CENTRAL ETHICS REVIEW BOARD
2023 SUBMISSION GUIDE

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*Please note, not all sections of this document apply to BA/BE or Other Studies.

1. INTRODUCTION AND PURPOSE

Optimum Ethics Review Board is an Independent Central **Ethics Review Board** (ERB). The Board was formed in 1995 to meet the needs of the pharmaceutical industry and Canadian Investigators. The Board is constituted according to the ICH and FDA Guidelines and the Canadian Food and Drug Regulations (Division 5), and consists of experienced members with diverse and varying backgrounds.

The purpose of this guide is to **provide an explanation of the procedures** followed by our Board, to **assist the submitter in preparing a submission** for Ethics Review, and to **assist in maintaining contact** with the Board **for the duration of the study** to completion.

2. BOARD MEETINGS/TURN-AROUND TIME

The Board generally meets once weekly, and **turn-around time** from submission to receipt of documented ethics approval is usually about **one week**. Occasionally, due to holidays or other scheduling conflicts, meetings may be rescheduled or cancelled. **It is best to call our office to confirm that a meeting date is set for your project review, and to confirm that there is room on the agenda for your item.**

The turn-around time may be affected by completion of your submission package. Please ensure that all of the required documents are submitted. Turn-around time may also be extended if the Board requires clarifications regarding the protocol after the Initial Review.

3. SUBMISSION

The "Submitter" of the Initial protocol package may be: The Investigative Site, the Sponsor, or a Third Party (Contract Research Organization (CRO), Site Management Organization (SMO), Independent Contractor, etc.).

The Submitter must provide Optimum with the documentation listed on the **"Submission Checklist"** (available on our website). These documents are promptly organized at Optimum, assigned a review date and forwarded to our members accordingly. Board members require one week to review the initial documents (protocol, consent form, etc.).

The Investigative Site should be aware of who will be submitting the Initial Package and any items which require concurrent review, throughout the study, to avoid any duplication of efforts and unnecessary duplication of documentation. Optimum should be informed as to which party will responsible for submission of these items. (See "8. Concurrent Review")

4. ERB FILE NUMBER

Once your study documentation is received by the ERB Coordinator, the project will be assigned a File Number. This file number will appear on all correspondence from the ERB after the Initial Review. Please reference this file number on all of your correspondence to the ERB.

5. APPROVAL DOCUMENTATION/CONSENT FORM

At the scheduled Board meeting, the initial protocol review will be conducted. Any necessary changes to the consent form template will be made, and the Investigator/Site documentation will be reviewed.

Your project will receive one of the four following designations (outlined below):

-unconditional approval
-conditional approval
-deferred
-disapproved

-If the protocol receives **"unconditional approval"**, this means that it has been approved as submitted. After the meeting, our Ethics Coordinator will make all Board-requested changes to the consent form. This **draft version is then reviewed by the sponsor**, and approved before it is deemed to be the "final, approved consent form". This **final version will accompany the approval letter** that you will receive first by fax, and then a hard copy. An **electronic version** of the finalized, approved consent form **can be supplied** to you/your sites, either by e-mail or on diskette, **upon request**.

The initial approval is valid for one year (unless the board determines that more frequent review of the protocol is appropriate). The time period for which approval is valid will be stated in the approval letter. Please see "Annual Review" section if your study will continue for more than one year.

-If the protocol receives **"conditional approval",** this means that the Board requires clarifications to the protocol. You will be notified of the outcome of the meeting and these questions/clarifications will be forwarded to you (or directly to the sponsor) in writing, as soon as possible after the meeting. The response to these questions may be reviewed by the Chair of the Board, or at the next scheduled meeting of the Ethics Review Board, depending upon the information requested. If the response to the Board's questions is acceptable, the protocol will be granted unconditional approval.

-If the protocol review is **"deferred"**, this means that the review is on hold, and the Board will not continue their review of the protocol until certain questions are answered, or specific information is received. A letter or email will be forwarded to you (or the sponsor), outlining the Board's concerns, and requesting specific information. The response will be reviewed at the next scheduled meeting of the Ethics Review Board.

-If the protocol is **"disapproved"**, this means that the Board feels that the study is not acceptable. This decision, along with the reasons for such decision will be forwarded to you (or the sponsor) in writing. You can appeal the Board's decision in person or in writing within 30 days of the date of the disapproval letter. If you decide to submit the protocol to another Ethics Review Board after disapproval by Optimum ERB, **you must** notify the subsequent ERB of the previous disapproval.

6. PROTOCOLS WHICH HAVE NOT RECEIVED TPD APPROVAL

Please note that protocols which have not received TPD approval will not be provided unconditional approval until such time that TPD approval is received. The Board may review a protocol which has not received TPD approval to initiate the review process, but will defer further review of the protocol

or provide conditional approval until confirmation is received that the project has received TPD approval.

7. INITIAL APPROVAL DOCUMENTATION

The Initial Approval Package generally contains the following items:

Site package (if being sent directly to Site) will include:
• Cover Letter from ERB Coordinator - instructs the site on what needs to be done with the documentation contained in the Approval Package
• Original Approval Letter
• Copy of the approved site-specific, stamped consent form containing the appropriate name and address in the header and all contact information completed.
• List of Ethics Board members
• Annual/Final Study Status Report Form

Submitter (if other than the investigative site):
• Will receive a copy of all documents sent to the site(s) listed above

The Invoice for review will be forwarded to the party specified on your submission checklist.
Some of the Initial Approval documentation may be received by fax or email, and then hard copy via courier or mail.

8. CONCURRENT REVIEW

Throughout the year, the **following items must be submitted** to the Board **for continuing review**:

-amendments to the protocol
-amendments to the consent form
-changes in subject compensation
-new advertising/recruitment materials
-new/revised information provided to patients (ie. Patient letters, Patient Diary Cards, Questionnaires, etc.)
-new investigator information (ex. address change, changes of investigators, addition of sub-investigators or satellite sites)
-new information regarding the investigational product/safety reports
-Serious Adverse Event Reports
-significant protocol violations/deviations

(**A Significant Protocol Violation/Deviation is defined as any change that affects the scientific design of the study or negatively affects the rights, safety or welfare of study subjects. Protocol deviations/violations that affect only logistical or administrative aspects of the study are not considered significant.)**

Non-significant deviations/violations (that do not need to be reported)

-missed doses of study drug

-visits outside of study windows

-subject took dose(s) of an excluded drug (unless the amount is significant and affects the subject's health)

-missed lab tests

Significant deviations/violations (that do need to be reported)

-occurrences that result in a subject's withdrawal

You must provide a cover letter with all submissions of the above items, including the protocol number, sponsor, and **the Principal Investigator's name must be included on the documentation**. These submissions may be made by email or by mail/courier. All items which do not require approval by the Board, will be acknowledged in writing, by email.

Safety Reports - For studies in which there are multiple safety reports filed, you may submit these documents in batches rather than individually (ie. on a weekly basis). Please contact Optimum to confirm an appropriate safety report submission interval for your study. You must list in your cover letter which reports are being submitted (by date, number or adverse event *or* "reports from date A to date B").

9. MULTI-SITE/CENTRAL ERB

The Board is available to conduct single-site or multi-site reviews and act as a Central Ethics Review Board on studies conducted nation-wide. It is preferred that the initial submission includes all sites or as many of the sites' documentation as possible.

In some cases, a third party will submit documents on behalf of a site or a group of sites. If you are an Investigative site, and the sponsor or CRO/SMO has submitted on your behalf, it is best to check with your contact person at the pharmaceutical company or CRO/SMO, to determine whether they will also be submitting all follow-up documentation to the Board on your behalf, or if you will be expected to submit these items on your own, and notify Optimum accordingly.

10. REVIEW OF FACILITIES OTHER THAN A PRIVATE MEDICAL OFFICE

The Board may review a project on behalf of a study site which is located in an institution such as a hospital or other facility. However, the Board requires *written confirmation* that there is no in-house or other Ethics Review Board to which this site is responsible, for studies conducted in such facility, *or* permission from the facility authorizing Optimum to be the reviewing ERB.

11. CONSENT FORMS/CONSENT FORM REVISIONS/APPROVAL STAMP

Optimum Ethics Review Board has strict rules for the layout and wording of consent forms. Therefore, you can expect that your consent form template will be revised by the Board at the Initial Review. A document detailing the changes that have been made will be forwarded to the sponsor for review, as well as retained in Optimum's files for any future reference. The Board prefers, for consistency, that all sites use the same version of the consent form, the only differences being the letterhead, contact names and phone numbers, and compensation for participation information.

As part of the Site Submission Questionnaire, you are requested to insert the name and address information that will appear on your consent form, or you may send a copy of your site letterhead, on which you would like your copy of the consent form to be placed.

Optimum will prepare your site-specific consent form with the appropriate contacts information supplied by you, and will forward this final, approved version to your site, along with the initial approval package. This version will contain a stamp of the ERB's name, to indicate that it is the final version sent out by the Board for the Investigator's use.

During the course of the study, any changes to the consent form must be approved by Optimum ERB prior to being implemented. **You must submit a written request outlining the changes that you would like to be made.** Optimum will review the changes and will forward the revised approved consent form to you. Each new version of the consent form will contain a new "Version Date". It is very important that you ensure that you are utilizing the currently approved version of the consent form at all times.

If you are an Investigative site, and you receive a **new version of the consent form** from the sponsor, this **must be submitted to Optimum ERB** for review. **DO NOT use any version of the consent form for which you have not received an approval letter from Optimum ERB**.

Subject Compensation must be noted in the consent form where applicable. If subjects are being reimbursed for study expenses (ie. travel, time, etc.), these must also be defined in the consent form and approved by the ERB. For each submission, you must indicate whether you will be reimbursing subjects for study-related costs, or if a set amount per visit will be provided. Optimum will incorporate your site-specific compensation information into your site-specific consent form.

12. CONTACTS SECTION OF THE INFORMED CONSENT FORM

In the "Contacts" section of the Informed Consent Form, under "contact for questions about the **rights of research subjects**", please insert "Optimum Ethics Review Board at 604 Taunton Rd. W., Oshawa, Ontario L1L 0N9, or by email at info@optimumerb.ca", unless you have requested another contact, and this has been approved by the ERB. Optimum ERB will only accept questions/complaints from study subjects **in writing**.

For contacts **in case of research-related injury and for any questions regarding the study**, the name of the Investigator (and Study Coordinator if applicable), and the telephone number will be inserted.

13. INTERIM STATUS REPORTS/ANNUAL REVIEW

If your project continues for a year or more, **you must request annual review**. A study-specific Annual/Final Report Form is included in your Initial Approval Package. Optimum will review the project on or before the approval expiry date. **However, your site-specific information is required in order to apply the approval to your site.** Please make note of the expiry date on your approval letter (above the signature of the Chair). Optimum will attempt to remind you when this review is due. However, as with the submission of documents for concurrent review, **it is the Submitter's responsibility to supply your site-specific information for annual review**. If you do not submit your Annual Report Form before the expiry date, there may be a period of time for which you do not have valid ethics approval for your project.

For your annual review, complete an Annual Report Form, attach a copy of the signed consent form (*you may black-out the patient's name with a black marker - see next paragraph for more information*), and forward to Optimum ERB by email. The Board will re-review the protocol and Annual Report Forms from all pertinent sites, to ensure that the study can continue to be conducted for another one-year period. A blank Study Status Report Form is attached to this guide, for use if needed. You can also request additional copies of a study-specific report form by contacting the Ethics Coordinator.

The reason the Board requests a copy of the signed consent form with the Annual Report is to ensure that: (a) the proper version of the consent form was used, (b) to check that all signatories dated the consent form individually (c) to ensure that each page was initialed by the subject or person providing consent.

14. FINAL REVIEW

When your project is completed, a Final Report Form or letter of completion must be forwarded to the Board. A letter of completion notifies the Board that the study is completed at your site, and must include the number of subjects enrolled, completed, lost to follow-up, withdrawn, the number of serious adverse events at your site, and any other pertinent information that the Board has not previously been notified of.

15. INVESTIGATOR NON-COMPLIANCE/PROTOCOL VIOLATIONS

If an Investigator is not compliant with the Board's requirements, or if there appears to be a high number of protocol violations reported, the Board may request a written explanation from the Investigator, to explain the reasons for the non-compliance/protocol violations and to identify what measures have been implemented to resolve the issue. If there are outstanding non-compliance/protocol violation issues with an Investigator, this may delay approval of any further studies for this site, until the issues have been resolved. If the non-compliance/protocol violation is serious or chronic, the Board will notify the sponsor and/or CRO, and will consider withdrawing the Board's approval for conduct of the study at this site. If approval is withdrawn, the Board will notify the sponsor, the CRO and Health Canada of its decision.

16. ADVERTISING/RECRUITMENT MATERIALS

Advertisements or other items to aid recruitment must be submitted and approved by the Board before use. Some tips to keep in mind when preparing an advertisement:

- always include the words "research study"
- use the words "investigational medication/drug/treatment" instead of "new medication/drug/treatment" (if the study involves a non-approved drug)
  you may mention whether compensation is provided, but generally the amount is not included except in certain situations. Statements regarding compensation must not be bolded or hilighted in any way, and the font must be the same size as the rest of the advertisement.
- do not include statements such as "free medication" or "free medical treatment"

always include either the site name, investigator or study coordinator's name, and how to contact them

please include a version date on your ad. This will ensure that the proper version of the ad is referenced in the letter from Optimum.

Audio and video advertising wording can be submitted on paper initially, and then once the wording has been approved, the Board must receive the final ad, in audio or video form.

If you are preparing to submit an advertisement, and would like further advice, please contact the ERB Coordinator at Optimum.

17. ERB CONTACTS/QUESTIONS

If you have questions about this Guide, if you require any further information about the Board, or if you require any advice about a submission, please contact the ERB Coordinator by email, at info@optimumerb.ca.

18. QUALITY ASSURANCE AUDITS OF OPTIMUM

Quality assurance audits of Optimum ERB can be arranged. Please contact the ERB Coordinator if you wish to arrange a meeting with a representative, and a review of the board's Standard Operating Procedures.

19. BILLING FOR REVIEWS

Responsibility for the payment for Ethics Review Services varies from study to study, company to company. Some companies have all of the contact with the ERB, and are billed directly by the ERB. Other times, the funds for Ethics Review are included in the Investigator's study budget, and the Investigative site receives the invoice for Ethics Review. For some multi-center studies, the fees are shared between all participating sites, and all sites will receive an invoice from the ERB. Please make sure you are aware of who is responsible for the fees associated with each submission you make. An overdue account could result in a delay of the review of any further new studies for your organization.

20. SITE QUESTIONNAIRE

Please refer to the "2023 Site Questionnaire" that is available on our website. The purpose of this questionnaire is to obtain further information about the staff and the facilities, as well as to provide further information to the Board regarding the resources available to the staff who conduct the research studies. We appreciate your cooperation in filling out the questionnaire and returning it to us for our files**. Completion of the questionnaire and return of the listed, required documents is now mandatory**. The questionnaire must be completed by each site for each study submission.

Once you have completed the Site Questionnaire, you can copy it and revise the study specific information for future submissions, provided that none of the other information has changed since your last submission. **Please read the instructions at the top of the Site Questionnaire carefully!**