

McGILL UNIVERSITY HEALTH CENTRE
RESEARCH ETHICS OFFICE
- STUDY DOCUMENTS FOR REVIEW -

All research study documents described below require REB review or delegated review:

1. Final version of the clinical research protocol;
2. Specific grant application that includes the research protocol(s) submitted for review;
3. Executive Summary of the research project (*single page for filing in the medical record*) that contains a study description (*not to exceed 100 words*) for inclusion in the REB Annual Report to the MUHC Board of Directors and MSSS;
4. MUHC version of the consent document(s), French and English;
5. MUHC version of the assent document(s), French and English;
6. Correspondence describing favorable or unfavorable scientific or scholarly merit review and/or prior ethics review;
7. Health Canada “No Objection Letter” (NOL) to the sponsor, where appropriate;
8. Amendment(s) to research protocol, consent/assent document and/or study agreement;
9. Study advertisement(s) (*poster, flyer, press release, electronic publicity, video*) that complies with “MUHC Posting Policies” presented in the intended public format;
10. Study addenda and all information handout(s) (*printed and recorded material*) prepared for study subjects (*recruitment script, subject diary, interview schedule, test schedules, letter of solicitation or invitation to participate, etc.*);
11. Study survey instruments (*questionnaire(s), scales of measurement, indices etc.*);
12. Investigator’s Brochure (*IB*) corresponding to the clinical trial protocol version submitted for initial review involving the investigational drug or a medical device;
13. Product monograph can be submitted only if the research is a “post-marketing study”;
14. Study agreement and/or the grant application including the study budget;
15. Resource Utilization form reviewed and approved by Director of Professional Services;
16. All reportable Adverse Event Report(s) and safety information subject to review of the REB (*source data to be made available upon request*);
17. Correspondence describing favorable or unfavorable information from the sponsor, other REBs and/or regulatory authorities;