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Effective Date: ~~05~~ 16

2. INITIAL REVIEW PROCEDURES

Supersedes:	Version 3
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Approved by:	DR. ZHARLAH G. FLORES Chair of the Board
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Approval Date:	June 14, 2021~~April 5, 2021~~

~~9.1.~~2.1. Management of Protocol Submission

~~9.1.1.~~2.1.1. Purpose

To describe the initial review procedures of the Ethics Review Committee (IRB) from the time that the IRB receives the protocol and related documents until the approval letter is sent by the IRB to the Principal Investigator

~~9.1.2.~~2.1.2. Scope

The Jose R. Reyes Memorial Medical Center IRB accepts the following protocols for review: 1) Jose R. Reyes Memorial Medical Center funded researches, 2) researches done in Jose R. Reyes Memorial Medical Center, 3) researches referred from the PNHRS, PHREB, DOH, industry organizations, etc., on the condition that the host hospital/ institution where the proposal will be done accepts the review of Jose R. Reyes Memorial Medical Center IRB and agrees to abide by the rules and regulations that the Jose R. Reyes Memorial Medical Center IRB follows (based on PHREB and FIRBAP rules). The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/institutions that accept Jose R. Reyes Memorial Medical Center IRB review.

~~9.1.3.~~2.1.3. Responsibility

The IRB Secretariat manages all protocol submissions to the IRB. It covers the actions to be done from the time of submission to the filing of the original protocol package in the Active Study File cabinet and the preparation of copies of the documents for distribution to the reviewers.

2.1.4. Process Flow/Steps

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the initial protocol package for review and check the completeness of the documents together with the IRB application form signed and a letter certifying it has undergone technical review	Secretariat	To be done in 7 days
2	Assigns a permanent code to the package		
3	Make a duplicate of the application form and give the duplicate to the person submitting the package and attach the original copy to the IRB's copy		
4	Log the received protocol in the IRB database		
5	Inform the Chair/Member-Secretary of the submission for classification as a full board or expedited review		
6	Make copies of the protocol package and prepare them for distribution to the reviewers		7 days
7	File the original package in a properly coded Protocol File folder and place it in the Active Files		1 day

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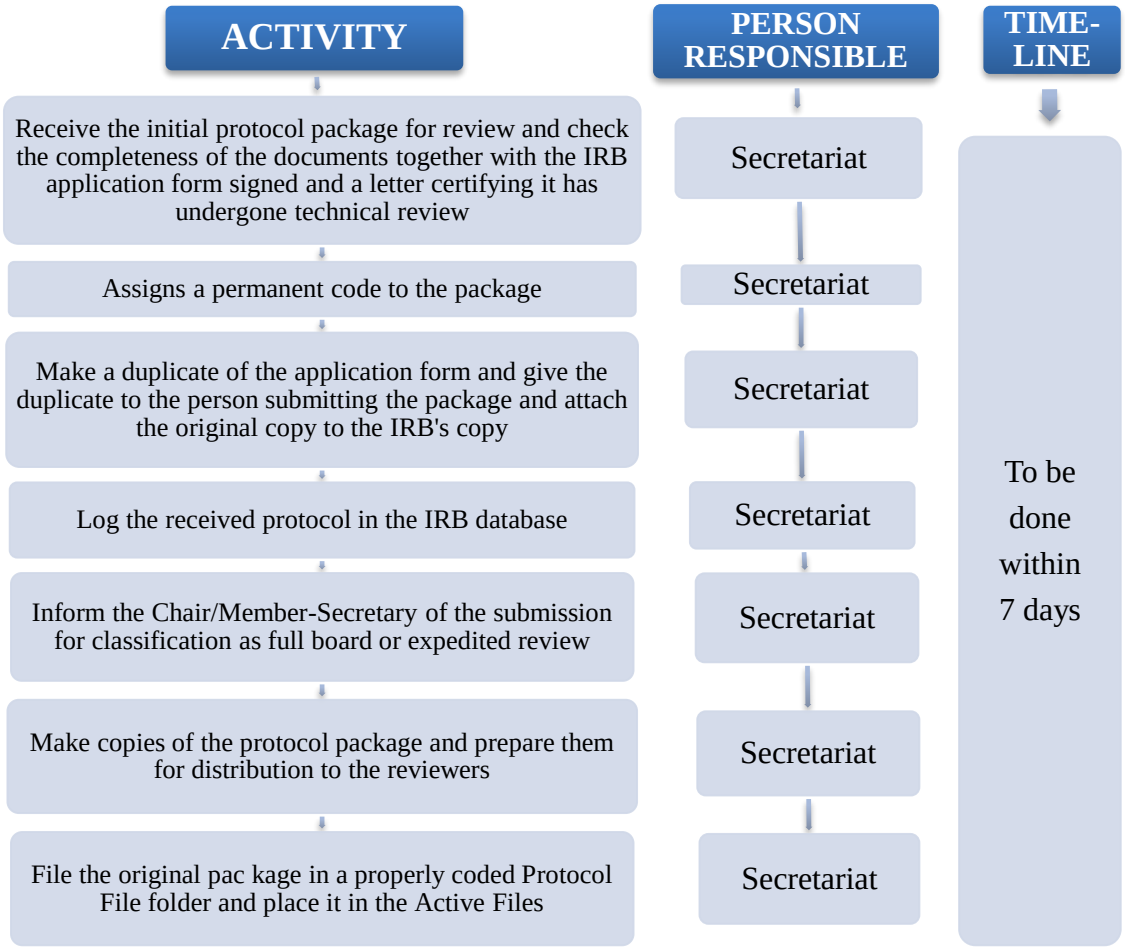
9.1.23.



2.1.5. Detailed Instructions

2.1.5.1. All protocols need technical approval prior to ethical review. For Jose R. Reyes Memorial Medical Center IRB-funded or initiated protocols, the Technical Review Committee should have addressed the technical issues apparent to the study protocol. For non-Jose R. Reyes Memorial Medical Center IRB-funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.

2.1.5.2. The secretary checks that the PI has signed the Jose R. Reyes Memorial Medical Center IRB Application Form for Protocol Review (Form 2.1)

2.1.5.3. Secretary checks the documents being submitted based on the IRB checklist.

A protocol package has to include the following:

- Full protocol
- An e~~E~~xecutive summary that follows the research project proposal format
- Declaration of conflict of interest
- Data collection form/s
- Informed Consent form (English and local dialect)
- Budget

- CV of the PI and co-investigators and their GCP Certificate (as necessary but mandatory for sponsor-initiated studies)
- GANTT Chart (as necessary)
- Ads for recruitment, if applicable
- Technical approval document

2.1.5.4. Upon submission of the initial protocol for Jose R. Reyes Memorial Medical Center IRB review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet (Form 2.3)

2.1.5.5. A code is assigned to the package. The code will be communicated to the principal investigator in subsequent communications regarding the protocol

2.1.5.6. The secretary makes a copy of the filled-in application form, keeps the original copy for the IRB files, and gives the duplicate to the principal investigator (PI) or his/her representative.

2.1.5.7. Log the protocol in the IRB database.

2.1.5.8. The chair or member secretary is informed about the submitted protocol so that it can be classified whether for full board or expedited review.

2.1.5.9. Manage the protocol package:

For protocols requiring a full board review:

- Make sufficient copies of the protocol package for ~~the IRB files, for~~ each of the primary reviewers~~, and for each IRB member.~~ Put the original copies in a protocol file folder.
- Primary reviewers will have the full protocol package while the other members will be provided with a protocol summary.
- Put the code of the protocol on the side of the file folder.
- File the folder in the Active Study Files cabinet.

~~Primary reviewers will have the full protocol package while the other members will be provided with protocol summary.~~ 25 6

For protocols that can be subjected to expedited review:

- Make 3 copies of the protocol package for the IRB files and ~~for~~ each reviewer. Put the original copies in a protocol file folder.
- Put the code of the protocol on the side of the file folder.
- File the folder in the Active Study Files cabinet.

2.1.6. Prepare the copies of the protocol for distribution to the reviewers. Include blank copies of the "Reviewer Assessment Form" (Form 2.4) and the "Informed Consent Evaluation Form" (Form 2.5) in the package.

2.1.7. Enter in the IRB database the names of the primary reviewers to whom the packages are to be delivered. Prepare a transmittal letter with the name of the reviewer, the date of actual delivery to be signed by the reviewer or a representative upon receipt.

Note: Primary reviewers are selected ~~on the basis of~~based on expertise related to the protocol. Research proposals are given to both medical and non-medical or lay members, institutional and non-institutional members for review. The medical/scientific members analyze the scientific and ethical procedures in the

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protocol while the lay/non-institutional members focus their assessment on the informed consent form.

2.2. Use of Study Assessment Forms

2.2.1. Purpose

To describe the procedures related to the use of study assessment forms in ethics review

2.2.2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to Jose R. Reyes Memorial Medical Center IRB for initial review and approval by the IRB. The IRB uses two study assessment forms. The two assessment forms are accomplished by individual reviewers. Any comments, evaluation, recommendations, and the initial decision of each reviewer regarding a protocol are all noted in these two forms.

The Study Assessment Forms are designed to standardize the review process and to facilitate reporting of the recommendation and comments given to each individual protocol and related documents.

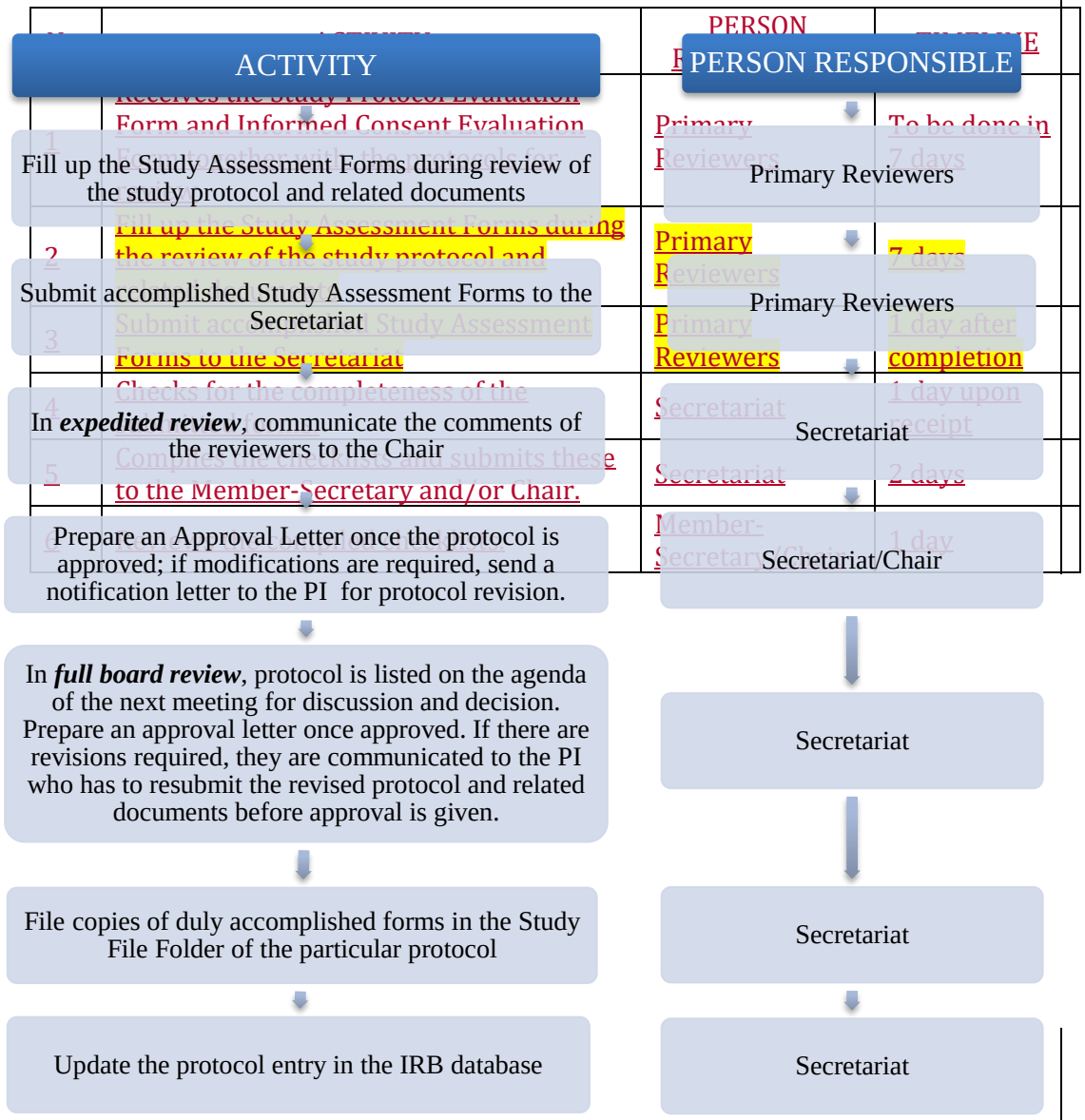
There are two (2) Jose R. Reyes Memorial Medical Center IRB Assessment Forms for protocol review (see Annex for samples):

a. Study Protocol Evaluation Form (Form 2.4)
b. Informed Consent Evaluation Form (Form 2.5)

2.2.3 Responsibility

It is the responsibility of the Jose R. Reyes Memorial Medical Center IRB reviewers to individually fill in the assessment forms after reviewing each study protocol. The Secretariat is responsible for recording and filing the Jose R. Reyes Memorial Medical Center IRB's action, relevant points, and deliberation about a particular protocol, including the comments for specific action. The consensus/agreements regarding the decisions on each reviewed protocol will be reflected in the Minutes of the Meeting.

2.2.4. Process Flow/Steps



2.2.5. Detailed Instructions

2.2.5.1. The Jose R. Reyes Memorial Medical Center IRB reviewer checks if the two Study Assessment Forms (Study Protocol Evaluation Form and Informed Consent Evaluation Form) are attached with each protocol package received for review.

2.2.5.2. The IRB primary reviewers individually fill in both forms for each protocol.

2.2.6. The Evaluation Forms include some important items.

2.2.6.1. The Study Protocol Evaluation Form ensures assessment of the *scientific and ethical aspects* of the protocol that may include:

- Rationale and significance of the study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria

2.2.6.2. The *Informed Consent Evaluation Form* checks if the following are complied with:

- Full disclosure of information, including risks
- Benefits that may be derived from the study
- Use of understandable language
- Voluntary participation
- Confidentiality
- The aAppropriate person to sign the consent form
- Vulnerability determination
- Risk/benefit assessment
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2.2.7. The primary reviewer signs and submits the evaluation forms together with the reviewed protocol back to the Secretariat within 7 working days.

2.2.8. The Secretariat checks whether the forms are complete, compiles the checklists, and submits these to the Member-Secretary and/or Chair.

2.2.9. The Member-Secretary and/or Chair reviews the compiled checklists.

2.2.10. In expedited review, if the protocol is approved, the Secretariat prepares the approval letter that is signed by the Chair and sent to the principal investigator. If there are revisions required, they are communicated to the PI who has to resubmit the revised protocol and related documents before approval is given. A lIist of expedited protocols will be listed in the agenda of the nearest meeting.

2.2.11. In full board review, the Secretariat includes the protocol in the agenda of the ~~next Jose R. Reyes Memorial Medical Center~~ IRB meeting for discussion and decision. An approval letter is prepared, signed by the Chair, and sent to the PI once a protocol is

approved. If there are revisions required, they are communicated to the PI who has to resubmit the revised protocol and related documents before approval is given.

2.2.12. A copy of the signed letter is retained in the protocol file folder.

2.3. Exempt from Review

2.3.1. Purpose

To describe the JRRMMC IRB procedures for the review of protocols that qualify for exemption from review.

2.3.2. Scope

This SOP applies to the review of a study protocol submitted to the IRB that qualifies for exemption from review.

Exempt Categories:

1. Education research
2. Surveys, interviews, educational tests, public observations (that do not involve children)
3. Benign behavioral interventions
4. Analysis of previously collected, identifiable info/specimens
5. Taste and food evaluation studies
6. Meta-analysis

Category 1 – Education research

Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact medical residents/fellows or nurse's opportunity to learn or assessment of educators

Examples:

- ✓ Evaluating the use of accepted or revised standardized tests
- ✓ Testing or comparing a curriculum or lesson
- ✓ A program evaluation of pharmacy continuing education

Category 2 – Surveys, interviews, educational tests, public observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior and:

- Recorded information cannot readily identify the subject (directly or indirectly/linked) OR

- Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)

Examples:
✓ Surveying doctors, or nurses about a technique or an outcome
✓ Interviewing specialists or managers about a management style or best practice
✓ Conducting a focus group about an experience or an opinion of a community program

Category 3 – Benign Behavioral Interventions
Research involving Benign Behavioral Interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agrees and ONE of following met:

- The recorded information cannot readily identify the subject (directly or indirectly/linked) OR
- Any disclosure of responses outside of the research would NOT reasonably place the subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)

Example:
✓ Solving puzzles under various noise conditions
✓ Playing an economic game
✓ Being exposed to stimuli such as color, light, or sound (at safe levels)
✓ Performing cognitive tasks

Category 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens
Secondary research with identifiable Information/specimens collected for some other initial activity, if ONE of the following:

- Biospecimens or information is publically available
- The information recorded so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects
- Collection and analysis involving Investigators Use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes.

Category 5 – Taste and food quality evaluation studies
Taste and food quality evaluation and consumer acceptance studies,
- If wholesome foods without additives are consumed OR
- If food is consumed that contains a food ingredient at or below the level and for 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 DOA or DENR.

Example:
✓ Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

Category 6 – Meta-Analysis

Meta-analysis is a quantitative, formal, epidemiological study design used to systematically assess previous research studies to derive conclusions about that body of research. Outcomes from a meta-analysis may include a more precise estimate of the effect of treatment or risk factor for disease, or other outcomes, than any individual study contributing to the pooled analysis. The examination of variability or heterogeneity in study results is also a critical outcome. The benefits of meta-analysis include a consolidated and quantitative review of a large, and often complex, sometimes conflicting, body of literature. The specification of the outcome and hypotheses that are tested is critical to the conduct of meta-analyses, as is a sensitive literature search. A failure to identify the majority of existing studies can lead to erroneous conclusions; however, there are methods of examining data to identify the potential for studies to be missing; for example, by the use of funnel plots. Rigorously conducted meta-analyses are useful tools in evidence-based medicine. The need to integrate findings from many studies ensures that meta-analytic research is desirable and the large body of research now generated makes the conduct of this research feasible.

Reviews, meta-analyses, or descriptions of educational materials do not involve human subjects and do not require IRB review. Unless you are systematically collecting quantitative or qualitative information to share outside your institution (e.g. for publication or at a meeting) and your research involves human subjects.

2.3.3 Responsibility

The Chair or an IRB Member designated by the Chair is responsible for the assessment of whether the submitted protocol qualifies for exemption for review. Exempt reviews are conducted by at least one reviewer.

2.3.4. Process Flow/Steps (to be done within 7 days)

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Review a study protocol applying for exemption from review	Chair/Designated Member	To be done within 7 days
2	Issue Certificate of Exemption or recommend expedited or full board review	Chair	
3	Prepare a report of protocols that are exempt from review to full board	Secretariat	
4	Communicate the REC decision to the PI	REC Staff	
5	File copy of the documents in the protocol binder and update protocol database for exemption from review	REC Staff	

2.3.5. Detailed Instructions

2.3.5.1 Review a study protocol applying for exemption from review

- The IRB Chair or a designated IRB member who does not have any conflict of interest should review the study protocol applying for review exemption.

- The IRB Chair or a designated IRB member shall then evaluate the study protocol using the Exemption Criteria.

2.3.5.2 Issue Certificate of Exemption or recommend expedited or full-board review

- If the protocol qualifies for exemption from review, the reviewer submits the results of the assessment to Secretariat for the REC staff to prepare a Certificate of Exemption from Review.
- If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review.

2.3.5.3 Prepare a report of protocols that are exempt from review to full-board

- The IRB staff prepares a report for~~to~~ the next full board meeting to include details of all protocols exempted from review.

2.3.5.4 Communicate the IRB decision to the Principal Investigator

- The IRB staff prepares the *Certificate of Exemption* from review and forwards it to the Chair for signature.
- The IRB staff issues the *Certificate of Exemption* to the Principal Investigator

2.3.5.5 File copy of the documents in the protocol binder and update protocol database for exemption from review

- Prepare a binder to contain all protocols exempt from review.
- File the properly- labeled binder in the appropriate shelf of the storage cabinet.
- Update protocol database for exemption for review.

2.4. Expedited Review

2.4.1 Purpose

To describe the procedures for the review of protocols that qualify for expedited review.

2.4.2 Scope

This SOP applies to the review and approval of study protocols or amendments with minimal risk to study participants and minor revisions in the protocol or informed consent. The submission procedures are the same as for the first-time submission.

The following are types of protocols ~~which~~ that can be subjected to expedited review after initial submission:

2.4.2.1. Protocols of a non-confidential nature (not of a private character, e.g. related to sexual preference, etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.

2.4.2.2. Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to ~~2.4.2.2.~~ retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergencies~~cy situations~~,

ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent).

2.4.2.3. Protocols that involve the collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids, or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

2.4.2.4. Research involving data, documents, or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

2.4.2.5. Proposed continuing reviews, protocol amendments, and end of study reports that have minor modifications and no significant risk to study participants.

2.4.3. Responsibility

Expedited review is the responsibility of primary reviewers appointed to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

~~2.4.4.~~ Process Flow/Steps
2.4.4.

	~~ACTIVITY~~	~~PERSON RESPONSIBLE~~	~~TIMELINE~~
~~1~~	~~Receive the submitted documents and forward to the Chair or Member-Secretary~~	~~Secretariat~~	~~3 working days~~
~~2~~	~~Determine that the protocol is for expedited review~~	~~Member-Secretary/ Chair~~	
~~3~~	~~Assign reviewers for the expedited review~~	~~Member-Secretary/Chair~~	
~~4~~	~~Do the expedited review and submit the decision to the Secretariat~~	~~Primary Reviewers~~	~~7 days~~
~~5a~~	~~Communicate the decision for approval or revision to the Chair~~	~~Secretariat~~	
~~5b~~	~~If modifications are required, revise the protocol or related document and resubmit to the IRB~~	~~Principal Investigator~~	~~7 days~~

~~No.~~	~~ACTIVITY~~	~~PERSON RESPONSIBLE~~	~~TIMELINE~~
~~6~~	~~Prepare an Approval Letter to be signed by the Chair and sent to the PI. Report of results of expedited review to full board~~	~~Secretariat and Chair~~	
~~7~~	~~Keep copies of related documents in the files~~	~~Secretariat~~	~~7 days~~
~~8~~	~~Update the IRB database~~	~~Secretariat~~	
~~5c~~	~~Check and review revisions~~	~~Primary Reviewers~~	~~7 days~~

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the submitted documents and forward them to the Chair or Member-Secretary	Secretariat	3 working days
2	Determine that the protocol is for expedited review	Member-Secretary/ Chair	
3	Assign reviewers for the expedited review	Member-Secretary/Chair	
4	Do the expedited review and submit the decision to the Secretariat	Primary Reviewers	7 days
5a	Communicate the decision for approval or revision to the Chair	Secretariat	
5b	If modifications are required, revise the protocol or related document and resubmit to the IRB	Principal Investigator	7 days
5c	Check and review revisions	Primary Reviewers	7 days
6	Prepare an Approval Letter to be signed by the Chair and sent to the PI. Report of results of an expedited review to the full board	Secretariat and Chair	2 days
7	Keep copies of related documents in the files	Secretariat	1 day
8	Update the IRB database	Secretariat	1 day

2.4.5 Detailed Instructions

2.4.5.1. The Secretariat receives the documents submitted for initial review. Receive the application documents submitted by investigators.
Check items received using the checklist as a guide.
~~_____~~Sign a copy of the application form to acknowledge receipt of the documents and return a copy to the principal investigator or a duly designated representative.

2.4.5.2. The Chair should classify the protocol whether for full board or expedited review within 2 days after receipt by the Secretariat. He/She or the Member Secretary then assigns two Jose R. Reyes Memorial Medical Center IRB members (a m~~M~~edical member with related expertise to review the protocol and a non-medical person to review the informed consent.) to do the expedited review. Once classified as for Expedited review, The Secretariat sends the protocol and related documents to the selected primary reviewers within 24 hours. An independent consultant may be invited to provide an expert opinion about a protocol.

2.4.5.3 The members carry out the expedited review o~~f~~n the protocol and related documents (patient information sheet, consent form, advertisements, etc.) and return~~s~~ their assessment to the secretariat in 7 working days.

2.4.5.4 If consensus cannot be reached, the Chair will refer the protocol to the IRB board for the full review.

2.4.5.5 If the reviewers did not require full board review, the secretariat shall prepare a transmittal letter with the comments and after being noted by the Chair, the decision will be sent to the principal investigators. If modification is required, the PI makes the necessary revisions and resubmits to the IRB.

2.4.5.6 The reviewers check the modifications for approval.

2.4.5.7 An approval letter is prepared and signed by the Chair and sent to the principal investigator.

2.4.5.8 The Secretariat will include only the approved expedited which will be included in the agenda of the next meeting.

2.4.5.9 The Secretariat keeps copies of related documents in the files and updates the database.

2.5. Full Board Review of Submitted Protocols

2.5.1 Purpose

To describe the procedures when protocol submissions are classified for full board review

2.5.2 Scope

This SOP applies to the review and approval of study protocols or amendments with medium to high risk to study participants and major revisions in the protocol or informed consent. The submission procedures are the same as the first-time submission.

The following are types of protocols that should undergo full board review after initial submission:

2.5.2.1. Clinical trials about investigational new drugs, biologics, or devices in various phases (Phase 1, 2, 3).

2.5.2.2. Phase 4 intervention research involving drugs, biologics, or devices.

2.5.2.3. Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences, etc., or about sensitive issues that may cause social stigma) that may cause psychological, legal, economic, and other social harm.

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2.5.2.4. Protocols involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent) that require additional protection from the IRB during the review.

2.5.2.5. Protocols that involve the collection of identifiable biological specimens for research.

2.5.3 Responsibility

It is the responsibility of the Secretariat to manage the document submission, send protocol documents to the primary reviewers, refer the protocol to a full board meeting for discussion and decision, communicate the review results to the Principal Investigator, keep copies of the documents in the protocol files and update the protocol entry in the IRB database.

It is the responsibility of the primary reviewers to review the protocol and related documents by using the assessment forms and make a recommendation for appropriate action. They should submit their assessment within 7 working days.

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The Secretariat is responsible for receiving, verifying, and managing the contents of both the hard copies and the electronic version (if any) of the submitted protocol package. In addition, the Secretariat should create a specific protocol file, make copies of the file and then distribute the copies to the Jose R. Reyes Memorial Medical Center IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated.

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments and put all of this in the Study Assessment Forms before returning the reviewed protocol and assessment form to the Secretariat on the due date.

2.5.4 Process Flow/Steps

~~NO.~~	~~ACTIVITY~~	~~PERSON RESPONSIBLE~~
~~1~~	~~Receive the submitted documents and forwards to the Chair or Member-Secretary~~	~~Secretariat~~
⬇		

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the submitted documents and forward to the Chair or Member	Secretariat	1 day
2	Determine that the protocol qualifies for Full Board review	Member-Secretary/ Chair	1 day
3	Assign reviewers to review the protocol and related documents	Member-Secretary/Chair	1 day
4	Review the protocol documents using the assessment forms and submit the decision/ recommendation to the Secretariat	Primary Reviewers	7-10 days
5	Include the protocol in the meeting agenda for discussion to decide on through full board	Secretariat/ Members	1 day
6	A letter containing the recommendations and decision about the given protocol is sent to the PI one week after the meeting.	Principal Investigator	1 day
7	Check and review revisions	Primary Reviewers	2-3 days
8	Prepare an Approval Letter to be signed by the Chair and sent to the PI. Report of results of an expedited review to the full board	Secretariat	2-3 days
9	If modifications are required, revise the protocol or related document and resubmit to the IRB within three months after which the initial review will be considered void; hence, the PI has to re-apply again.	Principal Investigator	Within 3 months
10	Check and review revisions and refer to full board for decision	Primary Reviewers	1-2 days
11	After board approval, prepare the Approval Letter to be signed by the Chair and sent to the PI	Secretariat	2-3 days
12	Keep copies of all documents in the files	Secretariat	1 day
13	Update the protocol entry in the IRB database	Secretariat	2 days

8	Check and review revisions and refer to full board for decision	Primary Reviewers
	⬇	

9	After board approval, prepare the Approval Letter to be signed by the Chair and sent to the PI	Secretariat
⬇		
10	Keep copies of all documents in the files	Secretariat
⬇		
11	Update the protocol entry in the IRB database	Secretariat

2.5.5 Detailed Instructions:

2.5.5.1. Secretariat receives the protocol package and checks the completeness of the protocol package. The Document Receipt Form 2.2 is filled up upon receiving the package, indicating the date and receivers' signature is affixed.

2.5.5.2. Return the signed acknowledgment form back to the representative of the principal investigators./

2.5.5.3. Determine if the protocol qualifies for full board review, select primary reviewers with appropriate qualifications (clinician/scientist with expertise related to the protocol and a non-medical person to review the consent form). An independent consultant may be invited to provide an expert opinion.

2.5.5.4. Send the protocol files together with the assessment forms to the primary reviewers/independent consultant.

2.5.5.5. Note the due date for submitting the results (accomplished checklists) and the protocols back to the IRB Secretariat.

2.5.5.6. Protocol Review

2.5.5.6.1. Use the Protocol Evaluation Form (**Form 2.4**) for the protocol and the Informed Consent Evaluation Form (**Form 2.5**) to review the protocol and the consent form and write relevant comments.

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2.5.5.6.2. Check the CV or information about the investigators (including GCP training for clinical trials), the study sites, and other protocol-related documents, including advertisements.

2.5.5.6.2.1. Consider whether the study and training background of the principal investigator/s are related to the study.

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2.5.5.6.2.2. Look for disclosure or declaration of potential conflicts of interest.

2.5.5.6.2.3. Non-physician principal investigators should be advised by a physician when necessary.

2.5.5.6.2.4. Determine if the facilities and infrastructure at study sites can

accommodate the study.

2.5.5.6.3. Check the "Assent Form" if the protocol involves children or other vulnerable groups as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

2.5.5.6.4. The primary reviewers are advised to note the following **Review Guidelines:**

2.5.5.6.4.1. The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.

2.5.5.6.4.2. In assessing the degree of risk against the benefit, determine whether the risks are reasonable in relation to anticipated benefits; and/or if the risks can be minimized.

~~2.5.5.6.4.2.~~

2.5.5.6.4.3. Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheets should be clear, complete, and written in understandable language.

~~2.5.5.6.4.3.~~

2.5.5.6.4.4. There is voluntary, non-coercive recruitment of study participants.

~~2.5.5.6.4.4.~~

2.5.5.6.4.5. The Informed Consent is adequate, easy to understand, and properly documented.

~~2.5.5.6.4.5.~~

2.5.5.6.4.6. There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.

~~2.5.5.6.4.6.~~

2.5.5.6.4.7. The procedure for getting ~~the~~ Informed Consent is clear and unbiased.

~~2.5.5.6.4.7.~~

2.5.5.6.4.8. The persons who are responsible for getting the Informed Consent are named and they introduce themselves to the study participants.

~~2.5.5.6.4.8.~~

2.5.5.6.4.9. The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.

~~2.5.5.6.4.9.~~

2.5.5.6.4.10. There are adequate provisions to protect the privacy of study participants and to maintain the confidentiality of data, where appropriate.

~~2.5.5.6.4.10.~~

2.5.5.6.4.11. There is a provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study-~~–~~related injuries, as well as compensation for participation to cover expenses like transport and lost wages because of participation.

~~2.5.5.6.4.11.~~

2.5.5.6.4.12. There are appropriate safeguards included protecting~~to protect~~ vulnerable study participants.

~~2.5.5.6.4.12.~~

2.5.5.6.4.13. Contact persons with addresses and phone numbers are included in the Informed Consent.

~~2.5.5.6.4.13.~~

2.5.5.6.4.14. There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.

~~2.5.5.6.4.14.~~

2.5.5.6.4.15. There are appropriate contracts or memoranda of understanding, especially in collaborative studies.

~~2.5.5.6.4.15.~~

2.5.5.6.4.16. Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:

~~2.5.5.6.4.16.~~

- Community consultation

~~2.5.5.6.4.16.1.~~

~~2.5.5.6.4.16.2.~~ Involvement of local researchers and institutions in the protocol design, analysis, and publication of the results

-

~~2.5.5.6.4.16.3.~~ Contribution to the development of local capacity for research and treatment in benefit to local communities

~~2.5.5.6.4.16.4.~~ Sharing of study results with the participants/ community

2.5.5.7. After reviewing the protocol and the documents, the reviewer recommends a decision.

2.5.5.7.1. Record the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision for ~~resubmissiona~~, or Disapproved.

2.5.5.7.2. Include comments and reasons for disapproval.

2.5.5.7.3. Check the completeness and correctness of marked items in the assessment forms. Indicate the date and affix the reviewer's signature in the decision form.

2.5.5.8. Submit the completed forms to the Secretariat together with the protocol documents.

2.5.5.9. Secretary includes the protocol in the next meeting agenda.

2.5.5.10 Conduct a full board meeting to discuss and make a decision about the protocol and related documents.

2.6. SJREB Review

2.6.1. Purpose

To describe the authority, composition, and structure of the Single Joint Research Ethics Board (SJREB) related to the ethics review of multi-site researches. To streamline and harmonized the review process of health-related protocols to be conducted in multiple sites in the Philippines. To shorten the turn-around time of ethics review of multi-site protocols SJREB is organized by the Department of Health (DOH) Health Policy Development and Planning Bureau (HPDPB).

2.6.2. Scope

SJREB is a joint review mechanism among PHREB duly accredited Research Ethics Committees (RECs) of DOH hospitals. SJREB is available to other non-DOH RECs from both public and private organizations that will accept the results of SJREB and sign a letter of intent with SJREB. It is a cooperative mechanism, rather than a stand-alone REC, that draws its review authority from RECs duly accredited by the Philippine Health Research Ethics Board.

SJREB conducts a joint review of study protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED, and other local organizations, including industry organizations and other foreign entities.

SJREB requires the site RECs to agree and abide by the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study

2.6.3. Responsibility

It is the responsibility of the Health Policy Development and Planning Bureau (HPDPB)with authority under DOH to organize the structure and composition of SJREB to enable it to perform its joint review functions.

2.6.4 Terms of Reference

The SJREB Chair presides over full board meetings and ensures appropriate review of protocol-related documents by following international and national guidelines and regulations. He/she may designate a representative from an accredited REC to preside over a meeting that he/ she cannot attend the meeting.

The SJREB Secretariat manages the day-to-day activities of SJREB to include office procedures, communication with various stakeholders, and ensuring appropriate REC and site representation during the conduct of the review. The SJREB Secretariat invites reviewers from RECs of sites selected by the sponsor or researcher to conduct the study. It checks whether the site REC has level 2 or 3 PHREB accreditation. Only level 3 REC representatives can vote during full board review of clinical trial protocols intended for FDA registration, while both levels 2 and 3 REC representatives can vote during the review of public health protocols and clinical research not intended for FDA registration. It issues a decision certificate that is binding on all DOH Hospital RECs that will conduct subsequent continuing review of protocols initially approved by SJREB.

The site RECs that participate in SJREB are all DOH Hospital RECs are duty-bound to accept the results of SJREB review were qualified DOH Hospital RECs participated in the deliberations and decision making. Site RECs participating in joint review agree to share their review responsibilities with SJREB. Authority is shared by a duly accredited site REC with SJREB to conduct the joint review with representatives from site RECs of multi-site researches. A joint review by SJREB is done only for initial review and renewal of approval. SJREB conducts a full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low-risk protocols may be exempted from

review or may go through expedited review procedures. Site RECs who will participate in a joint review should submit their membership list with their CVs and they should identify representatives qualified to do a scientific and ethical review for various types of protocols commonly submitted for review. There should be a parallel submission of protocol documents to SJREB and all site RECs are expected to conduct a preliminary review of the protocol DOH Hospital RECs accept the results of the joint review. Site RECs will issue a Certificate of Approval together with a Notice of REC decision from SJREB. The site REC, retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports, and final reports, all of which involve events at specific sites. The site REC maintains active collaboration and communication with SJREB for joint review to achieve its stated objectives and for the mutual benefit of improving the research environment in the Philippines.

2.6.5. Joint Review of Initial Submission

2.6.5.1 Purpose

To describe the Single Joint Research Ethics Board's (SJREB) procedures in conducting initial and continuing review of multi-site protocol-related documents.

2.6.5.2 Scope

This procedure applies to all multi-site protocols submitted to the SJREB for initial ethics review.

- The SJREB accepts protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB.
- SJREB accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED, and other local organizations, including industry organizations and other foreign entities.
- SJREB requires a Letter of Intent to regularly participate in joint reviews from non- DOH Research Ethics Committees when their sites are selected by the sponsors to conduct the study.
- SJREB requires the site RECs to agree and abide by the procedures that SJREB follows.
- All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.

2.6.5.3 Responsibility

The SJREB Secretariat manages all protocol submissions to the SJREB. It covers the actions to be done from the time of submission to the filing of the initial protocol documents in the SJREB office.

Classification of Protocols Submitted for Initial Review SJREB classifies protocols into 3 types to determine the appropriate type of review of multi-site protocols. Detailed procedures for classification into 3 types of review

1. For Exemption from Ethics Review:
   - ✓ SJREB will issue a Certificate for Exemption.
   - ✓ The SJREB Secretariat in consultation with the Chair or research ethics consultant decides if the protocol meets the exemption criteria as follows:
     a. Research about public behavior (voting trends, opinion surveys, etc)
     b. Evaluation of public programs by the agency itself
     c. Quality control studies by the agency itself
     d. Standard educational tests and curriculum development
     e. Surveillance functions of DOH
     f. Historical and cultural events
     g. Research involving large statistical data without identifiers
     h. Research not involving humans

2. For Expedited Review:
   - ✓ SJREB Secretariat in consultation with the Chair or research ethics consultant checks if the protocol qualifies for expedited review based on the following criteria:
     a. About a topic that should not result in causing social stigma
     b. Does not involve vulnerable populations
     c. Retrospective studies using anonymized data from medical records
     d. Studies using simple questionnaires without identifiers
     e. Laboratory research that uses anonymized human tissue/specimen SJREB Secretariat identifies two or more primary reviewers from the participating sites to conduct initial review through expedited procedures.
     f. SJREB may also call for a meeting of the sites to expedite the review.
     g. If there is agreement among the reviewers that the protocol is approvable through expedited means, the protocol remains with the expedited reviewers until the protocol documents are modified and finally approved by the primary reviewers.
     h. SJREB Secretariat prepares a Notice of Decision to be signed by the Chair and communicated to the sponsor/ coordinating investigator that submitted the protocol for a review and all the participating sites
     i. SJREB expects the participating sites to accept its decision.
     j. Each site REC will issue a Certificate of Approval.

3. For Full-Board Review:
   - ✓ SJREB Secretariat classifies more than minimal risk protocols for full board review and consults SJREB Chair to confirm its classification.
   - ✓ SJREB Secretariat informs the site RECs of its receipt of protocols for the full board of joint review.
     - ✓ SJREB appoints primary reviewers from site RECs or invites independent consultants to prepare their comments using SJREB assessment forms and lead the discussion about the protocol during the board meeting.
     - ✓ SJREB Secretariat schedules the date of the full board meeting, prepares the meeting agenda, and informs the SJREB Chair, PHREN representative, representatives of site RECs representatives of DOH specialty hospitals, as well as independent consultants to attend the meeting.

- ✓ The Coordinating PI, together with the Sponsor representatives are also invited to answer queries about the protocol.
- ✓ A full-board adopts one of the following decisions during the joint review.
  - Approval
  - Minor modification required
  - Major modification required
  - Disapproved
- ✓ SJREB Secretariat informs the Coordinating PI and Sponsor of the results of Joint Review, including recommendations for modification, if any.
- ✓ SJREB Secretariat informs all the sites selected to conduct the study of its decision for endorsement of site RECs that are expected to accept the SJREB decision.
- ✓ Each site REC will issue a Certificate of Approval or a notice of its decision if it chooses to disapprove the protocol.
- ✓ The site RECs can disapprove of the protocol only when they think that there were strong ethical issues that were not addressed.
- ✓ Reasons for disapproval should always be stated in the decision letter.

2.7. Decisions regarding reviewed protocols

2.76.1. Purpose

To describe the procedures involved in the discussion and decisions made regarding protocols during the IRB meeting

2.76.2. Scope

This SOP applies to the conduct of full board review wherein the assessment about the protocols reviewed will be discussed during the meeting to come up with a decision.

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2.76.3. Responsibility

The secretariat is responsible for preparing the agenda for the meeting and the collation of the assessment made by the different reviewers on the submitted protocols. It is the responsibility of the reviewers to be present when the assigned protocol is included in the agenda so that they can explain their assessment. The IRB members will deliberate on the findings and come up with a decision regarding the protocol.

2.76.4. Process Flow/ Steps

No.	ACTIVITY	PERSON RESPONSIBI	RESPONSIBILITY
1	board review in the agenda	ariat	1 day
2	explains his/her assessment	Primary Reviewers	1 day
3	IRB Members may ask to be clarified on	IRB Members	1 day
4	A decision about the protocol arrives at a voting	IRB Members	1 day
5	whichever is applicable	ariat	2 days
6	with the corrected protocol together with Form 2.8 (Summary of Revisions)	Principal Investigator	90 days
7	PI must re-apply again. Prepare an Approval Letter to be signed	ariat	2 days
8	board If modifications are required, revise the protocol or related documents and after which the initial review will be considered void; hence, the PI has to re-apply again.	Principal Investigator	90 days
9	If approved, the PI may start working on his research and comply with the requirements as stated in the approval	Principal Investigator	within its indicated timeline

Includes the submitted protocols for full board review in the agenda

Secretariat

Prepares a powerpoint presentation of the different protocols with the comments of the respective reviewers

Secretariat

Gives a summary about the protocol and explains his/her assessment

Reviewers

IRB Members may ask to be clarified on certain aspects of the protocol

IRB Members

Decision about the protocol is arrived by voting

IRB Members

Prepares action letter/approval letter whichever is applicable

Secretariat

Response to the action within 3 months with the corrected protocol together with Form 2.8 (Summary of Revisions) otherwise the review becomes void and PI must re-apply again

Principal Investigator

If approved, the PI may start working on his research and comply with the requirements as stated in the approval

Principal Investigator

2.~~7~~6.5 Detailed Instructions

2.~~7~~6.5.1. The secretariat includes the protocols assigned for full board review in the agenda of the meeting

2.76.5.23. The Primary Reviewer/Independent Consultant shall sit in the full board meeting to explain their assessment of the scientific and ethical aspects of the protocol.

2.76.5.34. The members of the IRB attending the full board meeting arrive at a decision on the protocol for any of the following decision points: approval, minor revision, major revision for resubmission, or disapproval by a majority vote.

Major revision needs to be done if significant ethical issues are not being followed by the protocol like addressing risk to the subjects, flawed methodology, no protection for vulnerable subjects, non GCP compliant ICF among others.

Minor revision needs to be done if the corrections involve grammar, semantics, or spelling errors.

A protocol may be disapproved if there is no scientific merit in doing the paper, no new knowledge or it poses a significant risk to the subject without any benefit.

2.6.5.5.2.7.5.4. The Secretariat sends an Action Letter/Approval Letter (**Form 2.7**) with a list of approved documents to the principal investigator depending on the decision made during the IRB meeting.

2.6.5.6.2.7.5.5. The letter contains the identification of the document approved with version numbers and dates, the frequency of continuing review~~–~~, and the responsibilities of the principal investigator throughout ~~the course of~~ the study.

2.6.5.7.2.7.5.6. If the study is approved, the Jose R. Reyes Memorial Medical Center IRB determines the frequency of continuing review. Clinical trials should apply for continuing review yearly to cover the duration of the study. Trainee-~~-~~initiated protocols need not apply ~~on a yearly basis~~every year for continuing review but must submit an annual progress report.

2.6.5.8.2.7.5.7. If the Jose R. Reyes Memorial Medical Center IRB votes not to approve the study, the Secretariat immediately notifies the principal investigator in writing about the decision and the reason for not approving the study.

2.7.5.8. ~~If the principal investigator wishes to appeal the IRB decision, he/she may do so through a written request submitted to the Jose R. Reyes Memorial Medical Center IRB.~~ If the principal investigator wishes to appeal the IRB decision, he/she should adopt appropriate decisions by submitting a new protocol~~,~~ or make ~~a~~ major modifications that are subjected to review by the IRB.
~~. (for reject appeal???)~~

2.6.5.10.2.7.5.9. If the Jose R. Reyes Memorial Medical Center IRB requires modifications to any of the documents, the Secretariat prepares a letter to the Principal Investigator and identifies the necessary revisions to the documents before resubmission to the IRB.

2.6.5.11.2.7.5.10. If the protocol is approved, the Secretariat drafts the approval letter, forwards it to the Chair to sign, then sends it to the principal investigator. There should be a file/received copy with a specific date. All information regarding the date of the Jose R. Reyes Memorial Medical Center IRB decision such as the date when the decision was written and signed by the Chair, and the date when it was delivered to the principal investigator, are entered in the IRB database.

~~2.6.6~~2.7.6. All meeting deliberations and decisions regarding a protocol are noted in the meeting minutes, with relevant sections filed in the specific protocol file.

2.7.7. ~~2.6.7~~ The IRB database is updated to record the decision. Copies of the assessment forms are kept in the protocol files.

~~2.7.~~2.8. Review of a Medical Device Protocol

2.~~8~~7.1 Purpose

To describe procedures in the review of medical device protocols submitted to the IRB

~~2.7.2~~2.8.2 Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the Jose R. Reyes Memorial Medical Center IRB.

Medical device protocols are reviewed through full board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the IRB. The IRB should make provisions to minimize the risks to human participants during a review of the protocol and related documents.

2.~~7~~8.3 Responsibility

It is the responsibility of the IRB members to review medical device protocols ~~in accordance with~~following international and national guidelines and regulations.

t

2.87.4 Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Receive the submitted documents and forward to the Chair or Member-Secretary	Secretariat
Assign reviewers to review the protocol and related documents	Member-Secretary/Chair
Conduct the review using the assessment forms and submit the decision/recommendation to the Secretariat	Primary Reviewers
Full Board Review: include the protocol in the meeting agenda for discussion and decision by full board	Secretariat
If modifications are required, revise the protocol or related document and resubmit to the IRB	Secretariat
Check and review decisions	Principal Investigator
Prepare an Approval Letter to be signed by the Chair and sent to the PI	Primary Reviewers
Keep copies of related documents in the files	Secretariat
Update the protocol entry in the IRB database	Secretariat

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the submitted documents and forward them to the Chair or Member-Secretary	Secretariat	2 days
2	Assign reviewers to review the protocol and related documents	Member-Secretary/Chair	1 day
3	Conduct the review using the assessment forms and submit the decision/recommendation to the Secretariat	Primary Reviewers	7-10 days
4	Full Board Review: include the protocol in the meeting agenda for discussion and decision by full-board	Secretariat	1 day
5	If modifications are required, revise the protocol or related document and resubmit to the IRB	Secretariat	1 day

6	Check and review decisions	Principal Investigator	3 days	
7	Prepare an Approval Letter to be signed by the Chair and sent to the PI	Secretariat	3 days	
8	Keep copies of related documents in the files	Secretariat	1 day	
9	Update the protocol entry in the IRB database	Secretariat	1 day	

2.87.5 Detailed Instructions

2.87.5.1. The same procedures are followed when the protocol is submitted for initial review.

2.87.5.2. When reviewing a medical device protocol, the reviewer should consider the following:

~~2.7.5.2.2.~~ 2.87.5.2.1. Proposed investigational plan

2.8.5.2.2. Informed consent form
2.8.5.2.3. Description of the device/product information
2.8.5.2.4. Description of study participant selection criteria
2.8.5.2.5. Safety monitoring procedures
2.8.5.2.6. Reports of prior investigations conducted with the device
2.8.5.2.7. Principal investigator's curriculum vitae
2.8.5.2.8. Risk assessment determination for the new investigational device (Significant Risk or Non-Significant Risk)
2.8.5.2.9. Statistical plan and analysis
2.8.5.2.10. Copies of all labeling for investigational use

~~2.7.5.2.3. Informed consent form~~

~~2.7.5.2.3. Description of the device/ Product information~~

~~2.7.5.2.3. Description of study participant selection criteria~~

~~2.7.5.2.3. Safety monitoring procedures~~
~~2.7.5.2.3. Reports of prior investigations conducted with the device~~

~~2.7.5.2.3. Principal investigator's curriculum vitae~~

~~2.7.5.2.3. Risk assessment determination for new investigational device (Significant Risk or Non-Significant Risk)~~

~~2.7.5.2.3. Statistical plan and analysis~~

~~2.7.5.2.3. Copies of all labeling for investigational use~~

~~2.7.5.3~~2.8.5.3. The Secretariat checks the information/communication from the principal investigator related to the Significant Risk (SR) or Non- Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The protocol is assigned to or full board review depending on the risk assessment.

~~2.7.5.4~~2.8.5.4. Primary reviewers with appropriate expertise are assigned to review the protocol-related documents. It is advisable that a bioengineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a lay-person/non-medical member reviews the consent form.

~~2.7.7~~**2.8.6.** For full board review, a decision is made after discussion. If the protocols are for revision, they are sent back to the principal investigator for modification. The documents are resubmitted and reviewed through an expedited channel for minor revision and sent to a full board for review of major revisions.

~~2.7.8~~**2.8.7.** Once an approval decision is reached, the approval letter is prepared, signed by the Chair, and communicated to the principal investigator. The frequency of continuing review is indicated in the approval letter.

2.8.8. The relevant documents are kept in the protocol file and the IRB entry about the ~~e~~ protocol is updated.

APPLICATION FORM FOR PROTOCOL INITIAL REVIEW~~APPLICATION FORM FOR PROTOCOL REVIEW~~ (FORM 2.1)

		IRB Protocol Number:	
Sponsor Protocol Number:		Submission Date:	

Protocol Title:	

Type of Research:

☐ Clinical Research
☐ Clinical Trial
☐ Laboratory Research
☐ Genetic Research
☐ Sociobehavioral
☐ Public Health
☐ Others

Study Duration:

~~Type of Submission:~~	☐ ~~Initial Review~~	☐ ~~Continuing Review~~
	☐ ~~Resubmission for re-review~~	☐ ~~Protocol Termination~~
	☐ ~~Protocol Amendments~~	☐ ~~Final Report~~

~~Protocol Title:~~			
Principal Investigator:			
Telephone number:		Fax :	
E-mail:		Preferred Contact	☐ Phone ☐ Fax ☐ Email
Institute:			
Sponsor:			

Conflict of Interest Declaration (Relationship with the sponsor)	Are you a regular employee of the sponsor?	☐ Yes	☐ No
	Did you do consultancy or part-time work for the sponsor?	☐ Yes	☐ Yes
	In the past year, did you receive P250,000 or more from the sponsor?	☐ Yes	☐ Yes
	Other ties with the sponsor		

Ethical Responsibility and Conflict of Interest Statement:
I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

Prinpial Investigator Signature:	

t

DOCUMENT RECEIPT FORM (FORM 2.2)

Sponsor Protocol Number:		IRB Protocol No.	

Basic Documents (must submit):

☐ 1. **Printed Registration and Application Form** (Form 02. Fill-out all items, put N/A if not applicable).
☐ 2. **Cover Letter** (request letter for review addressed to the IRB Chair signed by the Principal Investigator and noted by the Department Chairman).
☐ 3. **Study Protocol** (attached is the sample content/format).
☐ 4. **Curriculum Vitae of PI and study team members** (Updated resume).
☐ 5. **Good Clinical Practice (GCP) Training Certificate** of PI, Co-I, and the study team.
☐ ~~6.~~ 6. **Electronic copy of all the study documents** (~~in CD-rom with case with complete title and author).~~thru email or google drive).
☐ ~~7.~~ 7. **Study Budget** (include an honorarium of the investigators, compensation to subjects, operational expenses, and the ~~s &~~ number of subjects for recruitment).

Study-specific Documents (submit as needed):

☐ ~~1.~~ 1. **Data collection forms / Case Report Forms / Questionnaires / Survey Forms** (Any tool ~~([~~validated~~])~~ that will be used in the study).
☐ 2. **Patient Information Form and**
☐ 3. **Informed Consent Form (ICF) in English and Tagalog** (for studies with human participants). It should conform w/ the guidelines set by ~~the~~ Phil. National Ethical Guidelines on Health Research 2011.
☐ 4. **Assent form in English and Tagalog** (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form).
☐ 5. **Investigator's Brochure** (for Phase I, II, III) or **Basic Product Information Document** (for clinical trials phase IV); Published literature/medical device information (for Drug Trials only).
☐ 6. **Recruitment advertisements and/or other information or documents for participants** (such as diaries, etc. as needed by the study protocol).
☐ 7. **Memorandum of Agreement** (for collaborative studies).
☐ 8. **List of other sites** (local and international) **& assigned Principal Investigators** (for multicenter global clinical trials (with contact numbers and address).
☐ 9. **PFDA Approval Letter** (A certification that study has been approved by the Philippines Food & Drug Administration).
☐ 10. **PFDA Certificate of Product Registration** (for use of marketed study drug) or PFDA Import Permit (for use of study drug that is not yet Philippines Food & Drug Administration registered).

Type of Researcher: ☐ **JRRMMC Medical Staff**

☐ **Clinical Trial – Sponsored**
☐ **Outside Research – Student**
☐ **JRRMMC Non-medical Employees**

Received by: _____
_____Signature over Printed Name

Date Received: _____

PROTOCOL SUMMARY SHEET (FORM 2.3)

IRB Protocol No:	Title

Principal Investigator	Sponsor

Rationale	
Objectives	
Study Design/ Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
~~Study Outcomes~~Ethical Consideration (social value, vulnerability, risk/	

benefit, privacy/ confidentiality	
Study Outcomes	

PROTOCOL EVALUATION FORM (FORM 2.4)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Principal Investigators:			
Department		Contact no./ Email	
Co – investigator(s):		Contact no./ Email	
Total No. of Participants:		No. of Study Sites:	
Sponsor		Contact No/ Email	
Duration of the Study:		Status:	☐ New ☐ Amended

Type of the Study

☐ Intervention ☐ Epidemiology ☐ Observational study
☐ Document review ☐ Individual based ☐ Genetic
☐ Social Survey ☐ Others, specify

Description of the Study in brief: Mark whatever applies to the study.

☐ Randomized	☐ Drug	☐ Use of Genetic Materials
☐ Double--blind	☐ Medical Device	☐ Multicenter study
☐ Single--blind	☐ Vaccine	☐ Global protocol
☐ Open--label	☐ Diagnostics	☐ Sponsor Initiated
☐ Observational	☐ Questionnaire	☐ Investigator Initiated

(to be filled up by the IRB)

Reviewers:	

Review Status ☐ Full Board ☐ Expedited

PROTOCOL DOCUMENT REVIEW

1.	Objectives of the Study ☐ clear ☐ unclear	What should be improved?
2.	Need for Human Participants ☐ Yes ☐ No	Comment:
3.	Methodology: ☐ clear ☐ unclear	What should be improved?
4.	Background Information and Data ☐ sufficient ☐ insufficient	Comment:
5.	Risks and Benefits Assessment ☐ acceptable ☐ unacceptable	Comment:
6.	Inclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
7.	Exclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
8.	Withdrawal Criteria ☐ appropriate ☐ inappropriate	Comment:
9.	Involvement of Vulnerable Participants ☐ Yes ☐ No	Comment:
10.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	Comment:
11.	Sufficient number of participants? ☐ Yes ☐ No	Comment:
12.	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:
13.	Are the qualifications and experience of the participating investigators appropriate? ☐ Yes ☐ No	Comment:
14.	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
15.	Facilities and infrastructure of participating sites	Comment:

☐ Appropriate ☐ Inappropriate

16. Community Consultation
☐ Yes ☐ No
Comment:

17. Involvement of local researchers and communities in the protocol preparation and implementation
☐ Yes ☐ No
Comment:

18. Contribution to local capacity building
☐ Yes ☐ No
Comment:

19. Benefit to local communities
☐ Yes ☐ No
Comment:

~~Contribution to local capacity building~~
~~☐ Yes ☐ No~~
~~Comment:~~

20. Sharing of study results
☐ Yes ☐ No
Comment:

~~18.1. Contribution to local capacity building~~
~~Comment:~~

21. Are blood/tissue samples sent abroad?
☐ Yes ☐ No
Comment:

~~19.~~1.~~-~~ Is the Principal Investigator qualified to conduct the study?~~Are blood/tissue samples sent abroad?~~
2.
☐ Yes~~Yes~~ ☐ No~~No~~
Comment:~~Comment:~~

23. Is the site appropriate to the study?
☐ Yes ☐ No
Comment:

A. RECOMMENDATION

DECISION :	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Summary of Comments ~~(Identify items for revision.)~~			
Reviewer's Name		Date:	
Signature :			

INFORMED CONSENT EVALUATION FORM (FORM 2.5)

A. INFORMED CONSENT DOCUMENT REVIEW

1.	Does the Informed Consent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	Comment:
2.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
3.	Does the Informed Consent document contain comprehensive and relevant information? ☐ Complete ☐ Incomplete	Comment:
4.	Is the information provided in the protocol consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	Comment:
5.	Are study-related risks mentioned in the consent form? ☐ Complete ☐ Incomplete	Comment:
6.	Is the language in the Informed Consent document understandable? ☐ Clear ☐ Unclear	Comment:
7.	Is the Informed Consent translated into the local language/dialect? ☐ Clear ☐ Unclear	Comment:
8.	Is there adequate protection of vulnerable participants? ☐ Yes ☐ No	Comment:

9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?
☐ Complete ☐ Incomplete
Comment:

10. Are names and contact numbers from the research team and the IRB in the informed consent?
☐ Yes ☐ No
Comment:

~~11.~~ 1. Does the ICF mention privacy & confidentiality protection?
☐ Yes ☐ No
Comment:

~~12.~~ 2. Is there any inducement for participation?
☐ Unlikely ☐ Likely
Comment:

~~13.~~ Is there provision for medical-/ psychosocial support?
☐ Appropriate ☐ Inappropriate
Comment:

~~14.~~ 4. Is there provision for treatment of study-related injuries
☐ Appropriate ☐ Inappropriate
Comment:

~~15.~~ 5. Is there a provision for compensation?
☐ Appropriate ☐ Inappropriate
Comment:

B. Recommendation

DECISION :	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Summary of Comments ~~(Identify items for revision.)~~			
Reviewer's Name		Date:	
Signature :			

CHECKLIST FOR EXEMPTION (FORM 2.6)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Principal Investigators:			

A. Protocol Assessment	Comment/s:
1. Does this research involve humanparticipants ☐ Yes ☐ No	
2. Does this research involve use of non-identifiable human tissue/biological samples? ☐ Yes ☐ No	
3. Does this research involve use of non-identifiable publicly available data? ☐ Yes ☐ No	

**Protocols that neither involve human participants, nor identifiable human tissue, biological samples and data shall be exempted from review (NEGHHR 2017)*

4. Does this research involves interaction with human participants ☐ Yes ☐ No	
5. Type of research (please tick appropriate box	
a. Institutional quality assurance ☐ Yes ☐ No	
b. Evaluation of public service program ☐ Yes ☐ No	
c. Public health surveillance ☐ Yes ☐ No	
d. Educational evaluation activities ☐ Yes ☐ No	
e. Consumer Acceptability test ☐ Yes ☐ No	

*These 5 have been identified in the NEGHHR as exemptible, as long as it does not involve more than minimal risk.

6. What is/are the method/s of data collection (please tick appropriate box)	
a. Survey and/or questionnaire ☐ Yes ☐ No	
b. Interviews or focus group discussion ☐ Yes ☐ No	
c. Public observatons ☐ Yes ☐ No	
d. Research which only uses existing data ☐ Yes ☐ No	
e. Audio/Video recordings ☐ Yes ☐ No	

*These 5 have been identifiedin the NEGHHR as exemptible, as long as anonymity and/or confidentiality is maintained.

4. Will the collected data be anonymized as identifiable? ☐ Anonymized ☐ Identifiable ☐ De-identified	
5. Is this research likely to involve any foreseeable risk of harm or discomfort to participants; above the level experienced in everyday life? (NEGHRR 2018) *Please refer to section B. Risk Assessment, prior to answering this item ☐ Yes ☐ No	
*If YES, then this protocol does not quality for exemption.	

B. Risk Assessment

1. Does this research involve the following: (please check all that applies)	
a. Any vulnerable groups? ☐ Yes ☐ No	
b. Sensitive topics that may make participants feel uncomfortable (i.e. sexual behavior, illegal activities, racial biases, etc. ☐ Yes ☐ No	
c. Use of drugs ☐ Yes ☐ No	
d. Invasive procedure (e.g. blood sampling) ☐ Yes ☐ No	
e. Physical stress/distress, discomfort ☐ Yes ☐ No	

f. Psychological/mental stress/distress? ☐ Yes ☐ No	
g. Deception of/or withholding information from subjects ☐ Yes ☐ No	
h. Access to data by individuals or organizations other than the investigators ☐ Yes ☐ No	
i. Conflict of interest issues ☐ Yes ☐ No	
j. Or any other ethical dillemas ☐ Yes ☐ No	
k. Is there any blood sampling involved in the study? ☐ Yes ☐ No	

C. RECOMMENDATION

Decision:		Qualified for Exemption
		Unqualified for Exemption

Summary of comments:	

Reviewer's Name:		Date:	

Signature:	

NOTIFICATION OF IRB DECISION (FORM 2.~~6~~7)

Date _____

To: (Name of PI) _____

This is to inform you of the revision to your application for review of the following documents:

IRB Protocol No.		Sponsor Protocol No	
Type of submission	☐ Initial review ☐ Resubmission ☐ Amendment ☐ Others	Documents submitted	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

Type of review	IRB Decision
☐ Expedited	☐ Approved
☐ Full board	☐ Minor revisions required
☐ Exempted	☐ Major revisions required
Meeting Date:	☐ More information required
	☐ Others

Items for Revision	Details of Action~~/Revisions~~ required from the Principal Investigator
Protocol	
Informed Consent	
Others	

Please submit the revised documents on or before _____

IRB Chair Person	Name	Signature	Date

APPROVAL LETTER (FORM 2.78)

Date _____

This is to certify that the following protocol and related documents have been granted approval by the Jose R. Reyes Memorial Medical Center IRB for implementation.

IRB Protocol No.		Sponsor Protocol No	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			
Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From (date) To	Frequency of continuing review

IRB Chair Person	Name	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments for IRB approval before implementing them
- Submit SAE and SUSAR reports to the IRB within 7 days
- Submit progress report every 12 months
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation/ violation
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research
- This approval is valid for ~~a period of~~ one year from the date of issue. Therefore, the PI must re-apply for continuing ethics review.

Received by: _____

Name _____

Signature _____ Date _____

SUMMARY OF REVISIONS ON THE PROTOCOL (FORM 2.89)

Date _____

This is to submit the revised protocol and related documents to the IRB.

IRB Protocol No.		Sponsor Protocol No	
Principal Investigator/s		~~Sponsor~~Submission Date	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
~~Answer to comments with corresponding pages marked.~~			

Type of initial review	☐ Expedited	☐ Full board	☐ Exempted
Channel of review of resubmission	☐ Expedited	☐ Full board	☐ Exempted

IRB Recommendations	Revision made by the PI	Reviewer Comments

RESULT OF PROTOCOL REVIEW:

Summary of Comments:				
DECISION	☐	Approval	☐	Minor Revision
	☐	Major Revision	☐	Others

Reviewer	Signature	Date

Received by: _____

Name _____

Signature _____ Date _____

CERTIFICATE OF EXEMPTION from ETHICS Review (FORM 2.~~9~~10)

Date _____

This is to certify that the following protocol and related documents have been granted exemption from review by the Jose R. Reyes Memorial Medical Center IRB for implementation.

IRB Protocol No.		Sponsor Protocol No	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

This protocol is exempted from review for the following reasons: (check the NEGHHR)

IRB Chair Person	Signature	Date

Investigator Responsibilities after Approval:

- Final/Closure report should be submitted at the end of the study.
- Any amendment to the protocol should be submitted to the IRB for re-evaluation of exemption.

Received by: _____

Name _____

Signature _____ Date _____