# Clinical Study Protocol
# Study Synopsis
# 1st Stage Submission

*The assessment of a clinical research protocol encompasses a 2-stage process. During the first stage applicants are called upon to provide a study synopsis including background, design, objectives, outcome parameters, major inclusion and exclusion criteria, statistics, and co-variates not exceeding 4 pages. Within 6 weeks from receipt, ClinCom will respond to the applicant with a preliminary review, either encouraging or declining the submission of a full protocol within 6 months of the first feed-back to the applicant. This full protocol will be subjected to a final review by ClinCom within 8 weeks of receipt. We encourage submission in an early stage of the process of designing the trial.*

**SUMMARY OF THE PROPOSAL:**

**PROJECT TITLE:**

**PRINCIPAL INVESTIGATOR:**

APPLICANT NAME:
APPLICANT AFFILIATION:
APPLICANT ADDRESS:
APPLICANT ECCO MEMBERSHIP ID:

| **SUMMARY** |
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| (brief and precise, outlining only the most relevant topics and the proposed objectives)<br>**Maximum: 1 page** |
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| **1. BACKGROUND** |
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| **2. DESIGN** |
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| **3. OBJECTIVES** |
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| **4. OUTCOME PARAMETERS** |
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| **5. MAJOR INCLUSION AND EXCLUSION CRITERIA** |
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| **6. STATISTICS** |
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| **7. CO-VARIATES** |
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