

**Study Start-Up
SS-201.04**

**STANDARD OPERATING PROCEDURE FOR
Assessing Protocol Feasibility**

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04 Feb 2021

(Signature and Date)

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04 Feb 2021

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1. INTRODUCTION AND PURPOSE

A clinical protocol that meets scientific and ethical standards is a fundamental requirement of clinical investigations. Georgia CORE must determine the scientific, ethical, and financial merits of participating in any proposed research. Additionally, Georgia CORE considers the potential benefits of proposed studies to cancer control in Georgia and development of the research portfolio for the state. Compensation, research infrastructure, and clinical sites must be available to support the performance of all study-related procedures according to the requirements of Good Clinical Practice (GCP).

The purpose of this standard operating procedure (SOP) is to describe the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within the Georgia CORE Research Network.

2. SCOPE

This SOP applies to the activities involved in assessing protocols for studies subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPs

SM-301 Communication

5. ATTACHMENTS

- A. Georgia CORE Clinical Trial Development Process
- B. Georgia CORE Research Concept Proposal (RCP) Form
- C. Georgia CORE Scientific Review and Monitoring Committee (SRMC) Evaluation Form
- D. Site Solicitation Summary Report

6. RESPONSIBILITY

This SOP applies to Georgia CORE leadership, staff, and consultants involved in clinical trials. This includes the following:

- President and CEO
- Chief Medical Officer
- Georgia CORE staff and consultants

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B).

Protocol

Good Clinical Practice

Investigational Product

Well-being (of the trial subjects)

8. PROCESS OVERVIEW

A. Based upon the established review process, evaluation of the feasibility of carrying out the protocol.

9. PROCEDURES

A. Evaluate the Research Concept Proposal (RCP) and/or the protocol, assess the scientific, ethical and financial merits of the research and its potential impact upon subjects, cancer control, and the Georgia research portfolio.

Georgia CORE President and CEO/Designee

Create the Scientific Review and Monitoring Committee (SRMC).

Georgia CORE staff and consultants

Based upon the established review process (Attachment A), and determine the scientific, ethical, financial, and practical merits of conducting the study within the Georgia CORE Research Network.

- Review RCP form (Attachment B) submitted electronically to the Georgia CORE President and CEO.
- Distribute the RCP form and/or protocol electronically to members of the Scientific Review and Monitoring Committee (SRMC) to be reviewed with comments and recommendations within one week.

Members, Scientific Review and Monitoring Committee

Complete the Scientific Review and Monitoring Committee Evaluation Form (Attachment C) and return to the Georgia CORE President and CEO.

Georgia CORE President and CEO/Designee

Create a Summary Report which is a compilation of the individual responses from SRMC members.

Distribute the SRMC Summary Report to the Investigator, Chief Medical Officer and key research team members for their review and comment.

Compile comments from Investigator, Chief Medical Officer and research team and forward to the Investigator for review, response, and revisions to the protocol.

Once the Investigator returns the revised RCP/protocol, send the RCP/protocol to the Chief Medical Officer.

Chief Medical Officer

Determine the feasibility of advancing to the next phase of study development based on review of the revised RCP/protocol and discussions with the Investigator.

President and CEO/Designee

Upon CMO approval to proceed, work with the Investigator and Research Development Committee (RDC) to identify and complete outstanding study documents (e.g. protocol

summary, study budget, pharmaceutical plan and budget, data management and statistical plan).

Note: The Research Development Committee includes representatives from areas such as finance, operations, pharmaceutical, data management, and statistics.

President and CEO/
Designee

Forward completed documents to the President and CEO and Chief Medical Officer.

Review documents and provide approval to proceed to next phase or provide direction to the Designee and Investigator as to what changes need to be made.

Once documents are approved by the President and CEO and Chief Medical Officer, distribute the protocol and budget to the Research Network sites for review.

Collect feedback from Research Network sites through the Site Solicitation Summary Report (Attachment D).

President and CEO
Chief Medical Officer

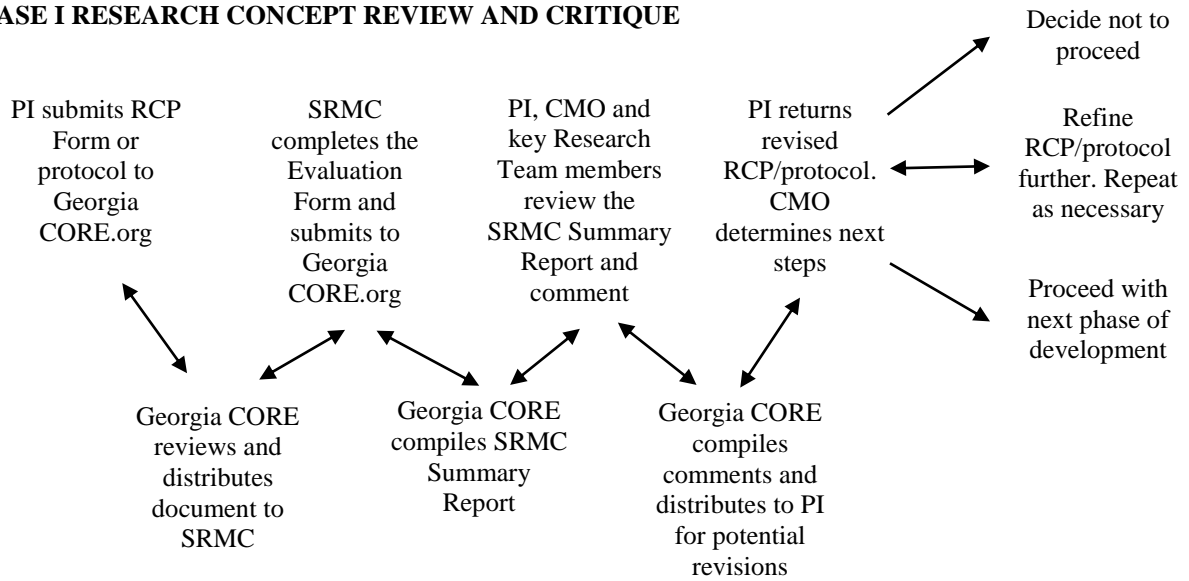
Assess feasibility of activating concept proposal. Notify Investigator, research team, and site representatives regarding next steps.

10. HISTORY OF CHANGES

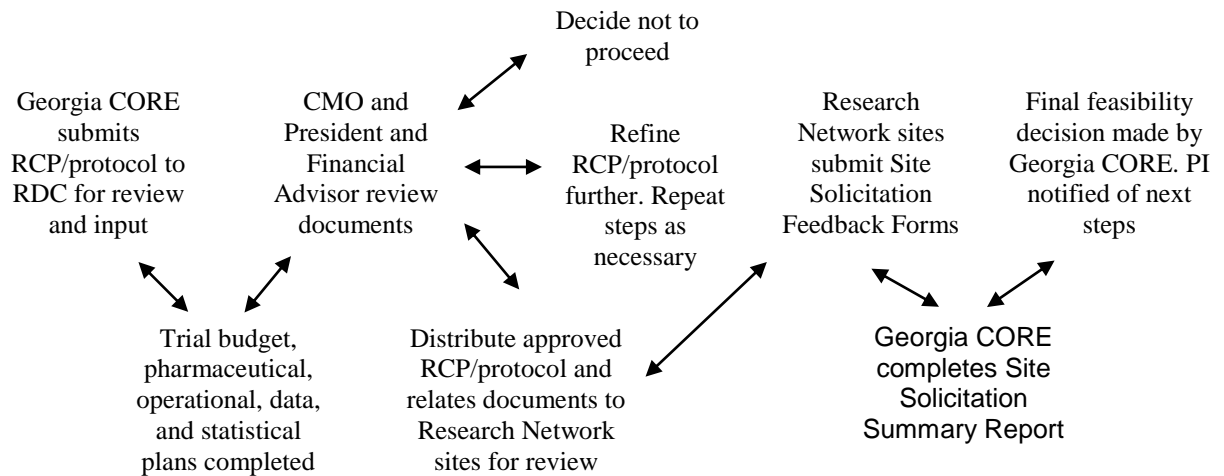
Version Number	Section Number	Modification	Approval Date
201.00	All	Original Version	
201.01	9	Updated the procedure to be consistent with new attachment A	17 May 2010
201.01	Attachment A	New process flow chart	17 May 2010
201.01	Attachment B, C, D	Updated the lettering and Title of each attachment	17 May 2010
201.02	Attachment B	Added PK sampling considerations	09 March 2012
201.02	Attachment B	Medical College of Georgia changed to Georgia Regents University	01 June 2014
201.03	3	Included additional guideline	03 March 2017
201.04	All	Edits for clarity and revisions to process of evaluation	30 June 2020

ATTACHMENT A
Georgia CORE Clinical Trial Development Process

PHASE I RESEARCH CONCEPT REVIEW AND CRITIQUE



PHASE II CLINICAL TRIAL DEVELOPMENT



Abbreviations:

RCP=Research Concept Proposal

SRMC =Scientific Review and Monitoring Committee (includes other investigators and scientific experts)

RDC =Research Development Committee (includes areas such as finance, operations, pharmaceutical, data management and statistics)

**ATTACHMENT B:
Georgia CORE Research Concept Proposal (RCP) Form**

Introduction

The Georgia CORE Research Concept Proposal (RCP) Form is designed to guide Investigators interested in submitting research ideas to Georgia CORE for consideration of protocol development or initiation of a study through the Georgia CORE Research Network. Information requested will assist the Georgia CORE to evaluate the concept relative to support of the goals of Georgia CORE, scientific merit, compatibility with Network resources, resource requirements, and potential funding sources. Please answer each section as completely as possible in the space provided.

Georgia CORE Tracking number:

Schema layout = (year) – (disease) – (sponsor/PI initials – 3 letters) – sequential numbering 001)
(Disease – M= melanoma, B=breast L=lung, C=colon, P=prostate)

Example: *RA Baron's Melanoma Protocol*
05-M-RAB-001

Date of Proposal Concept submission: MM/DD/YYYY

Study Title:

Please provide a brief two-paragraph description for each question and attach additional background in a Word document.

Study Description:

Statement of Need/Rationale:

Primary Objective/Outcome:

Secondary Objectives/Outcome:

Study End Points:

(Please include relevant terminology for NCI research database inclusion - Safety, efficacy, safety and efficacy, bio-equivalency, bio-availability, pharmacokinetics, pharmacodynamics,)

Expected Benefits to Cancer Control in Georgia:

Potential Risks:

Research Design/Methods/Schema:

IND Protocol Yes No

IND Number _____

Phase I _____ Phase II _____ Phase III _____ Phase IV _____

Randomized: Yes No

Interventional: Yes No

Intervention Type: (Check all that apply)

Drug Biologic Gene transfer Vaccine Behavioral

Device Procedure

Other: (Specify: _____)

Biological markers/tissue sampling: Yes No

If Yes, describe: _____

Pharmacokinetics: Yes No

Observational: Yes No

Masking: Open Label Single blind Double blind

Other: (Specify: _____)

Control: Placebo Active Dose Comparison Uncontrolled Historical

Other: (Specify: _____)

Assignment: Single group Parallel Crossover Factorial

Other: (Specify: _____)

Purpose: Prevention Diagnostic Treatment Palliative Care _____

Educational/counseling/training

Other: (Specify: _____)

Study Size and Timetable:

Estimated Study Sample Size: _____

Number of patients YOU would expect to enroll to the study in 12 months: _____

Projected Study start date: ____/____/____

Projected enrollment period: ____/____/____

Estimated First patient in: ____/____/____

Estimated Last patient in: _____/_____/_____
Estimated Last patient out: _____/_____/_____
Estimated Study Completion: _____/_____/_____
Long term follow-up: _____ Yes _____ No
If Yes, how long? _____

Target Population/Key Clinical Considerations/Inclusion/Exclusion Eligibility Criteria:

Highlight patient conditions, disease characteristics, and medical criteria.

Age: Minimum _____ Maximum _____
Gender: Male _____ Female _____ Both _____

Performance status: ECOG _____

Life expectancy in months: _____

Patient metabolic ranges for study inclusion/exclusion:

Hematopoietic: _____

Hepatic: _____

Renal: _____

Cardiovascular: _____

Pulmonary: _____

Other (i.e., child bearing, post-menopausal): _____

Prior/Concurrent Therapy: (Required or prohibited i.e., >3 weeks since prior chemotherapy)

Biological:

Chemotherapy:

Endocrine:

Radiotherapy:

Surgery:

Immunotherapy:

Other:

Financial/Funding Aspects:

Potential Funding Sources: _____

Sponsor/Collaborators:

Name	Address	Phone	Email	FAX

Unique personnel/equipment/resources required for study participation:

Estimated cost/per-patient: _____

Estimated total costs: _____

Estimated out-of-pocket costs to patients: _____

Study Development Needs requested of Georgia CORE:

Estimated number of participating sites: _____

Potential site participation sought for this study:

Augusta University _____ Emory _____ Mercer _____ Morehouse _____

Community Oncologists _____

Any specific sites requested: _____

Service requested from Georgia CORE:

Financial support negotiations: _____ Yes _____ No

Protocol writing: _____ Yes _____ No

Study design: _____ Yes _____ No

Statistical analysis: _____ Yes _____ No

Central IRB filing: _____ Yes _____ No

Data management: _____ Yes _____ No

Data Safety Monitoring Board
formation: _____ Yes _____ No

Interim analysis: _____ Yes _____ No

Final analysis: _____ Yes _____ No

Publication: _____ Yes _____ No

Other: _____

Contact Information:

Study Chair or Principal Investigator Name: _____

Preferred Contact: _____ Work _____ Home _____ Cell _____ Pager

Work Phone: () _____ - _____ Cell Phone: () _____ - _____

Home Phone: () _____ - _____ Pager: () _____ - _____

Preferred E-mail: _____ Fax: () _____ - _____

Organization/Institution: _____

Preferred Address: _____ Work _____ Home

Number/Street Apt/Room /Bldg. City State Zip Code

Best time/way to contact you: _____

**ATTACHMENTC:
Georgia CORE Research Concept Proposal Evaluation**

Concept: _____

Submitting Investigator: _____

Date: _____

Georgia CORE Tracking Number:

1. Define the proposed study population, Phase and number of patients:

Breast _____

Lung _____

Colon _____

Prostate _____

Other Specify: _____

2. How does the proposed study contribute to the prevention, diagnosis, treatment or quality of life for Georgia cancer patients?

3. Does the investigator present a robust scientific rationale in the proposed protocol?
____ Yes ____ No

If Yes, explain: _____

4. Do the data presented supply reliable, valid measures, and study end points for the study population? ____ Yes ____ No

If No, specify: _____

5. Do the outcome measures place an unacceptable burden on the patient (time, effort, risk, and cost)? ____ Yes ____ No

If Yes, why?: _____

6. Are potential benefits/risks of study participation clearly specified?
____ Yes ____ No

If No, specify: _____

7. Does the Investigator present justification for the sample size? ___Yes ___No

If No, specify:_____

8. Does the statistical design and/or analysis plan correlate to the study endpoints?
___Yes ___No

If No, explain:_____

9. Does the protocol correlate to reasonable enrollment time frames and associated study costs?
___Yes ___No

If No, explain:_____

10. Does the study include collection of tumor tissue for banking purposes?
___Yes ___No

If No, explain:_____+

11. Is the study schema complete (agents, doses, route, frequency, administration cycle)?
___Yes ___No

If No, explain:_____++

12. What is the estimated budget per patient? _____

13. How does this study purpose and design benefit the patients of Georgia?

14. Study accepted for Georgia CORE implementation? ___Yes ___No
If no, provide rationale:

15. Was a Scientific Review and Monitoring Committee Review Meeting held to discuss
this research concept? ___Yes ___No

**ATTACHMENT D:
Georgia CORE Site Solicitation Feedback Form**

Date: _____

Study Name:

GA-CORE Protocol #: _____

Study Phase: _____

Site, Stage, Study endpoint:

Investigator Name: _____

Institution/practice: _____

Contact information: _____
Number/Street Apt/Room/Bldg City State Zip Code

Study participation level:

Very interested Have competing protocols for this patient population

Lukewarm No interest

Would serve as investigator and enter patients on the trial.

Our practice sees # of patients per month who would qualify for the study trial

Would screen patients to the trial

Would refer patients to the trial

Would not recommend patients for the trial

Benefits of the trial (1-2 sentences):

Concerns/issues about the trial (1-2 sentences):
