

HOW TO SUBMIT DOCUMENTS TO THE U OF S BIOMEDICAL RESEARCH ETHICS BOARD

When submitting documents to the Research Ethics Office, a “Cover Memo” should accompany the appended documents. The Cover Memo should include the following information:

- *PI name*
- *Bio #, Protocol # (if applicable)*
- *Name of person filling out the information*
- *Reason for submission:*
 - *Details of any changes,*
 - *List of items to appear on the CofA*
 - *Any accompanying items requiring acknowledgement*

IF YOU HAVE NOT HEARD BACK FROM THE ETHICS OFFICE WITHIN TWO WEEKS OF YOUR ELECTRONIC SUBMISSION
PLEASE CONTACT US: ethics.office@usask.ca OR 306-966-2975

How to submit a NEW Study

Submissions Requiring Full Board Review:

SUBMIT TO: bonnie.korthuis@usask.ca , CC: ethics.office@usask.ca	
<i>The electronic copy of all items requiring full board review must be received in the office by 4:30 of the submission deadline day. Paper copies must be received no later than noon the Friday after the deadline.</i>	
Paper	<p>Submit one complete submission package inclusive of signatures on the application. Applications and consent forms should be single sided, collated and clipped, not stapled, together. Investigator Brochures, Protocols, Product Monographs, Questionnaires, Recruitment Material and other misc. information can be double sided and each item stapled individually. <i>A scanned PDF of the signature page is acceptable.</i></p> <p><i>*For second site submissions (twin studies) please indicate Bio # for the original site and indicate whether the consent forms mirror the approved consent forms of the original site or if any revisions have been made. The second site will be reviewed via delegated review.</i></p>

Electronic	<p>E-mail Subject line must specify: New Study requiring Full Board Review</p> <p>Submit one complete submission package electronically.</p> <p>The cover memo, application and consent forms can be in word format or converted PDF (not scanned). The remaining materials may be submitted either in PDF or Word format. <i>A scanned PDF of the signature page is acceptable.</i></p>
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Submissions for Delegated Review:

<p>SUBMIT TO: ethics.office@usask.ca, CC: bonnie.korthuis@usask.ca</p>	
Electronic Only	<p>E-mail Subject line must specify: New Biomedical Study</p> <p>Submit application and consent forms in word format or converted PDF (not scanned). The remaining materials may be submitted either in PDF or Word format. A scanned PDF of the signature page is acceptable.</p>

How to submit NER Responses

<p>SUBMIT TO: Personnel the NER was received from CC: bonnie.korthuis@usask.ca</p>	
Electronic Only	<p>E-mail Subject line must specify: Bio #, Response to NER</p> <p>All revisions must be highlighted, tracked or outlined in a summary of changes document. A clean copy is not required The documents may be submitted in either word or converted PDF format.</p>

How to submit an Amendment

Amendments Requiring Full Board Review:

<p>SUBMIT TO: darcie.earle@usask.ca, CC: bonnie.korthuis@usask.ca & ethics.office@usask.ca</p>	
Paper	<p>Submit a cover memo outlining the revisions and how and by whom the determination for Full Board review was made. Revisions of the application or consent form should be highlighted or tracked. A clean copy is not required. Applications and consent forms should be single sided, collated and clipped, not stapled, together.</p> <p>Investigator Brochures, Protocols, Product Monographs, Questionnaires, Recruitment Material and other misc. information can be double sided and each item stapled individually.</p> <p>*Twin cancer studies should include one memo referencing both Bio #'s</p>

Electronic	<p>E-mail Subject line must specify: Bio #, Full Board Amendment</p> <p>Submit complete amendment package with a cover memo outlining the revisions and how and by whom the determination for Full Board was made. All revisions must be highlighted, tracked or outlined in a summary of changes document. A clean copy is not required. These documents should be submitted in word or converted PDF format.</p> <p>*Twin cancer studies should include one memo referencing both Bio #'s</p>
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Amendments for Delegated Review:

<p>SUBMIT TO: darcie.earle@usask.ca, CC: bonnie.korthuis@usask.ca</p>	
<p><i>Please note that a change of PI is an amendment and must be submitted at the time of occurrence and not on the renewal. Although a change in sub-investigators and students doesn't necessarily initiate an amendment, the ethics office should be made aware of personnel changes when they occur.</i></p>	
<p>Paper Copy (e-mail memo with a list of items for the C of A)</p>	<p>Amendments that exceed 10 pages (accumulative) and include Protocols, IB's, Product Monographs or multiple Consent Forms</p>
<p>Electronic Only</p>	<p>Amendment documents that do not exceed 10 pages (total accumulation of all documents)</p> <p>E-mail Subject line must specify: Bio #, Amendment</p> <p>All revisions must be highlighted, tracked or outlined in a summary of changes document. A clean copy is not required. These documents should be submitted in word or converted PDF format.</p> <p>*Twin cancer studies should include one memo referencing both Bio #'s</p>

How to submit a Renewal or Closure

Renewals Requiring Full Board Review:

<p>SUBMIT TO: ethics.office@usask.ca, CC: bonnie.korthuis@usask.ca</p>	
<p>Electronic Only</p>	<p>E-mail Subject line must specify: Bio #, Full Board Renewal*</p> <p>Submit appropriate form fillable word document for renewal.</p>

	<p>Note: Items for acknowledgement must be listed on the cover memo.</p> <p>*Twin cancer studies should be submitted at the same time (even if only one site requires full board review). The criteria under Part 4 of the Renewal form should be applied to determine delegated or full board review for each site.</p>
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Renewals and Closures for Delegated Review:

<p>SUBMIT TO: ethics.office@usask.ca</p>	
<p>Electronic Only</p>	<p>E-mail Subject line must specify: Bio #, 'Renewal' or 'Closure'</p> <p>Submit appropriate form fillable word document for closures or renewals.</p> <p>Note: Items for acknowledgement must be listed on the cover memo.</p> <p>*Twin cancer studies should include one memo referencing both Bio #'s</p>

How to submit Items for Acknowledgement (Memos)

<p>SUBMIT TO: ethics.office@usask.ca. If documents relate to local patient safety CC: bonnie.korthuis@usask.ca</p>	
<p>Electronic Only</p>	<p>E-mail Subject line must specify: MEMO, Bio #, Description of the items to be acknowledged.</p> <p>Please clearly indicate if documents relate to local patient safety.</p> <p>The body of the e-mail should itemize the documents that are being submitted for acknowledgement. i.e., updated Investigator Brochures, Product Monographs with version number and/or date. List all studies the document(s) pertain to. Name the attachments to clearly indicate what is being submitted.</p> <p>Items sent to be acknowledged, either by the REB Chair or by Office, will be processed either by stamped acknowledgement or by email, respectively.</p> <p>When a CofA is being created (first time approvals, re-approvals, amendments [delegated or full board]), any accompanying items requiring acknowledgement will be acknowledged on the CofA. When submitting, please list both 'items for approval' and 'items for acknowledgement' separately on the cover memo.</p> <p>*Twin cancer studies should include one memo referencing both Bio #'s</p>

How to submit Unanticipated Problems and Protocol Violations

SUBMIT TO: bonnie.korthuis@usask.ca , CC: ethics.office@usask.ca	
Electronic Only	E-mail Subject line must specify: Bio #, Unanticipated Problem/Protocol Violation Submit a completed Unanticipated Problem/Protocol Violation Form in either Word or converted PDF. A scanned PDF of the signature page is acceptable.