedited Review

a. researches about a topic that should not result in causing social stigma
b. researches that do not involve vulnerable populations
c. researches that will use simple questionnaires without identifiers (i.e. name, age, sex, address, race, marital status, religion, contact numbers, political affiliations, etc.)
d. retrospective studies using anonymized data from medical records
e. laboratory research that uses anonymized human tissue/specimen
f. continuing review of previously expedited protocols, minor protocol amendments and end of study reports

9.5.1.3 **For resubmitted documents**, the IR-EC decision for minor modification shall qualify for expedited review

9.5.1.4 Types of submissions that shall qualify for expedited review:

a. administrative revisions, such as correction typographical errors
b. addition or deletion of non-procedural items, such as the addition/change in study personnel or changes in their address or contact number, change in laboratories, and the like
c. minor protocol amendments that do not change the risk/ benefit assessment
d. progress/final reports that were initially reviewed by expedited review and that do not deviate from approval given by the IR-EC
e. SAEs that are off-site provided these are not SUSARs

9.5.2 Assignment of Primary Reviewers

9.5.2.1 The Chair shall review the complete protocol documents forwarded by the Secretariat.

9.5.2.2 The Chair shall designate one (1) PCMC IR-EC medical/scientific member with related expertise to review the protocol as primary reviewer, and a non-medical/non-scientific member to review the informed consent and assent, if needed.

9.5.3 Distribution of Pertinent Protocol Documents to Primary Reviewers

9.5.3.1 The Secretariat shall inform the designated Primary Reviewers, prepare the protocol package and corresponding Assessment Forms and forward them to the designated Primary Reviewers.

9.5.4 Review of Protocol Documents using Assessment Form

9.5.4.1 The Primary Reviewers shall carry out the review on the protocol and related documents. The medical Primary Reviewer shall accomplish both the Protocol Assessment Form and ICF Assessment Form (Forms 10.1 and 10.2). The non-medical/non-scientific Primary Reviewer shall evaluate the informed consent documents by using the Informed Consent Assessment Form.

9.5.4.2 The Primary Reviewers shall make a recommendation as follows:

a. Approved
b. With Minor Modifications
c. For re-evaluation (major revisions)

9.5.4.3 When only minor modification/s is/are required, the protocol documents shall be returned to the principal investigator for revision and shall be re-submitted to the IR-EC for approval by the Primary Reviewers.

9.5.4.4 Protocols for re-evaluation (major revision) shall automatically be forwarded to full board for discussion and decision.

9.5.5 Submission of Accomplished Assessment Forms to the Secretariat

9.5.5.1 The Primary Reviewers shall sign and date the Assessment Forms and return them to the Secretariat within 5 working days from receipt of the protocol package.

9.5.5.2 The Secretariat shall check the completeness of the Assessment Forms and forward them to the Chair/Secretary who shall recommend the appropriate IR-EC follow up action.

9.5.6 Review of Assessment Forms for Appropriate Action

9.5.6.1 The Chair/Secretary shall review the completed Assessment Forms to determine if there is agreement with the review/decision. The comments and decision shall be collated and communicated to the PI.

9.5.6.2 In case of conflicting recommendations between the Primary Reviewers, the Chair/Secretary shall include the protocol in the next full board meeting for discussion and decision.

9.5.7 Notify PI of IR-EC Decision

9.5.7.1 The Secretariat shall communicate the Notice of Decision (Forms 27.1) from the IR-EC to the PI.

9.5.7.2 In case revisions are required, the PI shall comply with the required modifications and resubmit the revised documents to the Secretariat using the Protocol Resubmission Form (Form 12.1).

9.5.8 Preparation of Report to Full Board

9.5.8.1 The Secretariat shall prepare a list of protocols approved through Expedited Review and the Chair/Secretary shall report them during the full board meeting. The report shall be included in the Minutes of the Meeting. If an IR-EC Member raises concern about any of the protocols presented as expedited review, then that protocol shall undergo a full board review.

9.5.9 Preparation of Protocol Folder (SOP Management of Active Files)
Refer to SOP 28.0.

9.6 Forms

Form 10.1 Ver.2.0 Protocol Assessment Form
Form 10.2 Ver.2.0 Informed Consent Assessment Form
Form 12.1 Ver.1.0 Protocol Resubmission Form
Form 27.1 Ver.3.0 Decision Letter of IR-EC

9.7 Glossary

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/expedited_review.html