CHECKLIST FOR PROTOCOL SUBMISSION

Checklist	Clinical Trial Study	Non Clinical Trial	Postgraduate/Undergraduate
Covering letter listing all submitted documents	Yes	Yes	Yes
Protocol/Proposal: Clinical Protocol or research proposal	Yes	Yes	Yes
Questionnaire: Patient Questionnaires / Diary Cards in English	If applicable	If applicable	If applicable
Subject Information Sheet and Informed Consent Form(s): Document outlining the process for obtaining the informed consent	Yes	Yes	Yes
Approved Budget: Trial Payment Schedule / Clinical Trial Agreement	Yes	Yes	Yes
CV(s) for Investigator(s): CVs for all key personnel on the trial	Yes	Yes	Yes
IRB fees (attach confirmation of payment)	Yes	Yes	Yes**
Certificate of Analysis	Yes	No	No
Investigator's Drug Brochure	Yes	No	No
Delegation Log: Delegation Letters from Principal Investigators	Yes	Yes	Yes

Trial Insurance	Yes	No	No
Conflict of Interest: Declaration by the principal investigator, completed by all participating investigators	Yes	Yes	Yes
Evidence of completion of Human Subject Protection Training	Yes	Yes	Yes

Note:

Yes - Required for a submission

If applicable - Must be submitted if to be implemented in study

** Strathmore University Students will not be required to pay IRB fees, as the cost shall be covered from the students' fees.