New York Hospital Queens Theresa & Eugene M. Lang Center for Research & Education **Application for Initial & Expedited Review**

PLEASE NOTE: In accordance with Institutional policy, incomplete applications will be returned and may result in delay of IRB review. If you have any questions regarding this document, please contact the IRB office at 718-670-1194.

			Email
Principal Investigator (PI)			
Co Investigator(s)			
Coordinator:			
Address of PI:			
Геlephone:			
Department:			
Source of Funding:	orporate/Business Name:		
<u></u>	ederal/Grant Name/Number:		
□о	ther:		
s this research investigator-ir	nitiated? (i.e., no separate sponsor is involved):	□ No	□ Yes
Departmental Chief Signatur	e: Signature signifies review and consent of protocol submissi	ion to the IDD	
(If applicable)		ion to the IRB	
Department Chair Signature: (If applicable)	Signature signifies review and consent of protocol submiss	on to the IRB	

IMPORTANT:

According to NYHQ Institutional policy, the Principal Investigator and all key personnel (Co-Investigators, Research Assistants, Coordinators, etc.) involved with this Study must each complete the CITI Human Subjects Protection Course and a Financial Disclosure Form. Please be aware that the IRB determinations cannot be released until proof of completion is submitted. Please contact the IRB office if you need instructions on how to complete the course or the financial form.

Title of Protocol	
Sponsor	
Address	
Telephone #	
Has the Investigator	ever received an FDA "Warning Letter" that has not been previously submitted to the NYHQ IRB?
	□ No□ Yes If yes, please attach all relevant correspondence and reports
	General Study Design Questions (Retrospective studies please skip to question 4) ch involve a Drug, Biologic or Dietary Supplement? ¬ YES ¬ NO nas the FDA approved the Drug(s)?
⊓ yes, i	
	(Must submit the Drug Package Insert)
□ NO	Name:IND#:
The Investigation	onal Drug Brochure, FDA 1572 Form and FDA letter must be submitted to the IRB
NO YES F L	ch involve an Investigational Device? — Must provide the Investigational Device Brochure and one of the FOLLOWING: FDA letter granting an Investigational Device Exemption for the proposed use (unredacted copy), Letter from sponsor stating that the study is a non-significant risk device study, or Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt.
recombinant DN □ NO	rch involve any form of gene transfer (i.e. experiments involving the deliberate transfer of NA, or DNA or RNA derived from recombinant DNA, into human research participants) - Please Contact IRB office regarding review by an Institutional Biosafety Committee (IBC)

4.	Are you requesting a Humanitarian Use Device?
	 □ NO □ YES – Provide the HDE #:
	Note: FDA Labeling information or information from sponsor submitted to the FDA must accompany this application.
5.	List primary research question(s):
6.	Indicate where research will be conducted:
	☐ Hospital ☐ Ambulatory Care Centers ☐ Private Practice ☐ Schools
	☐ Prisons ☐ Other:
	Address(es):
7.	Projected number of subjects to be enrolled in protocol:
	Specifically for Investigator(s):
	Enrollment timetable:
8.	Projected duration of study:
	Duration of principal investigator participation:
	Duration of subject participation:
9.	Does the Principal Investigator have open research studies which are enrolling the same subject population as this study?
	 □ NO □ YES - Explain how the investigator will determine subject enrollment for each competing study

Recruitment

10.	Pleas	Advertising (All recruitment materials must be approved by the IRB before use) From Personal Contact (e.g., patients, students) If the investigator's own students, employees, or patient's are to be used, describe steps to be taken to					
		Other (Must S					
		Referrals*					
	NOT	disclo	se identifiable		earch screenin	er of authorization before you can use or g or recruitment purposes or you must our own.	
11.	Pleas	se indicate sub	jects from the	e following vulnerable c	ategories that	will be enrolled in this study:	
	□ M □ P	regnant Women linors risoners		☐ Fetuses ☐ Adults ☐ Elderly Persons		☐ Abortuses☐ Students☐ Mentally Disabled	
	□E	Outpatients Imployees Subjects that lack	capacity to give	☐ Referrals ☐ Poor/Uninsured //e voluntary consent		☐ In-patients ☐ Illiterate	
	If vuln	nerable populatio	ons are being e	enrolled, you must describ	e the additiona	I protections that will be afforded them:	
12.	I anti	cipate enrolling	g subjects wh	ose primary language i	s: <i>(check all th</i>	nat apply)	
	Г	□ English	_% 🗆	Chinese%	□ Greek _	%	
		□ Russian	% □	Vietnamese%	□ Spanish	n%	
	[☐ Korean	_% 🗆	Other%			
	ALL	translated inf	ormed conse	ent documents must b	e approved l	by the IRB prior to use.	
13.	Will enrollment into the study be based on gender or ethnicity?						
	□ N	I/A IO ES - Please pro	vide rationale:				
14.	Are v	vomen of child	bearing capa	city eligible for enrollme	ent into this stu	udy?	
	□ N/ □ N(wer the follow	ving:			

	Describe the process for determining pregnancy status:
	Will birth control be required to participate? □ Yes □ No
	List acceptable forms of Birth control:
	Note: Acceptable forms of birth control must be contained in the consent document
15.	Will pregnant women be enrolled in this study?
	 □ N/A □ NO □ YES - Research must meet criteria for Federal Regulations 45CFR46 – Subpart B
16.	Are minors eligible for enrollment into this study? *
	□ N/A □ NO □ YES - Research must meet criteria for Federal Regulations 45CFR46 – Subpart D
	Note: The consent of at least one parent or legal guardian will be required. In some cases, the IRI may require the consent of both parents
17.	Will this study involve children who are wards?
	 □ N/A □ NO □ YES - An advocate must be appointed for all wards
	Informed Consent Process
	N/A – Waiver of Consent Required (Skip to Question 26) (Must complete: Request for a Waiver of Consent and Waiver of Authorization under HIPAA-attached)
18.	Please describe the circumstances and location of the consent process, including who will be obtaining consent:
19.	Describe how subjects will be given sufficient opportunity to consider whether to participate or not: (Check all that apply)
	 □ Subjects will be allowed to take home the unsigned consent form for consideration prior to signing it □ Subjects will be allowed a waiting period of hours to consider their decision. □ Other (specify):

20.	Describe steps taken to minimize the possibility of coercion or undue influence in the consent process: (Check all that apply)					
		does in Subject of the second	ect will not be told or given the impression that he/she will lose access to needed health services if he or she not participate in the research. Ect will not be offered an excessive or inappropriate reward or other overture in order to obtain compliance. subjects to be enrolled are student or employees of the Investigator, he/she will not be told that a decision to ipate could affect performance evaluations or job advancement, even if it is only the employee's perception his is the case To (specify):			
	Note	S) Cl	the IRB may require additional safeguards study to protect the rights and welfare of subjects when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as hildren, prisoners, pregnant women, mentally disabled persons, or economically or educationally isadvantaged persons, additional safeguards have been included in the of these subjects.			
21.	ADL	JLT s	protocol require the use of a Legally Acceptable Representative (LAR) or a Health Care Proxy for ubjects who lack the capacity to consent? If an LAR is approved, you will be notified of the priority of the LAR.			
		N/A NO YES				
			participants who are incapable of providing effective informed consent due to some cognitive or decisional at, there are two ways in which their participation may be allowed:			
		A. B.	Health Care Proxy may consent to enroll a participant in any research protocol that has been approved by the IRB. If there is no health care proxy, a legally acceptable representative may permit the participant's enrollment in IRB-approved research if (a) the risk is minimal, regardless of whether the participant would derive any benefit; OR (b) the risk is greater than minimal, but the research potentially carries a direct benefit to the participant.			
	Note	e : /	nstitutional Policy requires that the following criteria must be met in order for the use of an LAR:			
		A. B. C. D.	There is potential benefit over standard treatment; Standard treatment has not being withheld; Enrollment in the study is in the best interest of the patient; and Participation in the research would not be contrary to the known wishes of the patient			
			may require that a physician, not affiliated with the research study, determine if a subject lacks the to consent. Additionally, you may be required to obtain Assent from the ADULT subject.			
22.	Will	l subj	ects be provided with any compensation for participating in this study?			
		N/A NO YES	Amount per visit:			
			When/How will subjects be paid:			
	Note	e: 7	This information must be contained in the informed consent document			

23.	Plan for monitoring the data collected to insure the safety of the participants:
	□ Data Safety Monitoring Board (DSMB) How often is the DSMB scheduled to meet?
	☐ A formal board has not been established Indicate how safety will be monitored:
24.	Plan for maintaining confidentiality of Subject's Protected Health Information: As required by HIPAA - Check all that apply:
	 □ Paper-based records will be kept in a secure location and only be accessible by study personnel □ Computer-based files will only be accessible by study personnel though protected passwords □ Study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. □ Whenever feasible, identifiers will be removed from study-related information
	Additional IRB Considerations
25.	Has another IRB reviewed this research project? (Prior approval has no bearing on the NYHQ IRB review)
	□ NO □ YES Was it approved? □ NO □ YES If yes, please provide the following IRB contact:
	IRB Name/Institution:
	Address:
	Contact Name:
	Telephone #:
26.	If off-site facilities will be used, please provide the name and address of the facility, as well as services to be rendered:
	Name of Facility:
	Address:
	Services to be provided:
	Name of Facility:
	Address:
	Services to be provided:
	(Attach a separate sheet if necessary)

Statement of Assurance by Investigator

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project, prepared in accordance with institutional policy for the protection of human subjects participating in research. I understand the Medical Center's policy governing review and approval of human subject investigation and research, and I agree:

- to accept responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Medical Center's Federalwide Assurance (FWA)
- not to be involved in any research involving human subjects without obtaining prior IRB approval
- not to delegate to others the treatment of subjects under the IRB approved protocol without prior IRB notification
- to comply with all applicable Federal, State, and Local laws, rules and regulations, including Right-to-Know, OSHA Hazard Communications, etc. and Medical Center policies
- agree to submit a sponsored research agreement to the Medical Center's Legal Counsel prior to initiation of the study for industrial sponsored research (if applicable)
- to obtain prior approval from the Board before amending or altering the scope of the project or implementing changes in the approved consent form
- to submit any advertising for research projects for approval by the IRB prior to submission to any agencies and before posting
- to obtain informed consent of all subjects (or representative, if applicable) who are to participate in this project (unless otherwise waived) with the proper IRB approved consent form
- to maintain records for a minimum of 3 years after closure, or as specified by the sponsor of the research or institution, whichever is longer
- to maintain documentation of consent forms and progress reports as required by institutional policy
- to provide annual and final reports of progress in a timely fashion and to cooperate with members of the Board charged with the review of these reports;
- to report to the Institutional Review Board any unanticipated effects on subjects which become apparent during the course or as result of experimentation and the actions taken as a result;
- to inform subjects to significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation.
- to cooperate with the Board on any audit/record review request.

In addition, by signing you are confirmed that neither you nor yo sponsor(s) and that you have submitted the required Financial D	
Principal Investigator Signature	 Date

New York Hospital Queens Theresa & Eugene M. Lang Center for Research & Education Financial Disclosure Form

						
Telephone #:						
Coordinator Other						
to financial conflicts of interest and do						
licy and Procedure for New York						
onsibilities under this policy? nily <i>(parent</i> s, <i>spouse, siblings,</i> ting/ sponsoring research at New York						
:						
·						
·						
:						
<u>:</u>						
:						
:						
:						
:						
·						
:						
:						
<u>:</u>						
:						
:						

New York Hospital Queens Theresa & Eugene M. Lang Center for Research & Education Human Research Billing Analysis Form

The study protocol, clinical trial agreement/notice of grant award and informed consent must be submitted with this form.

STUDY IDENTIFYING INFORMATION					
Investigator's Name					
Department					
Telephone #			Email Address		
Study Name					
Study Type		Sponsor Initiated		Physician Initiated	
Sponsor Name					
IRB#					
Contracted Enrollment					
		STUDY ANALYS	<u>IS</u>		
Is this a device study?	Yes	□ No			
What is the FDA status of the investigational device?	Device approved by FDA - Pre-Market Approval (PMA) process Device cleared by FDA – 510K process FDA approved IDE category B (Supporting FDA/Sponsor documentation must accompany this form)				
lo this a drug study?	•		uocumentatio	ii iiiusi accompai	iy tilis lorili)
Is this a drug study? □ What is the FDA status of the	Yes	□ No	□ Not Apr	arayad	
drug?		Approved	□ Not App	proved	
If approved, will it be used on or off label		On	□ Off		
If not approved, IND # must be provided	IND #	ing FDA/Sponsor	documentatio	n must accompai	nv this form)
If this study is not a drug or devic				p	.
	□ Retrospective Chart Review □ Retrospective Data Analysis Only □ Tissue Sample/Waste Analysis □ Patient involvement limited to interview/questionnaire				
		SIGNATURES			
Departmental Chair Signatures are required for all department performing services under this protocol (i.e. Pre-Admission, Pharmacy, Pathology, Radiology, etc.). All Signatures Must be Obtained Before the IRB Determination Letter Will be Released.					
List Department		Sigr	nature		Date

COVERAGE ANALYSIS (Please list each service separately) Insurance/ Subject Routine Research Sponsor Providing Non Care Service

New York Hospital Queens

Theresa & Eugene M. Lang Center for Research & Education

Principal Investigator (PI) Information

Request for a Waiver of Consent and Waiver of Authorization under HIPAA

(Must be completed for retrospective chart reviews, studies where a waiver of consent is being requested and as required by the IRB)

PI Name:					
PI Department:					
PI Email:	PI Telephone:	Sp	pectra:		
Protocol Information					
Title:			IRB Fi	lo #ı	
ride.			IKB FI	I C #.	
Waiver of Consent			I		
Describe why this research involve	es no more than minimal risk to the subjec	ots:			
Describe why this waiver will not a	dversely affect the rights and welfare of the	he subjects.			
Describe why this research could r	not practicably be carried out without the	waiver of conse	ent.		
Will subjects be provided with any	information on this study after participation			Yes	No
If so, what information will they		<i></i>			
Waiver of Authorization to Use an	nd Disclose Protected Health Information	on	•	1	
	ormation that will be accessed under this				
Who will have access to the inform	nation?				
Are the persons who have access	to the information required to sign confide	entiality	`	⁄es	No
statements?					
What identifiers are included on the	e information you plan to use and/or discl	lose?			
In what form will the information be	e maintained?				
□ Paper □	Electronic Bot	:h			
	t, describe the precautions you are taking	to protect the	identifie	rs from	NA
improper use and disclosure:					
If information is in an electronic me	edium, are passwords required?		NA	Yes	No
					Ιп

Is access to the information restricted to only those who have a need to know for performance of	Yes	No
their job?		
Is this electronic system used to transmit data outside of your site?	Yes	No
If information is transmitted, what safeguards does your system have to prevent inadvertent access	s to this d	ata?
When do you plan to destroy the identifiers? (Identifiers must be destroyed at the earliest oppo	rtunity)	
☐ End of Study		
 years after the end of the study.Other (please specify):		
□ Other (prease specify)	-	
Other than you and your research staff, who else will have access to this information?		
Please explain how your research meets the following criteria for a waiver:		
1. This research cannot be practicably carried out without the Waiver of Authorization.		
2. This research cannot practicably be conducted without the participants' PHI.		
By signing this statement, I am providing written assurance that only information es purpose of this research will be collected, and access to the information will be limit extent possible. Protected health information will not be re-used or disclosed to any entity.	ed to the	e greatest
oy.		
Principal Investigator's Name (Print)		
Principal Investigator's Signature	Date	

New York Hospital Queens Theresa & Eugene M. Lang Center for Research & Education Checklist/Instructions for IRB Submissions

Incomplete Submissions will be return and may result in a delay of your IRB review

Expedited reviews require one (1) copy of each of the following (as applicable). Review by the full board requires twenty-five (25) copies of each of the following (as applicable). Please be aware of the IRB deadlines in relationship to full board reviews.

Application for Approval of a Research Protocol (Must be filled out completely with all required signatures)		
Protocol- see attached for required elements of a research protocol		
Consent form see attached for required elements of an informed consent. (Must submit any translated consent for review and approval)		
Lay Summary The summary should be brief, about a page in length, comprehensible to a person with no medical background and should include the following topics:		
 Study purpose Study procedure Study subjects Method of recruitment Study procedure Any issues related to the study 		
Relevant Materials Submit all recruitment advertisements, questionnaires, statements to be read to the participants, letters to the participants, information sheets, etc. (advertisements that bear the Medical Center's name or logo must also be submitted to and approved by the Department of Public Affairs/Marketing).		
Human Research Billing Analysis Form (This is required for all protocols)		
Administrative Overhead Prior to research initiation, NYHQ Finance Department must approve a budget for research expenses including administrative overhead.		
Sponsored Research Agreement This is required for industry-sponsored protocols. Prior to research initiation, the trial agreement must be completed and approved by the NYHQ Office of General Counsel.		
Current CV for all investigators (Required for all studies)		
Financial Disclosure Form - for all key research personnel (Required for all studies)		
CITI Certification- for all key research personnel (Required for all studies)		
Submit additional relevant information, if applicable:		
 □ FDA 1572 form □ IDE letter from FDA □ FDA determinations of SR/NSR devices □ Investigational drug/device brochure □ Drug/device inserts □ HIPAA/informed consent waiver request □ Exempt status application 		

New York Hospital Queens Theresa & Eugene M. Lang Center for Research & Education Protocol Requirements/Template for IRB Submissions

Incomplete Submissions will be return and may result in a delay of your IRB review

NOTE: The following requirements apply to all research protocols, however, each research study is different and, as such, additional protocol requirements may be necessary. Please contact the IRB office if you have any questions. 718-670-1194

Study Purpose

Describe the purpose of the research study, the hypotheses to be tested and discuss why this research is important.

Background

Provide background material, which supports the purpose and the study design of the research. Include a summary of previously published data and pilot studies (including any data that does not support the study). For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternative modes of therapy.

Design & Procedures

Explain the study procedures, data collection, monitoring procedures and analysis process. Describe if study is prospective or retrospective; including initial evaluation procedures and screening tests, phases, procedures and sequence of the study. This section needs to differentiate between procedures that are done solely for research purposes and those that are required as part of a subject's standard care. Give detailed procedures for treatment, dose adjustments, etc. Describe any randomization procedure, if applicable.

Inclusion and exclusion criteria

These must be included in the protocol.

Rationale for Subject Selection

The protocol must include (a) a rationale for research subject selection based on a review of gender/ethnic/race categories at risk for the disease/condition being studied (b) and how those subjects will be included in the study (including retrospective chart reviews); strategies/procedures for recruitment (including advertising, if applicable); and (c) j justification for exclusions, if any.

Provide rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, cognitively impaired individuals, prisoners or other institutionalized individuals, or others who are likely to be vulnerable.

Criteria for Subject Selection

- Number of subjects. State the total number of subjects expected to participate.
- **Gender of Subjects.** Describe the intended gender distribution of the subjects. If there are any gender-based enrollment restrictions, explain the nature of the restriction(s) and provide justification.
- **Age of Subjects**. State the age range of the subjects. Provide the rationale for selecting this age range. Additional restrictions may apply to research involving minors.
- Racial and Ethnic Origin. Describe the intended racial and ethnic distribution of the subjects. If there are any enrollment restrictions based upon race or ethnic origin, explain the nature of the restrictions and provide justification.
- Inclusion Criteria. List the inclusion criteria. These should be based on the scientific rationale and safety considerations.
- **Exclusion Criteria.** List the exclusion criteria. These should be scientifically valid and help further define the subject population.
- **Vulnerable Subjects.** If vulnerable subjects (e.g., those with limited autonomy) are included, justify their inclusion. Children, pregnant women, nursing home residents or other institutionalized persons, students, employees, fetuses, prisoners, and persons with decisional incapacity are examples of vulnerable subjects who

may be in need of greater protection. Additional restrictions or requirements may apply to research involving vulnerable subjects.

Risk/Benefit Assessment -MUST not state there is NO risks to subject

(Determination as to the risks and benefits of the research to subjects is the responsibility of the IRB; however, the following information is still required in the submitted protocol)

Risk Category. State the risk that the research presents as one of the following: Minimal, or Greater than Minimal. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A Greater than Minimal risk is a potential harm associated with the research that a reasonable person would likely consider injurious. Describe the procedures for protecting against or minimizing any potential risks, such as violations of confidentiality, and assess their likely effectiveness..

Potential Risk. Discuss the possible risk that the research presents to the subjects, whether it is physical, psychological, social, legal, or economic or other and assess their likelihood and seriousness Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.

Protection Against Risks. Describe how the study design will prevent or minimize any potential risks or discomfort. Potential risks and discomforts must be minimized to the greatest extent possible such as by subject monitoring, appropriate subject withdrawal criteria and follow-up. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects

Potential Benefits to the Subjects

Describe potential medical benefit(s), if any, for subjects participating in the research. If there are no anticipated benefits, this should be stated.

Alternatives to Participation

This section should include a description of alternative therapies or courses of action which are available should the subject elect not to participate in the study.

Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study

Describe the types, frequency and duration of tests, admissions, questionnaires, telephone calls or outpatient visits. Define stop points and criteria for withdrawing subjects from the study.

Location

List all hospitals, clinics that are associated with this study

Process of Consent

(MUST address the process of consent; if requesting a waiver indicate that here)

Describe or list everyone who is authorized to obtain consent and how the process of informed consent will be obtained. If you are requesting a waiver of consent, state that here. The IRB makes the final determination of a waiver of consent.

Subject Capacity to Give Consent

If subject lacks capacity to give consent, describe how informed consent will be obtained.

Data Analysis and Data Monitoring

Describe the statistical or analytical methods to be used. For all studies involving greater than minimal risk, describe how the data will be monitored to ensure the safety of the subjects.

Data Storage & Confidentiality

Describe where the research data will be stored during and after the study and how it will be secured. State who will have access to the data and how the data will be used. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be released and the purpose of the release (e.g., routine verification of case report forms).

New York Hospital Queens

Theresa & Eugene M. Lang Center for Research & Education Informed Consent Requirements/Template for IRB Submission

Incomplete Submissions will be return and may result in a delay of your IRB review

Note: According to OHRP regulations, the following requirements apply to all consent documents, however, each research study is different and, as such, additional consent requirements may be necessary. Please contact the IRB office if you have any questions. 718-670-1194

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained:
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to
 which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty
 or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

Informed Consent Document Template

- Use a 12pt font for this document
- Write the document in the 2ond person (i.e. you) and keep the pronoun usage consistent throughout the
 document
- Use Page W of Y numbering on each page in the bottom right footer
- Include a version number in the bottom left footer
- Leave an area approximately 1 inch by 2 inches on the bottom of the first page for the IRB approval stamp
- Use understandable, non-technical language at an 8th grade or lower reading level

New York Hospital Queens
Principal Investigator's Name
Address
Telephone #(s)
Insert Title of Research Project

Informed Consent Requirements/Template for IRB Submission

Introduction/Background

An opening paragraph is customary to introduce the research study. If a cooperative study, add language that explains the group and their purpose(s).

Purpose -Explain the purpose of the study in non-technical language

State what the study is designed to discover or establish, and give some background information on the study hypothesis. Discuss why and how the subject was selected and express the time in terms of how much he/she must commit to the study (i.e. treatment & follow-up). If there is no direct benefit to the subject, it must be stated up front within this section as well as in the **Benefits** section.

Procedures

State that the study involves research. Explain what will happen to the subjects because of their participation in the study. Describe what the main procedure is and then continue with all the procedures that will be included. A clear distinction must be made between research and standard practice. The following should also be noted:

- How subjects will be assigned to the various study arms
- Estimate the amount of time involved in study participation.
- · Screening or examinations
- Method and schedule of administration of medications
- If applicable, explain what a Pilot, Phase I, II, III, or IV drug study is.
- State the total projected number of participants (e.g., individuals, records, specimens) to be enrolled by the investigator, and study wide for multi-center studies.
- Blood drawings (including the volume to be drawn described in lay terms, e.g. tablespoons)
- Ancillary tests (e.g. EKG, MRI, CAT, Urinalysis, etc.)
- Pregnancy testing
- Physical exams
- Medical history
- Whether participation will require extra visits to NYHQ
- Questionnaires to complete or diaries of activities, etc.

Risks

Describe the risks, discomforts and inconveniences that can reasonably be expected, including risk that the study treatment may not be as effective as standard treatment, or that the subject may be assigned to receive placebo instead of active treatment and that the subjects condition may worsens as a result.

If the study involves the use of either experimental or approved drugs, include the principal side effects, listed in order of frequency. Whenever possible, you should estimate the probability that a problem with occur. If percentages are used, they should be stated as "_____ out of every 100 persons". Words such as common, unlikely, occasionally or rare may be used when it is not desirable to use numerical estimates. Whenever possible, use a table format to summarize risk information.

Benefits

State any potential benefits to the participant or to others that may reasonably be expected from the research. If there is no potential for direct benefit to the participant, that should also be stated. **Do not** include medication, treatment, devices, or compensation information

Alternatives

List specifically any medication or treatment options that the subject might choose as an alternative to participate, and their comparative advantages and disadvantages. Indicate if any standard diagnostic procedure to treatment may be withheld as a result of study participation. The consent form should clearly state that the subject does not have to participate in the study to receive the treatments that are already available.

One alternative is always possible: to not participate in the study and, instead, receive routine treatment.

Participation/Withdrawal

State that participation in the study is voluntary and they may withdraw at any time without affecting their medical care at NYHQ.

Provide information about the consequences of a subject's decision to withdraw from the research and procedures for orderly termination.

Address any circumstances that might lead to early termination by the investigator as well as any significant new findings during the study will be made know to the subject so that continuation with the study can be determined.

Confidentiality

A statement regarding the degree to which confidentiality of the subject's participation will be maintained and the methods to be used is necessary.

If information will be release to anyone for any reason, details regarding the disclosure must be specified in the consent. This is particularly relevant in industry-sponsored trials. The sponsor of the study, the coordinating agency, the Food and Drug Administration (or other appropriate federal agencies) may require access to the records. The Institutional Review Board must always be listed in this section as having access authority.

Authorization to Use or Release Individual Health Information for Research

NYHQ/IRB requires the following statement be included in all consent forms:

The Health Insurance Portability & Accountability Act (HIPAA) is a federal law designated to protect the privacy of your health information. We understand that information about you and your health is personal, and NYHQ is committed to protecting the privacy of that information. Because of this commitment, we must obtain your special authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records
- New health information created from study-related tests, procedures, visits, and/or questionnaires, as
 described in the attached consent form

2. Why will protected health information about be used or shared with others?

The main reasons include:

- to conduct and oversee the research described in the attached form;
- to ensure the research meets legal, institutional, and accreditation requirements; and
- to conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm).

Other reason may include for treatment, payment or health care operations. For example, some medical information produced by this study may become part of your hospital record because the information may be necessary for your medical care.

3. Who will use or share protected information about me?

The researchers and entities participating in the research, as described in the informed consent form, will use and share your protected health information. In addition, the NYHQ Institutional Review Board that oversees the research and its affiliated staff who have need to access this information to carry out their responsibilities (for example, billing, oversight, quality improvement) will be able to use and share your protected health information.

- 4. With whom outside of the researchers may my protected health information be shared?

 All reasonable efforts will be made to protect the confidentiality of your protected health information, which may be shared with the following others for the reasons noted above:
 - The following research sponsor(s) and/or its agents: <PROVIDE SPONSOR'S NAME>
 - Federal and State regulatory agencies (for example, The Department of Health and Human Services, The United States Food and Drug Administration, The National Institute of Health) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
 - The members of the hospital's Institutional Research Board
 - Researchers, Coordinators and other health care providers participating in this research
 - Laboratories and other individuals that analyze your health information in connection with this
 research
 - Date safety monitoring boards organized to oversee this research (if applicable)

As well as, outside individuals or entities that have a need to access this information to perform functions on behalf of the researchers and its affiliates (for example, insurers, legal advisors, data storage companies). We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may re-disclose it, so we share this information only if necessary and we use all reasonable efforts to request that those who receive it take steps to protect your privacy.

5. For how long will protected health information about me be used or shared with others?

There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process, during which information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight or other purposes.

6. Statement of privacy rights:

- You have the rights to withdraw your permission for the researchers and participating entities to use or share your protected health information. We will not be able to withdraw all of the information that already as been used or shared with others to carry out the research or any information that has been use or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you want to withdraw your permission, you must do so in writing by contacting <INSERT PI NAME AND PHONE>
- You have the right to choose not to sign this form. If you decide not to sign, you cannot participate in this research study. However, refusing to sign will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact <INSERT PI NAME AND PHONE>
- You also have a right to receive a copy of this form after you have signed it.

Costs

Clearly explain the costs that may be charged to the participant or insurance carrier versus the charges which will be paid for by the sponsor. Distinguish between the costs of ordinary clinical care any additional costs that are incurred for research purposes. If there are no additional costs, this should be stated.

If standard medical care is being provided during the study, include the following statement:

"The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner."

Compensation

If subjects will receive compensation, describe the type of compensation, the amount, and when they will receive it, and if a subject withdraws from a study, they are entitled to a prorated reimbursement for the portion of the study they have completed. Any compensation should be in amounts are appropriate and would not be considered coercive. If there is no compensation, that should be stated.

Compensation for Research Related Injury

Address the appropriate information regarding the level of liability the sponsor will assume in case of research related injury or illness.

NYHQ/IRB requires the following statement be included in all consent forms:

"In the event of a research related question or injury, you should notify (list Doctor(s) name and phone number). Neither the New York Hospital Medical Center of Queens, nor any of its staff or agents, will provide any form of compensation to you if you sustain an injury as a result of research. However, this does not waive any of your rights.

For information concerning your rights as a research participant, you should contact the Institutional Review Board (IRB) at The New York Hospital Medical Center of Queens whose office telephone number is 718-670-1194"

Significant New Findings

Add the following: You will be told by your doctor or his staff if new information becomes available and might affect your choice to stay in the study.

Questions

Add the following:

If you have any questions, concerns, or complaints available treatments, please contact Dr.	about the research or a research- related injury including	
gnatures or signature below indicates that you agree to participate in	n this study. You will receive a copy of this signed documen	
Patient's Name (Print)		
Patient's Signature	Date	
Person Obtaining Consent (Print)		
Person Obtaining Consent	Date	
have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks nd discomforts as well as potential benefits and have answered any questions regarding the study to the best of my ability.		
Investigator's Name (Print)		
Investigator's Signature	 Date	

If appropriate, special consent/assent must be documented for minors and incompetent adults. Please review with IRB office prior to submission