Canadian SHIELD
Ethics Review Board
OHRP Registration IORG0003491
FDA Registration IRB00004157
Registered with CAREB, NCEHR

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INITIAL SUBMISSION REQUIREMENT CHECKLIST

To begin the initial review of your research study, the following is a general list of items needed. Please confirm any details for submission with the IRB / REB Administrator.

If you have submitted any of the required documents previously, or you are part of a multi-centre clinical trial already under review at CSERB, we have these documents on file and they are not required for submission.

Please check our WEB page (www.cserb.com) for further details or call us at (905) 681 8661 for further assistance.

INITIAL REVIEW CHECKLIST:

A. Central Review ☐ **B.** Local Review ☐

1. Initial Review Submission Forms (A or B)
- Study Information Form ☐
- Site Information Form (one per site) ☐

2. Protocol - one e-copy, by e-mail ☐

3. Investigators Brochure - one e-copy by e-mail, if available. Otherwise, please send a paper copy ☐ or
- Product Monograph(s) for Phase IV trials ☐
- CPS / PDR information for comparator(s), if applicable ☐ **N/A** ☐

4. Consent form / information sheets - one e-copy by email ☐

5. Data gathering instruments (diaries, scales, questionnaires, etc) ☐ **N/A** ☐

6. Advertising materials ☐ **N/A** ☐

7. Principal Investigator (Co-coordinating Investigator) ☐ **N/A** ☐
- Curriculum Vitae ☐
- Current professional license (COPY) showing the expiration date ☐

If you need to request a review of new or changed materials for a project currently under CSERB oversight, please e-mail us at admin@cserb.com, or call 905 681 8661 for more information.