

**MedStar Research Institute-Georgetown University
 Oncology Institutional Review Board
 Application (Protocol) IRB Review (D-1)**

Section One: Application Information

Principal Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
Mailing Address:	

Responsible Participant (member of faculty or official or administrative unit)	
Title:	
Phone/Pager:	
E-mail address:	
Research Nurse Assigned:	
Phone/Pager:	
E-mail address:	
Study or Data Coordinator:	
Phone/Pager:	
E-mail address:	
Biostatistician (If study is Institutional)	
Phone:	

Title of Project	Purpose of Project (one or two sentences)

Co-Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
Mailing Address:	

Research Nurse Assigned:	
Phone/Pager:	
E-mail address:	
Study or Data Coordinator:	
Phone/Pager:	
E-mail address:	
Biostatistician (If study is Institutional)	
Phone:	

Additional Co-Investigators/Consultants, if any	Department or Institution

Source of Funding/Grant Support for Project (if any) Please attach two copies of the Grant Application	Commercial Support (if any) for Project

Phase: I II III IV Pilot

Is either the Lombardi Cancer Center Clinical Research Management Office or the Washington Cancer Institute Clinical Research Department responsible for the data/does the data have to be entered into the database?
 Yes No

Is this a biological specimen collection study?
 Yes No

Has this study undergone previous scientific review?
 Yes No

If yes, state where reviewed:

Estimated duration of total project	
Estimated total number of subjects (including control subjects)	
Age range of subjects	
Sex of subjects	
Where will study be conducted?	
Source of subjects	
Experience of Principal Investigator: Brief summary (also attach a CV, biosketch, or Form 1572, if available)	

<p>Investigational New Drug (IND)</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> IND: FDA # _____</p> <p><input type="checkbox"/> Drug Name: _____</p> <p><input type="checkbox"/> Drug Sponsor: _____</p> <p><input type="checkbox"/> Significant (SR)</p> <p><input type="checkbox"/> Non-Significant Risk (NSR)</p>	<p>Investigational Device Exemptions (IDE)</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> IDE: FDA No. _____</p> <p><input type="checkbox"/> Device Name: _____</p> <p><input type="checkbox"/> Device Sponsor: _____</p> <p><input type="checkbox"/> Significant (SR)</p> <p><input type="checkbox"/> Non-Significant Risk (NSR)</p>
<p>If this project involves an FDA regulated drug or device, you must file an FDA form 3455. Please submit any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.</p>	

Section Two: Additional MedStar Research Institute-Georgetown University Regulatory Information

2.1 Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy? If so, Institutional Biosafety Committee (IBC) approval must be obtained. Contact (202) 687-4712 for assistance.
 Yes No

2.2 Has the Institutional Biosafety Committee approved the protocol?

<input type="checkbox"/> Approved	Date Approved:
<input type="checkbox"/> Application Pending	Date Submitted:

2.3 Does this project include the use of radioisotopes and/or radiation-producing devices regardless of whether the use is incidental to the project? If so, all GU protocols must be submitted to the GUH RSC along with a completed Form_0.30 for Radioactive or Form_0.31 for X-Rays. The forms require information on the use of radioisotopes and radiation-producing devices and must include dose calculations. Forms are on the IRB website: <http://www.georgetown.edu/gumc/ora/irb/irbForms.htm> or call 202-444-4657 to obtain forms or if additional information is required.
 Yes No

2.4 Has the Radiation Safety Committee approved the protocol?

<input type="checkbox"/> Approved	Date Approved:
<input type="checkbox"/> Application Pending	Date Submitted:

2.5 Does this project involve the use of fetal tissue?
 Yes No

2.6 Do any investigators or co-investigators have a conflict of interest as defined in the Georgetown University Faculty handbook (<http://www.georgetown.edu/facultysenate/handbook.html#financial>) or MedStar Research Institute policy?
 Yes No

Each “investigator” must submit a Georgetown University Study Specific Disclosure Form as part of this protocol application. “Investigator” includes the principal investigator and any other person who is responsible for the design, conduct, or reporting of research.

The Georgetown University Study Specific Disclosure Form is available for downloading from the IRB website: <http://ora.georgetown.edu/irb/irbDisclosure.htm>

Questions about the Georgetown University Study Specific Disclosure Form can be directed to the Office of Regulatory Affairs, Conflicts Regulation Office at 202-784-5313 or conflictsregulation@georgetown.edu

Guidance for Conflicts Disclosure in Publications and Presentations

Financial and/or Intellectual property interests (e.g. patents or patent applications) must also be disclosed in all related press releases, publications and presentations.

Section Three: Categories of Scientific Review for Project

Review Type:

- Expedited
- Full Board/Standard
- Waived CRC Review for Direct Submit to IRB

Category:

- National Coop Group
- External Peer Reviewed
- Institutional
- Industry Sponsored

Sub-Category:

- Pharmaceutical Industry
- Cooperative Group (If CALGB, are regulatory documents required?)
 - Yes
 - No
- NCI
- Multi-institutional
- LCC

Program Type:

- Breast
- Cancer Prevention & Control
- Developmental Therapeutics

Trial Type:

- Companion
- Chemoprevention
- Correlative
- Therapeutic
- Ancillary

Coop Group:

- CALGB
- CCG
- COG
- NSABP
- SWOG
- ACOSOG

Section Four: Information for Protocol Review

Please answer each specific question and use additional sheets as needed. A response of “See attached protocol or grant application” is not sufficient.

4.1 Required Summary: Please create a brief summary, in Layman Terms (8th grade language) of 200 words or less for this protocol outlining the salient features that may be useful to public and health care professionals. The Lombardi Cancer Center website will post this summary for researchers at the Lombardi Cancer Center. (<http://lombardi.georgetown.edu/>)

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4.2 Study Description (summarize the protocol according to the following format in less than 2 total pages)

Study Design (for example, hypothesis, research question, standard and experimental procedures, special or unusual equipment or procedures) :
Rationale and justification for study (for example, historical background, investigator’s personal experience, pertinent medical literature):
Primary study endpoint:
Primary objective:
Secondary objectives:
Treatment plan:
Statistical Considerations (justification for sample size or “n”, power or degree of change):

Relative importance/value of the trial, considering “standard” therapy and competing trials:

Are there any open trials that compete for this patient population?

Yes

No

If “Yes” please explain how recruitment will be prioritized.

Feasibility of study including projections for accrual of subjects (Total and MedStar/GUMC) and timeline for accrual:

Anticipated Accrual for local site(s)? _____

Overall Target Accrual? _____

How Long Will Study Be Open to Accrual? _____ month(s)

Duration of Study? _____ month(s)

4.3 Risks: Indicate what you consider to be the risks to subjects and indicate the precautions to be taken to minimize or eliminate these risks. Justify the need for a placebo control group if one is included in this study. Where appropriate, describe the data monitoring procedures that will be employed to ensure the safety of subjects. Use additional sheets as needed.

4.4 Does a Data Safety and Monitoring Board exist?

Yes

No

[A Data Safety and Monitoring Board, an independent group of experts, will review the data from this research throughout the study. Patients will be told about new information from this or other studies that may affect their health, welfare, or willingness to stay in this study.]

4.5 Does this study include a Placebo?

Yes

No

4.6 Data Safety and Monitoring Plan

4.6.1. Assignment of Risk Levels – Please select the risk level for your study and check the boxes that apply.

4. 6.1.1. Research involving minimal risk

<input type="checkbox"/>	Anthropomorphic evaluations	<input type="checkbox"/>	DEXA scans
<input type="checkbox"/>	Electrocardiograms (EKGs)	<input type="checkbox"/>	Exercise testing
<input type="checkbox"/>	Intravenous glucose tolerance tests	<input type="checkbox"/>	Intravenous catheter insertion
<input type="checkbox"/>	Magnetic resonance imaging (MRI) scans	<input type="checkbox"/>	Observational studies
<input type="checkbox"/>	Oral glucose tolerance tests	<input type="checkbox"/>	Pathology slide review
<input type="checkbox"/>	Special/prescribed diets	<input type="checkbox"/>	Venipuncture
<input type="checkbox"/>	Other <u>Level I</u> non-therapeutic tests or studies. Please list:		

Note: In the assignment of risk levels, a research survey may be considered more than minimal risk to subjects if dealing with very sensitive information.

4.6.2. Plans for Reporting of Adverse Events Including Subject’s Death.

Adverse events from this protocol will need to be reported to the IRB, GCRC RSA (if the study is being conducted on the GCRC), and GCRC Nurse Manager (if the study is being conducted on the GCRC). In the section below, please list other individuals and/or entities to whom adverse events will be reported.

Individual/Entity	
<input type="checkbox"/>	National Institutes of Health
<input type="checkbox"/>	Food and Drug Administration (FDA)
<input type="checkbox"/>	Other agency or sponsor
	Please specify:

4. 6.2.1. Who is the individual/entity primarily responsible for AE and to whom they are primarily reported.

Name	Position

4.6.3. Plans for Monitoring the Progress of Trials and the Safety of Participants

4. 6.3.1. Safety tests. In the section below, please indicate the summary of safety tests, particularly those that screen out ineligible research subjects and those that monitor for toxicity and other adverse outcomes.

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4. 6.3.2. Safety Contact Information. In the section below, please include a description of who will manage the patients and be responsible for assessing subjects’ responses including potential adverse events during their participation in the protocol. Please provide 24-hour contact information of the PI or other responsible member of the study team.

Name	Role on the Project	Can be contacted 24X7?	Contact Information
			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:

4. 6.3.3. Description of Individuals/Entities in Charge of Dispensing Drugs. In the section below, please include the description of individuals and/or entities in charge of dispensing the drugs.

Name	Role on the Project	Contact Information
		Phone:
		Pager:
		E-mail:
		Phone:
		Pager:
		E-mail:
		Phone:
		Pager:
		E-mail:

4. 6.3.4. Safety Monitoring Methods and Intervals

In the section below, please check all that apply.

Data to be Evaluated	Interval/Frequency of Evaluation*
<input type="checkbox"/> Age specific intervention(s)	
<input type="checkbox"/> Clinical test(s)	
<input type="checkbox"/> Subject interview and/or contact	
<input type="checkbox"/> Subject's physical exam	
<input type="checkbox"/> Subject's symptoms or performance status	
<input type="checkbox"/> Subject's vital signs	
<input type="checkbox"/> Other study parameters. Please list: 	

4. 6.3.5. Decision Making Criteria and Stopping Rules

In the section below, please describe data safety monitoring criteria for decision-making regarding continuation, modification, or termination of the clinical study.

4. 6.3.6. Monitoring of the Study

In the section below, indicate who will monitor the study and to whom the study will report. Describe the frequency of the monitoring. If a DSMB is required, describe the composition of the board, its role, and the frequency of meetings and methods of communications.

4. 6.3.7. Subject Withdrawals/Dropouts

In the section below, please describe how subject withdrawals/dropouts prior to study completion will be reported. Include examples of reasons that may prompt subject withdrawals/dropout.

Section Five: Selection of Subjects and the Informed Consent Process

5.1 Indicate whether this project involves any of the following subject populations?

- Children (Children are defined by local law as anyone under age 18.)
- Prisoners
- Pregnant women
- Cognitively impaired or mentally disabled subjects

Economically or educationally disadvantaged subjects

If you indicated any of the above, in the space below please describe what additional safeguards will be in place to protect these populations from coercion or undue influence to participate. (Use additional sheets as needed.)

5.2 Recruitment: Describe how subjects will be recruited and how informed consent will be sought from subjects or from the subjects' legally authorized representative. If children are subjects, discuss whether their assent will be sought and how the permission of their parents will be obtained. Use additional sheets as needed.

5.3 Does the review of this protocol include evaluation of patient population to ensure women and minorities are included, if appropriate?

- Yes. This study is open to both men and women, and to all racial/ethnic groups. Since there are no prior reasons to expect different effects of therapy in male and female patients, and in different racial/ethnic groups, this study will not have separate accrual targets for these groups. Subgroup analyses will be conducted to determine gender and race/ethnicity treatment effects and will document any interactions between treatment and these factors.
- No

Explain the rationale for excluding these populations in the space below.

5.4 Other Exclusions: Please check the corresponding box if any of the following populations is excluded.

- HIV
 Pediatric
 Other _____

Explain the rationale for excluding any sub-populations in the space below.

5.5 Will subjects receive any compensation for participation in cash or in kind?

- Yes No

If subjects receive any compensation, please describe amount or kind of compensation in the space below.

Section Six: Privacy and Confidentiality of Data and Records

6.1 Will identifiable, private, or sensitive information be obtained about the subjects or other living individuals? Whether or not such information is obtained from a covered entity (GUH, WHC, etc), describe the provisions to protect the privacy of subjects and to maintain the confidentiality of data. If the information does come from a covered entity, please attach a copy of the completed appropriate HIPAA General Authorization Form or Request for Waiver. Use additional sheets as needed.

HIPAA compliant forms for MedStar may be found at the following website:

<http://www.medstarresearch.org/body.cfm?id=87>

- I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

- I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

- I assure that the protected health information identified on the “Medical Records Release and General Authorization to Use and Disclose Health Information for Research” and the persons and entities that may use, give and receive protected health information is accurate and reflective of the known use and disclosure for this human clinical study.

_____ Printed/Typed Name of Investigator _____ Signature of Investigator	_____ Telephone number _____ Date
_____ Printed/Typed Name _____ Signature of Department Chair	Department Chair: <input type="checkbox"/> Approved <input type="checkbox"/> Disapproved _____ Telephone Number _____ Date

If more than one department or administrative unit is participating in the research and/or if the facilities or support of another unit, e.g., nursing, pharmacy, or radiation therapy, are needed, then the chair or administrative official of each unit must also sign this application.

_____ Authorized Signature _____ Title and Department	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved _____ Date
_____ Authorized Signature and Title _____ Title and Department	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved _____ Date
_____ Authorized Signature and Title _____ Title and Department	<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved _____ Date

Section Seven: Attachments

Please attach the following items in order for the IRB to review your research.

24 Copies of the Following for Full Board review, only 1 copy for Expedited or Exempt Review:

- IRB Application form (Form D-1)
- Informed Consent Document
- Any recruitment notices or advertisements
- Any research survey instruments, psychological tests, interview forms, or scripts to be used
- HIPAA In-house Authorization or Request for Waiver*
- Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.

One Copy of the following, when applicable

- Request for Expedited Review (Form D-3)
- Request for Exemption (Form D-4)

5 Copies of the Following for Full Board review, only 1 copy for Expedited or Exempt Review:

- Investigator's Brochure from the sponsor, if applicable**
- Research protocol and sample consent document from the sponsor or Cooperative Group, if applicable

2 Copies of the following, if applicable

- Grant application

One Copy of the following forms for Principal Investigator and **ALL** Co-Investigators

- Certificate of Completion for HIPAA training and HIPAA forms.*
- Certificate of Completion of Education in the Protection of Human Research Subjects***
- Study Specific Disclosure Form(s) for ALL
- Investigator's qualifications (CV, biosketch, or Form 1572 including CV, if available)
- If this project involves an FDA regulated drug or device, FDA form 3455

* HIPAA Training

All persons listed on the IRB application, Co-Investigators Page, Investigator's Agreement or 1572 of any research protocol will need to have completed the HIPAA training module for Researchers in order to secure IRB approval. Additionally, Investigators will need to assure that all key personnel involved in the research, especially personnel with data access and patient contact, have completed the HIPAA training module for Researchers. For more information and to download forms, please refer to the following MedStar website: <http://www.medstarresearch.org/departments/oars/hipaa/hipaatraining2.htm>

** Investigator's Brochure (where applicable)

The Investigator's Brochure must contain the following information. If it does not contain the information, then please attach a separate sheet of paper to address the item.

- ♦ Name of drug under study.
- ♦ Source of the drug.
- ♦ Experience with the drug in humans, including doses tested, toxicity observed, minimal toxic dose, pharmacokinetic data (absorption, elimination, metabolism, etc.).
- ♦ Description of toxicity in humans.
- ♦ Procedures for minimizing adverse reactions and dealing with those that might occur.

*** Information on Human Subjects Protection in Research Training:

<http://www.georgetown.edu/OSP/HumanSubjs.htm>