



COMMERCIAL INSTITUTIONAL REVIEW BOARD, LTD.

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CHECKLIST OF MATERIALS FOR STANDARD SUBMISSION

- Payment (or information as to whom to invoice)
- This Checklist of Materials for Submission
- Indemnification Agreement for Safety and Efficacy Studies Only (either the IRB form or as part of the Study Agreement)
- Submission Letter
- IRB Waiver Form (if an institutional site is involved)
- Financial Disclosure Form for each Principal Investigator, Co- and Sub-investigator
- Request for Waiver or Alteration of HIPAA Authorization, if needed
- Fox Commercial IRB Application Cover Form, **completed in its entirety**
- Protocol with Amendments, if any
- Sample Consent Form on Disk or by E-mail
- Sample Consent Form (Hard Copy)
- Advertising Copy and/or Patient Informational Material, if any
- List of Principal, Co- and Sub-investigators
- Signed and Dated *Curriculum Vitae* (or resume) for each Principal Investigator, Co- and Sub-investigator, and Research Coordinator Participating in the Study
- Current Medical or Professional License for each Principal Investigator, Co- and Sub-investigator and Research Coordinator
- Certificate of Training in Human Subject Protection for each Principal Investigator, Co- and Sub-investigator and Research Coordinator (must be current within the last two years)
- Site Questionnaire, completed, for each Principal Investigator

For Each Investigational Device

- IDE Letter from FDA (*or* “Contention of Non-Significant Risk” *or* statement of regulatory status of device)
- Report of Prior Investigations
- Investigator’s Agreement
- Instructions for Use

For Each Investigational Drug

- The most recent Investigator’s Drug Brochure or Prescribing Information, if an approved drug
- Form FDA 1572, signed and dated (for each Principal Investigator)
- IND Number

Documents not found on this website may be obtained by contacting the IRB at info@foxirb.com