

HUMAN SUBJECTS REVIEW FORM

DARTMOUTH COLLEGE/DARTMOUTH-HITCHCOCK MEDICAL CENTER

CPHS USE ONLY

STUDY #:

PRINCIPAL INVESTIGATOR: _____ DEPT: _____ PHONE: _____
CO-INVESTIGATOR: _____ DEPT: _____ PHONE: _____
CO-INVESTIGATOR: _____ DEPT: _____ PHONE: _____
CONTACT PERSON: _____ PHONE: _____ EMAIL: _____
TITLE (match title submitted to funding source): _____

POTENTIAL FUNDING SOURCE(S) _____
CONTRACT NEGOTIATOR: Dartmouth OSP Hitchcock Foundation Other: _____
LIST ALL SITES WHERE STUDY WILL TAKE PLACE: _____

NEW PROJECT PROPOSED PROJECT DATES: _____

RENEWAL (check as applicable): DATE STUDY FIRST APPROVED _____

- There are **no revisions** in the enclosed materials that have not yet been approved by CPHS
- There are **not yet approved sponsor protocol revisions** (describe in Study Renewal/Termination Form #2)
- There are **not yet approved consent form revisions** (describe in Study Renewal/Termination Form #2)
- There are other revisions not yet approved by CPHS (describe in Study Renewal/Termination Form #2)

STUDY MAY INVOLVE:

- Minors
- Fetuses
- Abortuses
- Pregnant Women
- Incompetent to Consent
- Prisoners

SUBJECTS WILL BE:

- A. Paid Unpaid
- B. Outpatients Inpatients
 Nonpatients (e.g. healthy volunteers, students)
- C. Estimated Age Range of subjects:
_____ TO _____
- D. Estimated Number of Subjects for **entire study duration**:
at Dartmouth (or local site): Female: _____ Male: _____
at ALL sites(if multi-center): Female: _____ Male: _____

- Conflict of Interest** Disclosures on file in Sponsored Projects Office (see item #29 in CPHS Study Plan)
- All investigators and key personnel have completed **IRB education**.

KEY WORDS

Disease: _____
Condition: _____
Drug Name: _____
Drug Class: _____
Radioisotopes: _____
Biologic: _____
Other: _____

DEPARTMENTS INVOLVED

PERSONNEL NOTIFIED (and date):

- Pharmacy
Will there be increased patient pharmacy charges relative to standard care? YES NO
How will subjects be notified of increased pharmacy costs? _____
- Nursing _____
- Radiation Safety Committee _____
- Environmental Health & Safety _____
- Institutional Biosafety Committee (IBC) _____
- IDE#:** _____
- IND#:** _____

Investigator Signature _____

Printed Name _____

Date _____

Departmental Scientific Review of Research Protocols Involving Human Subjects

v. 01/04

Principal Investigator _____

Project Title _____

CCRC: All clinical studies involving treatment of cancer patients must be reviewed by the Clinical Cancer Review Committee prior to submission to CPHS. Please contact Aline Coffey at the NCCC.

VA R&D: All clinical studies involving treatment of patients at the VA must be reviewed by the VA R&D Committee prior to submission to CPHS. Please contact Laura Miraldi at the VA.

All protocols must undergo scientific review by a departmental research group or other designated authority prior to submission to the Committee for the Protection of Human Subjects [CPHS]. The review must involve individuals qualified **to evaluate the scientific merit** of the study being proposed. If the departmental research review group does not include individuals who are capable of evaluating the scientific merit of a particular proposal, it is the responsibility of the department chair or designated representative to have the protocol reviewed by an appropriate authority not involved in the study in question. Please respond to items below and provide a statement related to the scientific merit of the study.

- a. The scientific questions addressed in this protocol have adequate merit to justify experimentation involving human subjects..... **YES** **NO**
- b. The potential risks of this study have been accurately and fully described..... **YES** **NO**
- c. The study design is adequate to answer the questions being asked..... **YES** **NO**
- d. Prior animal or *in vitro* studies are adequate to support human trials..... **YES** **NO**
- e. Is there a method to investigate this scientific problem without using human subjects? **YES** **NO**
(If **YES**, then please explain why human subjects are to be employed.)
- f. The principal investigator and co- investigator(s) have adequate experience to conduct the study..... **YES** **NO**
- e. Does the research project include an adequate data and **YES** **NO**
safety monitoring process?

Provide a statement related to the scientific merit of this project: Date of Review:

Check and complete as appropriate:

____ Departmental Review Committee: (printed name of the chairperson): _____

____ Individual Reviewer (printed name): _____

Signature (Departmental Review Committee Chair or Individual Reviewer) Date

Dartmouth Committee for the Protection of Human Subjects
CPHS Study Plan
Content Requirements for Full Committee Review

v.7.19.05

Instructions:

The following information in the format provided below is required for submission of a study for CPHS review. Read through each section and **respond to each item (even if to indicate NA - not applicable)**. Please also review the CHECKLIST for Full Committee Submission. We have provided guidance information under each category.

Attachments:

Complete and submit Attachment(s) ***when*** applicable to the research study:

Attachment A: Medical Device

Attachment B: Placebo

Attachment C: Genetic Research

Attachment D: Employees and Students

Attachment E: Illiterate Participants

Attachment F: Research Involving Children

Attachment G: Research Involving Incompetent Participants

Attachment H: Request for Waiver of Participant Consent

Attachment I: Request for Waiver of Participant Signed Consent Form

Attachment J: Investigational New Drug (IND)

Attachment K: Conflict of Interest Form

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Principal Investigator :

Department:

Study Title:

1. Purpose: A brief statement of the purpose of the research project. This section should include the hypothesis being tested.

2. Introduction: a) Explain the background of this project so that we will understand why it is important to perform this research project. b) Summarize previously published data and pilot studies. Be sure to include a discussion of any data that does not support the study hypothesis. If a study similar to the one being proposed has already been completed, explain why the proposed study is necessary. c) For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternative modes of therapy. d) If not obvious, explain why human subjects are necessary. *Include references for all published data cited.*

3. Design, procedures, materials and methods: Use a level of detail similar to what would be used when submitting an article for publication in a Peer reviewed journal. Another investigator should be able to replicate this study from the information provided in this section. Explain the study procedures and data collection and analysis process. Please define terms and explain concepts which might be confusing to reviewers who are not expert in the study subject.

4. List **all** sites where research will take place and the Dartmouth CPHS is the IRB of Record: (e.g. DHMC Alliance Hospitals, DHMC Clinics, WRJ VA, etc):

5. List **all** sites where research will take place and the Dartmouth CPHS is NOT the IRB of Record: or circle N/A

Note: each site taking part in the research must have appropriate IRB oversight. A Site Agreement or FWA (Federal Wide Assurance) may be required. Contact the CPHS office for further information.

6. Financial Considerations: Full disclosure of financial impact on the participant is critical to an informed consent. Insurance CANNOT be billed for research related costs falling outside the standard of care and/or already covered by sponsor dollars. Either the Department or participant is responsible for research related costs not paid for by the sponsor and not billable to insurance. Participants must know which tests, visits, or procedures will be billed to either them or their insurance and which ones will be covered by the study sponsor/department.

6a. List all additional tests/visits/procedures performed for research purposes only. (i.e., those falling outside the standard of care, would not be performed if the patient were not a participant and therefore would not be billable to third party payers such as Medicare.)

Note: 6a information must also be in the "How is this different." consent section.

6b. List items that may be standard care but are paid for by the sponsor:

7. Will the sponsor be responsible for the above costs? **Yes** **No**

If No, describe who will be responsible (i.e., department or participant).

PLEASE ENCLOSE THE DHMC BILLING GRID/PLAN. Also enclose the schedule of events or table listing all procedures from the sponsor protocol.

8. Responsibility for costs of injury or illness related to research:

Will the sponsor be responsible for costs of injury or illness related to the research? **YES** **NO** **OTHER:**

If applicable describe whether or not the sponsor will be responsible for device removal if required:

If the sponsor will not be responsible for costs of injury or illness related to research please complete :

a) The reason for no liability:

b) Summary of potential risks as related to potential costs which could be incurred as a result of research related injury or illness:

c) Describe reason(s) for request of DHMC to provide coverage for research related injury or illness (which is not standard DHMC policy):

9. Timetables:

- (a) Indicate length of participant involvement in the study: _____
- (b) Estimate how long it will take to enroll enough patients to complete this study: _____

10. Medical Device: Respond to items below or circle N/A

Is this device approved by the FDA for this indication ? _____

If no or not fully approved by the FDA for this use, i.e., if this study is being done under an Investigational Device Exemption from the FDA please provide:

IDE# (#) : _____ *and provide the*

FDA Device HCFA Reimbursement Category: A_____ B2_____ B3_____

OR

If the device(s) used in this study are not FDA approved for the indication in this study but an IDE# has not been obtained please **complete Medical Device Attachment A.**

Is the device provided free of charge by the sponsor? Yes_____ No_____

11. Investigational Drug: Respond to items below or circle N/A

Are these drug(s) approved by the FDA for the indication in this study? _____

If no, provide IND # (Investigational New Drug): _____

OR

If the drug(s) used in this study are not FDA approved for the indication in this study but an IND # has not been obtained please **complete Investigational New Drug Attachment J.**

12. Placebo/Standard Care: If any part of the study involves placebo or procedures which may be considered less than the standard of care at DHMC:

Respond to **Placebo Attachment B** or circle N/A

13. Genetics: Respond to **Genetics Attachment C** or circle N/A

14. Participant Population: Certain populations are vulnerable and require special protections when asked to participate in a research study. If any of the following populations will be eligible to participate:

Prisoners, Fetuses, Human embryos, Elderly persons, Mentally disabled persons (also see #17 below), Economically disadvantaged persons, Educationally disadvantaged persons.

Refer to: **Students, Employees Attachment D**
Illiterate Subjects Attachment E

List vulnerable groups:

Describe special protections: _____ or circle N/A

15. Children: Are children eligible for enrollment into this study? _____

*If yes, respond to **Children Attachment F***

If no, present an acceptable justification for the exclusion:

Note: Effective October 1, 1998, NIH guidelines require that research involving human participation include children unless there is appropriate justification for their exclusion. All proposals for human subjects research must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. The investigator should address the rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

16. Pregnancy:

Are pregnant women eligible for enrollment into this study? _____

If yes, justify and include potential harm to unborn fetus:

Note: Pregnant women may not be involved as participants in a Biomedical research study unless 1) the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs or 2) the risk to the fetus is minimal.

If no, explain and include process for determination of pregnancy status.

If a pregnancy test is required, note who will pay:

17. Women of child bearing capability

Are women of child bearing capability eligible for enrollment into this study? _____

If yes, describe potential harm to unborn fetus and process for determination of pregnancy. If a pregnancy test is required, note who will pay. If there is potential harm to an unborn fetus the investigator should review with each man/woman his/her plans to avoid pregnancy. If the investigator regards these contraceptive plans as inadequate, the man/woman should be advised on how to make them adequate or should be excluded from the study.

If no, explain and include process for determination of pregnancy. If a pregnancy test is required, note who will pay:

18. Competency:

Will participants potentially incompetent to provide informed consent be eligible to enroll in this study? _____

*If yes, respond to **Incompetent Participants Attachment G***

19. Gender and Racial/Ethnic distribution: NIH guidelines require that research involving human participation include minorities and both genders.

Note: If one gender and/or minorities are excluded or are inadequately represented in this research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided.

Will eligibility into the study be based on gender and/or racial /ethnic group? _____

If yes, explain:

20. Inclusion/Exclusion Criteria: Please provide detailed description of inclusion/exclusion criteria:

21. Recruitment: Researchers may not share patient protected health information outside of Dartmouth Hitchcock Medical Center without a formal review of this process (contact the CPHS Office for further information). All information collected for potential recruitment purposes must remain within DHMC (and/or formally affiliated sites) unless a specific request is review and approved by the CPHS Office. *Please note, in general, patients may not be contacted for recruitment into a research study by an individual unknown to the patient.*

- Complete as applicable:
[] A. Participants eligible for recruitment are patients of the department conducting this study. *Describe the recruitment process: (e.g. will pt. records be reviewed to determine eligibility? CPHS approval of this protocol indicates approval to review patient records)*

[] B. Participants eligible for recruitment are not necessarily patients of the department conducting this study. *Describe the recruitment process: (e.g. will pt. records be reviewed to determine eligibility? CPHS approval of this protocol indicates approval to review records). Specifically include how names will be obtained and how potential participants will be contacted.*

- Include all advertisements

Note: Advertising should not use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational. A phrase such as “receive new treatments” implies that all research participants will be receiving newly marketed products of proven worth. Advertisements should not promise “free medical treatment,” when the intent is only to say participants will not be charged for taking part in the investigation. The CPHS will determine if the promise of treatment without charge is coercive to financially constrained participants. Advertisement may state that participants will be paid, but should not emphasize the payment or the amount to be paid. The advertisement should include: the name and address of clinical investigator and/or research facility; the condition under study and/or the purpose of the research; in summary form, the criteria that will be used to determine eligibility for the study; a brief list of participation benefits, if any (e.g., a no cost health examination); the time or other commitment required of the participants; and the location of the research and the person or office to contact for further information.

- Describe any process involving "finder fees" or incentives (bonus payment, gift certificates etc.) to study personnel for enrollment of participants.

Note: As a rule finder fees or incentives are not allowed under any circumstance. Please describe the process if approval is requested. If incentives become available anytime during the course of the study please notify the CPHS.

22. Participant Remuneration:

Will participants be paid for their time, reimbursed for travel or meal expenses or receive any sort of "gift" for participating in this study? _____

If YES, please describe in detail:

Note: Participant remuneration is not considered a benefit of being in a research study. CPHS will consider the amount of payment in relation to the amount of time needed and any inconvenience to participants. Payment, reimbursement, or gifts may not be such that they would be coercive of the participant population.

If study is to be done at the VA, specific items need to be addressed if a participant is being paid "in excess of reimbursement for travel." Please contact the CPHS office if you need more information.

23. Consent Process: The Principal Investigator is responsible for ensuring all participants enrolling in this study have provided informed consent (unless formally waived or altered by the CPHS). The PI may authorize other appropriately trained individuals to obtain informed consent. Please also ensure the consent form is filed in the circulating medical record of the research participant.

Describe the consent process. Specifically include when consent will be obtained and who has been authorized by the PI to obtain consent:

24. Risks: Describe any potential risks (physical, psychological, social, legal, financial, or other) and assess their likelihood and seriousness. Describe the procedure for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Please list risks from most severe/likely to least severe/unlikely.

25. Risk/Benefit analysis: Describe why the risks to subjects are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing the study.

26. Privacy and Confidentiality: Describe the plan to ensure the privacy of subjects and confidentiality of the data is maintained:

Note: The consent form template includes HIPAA compliant language. Please ensure the research participant is made aware of all uses and disclosures of their protected health information (PHI). Under certain circumstances, an invasion of privacy or breach of confidentiality may present a risk of serious harm to subjects (e.g., as when the research obtains information about subjects that would, if disclosed by the researcher, jeopardize jobs or lead to prosecution for criminal behavior). Under other circumstances, an invasion of privacy or breach of confidentiality can be a moral wrong, or, at least in theory, provide cause for legal action against a research or institution. It is the responsibility of the researcher to be sensitive to the issues involved with privacy and confidentiality and to consider them appropriately in designing the study.

Any person engaged in research collecting sensitive information from human research subjects may apply for a Certificate of Confidentiality. NIH provides detailed instructions for investigators wishing to make an application. Detailed application instructions can be found at <http://grants.nih.gov/grants/policy/coc/index.htm>. You may also contact the CPHS office.

27. Data and Safety Monitoring: Describe plans for data and safety monitoring to ensure the safety of subjects. As described in federal regulations "... a variety of types of monitoring may be anticipated depending on the nature, size, and complexity of the trial. In many cases, the principal investigator would be expected to perform the monitoring function." This will include monitoring to determine:

The progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

Note: this section does not request information related to sponsor study monitor visits. This section requires a description of an adequate data and safety monitoring plan to ensure the safety of subjects:

28. Statistical Methods and Review Statement:

- a. Specify the primary endpoint, as well as other endpoint(s).
- b. State the statistical analysis plan, including all hypothesis tests (e.g., t-test, chi-square), and estimation methods related to the primary endpoint.
- c. Justify the sample size, using the concepts of power, type I error and effect size if applicable.

29. Conflict of Interest Review for Researchers:

To ensure compliance with the principle that the welfare of human subjects and the integrity of research should not be compromised by financial or other personal interests, Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital and Dartmouth College have adopted a Conflict of Interest Policy for Human Subject Research. Copies of the policy may be obtained from the Committee for the Protection of Human Subjects. The policy is also available on the Dartmouth College web site at <http://www.dartmouth.edu/~osp/policies.html>.

Under the policy, a potential conflict of interest occurs when an individual's personal or private interests might lead an independent observer reasonably to question whether the individual's professional actions or decisions are influenced by considerations of personal interest, financial or otherwise.

To enable the institutions to determine whether the proposed research would raise a conflict of interest, please respond to the questions below. For purpose of these questions, "*Principal Investigator and Other Key Personnel*" shall mean a Principal Investigator and any other person (including students) who is responsible for the design, conduct, or reporting of research involving human subjects.

Does the Principal Investigator or Other Key Personnel, or any of their spouses, domestic partners, or dependent children, hold any financial interest that would reasonably appear to affect or be affected by the proposed research, including but not limited to the following:

- a. compensation for services (e.g., consulting fees or honoraria), or in-kind payments, other than from the researcher's primary employer, in the prior calendar year or projected over the next twelve months;
- b. royalty income or the right to receive future royalties under a patent license or copyright, where the proposed research is directly related to the licensed technology or work;
- c. equity interests (e.g. stocks, stock options or other ownership interests, including equity holdings where the value cannot readily be determined by reference to public prices);
- d. intellectual property rights (e.g., patents, copyrights and royalties from such rights);
- e. gifts or funds available to the researcher from this sponsor beyond the current research project;
- f. funding expected to significantly exceed the projected costs of conducting the current research project; or
- g. any other financial or personal interest which presents an actual or perceived conflict of interest.

Note: The above list of financial interests does not include: salary and benefits from Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, or Dartmouth College; income from seminars, lectures, teaching engagements or publishing sponsored by Federal, state, or local entities or from non-profit academic institutions, where the origin of the funds is not from corporate sources; income from service on advisory committees or review panels for governmental or non-profit entities; investments in publicly-traded mutual funds; or gifts and promotional items of nominal value, and meals and lodging for participation in professional meetings.

No: The Principal Investigator and Other Key Personnel **do not** have a financial interest described in items a. - g. listed above.

Yes: The Principal Investigator and/or Other Key Personnel **do** have a financial interest described in items a. - g. listed above. If yes, complete the following:

Name(s) of applicable individual(s): _____

The applicable individual(s) listed above must complete a Conflict of Interest Disclosure Form for Human Subject Research, **specifically applicable to this research study** before final IRB approval can be granted.

The form is available herein as Attachment K.

Please sign and return the completed form in an envelope marked "Confidential," to Nancy Wray, Director of the Office of Sponsored Projects, Hinman Box 6210.

Please also email this CPHS study plan with completed Attachment K to Nancy Wray, Nancy.J.Wray@Dartmouth.EDU

Please use this subject line in your email: "COI-HS"

Attachment A **Medical Device**

1. The CPHS protocol requires a description of the "FDA status" of the medical device. This information should include **non significant risk (NSR)** or a **significant risk (SR)** designation by the sponsor, and the filing date if a 510K or IDE has been applied for from the FDA.
2. The CPHS will decide if the sponsor designation is appropriate. The CPHS may ask the manufacturer/sponsor for further information regarding the classification. The sponsor will provide an explanation of why the study is NSR, and other supporting information, e.g. reports of prior investigations. The sponsor will also inform the CPHS if the FDA or any other IRB has determined the study to be SR or NSR.
3. A **significant risk** medical device is a device that "presents a potential for serious risk to the health, safety, or welfare of the subject". Risk level will be based on the seriousness of the harm that could result from the use of the device alone, or the conduct of the investigational protocol as a whole, relative to "everyday activities". Risk category will NOT be based on a comparison with alternate devices or therapies, including "standard therapy".
4. Protocols that involve a **significant risk** medical device are not permitted, by federal regulations, to enroll participants until the study been approved by both the CPHS and FDA. The CPHS will not approve a "significant risk" medical device study without written documentation that the study has been approved by the FDA. FDA approval means that the device has been granted "substantial equivalence" under the 501(k) section of the Food, Drug, and Cosmetic act or been given an Investigational Device Exemption (IDE) number. After a protocol has been approved by the FDA, the CPHS will review all aspects of the protocol including the informed consent and it will determine the risk/benefit ratio for human subjects, as per the standard review process. A protocol that has been approved by the FDA may be approved, conditionally approved, or not approved by the CPHS.
5. Protocols that involve **non significant risk** medical devices do not require FDA approval (or FDA review) to enroll patients. The CPHS will review all aspects of the protocol to determine the risk/benefit ratio for human subjects and render a decision to approve, conditionally approve, or not approve the protocol.
6. The CPHS may agree or disagree with the sponsor's initial NSR assessment. If the CPHS agrees, the investigation may begin without FDA review. If the CPHS disagrees, the study can only be conducted as a SR investigation, and the sponsor must notify the FDA that a SR determination has been made (whether or not the sponsor ultimately conducts the study at this institution).

References:

1. OPRR/ NIH Protecting Human Research Subjects: Institutional Review Board Guidebook 1993 , Chapter 5 pages 18-22
2. Article: Medical Devices Significant vs Nonsignificant Risk
R.J. Sherertz,MD S.A. Streed, MS JAMA, September 28, 1994 - Vol 272, No.12
3. FDA list of significant and non significant devices
4. Oral communication (11/16/94) with FDA official Gary Chadwick (301-594-1026)
5. FDA IRB Information Sheets p60-61

Attachment B
Placebo

Discuss the ethical implications of using placebo instead of "standard of care" therapy in this situation. Specifically, explain what "standard of care" therapy is for this patient population and how the use of placebo therapy effects risks for participants. Also specifically address:

- a) the safety and efficacy of other available therapies (if any)
- b) the maximum total length of time a participant may receive placebo on study
- c) the greatest potential harm that may come to a participant as a result of not receiving effective therapy (immediate or delayed onset)
- d) protocols in place to safeguard participants receiving placebo

Attachment C
Genetic Research

For research studies involving genetic testing the CPHS has developed two basic categories to assist in the determination of further review. The researcher should determine if the research falls into category a. or b. as described below.

If the research falls into category a. indicate by circling below and add comments as appropriate to this project.

If the research falls into category b. please respond to questions that follow.

a. The study is looking for an association between a genetic marker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve participant counseling.

COMMENT:

b. The study is based on the premise that a link between a genetic marker and a specific disease or condition is such that the marker is clinically useful in predicting the development of that specific disease or condition. Respond to the items below:

Human Genetic Research Questions for CPHS Review

For studies involving genetic testing, the PI must respond to the following items (if an item is not applicable to the study, please state (NA)).

1. Are clear guidelines established for disclosure of information, including interim or inconclusive research results to the participants?
2. Will participants be told about what information (and its meaning) they may receive at what point in the research?
3. Will family members be protected against disclosure of medical or other personal information about themselves to other family members?
4. Will they be given the option not to receive information about themselves?
5. Will limits on such protections be clearly communicated to participants, including obtaining advance consent to such disclosures (e.g. when family members will be warned about health risks)?
6. Will the possible psychological and social risks of genetic research be adequately considered in the consent process?
7. Will appropriate counseling be provided, both as part of the consent process and when communicating test or other research results to participants?
8. Will participants be informed about the possibility of important incidental findings such as paternity, disease, or conditions other than the one(s) under the study ?
9. Will the data be protected from disclosure to third parties, such as employers and insurance companies?
10. Will the participant be told about the potential consequences of a third party, such as employer or insurance company, becoming aware of the study findings?
11. Will the data be stored in a secure manner?
12. Will the data be coded so as to protect the identity of subjects?

13. Is a request for a certificate of confidentiality appropriate?
14. Does the investigator plan to disclose research findings to subjects' physicians for clinical use?
15. Are such plans appropriate?
16. Will the possibility of such disclosures be discussed with and consented to by prospective participants?
17. Will vulnerable populations (e.g. children, persons with impaired mental capacities) be adequately protected?
18. Under what circumstances can a research participant serve to grant permission to involve a minor or an incapacitated adult in a study?
19. Have adequate provisions been made for protecting against misuse of tissue samples (e.g., confidentiality, obtaining consent for any use not within the original purpose of this study)?
20. What agreements with participants are necessary to use stored materials for new studies or for clinical diagnoses?
21. Have adequate provisions been made for the treatment of data and tissue samples in the event of subject withdrawal from the study?
22. Do the investigator's publication plans threaten the privacy or confidentiality of participants?
23. Has adequate consideration been given to ways in which participants privacy and confidentiality can be protected (e.g. providing for consent to publication of identifying information)?
24. If research may involve family members:
 - 24a. Has the appropriateness of various strategies for recruiting participants been considered?
 - 24b. Will information be obtained via clinical medical records of family members?
 - 24c. If so, should consent be obtained prior to use of the data, or is the permission of participant sufficient?

Information for consent document:

- Participants should be informed of the following:

- the kind of information they will be provided (e.g. that they will receive only information the investigator feels is significant and reliable, or that no genetic information will be provided) and at what point in the study they will receive that information
- that they may find out things about themselves or their family that they did not really want to know, or that they may be uncomfortable knowing;
- that information about themselves may be learned by others in their family;
- whether information they learn or information generated about them during the study may compromise their insurability;
- that actions they may take as a result of their participation may expose them to risks (e.g. submitting insurance claim forms for reimbursement for costs of genetic counseling or procedures whose costs are not covered by the protocol)
- about what assurance can be given to protect confidentiality and what lack of assurance can be given;
- about the rights they retain and the rights they must give up regarding control over what can be done with tissue they donate (e.g. blood samples);
- what the consequences of withdrawal from the study will be; and
 - of any costs associated with participation (including , for example, the cost of genetic and/or psychological counseling, if those costs will not be covered by the investigator or the institution).

Attachment D
Employees and Students

One of the primary responsibilities of the CPHS is to ensure that a participant's decision to participate in research will be voluntary and that consent will be sought "only under circumstances that provide the prospective subject... sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence." Students and employees may be vulnerable to "subtle inducements to participate".

The researcher who plans to recruit either population must define clearly the participants to be enrolled and the rationale for their participation. In addition, the mode and timing of recruitment must be explained.

Another special consideration for employee and student populations is the issue of confidentiality of research data. Depending on the nature of the research and the data collected, a break of confidentiality could affect a person's employment, career path, educational plans, or social relationship with the hospital/academic community. Therefore, the researcher should document carefully the methods to protect the subjects' identity and research data (e.g., coding, storage of research files, limits of accessibility to research data, etc.).

Attachment E
Illiterate Subjects

Subjects who are unable to read should not be excluded from research on the grounds of illiteracy. If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written consent form and any other written information to be provided to subjects is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial, and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

Attachment F
Children

If a study involves minors (in NH < 18yrs) please complete sections 1, 2 and 3 below:

Section 1. Designation Risk / Benefit: Check the risk designation as you deem appropriate:

1. Research not involving greater than minimal risk [45 CFR 46.404].

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parent or guardians, as set forth in 46.408.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. Research involving greater than minimal risk but presenting the prospect of direct benefit.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well being, only if the IRB finds that:

a) the risk is justified by the anticipated benefit to the subjects;

b) the relation of the anticipated benefits to the risk is at least as favorable to the subjects as that presented by available alternative approaches [45CFR46.405]

3. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the subjects' disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds;

a) the risk represents a minor increase over minimal risk;

b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding of the participants condition [45CFR46.406].

4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. DHHS will conduct or fund research that the IRB does not believe meets the requirements of 404, 405, 406

Only if : a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children; and The panel of experts must also find that the research will be conducted in accordance with sound ethical principles [45 CFR 46.407].

Section 2. Parental consent - Please circle as you deem appropriate for this study:

(The IRB will confirm or discuss)

- a. Request one active parental consent for research designated (1) 404 or (2) 405 above.
- b. Request one active parental consent required for research designated (3) 406 or (4) 407 above, approvable if one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
- c. Parental consent waived (see Attachment H / waiver of consent)
- d. Two parental active consent required. (e.g. if the research is designated (3) 406 or (4) 407 above both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child

Section 3. Assent of Minor - In determining whether children are capable of assenting take into account the ages, maturity, and psychological state of the children involved. If it is determined that the research holds out a prospect of direct benefit the assent of the children is not a necessary requirement.

It is important the PI includes the minor in all aspects of the research as appropriate for his/her maturity level. The Assent signature line may be included on all consent forms where minors may be enrolled. However the requirement for obtaining a signature is determined on the nature of the study. Please indicate below your view the requirement of assent for this study:

- a. Assent signature required: This study does not involve interventions likely to be of benefit to minors. However, they should be able to comprehend and appreciate what it means to be a volunteer for the benefit of others
- b. Assent signature **not** required: The inclusion of the minor in all aspects of the research will be conducted as appropriate. However the possibility of direct benefit that is important to the health or well-being of the minor is available only in the context of this research and/or the minor is unlikely to understand the situation well enough to give meaningful assent.

Attachment G
Incompetent Subject Form

Introductory Information:

When a subject is not competent to give informed consent, Federal Regulations state that the investigator must obtain written permission from a **legally authorized representative** prior to enrolling the subject in a research study. Federal Regulations define **legally authorized representative** as an "individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research" (45CFR46.102(c)). Neither Federal Regulations nor New Hampshire State Law provide specific information about who may or may not qualify as a **legally authorized representative** in a research setting. For the purposes of this policy statement, the options of defining a legally authorized representative include:

- a) Durable power of attorney for health care (DPAHC),
- b) Court appointed legal guardian
- c) Next-of-kin.

A strict interpretation of NH state law does not provide for the use of next-of-kin as a surrogate decision maker for investigational activity. The argument for allowing next-of-kin to consent to participation in research activity for an incompetent individual is that, without such an option, it is often impractical or impossible to conduct important medical research on conditions where results with the best current therapy are suboptimal. When investigational therapy represents the best treatment option or when risks to the subject are small in relation to the potential benefit of research to society, a policy which creates a major obstacle to the conduct of important research activity is ethically unsound.

With the above issues in mind, the Dartmouth CPHS has established the following policy for research studies that may involve adult subjects who are not competent to give informed consent to participation in a research study. **Please carefully review all items.**

Submission requirements:

When initially submitting a protocol for review by the CPHS, the investigator will inform the CPHS in the appropriate section of the CPHS Study Plan (item #18) if the study may involve subjects who are NOT competent to give informed consent to participate in the study being proposed.

In addition, when a study may involve subjects who are not competent to give informed consent, the investigator will use the form provided below to inform the CPHS of the requested options to provide permission for an incompetent individual to participate in research study and respond to specific CPHS questions.

For all requests:

Even with the permission of a DPAHC, or court appointed legal guardian, the CPHS will not permit a subject who is not competent to give informed consent to participate in a research study that offers little chance of DIRECT BENEFIT to the research subject over what they could receive outside the research setting and involves a meaningful increase in the risk of harm or discomfort, regardless of the potential gain to future subjects or society in general.

Please complete a) and b):

- a) Does participating in this study offer the subject a chance of direct benefit over what they could receive outside the research setting?
- b) Is there an increase in the risk of harm or discomfort for the subject over what they would experience outside the research setting?

When there is a meaningful chance of DIRECT BENEFIT to the research subject over what they could receive outside the research setting, the CPHS will make a judgment decision about who may consent to participation in the study. The options include: DPAHC, court appointed legal guardian, and a properly motivated next-of-kin.

Please underline the option(s) requested to allow for consent if a subject is incompetent to provide consent:

Durable power of attorney for health care (DPAHC)	YES	NO
Court appointed legal guardian	YES	NO
Next-of-kin.	YES	NO

If a study requests the use of Next-of-Kin as the legally authorized representative, Please complete a) through e) below:

- a) Could the subject receive the same management that they will receive in the research study outside the setting of a research protocol?
- b) Will participation in the study increase the risk of harm or discomfort compared to what is expected with the management that the subject will receive if they do not participate in the research study?
- c) Will participating in the study increase the chance that the subject will experience a favorable outcome compared to what is expected with the management that the subject will receive if they do not participate in the research study?
- d) What is the magnitude of the benefit that future patients, or society in general, may experience as a result of the subject participating in this study?
- e) The process of appointing a legal guardian may take several months. Would this type of delay compromise patient care?

The CPHS will use the responses to the items a) – e) when discussing the option of allowing Next-of-Kin to enroll subjects into a research study.

Signature section of the consent form:

Below is the signature line to use when incompetent participants may be enrolled into a research study. As described above, use of the next-of-kin option requires special CPHS approval:

Participant Signature and Date

Printed Name

If participant is not competent to provide informed consent, sign below as appropriate:

Attachment H
Request for Waiver of Participant Consent

If you are requesting the waiver for participant consent, the following items must be addressed and deemed appropriate by the CPHS. Please respond to each item as applicable:

- (1) the research involves no more than minimal risk to the subjects:
- (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects:
- (3) the research could not practicably be carried out without the waiver or alteration:
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation:

If you are using protected health care information please also respond to the following:

- (5) Research could not practicably be conducted without access to and use of PHI:
- (6) Adequate plan to protect identifiers from improper use and disclosure:
- (7) Adequate plan to destroy identifiers at the earliest opportunity, unless there is a health or research justification or legal requirement to retain them:
- (8) Adequate written assurances that PHI will not be reused or disclosed for other purposes.

IRB review: If the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waives the requirements to obtain informed consent, the IRB finds and documents that:

- (1) the research involves no more than minimal risk to the subjects;
 - (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - (3) the research could not practicably be carried out without the waiver or alteration;
- and
- (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Attachment I
Request for Waiver of Participant Signed Consent Form

If you are requesting the waiver of the requirement for a signed consent form, the following items must be addressed and deemed appropriate by the CPHS.

(I) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Attachment J
Investigational NewDrug (IND)

The FDA requirements to qualify for an exemption status from filing an IND may be found in 21 CFR 312.2(b). These are as follows:

(b) Exemptions.

The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part [filing for an IND] if **ALL** the following apply:

Please indicate if whether or not the following items apply to the proposed research:

(i) The investigation is not intended to be reported to FDA as a well controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;

(ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;

(iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(iv) The investigation is conducted in compliance with the requirements for institutional review set forth in Part 56 and with the requirements for informed consent set forth in Part 50; and

(v) The investigation is conducted in compliance with the requirements of 312.7. 21 CFR 312.7 outlines promotion and charging requirements for investigational new drugs. Investigators and sponsors may not promote investigational new drugs as being safe and effective and they may not charge for, distribute or test market these drugs without FDA approval.

Attachment K
DARTMOUTH-HITCHCOCK CLINIC,
MARY HITCHCOCK MEMORIAL HOSPITAL
AND
DARTMOUTH COLLEGE

**CONFLICT OF INTEREST DISCLOSURE FORM
FOR RESEARCH INVOLVING HUMAN SUBJECTS**

This form is issued in accordance with the Conflict of Interest Policy for Human Subject Research adopted by Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, and Dartmouth College. Copies of the policy may be obtained from the Committee for the Protection of Human Subjects (“CPHS”) or from the Dartmouth College web site at <http://www.dartmouth.edu/~osp/policies.html>.

This form should be completed by individuals with respect to whom a financial interest that could reasonably appear to affect or be affected by proposed human subject research has been listed in Section 29 of a CPHS Study Plan.

With regard to the research study referenced below, please describe financial interests held by the Principal Investigator, Other Key Personnel, or any of their spouses, domestic partners, or dependent children. You do not need to include: salary and benefits from Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, or Dartmouth College; income from seminars, lectures, teaching engagements or publishing sponsored by Federal, state, or local entities or from non-profit academic institutions, where the origin of the funds is not from corporate sources; income from service on advisory committees or review panels for governmental or non-profit entities; investments in publicly-traded mutual funds; or gifts and promotional items of nominal value, and meals and lodging for participation in professional meetings.

Title of Study: _____

PI of Study: _____

Name of Person Submitting Form (if different): _____

Sponsor: _____

CPHS #: _____

- A. Compensation for services (e.g., consulting fees or honoraria), or in-kind payments, other than from the Reporting Person's primary employer, in the prior calendar year or projected over the next twelve months
___ YES ___ NO
- B. Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work
___ YES ___ NO

- C. Equity interests (e.g. stocks, stock options or other ownership interests, including equity holdings where the value cannot readily be determined by reference to public prices)
 YES NO
- D. Intellectual property rights (e.g., patents, copyrights and royalties from such rights)
 YES NO
- E. Gifts or funds available to the researcher from this sponsor beyond the current research project
 YES NO
- F. Funding expected to significantly exceed the projected costs of conducting the current research project
 YES NO
- G. Any other financial or personal interest which presents an actual or perceived conflict of interest.
 YES NO

If the response to any item is YES, please provide below a full description of the financial interest (including amount of compensation and other information related to compensation) and how the financial interest might affect or be affected by the proposed research. (Attach extra pages if necessary.)

The above is an accurate and current statement.

Signature _____ Date _____ 200

Printed Name _____ Title _____

Please sign and return the completed form in an envelope marked "Confidential," to Nancy Wray, Director of the

Office of Sponsored Projects, Hinman Box 6210. Please also email the CPHS

_____	There is no actual or potential conflict of interest. The Director of the OSP shall so inform the CPHS and the reporting person.
_____	There is an actual or potential conflict that could affect the objectivity of research, the reporting of results, or human subjects. The matter shall be referred to the Conflict Review Committee.

study plan with completed Attachment K to Nancy Wray, Nancy.J.Wray@Dartmouth.EDU

Please use this subject line in your email: "COI-HS"

Review by Director of OSP, Vice Provost for Research, and Director of CPHS

Comments:

Signature _____ Date _____ 200

Director of Office of Sponsored Projects,
Vice Provost for Research, or
Director of CPHS

Consent Form Template

General Instructions: *The consent form is one part of an ongoing dialogue between researchers and participants. Please describe the consent process in item #23 of the CPHS Study Plan.*

- *The consent form should be written at an eighth grade level. Avoid dense paragraphs using lengthy sentences. Use 'bullets' and tables to clearly explain topics such as what the study involves and financial considerations.*
- *Suggested wording is contained in the consent template below. Please carefully review all the language to ensure correct information specific to your project is relayed to potential participants.*
- *The bold questions are to be kept as part of the consent form. The information after the question should be edited/deleted/revise to be specific to your project.*
- *The signed consent form must be filed in the general circulation medical record and a copy must be given to the participant. Research records (specifically the signed consent form must be maintained for six years after the completion of the study).*
- *Please number the pages of the consent form as in this template.*
- *Use 12 point Palatino font as is used in this template.*
- *The CPHS office will 'pre-review' a consent form at anytime via email. Please email to Rebecca Carson Rogers.*
- *This consent form template language focuses on clinical treatment related research. Please edit wording as appropriate for your study. Contact Rebecca Carson Rogers at the CPHS Office if you need help.*

*HIPAA: Health Insurance Portability and Accountability Act.
As of April 14, 2003 all consent forms must contain the following information. Please carefully review the wording in your consent form to ensure all elements are adequately described. We have provided some sample template wording however since each study is unique the researcher must complete the consent form such that the methods and processes contained in the protocol and/or contract are translated to the patient.*

1. Description of Health Information to be gathered.
2. Identification of Person authorized to disclose
[e.g. researcher, research team]
3. Identification of Recipient [e.g. sponsor, CRO]
4. Description of Purpose(s)
5. Expiration date - "end of research study," "none," or similar language is sufficient if the disclosure is for research, including for the creation and maintenance of a research database or research repository
6. Statement of Right to Revoke
7. (In)Ability to Condition Treatment on the Authorization statement
8. Statement Regarding Re-disclosure
9. Remuneration for Marketing Activity (if applicable)
10. Dated Patient Signature
11. if signed by Personal Representative, a description of that person's authority

CONSENT TO PARTICIPATE IN RESEARCH

*As applicable: Dartmouth-Hitchcock Medical Center or Dartmouth College
or VA (VA research requires VA template)*

Study title:

Introduction: You are being asked to participate in a research study. Your participation is voluntary.

Note: if the study includes minors - add the sentence: "You" in this study may refer to your child to be enrolled in the study. If the study involves minors only use "Your child" throughout the consent form.

You are being asked to participate in this study because ...(complete as appropriate, e.g. you have been diagnosed with...)

Your decision whether or not to participate will have no effect on the *quality of your medical care, academic standing, job status, etc. (whatever phrase is appropriate)*. Please ask questions if there is anything you do not understand.

What is the purpose of this study?

The purpose of the study is to learn about*explanation in lay language the purpose of the study.*

Suggested conclusion wording, if applicable:

In order to learn about xxxxx, half the participants in this study will receive xxxx and half the participants in this study will receive a placebo (no medication).

Are there any benefits from participating in this study?

First sentence as appropriate to the specific study: choose one of the following:

You will not benefit from being in this research study.

There is little chance you will benefit from being in this research study.

You might not benefit from being in this research study.

Second sentence, if applicable:

We hope to gather information that may help people in the future.

What does this study involve?

Include a sentence indicating length of time of study for participation:

Your participation in this study may last up to _____. You will be asked to return to the clinic _____ times.

Briefly explain in lay language the visits, procedures, therapies, tests, etc. involved in this study. When applicable, clearly describe:

- *whether or not the drugs or devices are being used in ways that are not FDA approved*
- *the use of placebo- if placebo is used, throughout the consent form use terms such as study pills/study tablets/study solution/study gel. Do NOT say study drug or study treatment, since not all participants will get the study drug or treatment.*
- *whether or not all participants will receive the same therapy,*
- *and the process of randomization.*

Please avoid describing study procedures in lengthy narrative form. If study procedures are very lengthy and complex, consider generating a separate page which can be attached to the consent (e.g., something like a lay version of the schedule of events from sponsor protocol) to describe study visits in detail for the patient. The body of the consent form should summarize the procedures in table format.

OR

If procedures are all to be listed in the consent form and there are multiple visits - use headers and bullets as follows:

Screening visit (Visit 1): approximately one hour

- review and sign consent form
- chest xray
- blood draw
- etc, etc

Treatment Visit (Visit 2): approximately three hours

- brief physical exam
- etc

If there are multiple study groups, clarify this by listing the groups as follows:

If you decide to enroll into this research study you will be assigned by chance to one of the following groups:

Group A - receives xxx

Group B - receives xxx

Neither you nor your doctor can control or will know into which group you will be assigned. Your doctor may obtain this information if needed.

How is this different from what will happen if you do not participate in this research?

For treatment consents:

1) The standard of care (common treatment plan) for your condition is... *(complete as appropriate).*

2) *Include a list of the additional tests/visits/procedures to be performed for research purposes only:*

If you enroll in this study the following additional tests or procedures will be performed: *(this information should correspond to item #6, # 7 in CPHS study design)*

3) *Explain whether or not the research therapy can be obtained off study:*

The therapy offered in this research project is available to you without enrolling in this study .

Because it is experimental, this therapy is only available to you in the context of a research study

4) *Briefly explain alternative therapies in lay language.*

What are the risks involved with being enrolled in this study?

sample wording:

We cannot be sure how your body may respond to the (medications or procedures) used in this study. The researchers will discuss possible difficulties and the chances that they will happen. Unknown problems may happen. Problems may range from a minor inconvenience or may be so severe as to result in death *(indicate highest severity level if death is not applicable).* You should report any problems to your doctor or to the director of this study: *(PI name and phone number).*

Focus on the risks specifically related to enrollment in the research study.

With drug studies involving a multi-drug regimen, list the problems associated with the entire regimen rather than providing separate information for each individual medication. Whenever possible, you should estimate the probability that a problem will occur. 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.

Be sure to include risks of being in a placebo or observation group.

Example of table format:

RISKS/SIDE EFFECTS OF XXX DRUG(e.g. tamoxifene) OR XXX PROCEDURE (e.g. blood draw) - use as many of these headers as needed for all of the drugs and/or procedures in the study

Common

- use bullets to list

Occasionally

- use bullets to list

Rare

- use bullets to list

if applicable:

RISKS OF PLACEBO

- use bullets to list

if applicable include the following section using suggested wording as appropriate:

Pregnancy:

The risks of name of drug to an unborn child are unknown. Pregnant women may not take part in this research study. Pregnancy tests will be conducted on all women of child bearing potential.....every....xxx The sponsor - or your insurance company (indicate which one) will pay for pregnancy tests.

All *women of child bearing potential* are required to use a medically approved method of birth control in order to take part in this research study. Please discuss options with the researcher.

If you or your partner become pregnant, you should notify (*name to notify*) immediately.

Other important items you should know:

Complete each section as appropriate:

• Your decision whether or not to participate in this study, or a decision to withdraw will not involve any penalty or loss of benefits to which you are entitled.

• *If applicable:* You will not receive any compensation if the results of this research are used towards the development of a commercially available product.

• **New Information:** To the best of our ability, any significant new findings during this research study will be made known to you. You can then decide if you want to continue in this study.

• **Withdrawal from the study:** *Describe appropriate potential withdrawal for this study. See below:*

You may choose to stop your participation in this study at any time. *{if withdrawal could affect medical treatment describe how, here}* . Your decision to stop your participation will have no effect on the *quality of medical care, academic standing, job status, etc. (whatever phrase is appropriate).*

• *if applicable add here information about possibility of termination by investigator without participant consent.*

• *if applicable add here information about the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation.*

• **Data Collection:**

The data collected in this study includes : describe here

Complete as applicable:

The data collected in this study will be used only for the purpose described in this form. Patient identifiable data will not be released beyond that required for the purposes of conducting this research study. By signing this form, you are allowing the research team access to your medical records. The research team includes the researchers listed in this consent form and other personnel involved in this study at DHMC and other entities as described in the "Confidentiality" section of this consent form.

If you choose to withdraw from the study, you may revoke your approval for the use of your future medical information. To do this, you may contact the researcher in writing. Data which has already been collected will be maintained with the research records.

Explain how long data will be maintained: Examples:

Data gathered from this study will be maintained for as long as the sponsor needs to obtain approval from the FDA.

or

Data gathered from this study will be maintained indefinitely or as required by federal or state regulations.

If there are limits to the patient access to research records describe here: Example:

During the course of this study participants may not have access to research records. If you chose, you may request this information after the research is completed.

• **Confidentiality:** Every effort will be taken to protect the names of the participants in this study. *(describe methods to be used: coding, certificate of confidentiality, etc.)*
However, there is no guarantee that the information cannot be obtained by legal process or court order.

Describe as applicable who may have access to patient identifiable health care information:

Research data may be shared, as required by law, with Dartmouth-Hitchcock Medical Center authorities and...

Examples: Federal agencies such as the Food and Drug Administration, add as appropriate: National Co-operative Study Group, Multi-center site, Insurance Company. The sponsor of the study, xxx, and any entities involved in the monitoring of this study (name of CRO if applicable) or Data and Safety Monitoring Committee if applicable will also have access to this research data. Outside organizations may not have a regulatory obligation to protect the data.

• **Funding:** *name of sponsor* provides funding to the Dartmouth-Hitchcock Medical Center for this research. *This section of the consent form will also be used to describe any other information deemed necessary to relay to potential participants related to financial disclosure as requested in item #29 of the CPHS Study Plan.*

• **Number of participants:** We expect (##) of participants to enroll in this study here and (##) nationwide. *(These numbers should correspond with those on the Human Subject Review Form and in the CPHS Study Plan.)*

Who should you call with questions about this study?

Questions about this study may be directed to your doctor or to the researcher in charge of this study: Dr. xxx at (603) 650-xxxx during normal business hours.

If Dr. xxx is not available, other *members of the section of xxxxx* will be available to answer your questions during normal business hours.

Please provide here a 24 hour contact number for treatment relates research projects.

If you have general questions about being a research participant, you may call the Office of the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-3053 during normal business hours.

What about the costs of this study?

Clearly explain who will be responsible for the costs of the care described in this consent, i.e., sponsor, department, patient, insurance. Use suggested wording as applicable:

This information should correspond with items # 6 and #7 in the CPHS Study Plan.

The (study medication) will be supplied free of charge.

All *additional* tests/visits/procedures as described in the “How is this different” section will be paid for by xxxxxx (e.g., sponsor, dept, or patient).

Insurance companies or other third party payers will not be billed for research procedures that are not standard of care.

The rest of the medical care that you will receive in this study is considered standard care for your situation and thus would be recommended regardless of your decision to participate in research. These costs will be billed to you or your insurance carrier.

Will you be paid to participate in this study?

yes or no. if yes describe payment schedule / travel reimbursement etc. This information should correspond to #22 in the CPHS Study Plan.

What happens if you get sick or hurt from participating in this study?

SPONSOR (SPONSOR NAME) POLICY: The sponsor of this research is XYZ Company. If you develop an illness or an injury happens because you are in this research study the XYZ Company will.....*enter the appropriate information regarding the level of liability the sponsor will assume in case of research related injury or illness.*

DHMC POLICY: It is the Dartmouth-Hitchcock Medical Center policy that if you are injured or become ill as a result of research procedures, medical treatment will be provided to you but DHMC will not pay for this treatment.

If you have any questions about the legal responsibility of DHMC, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at 603-650-7864 between the hours of 8:00 A.M. and 5:00 P.M. on Monday through Friday.

CONSENT - Signature lines need to directly follow the statements below.

I have read the above information about (*complete title of study*) and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this signed consent document for my own records.

SIGNATURE OPTIONS (choose one block) - Note: The Principal Investigator is responsible for ensuring all participants enrolling in this study have provided informed consent. The PI may authorize other appropriately trained individuals to obtain informed consent and sign as 'designee.' These individuals must be listed in the CPHS Study Plan (item #23.) The individual signing below should be the individual obtaining consent.

=== **Option 1** if study includes competent participants only =====

Participant's Signature and Date

PRINTED NAME

Researcher or Designee Signature and Date

PRINTED NAME

=== **Option 2** if study may include incompetent participants =====

If your study receives CPHS approval to include incompetent participants, include the following lines to signature section as the CPHS has indicated is appropriate. CPHS approval is required to add Next-of -Kin option - complete item #18 in CPHS Study Plan.

Participant's Signature and Date / PRINTED NAME

If participant is not competent to provide informed consent, please sign as appropriate:

Durable Power of Attorney for Health Care / PRINTED NAME
or

Legally Court-Appointed Guardian PRINTED NAME
or

Next-of-kin PRINTED NAME

Researcher or Designee Signature and Date PRINTED NAME

=== **Option 3** if study may include minors =====

If study may include minors add the signature line for assent. The parent or legal guardian should sign as Legally Authorized Representative and the minor should sign the Assent line.

I have explained to this child what participating in this study will involve and have answered any questions that he or she has asked.

Researcher or Designee Signature and Date PRINTED NAME

Assent of minor (age x-17 as appropriate for your study) PRINTED NAME

Legally Authorized Representative (Parent/legal guardian) and Date PRINTED NAME

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