1.0 Purpose:

1.1 It is the policy of Hartford HealthCare Human Research Protection Program (HHC HRPP) and Institutional Review Board (IRB) that recruitment plans for research projects will ensure appropriate selection of subjects across age, gender, and ethnicity.

1.2 The HHC IRB is authorized to review the purposes of the research, the setting of the research, and whether the population to be recruited is vulnerable to coercion or undue influence. Regulatory determinations will be made if a project proposes to recruit pregnant women (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C), or children (45 CFR 46 Subpart D, and 21 CFR 50 Subpart D).

2.0 Definitions:

2.1 **Advertisements** - Flyers, notices, posters, radio/TV spots, newspaper ads, signs, brochures, internet postings, etc. that are intended to attract potential participants into research studies.

2.2 **Coercion** - The act of using force or threats, whether actual, implied, perceived or indirect, to encourage an individual to participate in a research study.

2.3 **Convenience Sample** - Convenience sampling selects a particular group of people based on aspects of the potential participants' situation which renders them more easily accessed by the investigator or more likely to complete research participation without regard for the representativeness of the sample. Convenience sampling does not come close to sampling all of a population or a representative sample of a population. Convenience sampling may unfairly expose a population to research related risks.

2.4 **Exculpatory Language** - Language that waives or appears to waive any of an individual's legal rights or which releases or appears to release the investigator, sponsor, the institution or its agents from liability for negligence.

2.5 **Health Care Provider** - A person considered to be engaged in the patient's medical care.

2.6 **HIPAA** - Health Insurance Portability and Accountability Act of 1996. HIPAA establishes security and privacy standards for the use and disclosure of "protected health information" (PHI).

2.7 **Privacy** - In the context of research, privacy refers to an individual's right to control access to personal information about him or herself.

2.8 **Therapeutic Misconception** - The belief that research studies are intended to benefit the participants who enroll in them and that an individual is asked to participate in a research trial as part of his or her routine care.

2.9 **Undue Influence** - The inappropriate use of prestige, wealth, ability or position to directly or indirectly affect the potential participants' decision to participate.

3.0 Procedure:

3.1 In order to ensure equitable selection of research participants, the HHC IRB requires that the Principal Investigator (PI) provide the characteristics of the participant population, anticipated accrual, age ranges, health status, gender, and criteria for inclusion or exclusion in the protocol. As such , all recruitment methods must be thoroughly described in the protocol. The investigator must carefully consider the targeted research population, study aim, participant privacy, and potential for bias and influence when designing recruitment activities for specific protocols.

3.2 Health care providers who also serve as researchers and wish to enroll their patients into research must ensure that recruitment methods do not inappropriately promise or suggest therapeutic benefit to the patient beyond what is written in the protocol and consent form as a means to entice their participation.

3.3 The HHC IRB will assess the recruitment plan to ensure that it is compliant with federal regulations as well as HHC HIPAA Privacy Policies.

3.4 Investigators are prohibited from using the amount of payment and/or the proposed method and timing of the disbursement of the payment in a manner that may be perceived as unduly influential or coercive.

3.5 HHC researchers and staff are prohibited from receiving or dispersing bonuses or incentives for recruitment, referral, or enrollment.

3.6 <u>ADVERTISEMENTS</u>

3.6.1 Both the Department of Human Services (DHHS) and the Food & Drug Administration (FDA) consider advertising (subject recruitment) to be the first component in the informed consent process. Therefore, the HHC IRB must review and approve recruitment methods and content of the materials to ensure adequate subject protection. Under Federal regulations, the IRB must review and approve methods used to recruit subjects, one of which is the use of advertisements in various media.

3.6.2 The text of all direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed and approved by the IRB prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to, notices aimed at recruiting research subjects that investigators intend to place in newspaper, radio, TV, bulletin boards and the internet/world wide web. Advertisements developed by coordinating centers for multi-center study recruitment also require HHC IRB approval if the HHC sites intend to enroll from among the pool of prospective subjects responding to these ads. Notices directed to clinical colleagues seeking study referrals also require IRB approval. These include, but are not limited to, letters, electronic and other postings, or notices in professional publications.

3.6.3 The IRB must review the information contained in all advertisements and the mode of their communication. Advertisements cannot be displayed or put to use until the IRB has approved the final copy of printed ads and the final version of audio/video tape recorded advertisements.

3.6.4 The HRPP has prepared the following guidelines to assist investigators in the development of appropriate materials to recruit volunteers into research studies.

3.6.5 Developing Advertisements:

3.6.5.1 **Ethical Considerations** - Advertising for research enrollment is considered the start of the subject selection process. It is also considered the prelude to the informed consent process. Therefore, advertisements, like consent documents, must not unduly coerce or imply a guarantee of benefits beyond what is outlined in the protocol and consent form.

3.6.5.2 Advertisements should be limited to the information needed by prospective subjects to determine their eligibility and interest.

3.6.5.3 Advertisements should be designed with the following in mind:

3.6.5.3.1 No claims should be made, either explicitly or implicitly that the drug or device is safe or effective for the purposes under investigation, or that the test article is known to be comparable or superior to any other drug or device.

3.6.5.3.2 Advertisements for studies using investigational drugs or devices must also not use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.

3.6.5.3.3 Advertisements should not promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the study.

3.6.5.3.4 Advertisements may state that subjects will be paid but should not be coercive by emphasizing the payment or the amount to be paid by such means as larger or in bold font.

3.6.5.4 **Considerations for Advertisement Content (DO’s):**

- The condition being study and/or the purpose of the study including a clear statement that it is research and that it includes the use of an investigational drug or device, if applicable. (The word "research" should appear somewhere prominent in the advertisement. The terms "Study" or "Treatment Study" do not convey the same message.)
- A summary of the key eligibility criteria (e.g., males, females, adults, children, age range, taking no medications, etc.)
- A brief list of procedures involved, including all significant study procedures (e.g., X-rays, MRIs, exercise testing, overnight stays, frequent blood sampling, etc.)

- A brief description of benefits. This description should be a straightforward description of potential benefits to study participation. Do not overstate.
- The time or other commitment required (e.g., duration of study, number of visits and/or length of visits, if only one or two visits)
- Compensation or reimbursement; All advertisements should be tastefully composed and not inappropriately emphasize monetary compensation. Advertisements may state that subjects will be paid but should not use bold or enlarged print or other means to emphasize payment or the amount to be paid. Do not refer to payment in the header of the ad.
- The name of the research facility and the specific location of the study
- The name and contact information of the PI and the person responsible for explaining the study to the subjects
- The IRB protocol number (in the lower right hand corner of the ad in a small font size)
- Use the term "healthy volunteers" instead of "normal volunteers"
- Use simple lay language (6-8th grade reading level) without acronyms or abbreviations unless these are well known to the public or to the special patient group you are targeting, e.g., patients with ALS or women with PMS will understand these abbreviations.
- Provide simple symptom complexes if you are looking for subjects who do not already carry the diagnosis
- Provide basic exclusion criteria whenever possible to reduce unnecessary calls.
- Use the term "investigational" rather than "experimental"
- Name drugs used if approved and/or known to the public, e.g., Aspirin, St. John's Wort
- Use the words "at no cost" rather than "free" where relevant
- Specify amount of monetary compensation (if you wish)
- Use the words "up to" if pro-rated compensation is likely
- Specify hospital affiliation (e.g. Cardiovascular Division, MidState Medical Center)

3.6.5.5 **Things that should not be included in an advertisement (DON'Ts)**

- Feature monetary compensation as a lead in before the description of study purpose and procedures
- Bold, italicize, underline or enlarge fonts on type describing monetary compensation
- Imply treatment benefit if the primary focus of the study is safety and tolerability, drug kinetics, or basic physiological processes rather than efficacy
- Imply treatment benefit for chronic problems if the study involves only short-term interventions
- Emphasize no cost treatment if a placebo is involved (you don't need to explicitly state that placebos are used in ads) and/or the protocol involves drugs, biologics, or devices not FDA approved for the condition under study
- Provide detailed lists of risks and benefits (this should be done in person)
- "Hype" the study with overly optimistic or effusive language implying benefit (commercially designed radio ads occasionally do this)
- Use words describing broader affiliations (e.g., "HHC researchers") which tend to mistakenly convey endorsement and/or direct oversight of study treatments and procedures by the hospital and its affiliates
- Notices or letters sent to other health care providers
- A statement or an implication of IRB or other HH institutional endorsement of the study.
- The use of any inappropriate pictures or images that would be inconsistent with HH IRB policies on equitable subject recruitment.
- Offer of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it had been approved for marketing.
- Exhibition of the ad in inappropriate venues.

3.6.6 **Submitting Advertisements to the IRB**

3.6.6.1 Advertisements should be submitted to the IRB at the time the investigator is submitting the initial protocol. However, should an investigator decide at a later date to advertise for subjects, the advertising may be submitted to the IRB as a

modification/amendment to the protocol. Changes to previously approved advertisement methods must be formally submitted to the IRB as an amendment.

3.6.6.2 Investigators should remember the following when submitting an advertisement for review and approval to the IRB:

3.6.6.2.1 Print advertisements, web pages, newspaper advertisements, posters, and flyers should be in final format, including any graphics or photographs to be used.

3.6.6.2.2 For advertisements that will be used in the media, such as radio or television, submit all text, graphics and other substantive materials. A copy of video clips should be provided to the IRB. Alternatively, the wording for advertisements that will be taped should be reviewed and approved by the IRB prior to the taping to avoid having to re-tape the advertisement. However, if the IRB requires revisions, the investigators may tape the advertisement with the appropriate revisions prior to re-submitting the advertisement script to the IRB. The version used for the final taping must be submitted to the IRB for approval.

3.6.6.2.3 All advertisements should conform to commonly accepted standards of "good taste," meaning the use of standards, graphics, and verbiage that the general public finds non-offensive.

3.6.7 **Submitting an Announcement, Event or News Item to the Hartford HealthCare Planning & Marketing Department:**

3.6.7.1 The Planning & Marketing has created an email "in-box" to make it easier to publicize announcements, events, or news items within the hospital as well as to outside media: announcements@hhchealth.org

3.6.7.2 Please send information to this e-mail account at least two (2) weeks before the event; the earlier, the better. Please use the "Event / News Publicity Submission Form" available on the hospital Intranet on the Planning & Marketing General Information & Forms page.

3.6.7.3 Please complete all of the relevant items on the form before submitting it.

3.6.7.4 The media staff in Planning & Marketing oversees a number of internal and external platforms and channels and will sift through the submissions and determine the correct media for each item. Planning and Marketing platforms include:

3.6.7.4.1 "Corporate Communications" email broadcasts
3.6.7.4.2 HHC Internet (and Intranet web pages

3.6.7.4.3 Rounds Magazine
3.6.7.4.4 Rxtra Newsletter
3.6.7.4.5 Telephone messages on hold
3.6.7.4.6 Press releases
3.6.7.4.7 Paid advertising (TV, radio, print media)
3.6.7.4.8 Hospital display windows
3.6.7.4.9 Cafeteria tabletop tent and easel-back cards
3.6.7.4.10 Banners/posters
3.6.7.4.11 Digital display screens* (located in the main lobby, Jefferson lobby and the cafeteria)

3.6.7.4.12 Please keep in mind that each of the digital display screens is located in an area open to the public. Although the cafeteria screen is oriented toward in-house news and information, each item must be suitable for public consumption. Some items may be more appropriately broadcast via ”Corporate Communications” or posted on the Intranet. In addition, some worthy events or news items may not “make the cut” for the screens. The looped slideshow on these screens needs to be kept to a reasonable length.

3.7 **CLINICAL TRIAL WEBSITES/INTERNET POSTINGS**

3.7.1 IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.

3.7.2 Examples of clinical trial listing services that do not require prospective IRB approval include ClinicalTrials.gov, the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS). However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document

3.7.3 In keeping with DHHS and FDA Guidance, the HHC IRB has determined that IRB review/approval for brief internet postings is not necessary provided that the information is limited to the basics, such as:

3.7.3.1 Study title
3.7.3.2 Purpose of the study
3.7.3.3 Protocol summary
3.7.3.4 Basic eligibility criteria
3.7.3.5 Study site location(s), and
3.7.3.6 How to contact the study site for further information.

3.7.4 When information posted on a clinical trial website goes beyond directory listings with the basic descriptive information given above, such information is considered part of the informed consent process and

therefore requires IRB review and approval. Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits, or solicitation of identifiable information from potential research subjects.

3.7.5 OHRP guidance states that IRBs, in their review of all advertising/recruitment materials, should pay particular attention to risk and potential benefit information to ensure it is presented in a balanced and fair manner. The information presented should not mislead, for example, by promising benefits or implying a benefit beyond that potentially provided by the research.

3.7.6 The HHC IRB, when reviewing clinical trial websites, also will assess the types of incentives, if any, that are being offered to prospective subjects. Monetary and non-monetary incentives (e.g., access to services or programs) can create undue influence on a potential subject's decision about research participation. The HHC IRB will ensure that the clinical trial website makes clear that participation in a trial is voluntary, and that incentives for participation are not so great that they compromise a prospective subject's assessment of the risks or affect the voluntariness of his or her choices.

3.7.7 Some clinical trial websites ask viewers to answer questions regarding eligibility for a specific clinical trial. If identifiable private information is collected via the clinical trial website, the IRB will review plans for protecting the confidentiality of that information. The IRB will assess whether the website clearly explains how identifiable private information might be used.

3.7.8 Informed consent must be obtained for the collection of any identifiable private information about the respondent unless the IRB has determined that the informed consent requirement can be waived. Respondent authorization must also be obtained if protected health information is collected unless the IRB has determined that the authorization requirement can be waived.

3.8 **USE OF INTERNET SOCIAL NETWORKING SITES (Facebook, Twitter, LinkedIn, MySpace, etc.)**

3.8.1 Prior IRB approval is required before posting anything to any social network.

3.8.2 Further approval or notification of the HHC Planning & Marketing Department may also be required.

3.8.3 Facebook specific considerations:

3.8.3.1 "Open" groups are acceptable.

3.8.3.2 "Friends" of the group should be reminded that this is a sensitive topic area and they should check their privacy settings if they are concerned about others knowing that they are members of this group (carrying the implication that they may have SZ/Bipolar, etc.)

3.8.3.3 If the wall is enabled, again they should be reminded that they are voluntarily disclosing information about themselves in a "public" forum.

3.8.3.4 They should be reminded that if they are participants, that any specific questions/comments about their participation should be directed to the study staff's personal e-mail or the Facebook "inbox".

3.8.3.5 Please provide the IRB with the kinds of information you plan to share on the page (i.e. a list such as... links to newly published research relevant articles, reminders about study appointment requirements, etc.)

3.8.3.6 You may also set up a Facebook page/profile.

3.8.3.6.1 The HHC logo should appear on the page (The specific HHC entity's logo should also appear on the page, e.g., IOL)

3.8.3.6.2 Links to HHC (and the specific HHC entity) should also appear on the page

3.8.3.6.3 Jerry Belanger (HHC's web developer) should be named as an administrator on the page/profile for monitoring purposes.

3.8.3.6.4 The person responsible for the page/profile needs to monitor wall posts regularly for any"negative press" issues and remove them immediately.

3.8.3.6.5 The page/profile should be removed from Facebook when it is no longer needed

3.9 **RECRUITMENT OF SUBJECTS IDENTIFIED THROUGH PRIVATE MEDICAL INFORMATION**

3.9.1 At Hartford HealthCare, the IRB always has required approval of the research protocol before patient screening and recruitment could begin. However, the Health Insurance Portability and Accountability Act (HIPAA) has changed the ways a treating physician or treatment personnel may refer patients to a researcher for screening and recruitment. The Privacy Rule under HIPAA regulates how identifiable health information created or received by a covered entity may be used or disclosed in connection with research. Under HIPAA, the use of this protected health information or "PHI" in research generally is not permitted without an authorization from the subject or an IRB waiver of authorization. Therefore, HIPAA requires either that an authorization from the subject or a full or partial IRB waiver of HIPAA authorization for recruitment be obtained.

3.9.2 Recruitment efforts frequently target individuals known to have a specific medical condition. Medical records, patient registries, clinical databases and referrals from treating physicians can be useful resources to identify potential subjects; however it is essential to take special precautions to

ensure that patient privacy is protected and that the individual patient is appropriate to participate in the research. It is not appropriate for investigators to make the first contact with potential subjects identified through their private health information. Rather, active participation by the patient's primary/specialist health care provider in the recruitment process ensures that consideration is given to the appropriateness of an individual patient's participation in the research prior to recruitment and that the patient's privacy is respected.

3.9.3 Health care providers who also serve as researchers and wish to enroll their patients into research must ensure that recruitment methods do not inappropriately promise or suggest therapeutic benefit to the patient beyond what is written in the protocol and consent form as a means to entice their participation.

3.9.4 Below are two mechanisms for recruitment permitted under HIPAA. Under Hartford HealthCare policy these mechanisms must be approved by the IRB as “processes for recruitment” under the applicable protocol.

3.9.4.1 ***Recruitment by the Clinician or the Treatment Staff***

3.9.4.1.1 A physician who has a treatment relationship with the patient (the “clinician”) and who is also the researcher may approach a patient about participation in any IRB approved trials in which the clinician participates as a researcher. The clinician’s treatment personnel (those who have “reason to know” identifiable health information by virtue of the treatment relationship) also may approach the patient about this research. The clinician and his/her treatment personnel must note the communication in the patient's medical record.

3.9.4.1.2 When recruiting potential subjects from among their own patients, investigators must consider the possibility that their patients may feel obligated to participate because they are being asked by their treating physician. For the investigator, maintaining a dual role as investigator and treating physician may create subtle conflicts and ethical tension, while for the patient/subject it may create some uncertainty. Investigators should reinforce with their patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future. Further, the Committee asks researchers to describe any plans that are in place to minimize the possibility that patients will feel obligated to participate, e.g., initially contacting patients about the research in writing and allowing patients to make further inquiries if they are interested, etc.

3.9.4.1.3 The primary/specialist health care provider, usually a physician, who is known to the potential subject and has first hand knowledge of the patient's medical

history must (1) give approval for his/her patient to be contacted for research purposes, (2) initially introduce the study to the patient AND (3) obtain the patient's permission to be contacted by study staff.

3.9.4.1.4 A clinician who is not the researcher (and the clinician's treatment personnel) may approach a patient about participation in another researcher's study. The clinician or his/her staff must note the communication in the patient's medical record. If the patient agrees to a referral to the researcher, suggested language is as follows:

3.9.4.1.4.1 "I discussed the referral of the patient to [team or doctor] for [describe research study]. The patient agreed to the referral, including sharing information about the patient's condition."

3.9.4.1.5 A clinician who is not the researcher (and the clinician's treatment personnel) may give the patient another researcher's name and contact information, and the patient may contact the researcher.

3.9.4.1.6 A clinician who is not the researcher (and the clinician's treatment personnel) may discuss possible patient eligibility with the research personnel in a de-identified manner, i.e., with all specified subject identifiers removed. If the research personnel believe the de-identified patient would be eligible for the trial, the treatment personnel could then obtain the patient's permission to give the research personnel the patient's name or give the patient the researcher's contact information.

3.9.4.1.7 A clinician who is not the researcher (and the clinician's treatment personnel) may send a letter to the patient about how to join an IRB approved study so long as the content of the letter is approved by the IRB.

3.9.4.1.8 As previously noted, direct recruitment for a study by a clinician/researcher or his/her treatment personnel is not affected by HIPAA. These personnel already have a reason to know the patient's PHI and, assuming the study (and the recruitment process) has been approved by the IRB, these personnel may approach the patient about participating in the trial without a HIPAA authorization.

3.9.4.1.9 Also, as previously noted, these treatment personnel also may discuss the patient's PHI with other research personnel, such as the coordinator, so long as the patient first has given his/her verbal or written consent to wanting to learn more about the study

and the proper note has been made in the patient's record.

3.9.4.1.10 The primary/specialist health care provider can introduce the study and obtain the patient's permission to be contacted by study staff either (1) verbally during the course of providing medical care OR (2) through the use of a recruitment letter

3.9.4.1.10.1 Guidelines For Use of Recruitment Letters

- Although recruitment letters are frequently prepared by the study staff, they must be signed by the patient's physician, or the patient's physician and the investigator, but not the investigator alone. In some cases, it may be appropriate for a physician representative on behalf of an entire practice/clinic staff to sign the letter rather than the potential subject's primary/specialist physician. It is never appropriate for recruitment letters to come from study staff, such as research assistants or data managers.

- In the letter, the primary/specialist physician should indicate that one of his/her medical colleagues is conducting a research study. The letter should explain the purpose of the research, and provide a brief description of the nature and extent of involvement, e.g., duration of participation and study procedures.

- The recruitment letter should include a telephone number to call or a postcard to return if the subject is interested in learning more about and/or participating in the study.

- Care should be taken to ensure that letters are properly addressed to avoid delivery to an incorrect party.

- Recruitment letters must be submitted for review and approval by the IRB.

3.9.4.2 ***Recruitment by the Researcher***

3.9.4.2.1 The IRB may grant the request of a researcher for a partial waiver of the patient's authorization for recruitment purposes if the IRB determines that the treating physician's direct approach to the patient or obtaining the patient's prior authorization is impracticable. The request for waiver of authorization may include several possibilities:

3.9.4.2.1.1 A partial waiver of authorization for treatment personnel to refer patients to the researcher or share PHI with the researcher without first speaking to the patient about the referral.

3.9.4.2.1.2 A partial waiver of authorization for the researcher to look at medical records, or schedules, patient lists, etc., and then contact potential subjects.

3.9.4.2.1.3 A partial waiver of authorization to advertise about the study and screen by phone potential subjects for the study.

3.9.4.2.1.4 A partial waiver of authorization to advertise about the study and screen potential subjects for the study and to keep the screening database for use in screening for future studies.

3.9.5 USE OF THIRD PARTY FOR RECRUITMENT OF POTENTIAL SUBJECTS

3.9.5.1 HHC IRB review and approval is required when a third party is used to inform potential subjects of a research opportunity. Examples of a third party would include community physicians or school administrators who are asked to provide their patients or students with information regarding a research study. Third parties may also include commercial entities hired to aid in recruiting research volunteers.

3.9.5.2 IRB review and approval is also required of all materials used by the third party to inform potential research participants of the study, such as “Dear Colleague” or “Dear Patient” letters.

3.9.5.3 Third party recruiters may provide the research contact information directly to the potential participant. The collection of additional research-related information used to determine eligibility can not be conducted by the third party.

3.9.5.4 The use of currently enrolled research participants to recruit additional research participants (sometimes referred to as “snowball sampling”) may be approved by the IRB provided that certain conditions are met. Specifically, current participants do not receive rewards for referral or any rewards are determined by the IRB to be unlikely to induce coercion and undue influence and such rewards do not adversely impact the confidentiality and privacy of future participants. However, the HHC IRB prohibits payments to a non-participant in exchange for the referral of a potential participant (“finder’s fees”).

3.10 DEVELOPMENT AND USE OF RECRUITMENT LISTS (INCLUDING RECRUITMENT DATABASES, AND RECRUITMENT REGISTRIES, ETC.)

3.10.1 Investigators may create and maintain lists of research participants who previously took part in, were screened for but deemed ineligible for other research studies or who have expressed interest in future research participation. In each of these scenarios, however, the individual must provide consent for their name to be retained for recruitment for future research participation.

3.10.2 The development of such a recruitment registry requires IRB approval. The IRB must ensure the appropriateness of the data elements to be maintained on the individuals as well as the confidentiality and security measures associated with the data set.

3.10.3 Investigators may contact individuals in IRB-approved recruitment registries directly for future research consideration.

3.10.4 Investigators must provide such individuals the opportunity to remove their name and any information from the list at any time.

3.11 RECRUITMENT OF STUDENTS AND STAFF

3.11.1 Researchers wishing to recruit their own students or staff to participate in research must ensure that the recruitment plan minimizes any perception of coercion or undue influence. The recruitment plan must assure the potential participant that his/her job, promotion, grade, etc., is not dependent upon their participation.

3.12 PRE-SCREENING OF RESEARCH SUBJECTS DURING RECRUITMENT

3.12.1 **Health Insurance Portability and Accountability Act (HIPAA) Considerations**

3.12.1.1 Many investigators use telephone screening as a method of recruitment and/or eligibility screening for their studies. When done properly, this can be a useful and effective tool. What's important for investigators to remember is that depending on the type of information collected and recorded during this initial conversation, HIPAA regulations may apply- even if the potential research participant is the one initiating the contact.

3.12.1.2 Pre-screening of potential subjects over the telephone or in person to determine their initial eligibility for and interest in a study is a common strategy in the recruitment process. When using this strategy, investigators must adhere to the following guidelines to protect the privacy of the potential subject and the confidentiality of information collected about him/her.

3.12.1.3 The reason that HIPAA may apply is that once an investigator collects and stores identifiable health information it effectively "enters" Hartford HealthCare and is therefore subject to HIPAA requirements as protected health information (PHI). PHI would include information that is typically collected during a phone screen or "pre-screen" such as, name, date of birth, address, medical conditions, etc. Therefore, investigators should design phone screening procedures to avoid, or minimize, the

collection and retention of PHI when possible (for example, collecting age rather than birth date).

3.12.1.4 However, when it is necessary to collect PHI then the investigator must indicate this in the IRB protocol application and request a partial waiver of HIPAA Authorization to collect and store the information during such recruitment activities. The waiver is considered effective until the potential subject presents to the research office and signs a Research Authorization Form or until the study ends. Note that HIPAA only recognizes written authorization, so verbal authorization from the potential subject to permit the investigator to retain the information as required for the purpose of the immediate single study also requires a waiver approved by the IRB prior to initiating the recruitment/screening plan in the conduct of research.

3.12.1.5 In cases of verbal authorization, the investigator should consider incorporating the following language into telephone scripts used to screen potential subjects: “We will keep the information we just talked about in our files until you come in to screen for the study. If you qualify and choose to be part of the study, this information will become part of your study file. If you don't come in or if you don't qualify for the study, we will keep this information until [the duration can be modified but as a suggestion- the study is over] and then we will destroy it. We are required by law to keep this information confidential and we will not use it for any purpose other than to see if you qualify for this study.”

3.12.1.6 Investigators who wish to retain phone screening information to recruit individuals for future studies or to keep a record of ineligible subjects will also need a waiver. Additionally, a protocol to maintain a subject recruitment database may be necessary.

3.12.2 **Acceptable Information to Gather During Pre-screening**

3.12.2.1 Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times. It is not appropriate at this point in the process (i.e. prior to obtaining informed consent/enrollment) to gather information that is not directly related to assessing eligibility and suitability (e.g. obtaining complete medical histories).

3.12.3 **Methods for Conducting Pre-screening**

3.12.3.1 Conducting Pre-screening over the Telephone

3.12.3.1.1 At the beginning of a phone pre-screening conversation, potential subjects should be informed of the nature and sensitivity of the questions, asked whether this is an appropriate time for them to answer these questions, and told how long the

phone call is expected to take. The questionnaires or screening tools that will be used must be submitted to the HHC IRB for review. In most cases if a non-physician conducts the screening, a script of what will be said by study staff must also be submitted for review and approval. Subjects should be offered the option of completing the pre-screening in person, if they wish and if it is feasible.

3.12.3.1.2 In the interests of confidentiality, the researcher should record only the subject's first name or initials at the beginning of the screening conversation; explain to the subject that s/he will be asked a set of questions to determine eligibility and that at the end, only if s/he appears to be eligible and is interested in pursuing the study, will s/he be asked to provide contact/identifying information (e.g. last name, address, birth date, phone number). By following this procedure, identifiable healthcare information is only created for those persons who likely meet eligibility criteria. And for those persons who do not meet entry criteria, only non-identifiable health information is created. This distinction is of particular import in light of Health Insurance Portability and Accountability Act (HIPAA) privacy regulations. Under the new privacy requirements (effective April 14, 2003), the distinction between identifiable and non-identifiable health information is important. The collection of non-identifiable health information is not subject to the new privacy regulations. But the collection of identifiable, historical medical information (even by telephone) creates new "Protected Health Information" and obligates the researcher to provide all of the HIPAA Privacy protections.

3.12.3.2 Conducting Pre-screening over the Telephone utilizing Centralized Phone Banks

3.12.3.2.1 National advertisements are sometimes used to recruit subjects for large multi-center studies. Typically, centralized phone banks or operators receive calls from individuals who see such advertisements, and then screen subjects and refer those eligible and interested to local investigators. Phone screeners interacting with potential subjects in this setting are obviously not employees of our hospitals, are usually not healthcare providers, and typically work from a script or data collection tool which must be reviewed and approved by the HHC IRB before use. Use of third party screeners must be explicitly noted in the protocol. Under HIPAA privacy regulations, the use of such a centralized phone bank or operators requires a business associate

agreement. Potential subjects should be told they are speaking to a non-medical screener at a centralized phone bank, and not erroneously be led to believe they're speaking with a physician or member of the actual clinical research team at our hospitals. This is especially relevant to protocols involving depression or other psychiatric illness. Industry screeners should have policies on what will happen if subjects calling are found to be at serious risk of harm to self and others (e.g. suicidal) and provide such plans for HHC IRB review.

3.12.3.3 Conducting Pre-screening in Person

3.12.3.3.1 Investigators may choose to conduct pre-screening in person, for example, if potential subjects are finding out about research during routine clinical care or while visiting the hospital. All of the questionnaires and checklists that would be used during phone pre-screens are appropriate in this setting as well. Complete medical histories and screening physical exams are not considered acceptable pre-screening activities but rather part of actual research procedures, and should be conducted only after an individual has signed a consent form. That said, it is acceptable to perform very limited routine clinical procedures as part of a pre-screen if they directly relate to eligibility determinations and an individual verbally consents to have them performed before signing a consent form for a study. For example, it would be acceptable to weigh an individual in order to ascertain whether s/he qualifies for a dietary study or acceptable to briefly view a pigmented lesion or a subject's skin type to see whether s/he qualifies for a dermatology study. Such exceptions are made in the interest of the convenience of the research subject, if s/he agrees. Complete physical exams, full body skin exams and any sample collection or laboratory testing must not be undertaken until a subject has given informed consent and has signed the consent form.

3.12.4 Alternative Pre-screening Approaches

3.12.4.1 The guidelines listed above may not be applicable to every situation that arises in the research process. Carefully justified alternative approaches will be considered on a case-by-case basis. The HHC HRPP staff will offer guidance to investigators upon request.

3.12.5 Retaining Information from Individuals who are Pre-Screened but not Enrolled

3.12.5.1 It is acceptable to retain non-identifying information about individuals who are pre-screened for a study, but do not actually pursue the study or enroll. In fact, this is often desirable or even requested by industrial or academic sponsors to obtain information about the entire pool of individuals interested or potentially eligible for the study. Pre-screening sheets from individuals who did not provide identifying information can be retained with no further action. Pre-screening sheets with identifying information gathered to obtain written authorization and prior to enrollment (signing of informed consent form) may also be retained in research files, but must have segments containing identifiable information redacted (i.e. blacked out or cut off)as soon as it is clear that the individual will not be enrolled. If identifiable health information is to be retained, the investigator must obtain an authorization from each of the persons screened.

3.13 RECRUITMENT TIME FRAMES AND SETTING

3.13.1 Recruitment activities must be designed and conducted in a manner that permits potential participants sufficient time, determined by the nature and risks of the research, to consider whether or not they wish to participate. In approving a recruitment plan, the IRB will consider the proximity in time of the recruitment, informed consent process and research interventions so as to assure clear decision making and the avoidance of undue pressure or excessive inducements.

3.13.2 Additionally, recruitment activities must be carried out in a setting that provides privacy to the potential participants and that is free of situational or environmental influences or intimidations.

3.13.3 The investigator and the HHC IRB must consider whether or not the recruitment methods and activities proposed in a research project uphold the principle of Respect for Persons. For example:

3.13.3.1 Will a potential participant be upset when they learn that their private information has been shared with, or viewed by, investigators for research purposes?

3.13.3.2 Should a potential participant be invited to take part in research immediately after the individual has been told of a serious disease, illness or condition or behavior disorder?

3.13.3.3 Should a person be recruited to take part in a research study when he/she is in a strained state of mind, (e.g., a pregnant woman who is about to deliver her baby), or in a stressful location such as the emergency department?

3.13.3.4 Will the setting for recruitment provide subtle inducements to participate, for example, a classroom of fellow students, or an office of co-workers?

3.13.4 **General Guidelines and Considerations for the Timing of Recruitment:**

3.13.4.1 Recruitment methods should demonstrate a respect for a reasonable person's expectation of privacy and confidentiality regarding their private information.

3.13.4.2 Persons should be recruited for research in a manner that upholds their right to choose.

3.13.4.3 Investigators approaching potential subjects for research should ensure that persons are lucid and capable of making independent decisions.

3.13.4.4 As a general rule, recruitment of research participants should be conducted well in advance of the consent process and any research interventions.

3.13.4.5 In cases where it the Investigator believes that recruitment activities can only be conducted in suboptimal time frames and/or settings, the Investigator must explain and justify such arrangements in the IRB application as well as any steps to be taken to minimize the impact on potential participants.

3.14 IRB REVIEW AND APPROVAL OF RECRUITMENT PROCEDURES AND PROPOSED PAYMENTS

3.14.1 The IRB must review the mode and content of recruitment methods and activities for each research study and consider whether or not the recruitment is equitable, free from coercion, bias and undue influence. The IRB may also consider the inconvenience to the potential subject, such as, time required for participation, restrictions on diet or other activities, discomfort, and whether or not they need be mentioned in the advertisement to ensure a fair representation of the research project.

3.14.2 The IRB will review proposed payments to subjects to determine that:

3.14.2.1 Credit for payment accrues as the study progresses and will not be contingent upon the subject completing the entire study.

3.14.2.2 Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

3.14.2.3 All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

3.14.3 The IRB will notify the investigator in writing of its approval of recruitment methods and activities.

4.0 Documentation:

4.1 The HHC HRPP office will maintain all records related to the implementation of this policy, electronic communications and notifications to investigators, funding or regulatory agencies, etc.

4.2 Records will be archived for a period of at least six (6) years following the termination or completion of the research activities.

5.0 References:

5.1 45 CFR 17.92, 45 CFR 46.111(a)(3), 45 CFR 46.116

5.2 21 CFR 56.111(a)(3), 21 CFR 50.20, 21 CFR 56.111(a)(3)

5.3 ICH GCP: 3.1.8

5.4 OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites (September 20, 2005) - http://www.hhs.gov/ohrp/policy/clinicaltrials.pdf

5.5 OHRP/FDA Guidance - Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018) May 2018)

5.6 FDA Information Sheet - Recruiting Study Subjects, Guidance for Institutional Review Boards and Clinical Investigators (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm)

5.7 FDA Information Sheet - Payment to Research Subjects, Guidance for Institutional Review Boards and Clinical Investigators (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm)

5.8 Institutional Review Board Management and Function, Bankert, E. A., Amdur, R. J., 2nd Edition, 2006

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	SAB/CLB	7/1/11	Conversion to new policy template; significant expansion of policy
02	CLB	3/1/15	Updated contact information for the HHC Planning & Marketing Department
03	CLB	7/22/15	Addition to section 3.14 regarding the IRB review of proposed payment to subjects for research participation
04	CLB	3/15/20	General review and minor administrative corrections

Element II.3.C.1. and III.1.E.