FORM 1
FOR NON-INTERVENTIONAL STUDIES NOT MANAGED BY THE WINSHIP CLINICAL TRIALS OFFICE

INSTRUCTIONS:

This form serves as application to the Clinical Translational Research Committee (CTRC) for protocol review. It is designed to be a tool for the investigator(s), to ensure that before the approval process begins, the many facets surrounding the initiation of clinical trials are carefully thought through, understood and agreed upon by all of those involved in the trial. The form is designed in such a way that a completed form will provide the Winship regulatory department with all of the information needed for IRB submission, and application can be made to the IRB immediately following CTRC approval**. Please complete this application electronically, print it, and obtain the necessary signatures. The form is available on the Winship Cancer Institute website under Clinical Trials - http://www.cancer.emory.edu.**

WHAT TYPE OF REVIEW ARE YOU SEEKING?

☐ **EXPEDITED – For NCI cooperative group trials, or expanded access trials only.** Protocols of this type are routed directly to the CTRC chairman or designee. Approval can be given without presenting the protocol formally at CTRC meeting. There are no submission deadlines; however, the chair (or designee) may send the protocol to the Committee for review at his discretion.

Submission requirements: Signed CTRC submission application, protocol, investigational new drug brochure (if applicable), consent form template. Electronic copies of all documents sent via email to winshipctrc@emory.edu with signature page of CTRC form delivered (see page 11).

☐ **LIMITED – For non-therapeutic/non-invasive trials including non-interventional studies that are part of peer-reviewed grants**. Protocols that qualify for limited review would likely fall under the IRB review category of "expedited" or "exempt" [chart review, laboratory (tissue/blood draw), behavioral, quality of life, etc.] These submissions will be sent to the CTRC chairman (or designee), one additional CTRC reviewer, and statistician. The reviewers may present their recommendations to the next CTRC meeting, or may determine that protocol needs to be reviewed by the full committee. **The reviewer may request that you be present at the CTRC meeting at which your protocol is being discussed, in which case you will notified of the time and date.**

Submission requirements: Signed CTRC submission application and protocol, consent form template (if applicable), any other study related documents (questionnaires, assessment tools, etc. Electronic copies of all documents sent via email to winshipctrc@emory.edu or with signature page of CTRC form delivered (see page 11).

☐ **FULL COMMITTEE – Required for all studies that do not fall under one of the above categories. The principal investigator is invited to the CTRC meeting at which their protocol is being discussed. The meeting dates/times and submission deadlines are posted on the Winship website.**

Submission requirements: Signed CTRC submission application, protocol, investigational new drug (if applicable), consent form template. Electronic copies of all documents sent via email to winshipctrc@emory.edu with signature page of CTRC form delivered (see page 11).

DATA/STUDY LOGISTICS *(Please note that this information will be utilized to develop and negotiate the budget by SOM CTO. For assistance in calculating effort, please contact Janet Davis at 404 778-4770.)*	
1) Is a nurse/coordinator needed for this study? If so, what % of his/her time is needed for this study?	
2) Please list all procedures required for this study that are not standard of care.	
3) Does the funding cover the costs of the study? Please discuss the financial soundness of the study.	

GENERAL PROTOCOL INFORMATION	
Protocol Number (sponsor-assigned)	
Full Title	
Short Title	
Principal Investigator	***Dept/Div:*** ***Phone:*** ***Pic***: **Email:**
Design *Primary Objective:* *Secondary Objectives:*	

Check all locations where subjects will be seen:

- ☐ Children's Healthcare of Atlanta (CHOA)
- ☐ Emory University Hospital Midtown (EUHM)
- ☐ Emory Children's Center (ECC)
- ☐ Emory Clinic (TEC)
- ☐ Emory University Hospital (EUH)
- ☐ Emory University (non-clinical) location
- ☐ Grady Memorial Hospital (GMH)
- ☐ Hope Clinic
- ☐ Ponce de Leon Clinic
- ☐ Veterans Administration Medical Center (VAMC)
- ☐ Wesley Woods (WW)

Other: _____

1) PHASE	☐ Phase I ☐ Feasibility/pilot ☐ Phase II ☐ Extended Access ☐ Phase III ☐ Prevention ☐ Phase IV ☐ Other – Explain
2) STUDY TYPE	☐ Therapeutic (involves an intervention) ☐ Cancer Prevention (involves the use of medications in persons who do not have an active cancer) ☐ Ancillary/Companion (QOL or tissue study that is appended to a therapeutic trial) ☐ Laboratory only (uses previously banked human blood or tissue – no patient interaction) ☐ Non-therapeutic studies that assess QOL, symptom control, behavior...

3) TUMOR SITE (Disease Site from NCI guidelines):
N/A ☐

4) Date of working group approval: **Approved by:**
Note: Disease site Working Group approval is required prior to CTRC submission. Questions? Contact Lydia Cox at (404) 778-5569. In cases where the study plan involves patient accrual across multiple tumor types, it is recommended to obtain approval from a single working group that oversees the disease site where the major bulk of participants will be recruited from.

Working Group Priority Score:
- ☐ 1 – Highest (The highest priority study this year for this working group)
- ☐ 2 - High (One of the top 5 studies for the year for this working group)
- ☐ 3 – Medium (Majority support for the study but moderate enthusiasm)
- ☐ 4 – Low (Mixed opinion from the group about opening this study)
- ☐ 5 – Lowest (The majority in the working group did not want to open this study)

Comments (optional):

5) Are there any protocol priority conflicts?
☐ **No** If no, explain how this study does not compete with any existing protocol that enrolls a similar patient population:

☐ **Yes** If yes, please list all conflicting protocols in order of priority and their current patient accrual:

6) SCHEMA - Please attach or paste a copy of the study schema or grant abstract here.
☐ Not attached – Reason:

7) FOLLOW-UP	Does this study involve long term follow-up of subjects? ☐ Yes ☐ No

8) What is the expected termination date?

9. INTERVENTIONS PLANNED?

Investigational Drugs	**Yes** ☐;	**No** ☐
Investigational Devices	**Yes** ☐;	**No** ☐
Radiation	**Yes** ☐;	**No** ☐
Behavioral Therapy/Counseling	**Yes** ☐;	**No** ☐

If you answer "Yes" to any of the above, please use CTRC form 2

10. Study Origin

1) INITIATION	Is this an investigator-initiated study? (If the PI is the sponsor or if the PI and or Co-investigators design, or participate in designing the study) ☐ Yes ☐ No (If NO, please skip this section) **Winship Investigator-Initiated Research** ☐ Yes ☐ No If Yes: Winship Biostatistics Core consult recommended prior to submission Specify Study statistician: Name: Email: Date of Consult: Did you use a non-Winship Core Biostatistics support? ☐ **Yes** Name and contact information: High Throughput Genomic-based research? ☐ Yes ☐ No If yes, Cancer First Studio consult with the Genomics and or Bioinformatics Core recommended. Specify Core Collaborator: Name: Email: Date of consult:
Funding Source (Please select all that apply)	☐ National Group (e.g. ECOG, PrECOG, etc) – Please specify which group below: Name of National Cooperative group: **-** (qualifies for expedited CTRC review)

	☐ Consortium – Name: ☐ Other Externally Peer-Reviewed Trial (R01, P01, other funded by NIH, ACS, Komen Foundation, etc) Name: ☐ Institutional Trial (in-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship or participation in a multi-site trial initiated by an investigator at another center. Initiation by: Funded by: ☐ Industry Trial (design and implementation of the study by the pharmaceutical company) Sponsor Name:
Winship Program	
PRIMARY SCIENTIFIC PROGRAM	☐ CCB - Cancer Cell Biology ☐ CGE - Cancer Genetics & Epigenetics ☐ CPC - Cancer Prevention and Control ☐ DDT - Discovery and Developmental Therapeutics
TEAM *(Working Group)*	☐ Breast ☐ GI ☐ Aero-digestive ☐ Melanoma ☐ Neuro ☐ Heme/BMT ☐ Heme/Leuk ☐ Heme/Lymph ☐ Heme/MM ☐ GU ☐ Phase I ☐ Other ☐ N/A

CO-INVESTIGATORS/STUDY PERSONNEL

List all co-investigators and support staff (clinic nurses, advanced midlevel practitioners, research nurse, coordinator, regulatory specialist) who will be participating in research activities, data collection or regulatory filing and administrative support on the study. Please note that all study personnel must have IRB certification. http://www.emory.edu/IRB/hsep.php

(add rows by hitting the TAB key from the bottom right cell)

Name, Degree	*Role*	*Dept/Div*

STUDY PARTICIPANTS

GENDER	☐ Both ☐ Male Only ☐ Female Only ☐ N/A (blood or tissue samples only)
AGE GROUP(S) *(Check all that apply.)*	☐ Infants or Children under age 6 ☐ Children aged 6-10 ☐ Children aged 11-16 ☐ Children aged 17 ☐ Adults 18 - 64 ☐ Adults 65 +

Indicate which of the following populations will be included in the research {mark all that apply}:

☐ Intellectually or emotionally impaired	☐ Patients	☐ Pregnant subjects or fetuses
☐ Prisoners, parolees, incarcerated subjects	☐ Students or trainees	☐ Employees of study sites

☐ Subjects whose 1st language is not English	☐ Normal Volunteers	☐ Employees or subordinates of investigators
☐ No subjects – e.g. chart or database review		

ACCRUAL

NOTE: The CTRC reviews accrual to open trials quarterly. If after one year of being open to accrual, the rate of accrual is ≤ 25% of what is proposed below, the study will be subject to closure.

1) How many subjects to do you expect to enroll annually?	
2) What is the planned total enrollment on this protocol	
3) When is the estimated study activation date	
4) If this is a multi-center study, what is the total number of subjects to be enrolled at all sites:	☐ N/A
5) Please explain how you will recruit participants.	
6) How many patients with this disease were seen at Winship in the past year?	

DATA SAFETY/HIPAA

1) If this is a phase III study, will a Data Safety Monitoring Board (DSMB) review the data?	☐ Yes ☐ No ☐ N/A ☐ External – Specify responsible entity ☐ Internal – List members
2) State data safety monitoring plan. If no DSMB is required, please **describe the plan to minimize the risks and ensure the safety of the subjects**.	
3) Please indicate how the safety and data integrity will be monitored. (Note: Winship DSMC review is required for all Winship investigator-initiated-trials)	☐ A - Winship DSMC and Monitors ☐ B - External DSMC and CRO Monitors ☐ C - External DSMC/Winship Monitors ☐ D – CTEP or Cooperative Group/Winship DSMC and Monitors ☐ Not applicable; please explain
4) External Data Monitoring. If noted above, please indicate the entity conducting the monitoring and the expected frequency:	Frequency:
5) State stopping rules (reference page and paragraph from the protocol.)	
6) Please explain how the study is HIPAA compliant:	☐ 1) You will obtain authorization from the participant for the use and disclosure of PHI (Personal Health Information) through obtaining informed consent. ☐ 2) The data will be completely de-identified and therefore the need of authorization from the individual is waived. (See attached list of 18 identifiers.) ☐ 3) This is a Limited Data Set and you are seeking a Data Use Agreement. (See attached list of allowed identifiers.) ☐ 4) This study involves only the use of decedent data.

BLOOD AND/OR OTHER TISSUE STORAGE/BANKING

1) Does this research involve blood/tissue storage or banking?	☐No ☐ Yes (If No, indicate so and move to next section)
2) Describe the nature and number of samples to be collected.	
3) For what period of time will these samples remain stored?	
4) Identify the primary custodian of the samples.	

5) Are the use of the samples for both current and/or future research activities clearly described in the informed consent form and process?	☐No ☐ Yes
6a) Describe any identifiers that will be linked to the samples.	
6b) If linked, are subjects able to request destruction of samples at a later date? (If so, this should be described in consent form).	☐No ☐ Yes
7) If the samples have direct or indirect links to the subject, describe the measures in place to maintain the confidentiality of information relating to the samples.	
8a) Are there current plans to make the samples available to researchers outside of the institution?	☐No ☐ Yes
8b) If yes, provide a list of recipients and a description of how decisions are made to release samples to researchers outside of Emory.	
9) Are there plans to re-contact the subjects to request additional samples?	☐No ☐ Yes
10) Will cells be immortalized?	☐No ☐ Yes
11) Do the subjects and/or their families receive information regarding the interpretation of research or other incidental findings?	☐No ☐ Yes
12) Are there any genetic findings recorded in the subject's medical record?	☐No ☐ Yes
13a) Are any genetic findings made known to third parties (e.g., subject's physician, family members, other researchers, insurance company)?	☐No ☐ Yes
13b) If yes, describe the conditions under which such disclosures are made.	
14. Will genetic counseling be offered to subjects and/or their families?	☐No ☐ Yes If no, please justify:

CONFLICT OF INTEREST

Does any participating research team member (or his/her spouse or dependent children) have any financial interest such as royalty, equity or any other payments (e.g. consulting, salary, etc) in the sponsor or other entities having a financial interest in the intellectual property, product, or service which is the subject of the proposed research?	☐No ☐ Yes
Please review the following information concerning Emory University's Conflict of Interest and Disclosure guidelines: http://www.or.emory.edu/share/policies/conflict.html **Any potential conflict of interest must be disclosed to the Dean's Office.**	

SIGNATURES

As Principal Investigator, I acknowledge responsibility for this project and assure that the faculty and staff who participate in it are qualified (or will be adequately trained) to conduct it.

Principal Investigator signature:		Date:	
Typed name of PI			
Working Group Chair signature or email if applicable		Date:	
Typed name of working group chair			

Submit form and all supporting documentation to:
Lydia Cox
CTRC Coordinator

Clinical & Translational Research Committee
Winship Cancer Institute
1365C Clifton Road, Suite 3012
Atlanta, GA 30322
(404) 778-5569 (phone)
(404) 778-4389 (fax)
Winshipctrc@EMORY.EDU

HIPAA IDENTIFIERS

DE-IDENTIFIED personal health information (PHI) does not fall under the HIPAA rule. Therefore you can waive authorization for its use and disclosure.

To de-identify PHI these 18 identifiers must be removed:

1. Names
2. Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip cope and their equivalent geocodes, except for the initial 3 digits of the zip code if, according to the current policy available from the Bureau of the Census
    - The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; AND
    - The initial 3 digits of the zip code for all geographic units containing 20,000 or fewer people is changed to 000.
3. Dates (except year) directly related to an individual (e.g., DOB, discharge date, date of death) and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security Number
8. Medical Record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic or code

LIMITED DATA SETS

A “Limited Data Set” is a set of data that is not fully de-identified. You do not need authorization from the patient, nor do you need to seek a waiver, however you must have a “data use agreement” with Winship that describes the permitted uses and disclosures of the information received, and prohibits re-identifying or using this information to contact individuals. This plan must be reviewed by the IRB.

Of the 18 identifiers listed above, the following MAY be used in a Limited Data Set

1. Dates
2. Geographic information (not street address)
3. Other unique identifying numbers characteristics, or codes that are not expressly excluded

(The other 15 identifiers must be removed.)