Objective:

To establish guidelines for the recruitment and enrollment of potential human subjects into research activities and for the use of protected health information (PHI) as it relates to research recruitment practices.

General Description:

Recruitment of subjects is one of the most challenging aspects of research involving human subjects. According to federal regulations on human subjects research, all research in which individuals are contacted or recruited for enrollment must be prospectively reviewed and approved by an Institutional Review Board (IRB). Because recruitment is an essential part of the research protocol, all matters of recruitment must be presented in sufficient detail to allow the IRB to assess fully the investigator’s plan. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition that is studied. Exclusion of any specific group (e.g., women of child-bearing potential) must be justified in the protocol. This is done in an effort to assure that both the benefits and risks of research participation are fairly distributed. The recruitment plan must avoid coercion or undue influence of subjects, which includes consideration of such matters as financial compensation, reimbursement for expenses, or other inducement for participation, each of which must be reasonable for the expenses, discomfort, or inconvenience of participating.

The Privacy Rule (HIPAA) mandates an additional privacy focus to this review. For a protocol to qualify for IRB approval, all recruitment efforts must respect personal rights to privacy and confidentiality and be compliant with HIPAA regulations and the policies and procedures of the institution and the IRB.

Procedure:

Recruitment Methods

The following are examples of common recruitment methods for human research studies. All recruitment methods must be described in the narrative of the IRB protocol and recruitment materials reviewed and approved by the IRB.

- **Use of advertisements, notices, and/or media to recruit subjects.** Examples include flyers posted in public settings, newspaper ads, radio and television advertisement. All advertisements and recruitment materials (e.g., video, audio, telephone scripts) require prior IRB approval.
• **Direct recruitment of subjects unknown to the researchers.** Examples include random digit dialing, approaching people in public settings, snowball sampling, use of social networks.

• **Maintain a separate IRB-approved recruitment protocol** to develop a database of potential subjects (preparatory to research). The subjects/patients provide consent ahead of time to be contacted for future research studies. Researchers contact patients about participation in IRB-approved studies in accord with the signed consent.

• **Utilize a clinical trial website.** Researchers posting information on such website should submit the content of postings to the IRB for approval.

• **Provide colleagues with an IRB-approved introduction letter** describing the study. This letter would explain the purpose and procedures of the study and inform individuals how to contact the research team. Researchers are prohibited from having access to subject/patient names, addresses, or phone numbers; interested individuals must initiate contact.

• **Send an IRB-approved letter to colleagues asking for referrals of eligible individuals/patients** interested in the study. The research team may provide the referring colleague an IRB-approved information sheet about the study to give to the individuals/patients. If interested, the individual/patient contacts the researcher, or with documented permission from the patient (e.g., note in medical record indicates primary care provider spoke with patient who agreed to be contacted), the researcher may be allowed to contact patients about enrollment. Note: A partial waiver of HIPAA authorization must be requested from the IRB.

• **Approach own patients, students, employees.** This method raises ethical concerns because individuals may have difficulty saying no to an authority figure. To protect against even the appearance of undue influence or coercion, Carilion researchers should use caution in actively recruiting research subjects from employees within their own department or students from their own classroom. A discussion must be provided in the IRB protocol narrative of what precautions will be taken to avoid undue influence during recruitment. Direct recruitment of patients by a treating clinician/researcher or his/her treatment personnel for his/her own research protocols is not affected by HIPAA provisions. 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 any further implications resulting from HIPAA.

There is benefit to involving the treating clinician in discussions of research participation even when these discussions are in reference to studies which he/she may otherwise not be involved in. This policy, acknowledging these benefits and an existing culture at Carilion, requires treating clinician involvement in recruitment discussions and processes.

Treating clinicians with an existing treatment relationship (who are not the researcher) may refer subjects for research participation in a variety of ways:

• A treating clinician (who is not the researcher) may give the patient under his/her care another researcher's name and contact information, thus permitting the patient to contact the researcher.

• A treating clinician (who is not the researcher) may approach a patient under his/her care 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: “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.”

• A treating clinician (who is not the researcher) 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. (See above bullets).

• A treating clinician (who is not the researcher) may send a letter to the patient indicating how to join an IRB approved study so long as this process and the content of the letter are approved by the IRB. While this letter can be co-signed by the investigator, absent a partial waiver for study recruitment purposes from the IRB, only the treating clinician/personnel (i.e. those who already have reason to know the patient’s identifying information) are authorized access to this PHI, and thus they must send the letters.
  o If the letter indicates that the prospective subject will be approached (usually via telephone) regarding study participation, the letter must clearly detail that participation is voluntary and that if they are not interested in discussing study participation they are free to say no. Prospective subjects must be afforded the opportunity to opt out.
  o Also, this process requires prior IRB approval of a telephone script that will be utilized as part of these discussions.

The IRB strongly discourages the use of per patient payment to recruiters (finders’ fees) for recruitment or identification of potential study subjects. If finders’ fees are proposed they must be justified in detail in the protocol including defining the work that is done by the recruiters. The protocol must also explain what measures are taken to be sure that finders’ fees will not lead to coercion of subjects. The use of finders’ fees will always be reviewed by the full Board and is not eligible for expedited review.

Per this policy, treatment relationships extend to group practices. At Carilion each department is considered a Group Practice.

• Request a Waiver of Consent/HIPAA Authorization, if applicable, for recruitment purposes. In all cases the waivers must be justified in IRB application and protocol narrative. Waivers may be granted under the following circumstances:
  o **Minimal risk studies** (i.e., expedited level of review) in which subjects will not be contacted (e.g., many chart review studies) researchers request a complete waiver of consent/HIPAA authorization, if applicable. Justification for the waiver must be included in the IRB Application.
  o **Chart review** to identify prospective subjects who will then be contacted and asked to participate in the study. Justification for the waiver to review charts must explain why the study cannot be done without the waiver. A partial waiver may be granted to allow collection of only the minimum amount of information needed to make contact; informed consent is obtained before additional information is gathered.

Patients identified through chart review must be approached by someone already involved in their care (e.g., treating physician, administrative and research staff working with the physician).
In some circumstances it may be necessary for members of the research team who are not involved in the patient's care to make the approach, either in person or by phone or letter. The application should explain why the study cannot be done unless the researchers approach subjects directly. Direct approach by someone not involved in the patient's care is unusual but may be approved only under exceptional circumstances (e.g., emergency care research).

- **Large-scale epidemiological studies and other population-based studies** may need to identify subjects through registries, medical records in multiple institutions, or other sources. The researchers may need to contact prospective subjects directly rather than through professionals involved in the prospective subjects' health care. This approach involves a greater invasion of privacy than other methods, because researchers without approval from patients gather significant personal health information about the patients, and then contact the patients directly. Justification in the application must explain in detail why it is impossible to do the study unless the IRB grants (1) a partial waiver of informed consent/ HIPAA authorization to obtain subjects' identities and (2) allows researchers to contact subjects directly. Written informed consent and HIPAA authorization is required before additional information is gathered and/or research procedures are initiated.

Note: If a prospective subject refuses to participate, no identifiable information may be kept about the individual unless s/he consents to allow retention of this information. The protocol narrative should include a description of this consent process. With IRB approval, de-identified information about those who refuse to participate may be retained/collected; otherwise all information obtained from charts, records, registries must be destroyed.

### Advertisements and Recruitment Materials Requirements

Advertisements and recruitment materials for human research subjects (posters, flyers, newspaper/magazine ads, scripts for radio/TV, electronic mail, or solicitations from outside sources) are considered an extension of the informed consent and subject selection processes. Accordingly, they require IRB review and approval.

Generally, such materials are included with the original application as part of the overall recruitment plan. Advertisements may also be submitted for approval at any time following approval of the human research study.

Recruitment materials are reviewed by the IRB to ensure that:

- They are neither misleading nor coercive to potential subjects.
- They make no claims either explicitly or implicitly that might lead a subject to believe that an investigational/experimental treatment is proven safe and effective and/or equivalent or superior to other treatments.
- If the study involves an investigational drug, biologic or device, the advertisement may not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. Phrases such as "receive new treatments" or "receive new therapy" mislead study subjects to believe they will be receiving newly improved products of proven benefit.
- They do not promise "free medical treatment," when the intent is only to state that subjects will not be charged for taking part in the study.
All Recruitment Materials Should Contain, at Least, the Following Information:

- The name of the institution, the name of the Department or Division, the name of the researcher and the name of a contact person with a telephone number (including area code) to call for information about the study;
- The purpose of the research and, in summary form, the eligibility criteria that will be used to admit subjects into the study (e.g., adults on medication for high blood pressure, diabetic patients on insulin; normal, healthy adults; etc.);
- A straightforward, truthful description of the benefits, if any; and
- The location of the research and time commitment, if appropriate (e.g., subjects will have to come to X on 4 separate occasions; the research will take 2 hours on one day, etc.)
- If monetary compensation is offered, it must not be presented as an inducement to participate. For example:

*Acceptable:* Subjects will be financially compensated for their participation; subjects will receive $5.00 for each blood sample; subjects will receive a free physical examination and blood tests.

*Unacceptable:* EARN $500! Get FREE medical care!

Submission and Approval

If not included with the original protocol submission, a copy of the advertising or recruitment materials should be submitted using a change/update form. The IRB will send a letter to the investigator stating which materials have been approved. A copy of the materials will be stamped as approved, dated and placed in the IRB protocol file.

Changes to Recruitment Materials

Any subsequent changes in the content of an approved advertisement must also be submitted for IRB review and approval prior to use.

 Occasionally, newspapers or magazines may alter copy to fit available space. Therefore, when submitting an advertisement to a newspaper or magazine, a cover letter should be included stating that the text has institutional approval and cannot be altered.

Payments to Subjects

Payment to research subjects for participation in studies is not considered a benefit; rather, it should be considered compensation for time and inconvenience or a recruitment incentive. The amount and schedule of all payments should be described in the IRB protocol at the time of initial review, including a summary of both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. Procedures for prorating payment should the subject withdraw should be included in the IRB application and informed consent document(s).

Timing of Payments

Credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive
practice, payment to subjects who withdraw from the study may be paid at the time the study would have been completed had they not withdrawn. For example, in a study lasting only a few days, it would be permissible to allow a single payment date at the end of the study, even to subjects who withdraw before completion. However, for a study lasting several months, it would not be permissible to allow a single payment date. Subjects who withdraw before completion of the study should receive accrued compensation in a timely manner.

**Completion Bonus**

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion is acceptable, providing that such incentive is not extreme. The IRB will determine whether the 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.

**Disclosure of Payments**

All information concerning payment, including the amount and schedule of payment(s), should be described in the informed consent document.

**Alterations in Payments**

Any changes in subject compensation or flexibility of the payment schedule must be reported to the IRB as a modification prior to implementation.

**Payment Methods and Fund Management**

Payments to research subjects must be in accordance with Carilion accounting policy and procedures for payments to research subjects.

**Reporting Payments to the IRS**

The Internal Revenue Service (IRS) requires that Carilion (or whoever is paying the subjects for their participation) report payments in excess of $600 per calendar year on Form 1099-Misc. The filing of these forms necessitates that the name and social security number of the subject be collected and released to the Accounting department to process the Form 1099-Misc. The collection and release of this information must be addressed thoroughly in the informed consent document so that it is clear to the subject that his or her identity will be released for the purpose of payment and reporting.

When the identity of the subject will be released to the Accounting department for payment, the following information should be included in the informed consent:

"Personal information about you, including your name, address, and social security number, will be released to the Accounting department for the purpose of payment."

Note: studies that involve a reimbursement of $600 or more in a year should also include:

"...and for tax reporting to the Internal Revenue Service (IRS)."