Novant
CLINICAL RESEARCH INSTITUTE

Working with Novant Clinical Research Institute

Instructions for Investigators

Introduction:

Novant Health in its mission to improve the health of the communities it serves has promoted and supported the development of new therapies and treatments through the conduct of clinical trials.

Through it's IRB and Novant Clinical Research Institute, provisions are made to assure the safe and compliant conduct of clinical research.

Included in this guide is instruction for investigators and their staff to work successfully with the Novant Clinical Research Institute in their research activities.

Information is provided in the continuum of research conduct from assessment of study feasibility through study startup and enrollment to study closeout.

This guide is not intended to be comprehensive. For additional clarifications and guidance, contact the Novant Clinical Research Institute at 336.277.0932 or NCRI@novanthealth.org.

I. Pre-enrollment activities

a. ***Confidentiality Disclosure Agreements***: Typically, CDA's are an agreement between the clinical investigator and the sponsor. As such, they typically do not require review by Novant authorities. There are two exceptions, under which CDA's should be submitted to the NCRI for review:
   i. A Novant facility is named in the CDA
   ii. An employed Novant physician is named in the CDA

b. ***Feasibility Assessments***: Typically a research site will conduct a careful feasibility assessment before agreeing to conduct a given clinical research protocol. Likewise, if the study will require the involvement of a Novant facility or practice, the NCRI will assist by providing input as to it's capacity and capabilities. Please contact the NCRI, especially if any of the following are included in the protocol:
   i. Unusual imaging or diagnostic procedures
   ii. Higher levels of care (for example – in phase I or II studies)
   iii. Areas or service lines unfamiliar with clinical research
   iv. Unusual pharmacy requirements
   v. Treatments that differ widely from standard care or include control arms that may represent second or third line treatments

c. ***PSV***: Novant welcomes sites assessment visits. The Novant Clinical Research Institute will assist in coordinating site visits by identifying the managers and leaders responsible for each area and scheduling the visit in each department. Please contact NCRI before scheduling a PSV or bringing a sponsor representative to a Novant facility.

d. ***Clinical Trial Agreements***: Any clinical trial agreement that includes a Novant facility or employed physician, must be approved by Novant's

legal department and/or NCRI. To expedite this process, the CTA should be submitted in Microsoft Word format as early as possible. If the CTA includes Novant, a non-Novant research group and a non-Novant principal investigator, its format will necessarily be a 3 or 4-way contract. In this situation, we will request a "facility agreement" from the sponsor to expedite approval. 3 and 4-way contracts may be acceptable, but require extensive review and editing to separate Novant's interests from the sponsor and investigator, especially in areas of liability.

e. ***Budget preparation***: The NCRI will provide rates for items and services to be obtained from Novant in the course of the clinical trial. Pharmacy fees will be assessed through the FMC Investigational Pharmacy. For Novant employed physicians, please contact the NCRI to assure Fair Market Value for the agreed upon rates. If services will be required from the FMC Lab, please submit the Clinical Trial Lab Assessment form* to the Lab and obtain the research rates listing from them.

II. Prior to Enrollment:

a. ***Immediately following IRB approval*** submit the following items to the NCRI.
   i. Copy of approved protocol and IRB-stamped consent form
   ii. Facility fee ($250)
   iii. Investigator Indemnification Agreement (signed)*
   iv. Original signed contract (if a Novant facility or employed physician is party)

b. ***Before enrollment begins submit***:
   i. Billing worksheet (including in-patient and out-patient visits)*
   ii. Payment schedule for investigator (if employed physicians are included in budget).

c. ***Other considerations***:
   i. Inform the NCRI of your training plans for Novant clinicians.
   ii. Discuss/disclose any incentive or enrollment "bonuses" intended for any Novant employee.

III. When Enrollment Begins:

a. Notify the NCRI by phone when first patient is enrolled.
b. Send fax/email enrollment notification form for first and subsequent enrollments.
   i. Be sure to include MR#, PI name, site contact number, date of enrollment and any study specific items that were not noted on the billing worksheet.*

IV. During Enrollment:

a. Submit physician payments to the NCRI within 30 days of service.
b. Contact NCRI with any billing issues that arise with Novant business office or study subject.
c. Notify NCRI of any SAEs that result in extended hospitalization or treatment for research injury.
d. Notify NCRI of each out-patient visit using fax notification form.

e. Fax the clinic or office practice a list of study patients per study each month.
f. Notify the NCRI of study closure.

V. Documentation:

a. Please complete the following documentation for ***hospitalized study subjects***:
   i. Place copy of signed informed consent form on patient chart.
   ii. Document the informed consent process in the progress notes, include any screen failure patients who sign consent.
   iii. Place brightly colored sticker in patient chart in progress notes. This sticker should be address-label size, brightly colored and contain the following information: Study number/ID, PI, contact person/number.
   iv. Document daily visits in progress notes.
b. Please complete the following documentation for ***out-patient visits***:
   i. Identify research subjects when making appointments for study subjects including protocol and research site.
   ii. Place study sticker on "problems list" page of patient chart.
   iii. Document visits in patient chart
   iv. Accompany study subject on visit and to checkout and identify study specific vs. standard-of-care charges with office personnel.

VI. **Medical Records**: Our medical records department is happy to provide access to study subject records when the following are provided:

a. IRB reviewed, HIPAA compliant medical records release form.
   i. This form can be part of, or separate from the informed consent form, but must meet HIPAA and Novant policies.
b. Sufficient notice: Call or email Larry Adler in Medical Records for chart requests at least 24 hours prior to retrieval.

Compliance activities:

The Novant Clinical Research Institute is audited yearly for billing and documentation compliance. Since compliance is partially determined by the cooperation of investigators and their respective clinical research coordinators/sites, you will be informed of relevant audit findings.

Please make every effort to include these findings in your process improvement and internal audit plans.

Persistent non-compliance will result in restrictions in research activity, including the denial of new protocol submission or enrollment suspension. Areas of non-compliance may include:

- Repeated failure to notify NCRI of subject enrollment

- Willfully allowing or promoting the billing of the study subject or commercial health insurance provider for study specific items, whether or not the site is receiving sponsor payment for these items.
- Persistenly poor documentation practices
- Failure to submit required fees within time allowances determined by each payee (pharmacy, lab, NCRI, IRB).

The IRB will impose it's own disciplinary actions or penalties for failures in subject protections policies/procedures.

The Novant Clinical Research Institute welcomes any correspondence that will help improve the processes that will make clinical research successful within Novant Triad Region facilities. Please forward any comments or questions to:

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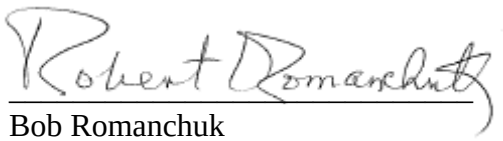
With you in the interests of clinical research,



Bob Romanchuk