

CLINICAL TRIAL PROTOCOL SYNOPSIS / RESEARCH PROPOSAL OUTLINE

If you intend to submit a clinical trial synopsis / research proposal for review and consideration please complete this form. The proposal will be reviewed by the appropriate Discipline Specific Advisory (DSA) and the Scientific Advisory Committee (SAC) and relevant feedback will be provided.

Lead Investigators and/or groups

Title

Brief Background and Rationale

Aim

Objectives

Hypothesis

Population and Setting

Interventions (if applicable)

Primary Outcome

Secondary Outcome

Study Design and Procedure – Outline Only

Statistical Considerations / Sample Size / Data Collection

Timeline

External / Internal Funding Sources

Feasibility / Recruitment

Request for Resources

Do you wish to apply for funding assistance to conduct this study/trial?

Will you require Project Management assistance with this study/trial?

Will you require Data Management or Data Management assistance during this study?

Will you require biostatistical advice or analysis conducting during this study?