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.

<table>
<thead>
<tr>
<th>Georgia CORE President and CEO/Desigee</th>
<th>Create the Scientific Review and Monitoring Committee (SRMC).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georgia CORE staff and consultants</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>• Review RCP form (Attachment B) submitted electronically to the Georgia CORE President and CEO.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td>Members, Scientific Review and Monitoring Committee</td>
<td>Complete the Scientific Review and Monitoring Committee Evaluation Form (Attachment C) and return to the Georgia CORE President and CEO.</td>
</tr>
<tr>
<td>Georgia CORE President and CEO/Desigee</td>
<td>Create a Summary Report which is a compilation of the individual responses from SRMC members.</td>
</tr>
<tr>
<td></td>
<td>Distribute the SRMC Summary Report to the Investigator, Chief Medical Officer and key research team members for their review and comment.</td>
</tr>
<tr>
<td></td>
<td>Compile comments from Investigator, Chief Medical Officer and research team and forward to the Investigator for review, response, and revisions to the protocol.</td>
</tr>
<tr>
<td></td>
<td>Once the Investigator returns the revised RCP/protocol, send the RCP/protocol to the Chief Medical Officer.</td>
</tr>
<tr>
<td>Chief Medical Officer</td>
<td>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.</td>
</tr>
<tr>
<td>President and CEO/Designee</td>
<td>Upon CMO approval to proceed, work with the Investigator and Research Development Committee (RDC) to identify and complete outstanding study documents (e.g. protocol</td>
</tr>
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</table>
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.

<table>
<thead>
<tr>
<th>President and CEO/Designee</th>
<th>Forward completed documents to the President and CEO and Chief Medical Officer.</th>
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<tr>
<td></td>
<td>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.</td>
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<td>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.</td>
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<td></td>
<td>Collect feedback from Research Network sites through the Site Solicitation Summary Report (Attachment D).</td>
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</table>

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

PHASE I RESEARCH CONCEPT REVIEW AND CRITIQUE

- **PI submits RCP Form or protocol to Georgia CORE.org**
- **SRMC completes the Evaluation Form and submits to Georgia CORE.org**
- **PI, CMO and key Research Team members review the SRMC Summary Report and comment**
- **PI returns revised RCP/protocol. CMO determines next steps**
- **Decide not to proceed**
- **Refine RCP/protocol further. Repeat as necessary**
- **Proceed with next phase of development**

**Georgia CORE reviews and distributes document to SRMC**

**Georgia CORE compiles SRMC Summary Report**

**Georgia CORE compiles comments and distributes to PI for potential revisions**

PHASE II CLINICAL TRIAL DEVELOPMENT

- **Georgia CORE submits RCP/protocol to RDC for review and input**
- **CMO and President and Financial Advisor review documents**
- **Refine RCP/protocol further. Repeat steps as necessary**
- **Decide not to proceed**
- **Final feasibility decision made by Georgia CORE. PI notified of next steps**

**Trial budget, pharmaceutical, operational, data, and statistical plans completed**

**Distribute approved RCP/protocol and relates documents to Research Network sites for review**

**Georgia CORE completes Site Solicitation Summary Report**

**Research Network sites submit Site Solicitation Feedback Forms**

**Georgia CORE compiles SRMC Summary Report**

**Research Network sites submit Site Solicitation Feedback Forms**

**Final feasibility decision made by Georgia CORE. PI notified of next steps**

**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:**

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<tr>
<th>Name</th>
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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

Email     Telephone     FAX

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):

________________________________________________________________________