

Rochester Regional Health
Human Research Protection Program
Policies and Procedures

Mission Statement:

The Human Research Protection Program provides a focus and guiding set of principles to assure patient safety, the provision of full and informed consent by participants, and guidelines for researchers as to the ethical conduct of research and the ensuing scientific publication.

I. Purpose

The Rochester Regional Health Clinical Investigation Committee (CIC) is a standing committee of Rochester Regional Health Medical Staff. Its purpose is to review, approve or disapprove, and to conduct continuing review of biomedical research involving human participants. The primary purpose of such review is to assure the protection of the rights and welfare of human participants. The Rochester Regional Health CIC consists of two institutional review boards (IRB's) for the review of biomedical research, designated as Boards A and B. Each board meets once monthly, Board A on the 2nd Wednesday, Board B on the 4th Tuesday. The Chairperson of the CIC chairs both boards. Both IRB's are properly composed and function according to the Code of Federal Regulations, Title 21, Part 56 and Title 45 part 46 (Attached as an appendix to this document). These documents will highlight major requirements of both titles as well as local requirements, however all aspects of the regulations apply to the activities of the Rochester Regional Health Clinical Investigation Committee IRB's.

Research involving human participants may not be conducted within a Rochester Regional Health affiliate without prior approval from a CIC Institutional Review Board unless the study meets the criteria for IRB exemption (refer to page 8 for an information regarding exempt protocols).

II. Membership

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by Rochester Regional Health. The Committee IRB's shall be qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The CIC will notify OPRR promptly when membership of either IRB is modified.

11/14 To comply with Nursing Magnet policies there will be one voting nurse member responsible for the protection of human research participants.

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In addition to possessing the professional competence necessary to review specific research activities, the Committee IRB's shall determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

1/12 Each committee member or their alternate is responsible for attending 75% of the scheduled Clinical Investigation Committee meetings.

The Committee IRB's may not consist entirely of men, or entirely of women, or entirely of members of one profession.

The Committee IRB's shall each include at least one member whose primary concerns are in nonscientific areas; for example, lawyers, ethicists, and members of the clergy.

The Committee IRB's shall each include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

In order to evaluate the performance of members, each member of the Committee will be required to complete the Human Subject Protection Program. In addition, attendance at meetings and number of protocols reviewed by scientific members will be reported annually to the Medical Director.

The Committee IRB's shall meet the quorum requirements of one half the boards plus one. This must include the presence of at least one member whose primary concerns are in nonscientific areas.

No member of a Committee IRB may participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the board.

The Committee IRB's may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the Committee. These individuals may not vote with the board.

Either or both Boards of the Committee may be called into an interim review session by the Chairperson at the request of any Committee member or institutional official to consider any matter concerned with the rights and welfare of any research participant.

An Acting Committee Chairperson will serve in the Chairperson's absence. In the event that the Committee Chairperson submits a protocol for consideration by a board, or has a potential conflict of interest, an Acting Chairperson must substitute for evaluation of that protocol.

Alternate Committee Members

The Rochester Regional Health Clinical Investigation Committee has approved the membership of alternate board members. The alternates' possess qualifications comparable to the primary

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board member. Alternates have the same responsibilities as board members and follow the same guidelines. Committee minutes will document when an alternate replaces a board member.

Informational packets to review and meeting agendas will be sent only to primary board members. It is the responsibility of the primary board member to forward the information to their alternate if they are unable to attend a meeting.

The Chairman's alternate is a voting member. A designated member of the Committee will be Acting Chairman in the Chairman's absence.

III. Qualifications of Investigators

The Committee IRB's will consider protocols submitted by qualified investigators who have an affiliation with or an appointment at Rochester Regional Health. For the purposes of the Committee, all physicians **and pharmacists** who have completed their training and are members of the Rochester Regional Health staff will be considered qualified investigators if they meet the requirements of this section. Residents, fellows and students are not qualified to be Principal Investigators

Physicians who are not members of the Rochester Regional Health staff must obtain approval from the Rochester Regional Health Department Chairperson in their field. Other health professionals (Nursing Practice, Respiratory Care, etc) must obtain approval from their Rochester Regional Health Department Chairperson, Manager, (or designee) before submitting proposals to the Committee. Following approval from the Department Chairperson or Manager the proposal can be submitted for consideration by the Committee.

Investigators from outside the hospital must obtain approval from the appropriate Department Chairperson even for exempt activities, such as examining hospital records, laboratory data, etc. In this case, approval by the Department Chairperson will be all that is required. These activities will not undergo additional consideration by the Committee.

Principal Investigator Training in Human Participants Protection

A. Purpose:

This policy is intended to assure that all Principal Investigators, Co-Investigators and research staff conducting human clinical research that involves greater than minimal risk, as defined by the FDA and OPRR, and approved by the Rochester Regional Health Clinical Investigations Committee have completed adequate training in the protection of human participants.

B. Applicability:

This policy applies to all researchers and research staff involved with a project requesting the approval by the Rochester Regional Health Clinical Investigations Committee regardless of the practice site where the study will be conducted.

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C. Requirements:

- Principal Investigators, Co-Investigators, and research staff conducting clinical research protocols submitted to the CIC for review and approval must provide documentation to the CIC of completion of an acceptable training program in human participant protection before their protocol will be reviewed.
- The recommended training program is the CenterWatch Publications (www.centerwatch.com) for a nominal fee. Acceptable alternative courses are available on line at <http://ohsr.od.nih.gov/cbt/> (NIH members only). Non-NIH members may access <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>. Upon successful completion of any of the HSPP programs, the investigator will receive a certificate which must be submitted to the IRB Administrator of the CIC to fulfill the requirements of this policy.
- Alternative training programs will be considered acceptable substitutes if they provide a similar depth and breadth of information. The acceptance of alternative programs will be at the discretion of the Chairman of the CIC.
- Documentation of completion of training in human participant's protection will be kept on file by the CIC. The investigator is not required to include this documentation with each protocol submission, but should indicate that documentation is on file.
- Principal Investigator's or study staffs who are not an employee of Rochester Regional Health or an affiliate of the Hospital must sign a Confidentiality Agreement in order to access any medical information related to a protocol conducted at this site.
- The Principal Investigator, Co-Investigator and research staff is responsible for maintaining an up to date HSPP or other documentation of training status and forwarding a copy of their current HSPP certification to the Rochester Regional Health Clinical Investigations Committee Office.
- Investigators must be sufficiently qualified by education, training and experience that is appropriate to their role in the research to assume responsibility for the proper conduct of human subject research.
- Investigators should have sufficient time and resources to properly conduct or supervise the research for which they are responsible.
- Investigators are responsible for the safe and secure storage of research data in both paper and electronic formats and protecting the confidentiality of the data.
- Investigators are responsible for the accuracy and completeness of the data recorded and reported in research and in publications about the research
- Investigators must maintain records appropriate to the research (e.g. the study plan, consent forms, and correspondence from the IRB) and permit inspection of the research records in accordance with 46.104(f)
- Investigators must maintain records for at least three years after the research ends or for the length of time specified in applicable regulations or applicable institutional or sponsor requirements, whichever is longer, and should take measures to prevent accidental or premature destruction of these documents.

Investigator/Research Unit Standard Operating Procedures

A. Purpose:

This policy is intended to assure that all Principal Investigators and/or research units conducting human clinical research that involves greater than minimal risk, as defined by the FDA and OPRR, and is approved by the Rochester Regional Health Clinical Investigations Committee have written Standard Operating Procedures (SOPs) for the conduct of key aspects of clinical research.

B. Applicability:

This policy applies to all investigators and/or clinical research units submitting clinical research protocols for approval by the Rochester Regional Health Clinical Investigations Committee regardless of the practice site where the study will be conducted.

C. Requirements:

- Principal Investigators for clinical research protocols submitted to the CIC for review and approval must provide documentation to the CIC of the existence of SOPs covering key aspects of clinical research activities before their protocol will be reviewed. Submission of a copy of the table of contents for their SOP manual will suffice as adequate evidence.
- At a minimum, SOPs for the investigator or research unit must include procedures for the following:
 - Informed Consent
 - Source Documentation
 - Regulatory Documents
 - Adverse Event Reporting
 - Records Retention
- SOP manuals will be reviewed as part of any routine or “for cause” audit conducted by the CIC.
- Documentation of the existence of SOPs will be kept on file by the CIC. The investigator is not required to include this documentation with each protocol submission, should indicate that documentation is on file.
- The Rochester Regional Health CIC, at the request of the investigator, will provide SOP templates for key operating procedures. These templates can be modified and revised by the investigator as needed.
- The investigator is required to submit an updated SOP table of contents on at least an annual basis

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D. Conflict of Interest

All research personnel who have a significant role in a research study (involved in development or impact on outcome) must complete RRHSS Conflict Reporting Form including:

- All students, post-doctoral fellows, residents, scientists and staff who are responsible for the administration, design, conduct or reporting of research; and

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- Any study coordinator or other employee actively involved in conducting sponsored research

Researchers who are not investigators but who play a significant role in the research are required to complete the Conflict of Interest form

IV. Committee Review

Each research protocol and accompanying documents will be assigned to either Board A or Board B for review. Throughout the life of the study the designated Board will be responsible for all review and approval activities including initial approval and review approval of modifications to the study protocol or consent documents, and continuing review.

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There is a limited number of new studies that can be reviewed at each meeting. Submission of new studies is on a first-come first served before the closing date – that submitting before the closing date doesn't automatically assure that a study will be reviewed at that meeting.

A. Full IRB Review

The designated Committee IRB shall review and have authority to approve, require modification (to secure approval), or disapprove all research activities which come under the jurisdiction of the Committee. See "Criteria for Approval" detailed below.

A protocol submitted for consideration by full board review must include all of the elements detailed on the Rochester Regional Health CIC Application (See Attached). Any protocol submission that does not contain all of the required elements as detailed on the application will not be forwarded to a Board for review. The submission will be returned to the investigator without further review.

The Committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure Committee IRB approval of the research activity. If the Committee decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The Committee's written notification of approval shall include the following specific elements: (1) title of research protocol; (2) name of investigator(s); (3) dates for the submission of progress reports; (4) the requirement to report any increased risk to participants; (5) the requirement that any change in protocol may not be implemented without prior Committee approval; (6) that failure to comply with any of the above requirements will result in the suspension or revocation of the Committee's approval.

Primary Reviewer

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The boards of the Rochester Regional Health CIC use a primary reviewer system. A Primary Reviewer from the board is identified and receives a complete copy of the CIC protocol submission and has access to all relevant documents for the study. The Primary Reviewer is responsible for reading the protocol in a detailed manner and contacting the Investigator with any questions. The committee chairperson is also responsible for reviewing all protocols. All other board members will receive a copy of the abstract and consent form. At the board meeting it will be the responsibility of the Primary Reviewer to present the protocol. The primary reviewer is responsible for completing the “Primary Reviewer Evaluation Form” and sharing this document with the CIC Board. This completed form will be filed with the meeting minutes. Investigators or designee will be required to attend the board meeting to answer questions. If a representative is not present the study may be tabled until the next meeting of that board.

The IRB Administrator will also have a copy of the protocol and all related study documents. Committee members who wish to review the entire protocol will be able to contact the CIC Office and make arrangements to review the protocol or receive a copy.

Each protocol shall be specific regarding the details of when and how the test article(s) or procedure(s) are to be used, the purpose of the study, how the results will be analyzed and interpreted, the risks involved and the monitoring procedures. When applicable, each protocol submission must be accompanied by an informed consent form that meets all requirements listed in CFR Title 21, Part 50, as well as local requirements detailed in the “Informed Consent” section of this document.

Protocols which include genotyping studies of genomic or mitochondrial DNA must undergo full board review.

B. Expedited Review – See Supplement to Application for Review

21 CFR 56.110, 45 CFR 46.110

The Committee may review some or all of the research appearing on the list established by the Food and Drug Administration and published periodically in the Federal Register. The research must involve no more than minimal risk and fall into one of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and

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external secretions (including sweat); (e) un-cannulated saliva collected either in a un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery (permission is required from pathology) (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3. a) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two times per week; or b) from other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 550 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than two times per week.
4. Collection of data through noninvasive procedure (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied to either the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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The Committee may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. A minor change in protocol or consent form meets the criteria for expedited review.

Under the expedited review procedure, the review and approval will be carried out by the IRB Administrator when the change is minor, and non-clinically significant. Examples of approval are: recognition packets for participants, formatting changes to the consent form, advertising, formatting changes to advertisements, administrative changes to a protocol and serious adverse events where there is a sponsor involved and the report from the sponsor states that the event is not related to the investigational agent and no changes to the protocol or consent are necessary.

Under the expedited review procedure, the review will be carried out by the Committee Chairperson or by one or more reviewers designated by the Chairperson from among members of the Committee. In reviewing the research, the reviewers may exercise all of the authorities of the Committee except that the reviewers may not disapprove the research. A research activity may be disapproved only after full IRB review.

The Chairperson of the Committee shall keep all members of the Committee advised of research proposals which have been approved under the expedited review procedure.

C. Continuing Review

The designated board of the Committee shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less often than once per year.

In conducting continuing review, the responsible board is required to review:

- Number of participants accrued
- Summary of adverse events – see adverse event form
- Unanticipated problems involving risk to participants
- Withdrawal of participants
- Complaints
- Summary of any relevant recent literature, interim findings
- Amendments or modifications since last review
- Any relevant multi-center trial reports
- Copy of last signed informed consent if a patient has been enrolled since the last review and any new revisions to the consent document
- If there are no changes in the Informed Consent document the version date on the ICF submitted for renewal should not be revised.
- If there are changes to the Informed Consent Form document, a highlighted copy of the document noting the changes must accompany a cover letter requesting review and approval of the highlighted changes

The above information is listed on the Application for Continuing Review form (see attached) which must be filled out in its entirety by the investigator. If supplemental information is needed to explain any responses on the Application for Continuing Review, the investigator must forward this information to the Committee. Applications for Continuing Review that are not fully completed including, as appropriate, the provision of supplementary information will be

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returned to the investigator. This will potentially result in a delay in the board's continuing review and re-approval. If the study is to be terminated, the Principal Investigator is to notify the CIC as soon as possible and submit a completed continuing review form indicating termination.

An expedited continuing review from the Chairperson of the Committee or a designated member of the board is permissible when:

- The protocol is permanently closed to the enrollment of new participants,
- All participants have completed all protocol-related interventions, and
- The protocol remains active only for long-term follow-up of participants.

Or,

- The study was originally approved by expedited review

C. Exempt Activities – see supplement to application
45 CFR 46.101B

Research activities free of risk will not require Committee review. These may include: (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation. (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the paragraph (2) of this section, if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the participants cannot be identified, directly or through identifiers linked to the participant. (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Just as with expedited studies, determination is made by Chairman of the CIC. The investigator does not make exempt determinations regarding their own research. Any modifications of exempt research activities must be submitted to the CIC for prospective review.

E. Annual Report

Annually, at the end of each calendar year, the IRB Administrator shall prepare a report reviewing the status of protocols that have been considered by the Committee in the past year. A copy of this report will be sent to the Committee members and Medical Staff Offices.

V. Criteria For Approval (45 CFR 56.111)

The Committee shall determine that all of the following requirements are satisfied before approval of clinical research protocols is granted.

- A. Risks to participants are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (b) whenever appropriate by using procedures already being performed on the participants for diagnostic or treatment purposes.
- B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The Committee should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- C. Selection of participants is equitable. In making this assessment, the Committee shall take into account the purposes of the research and the setting in which the research will be conducted.
- D. Informed consent will be sought and documented from each prospective participant or the participant's legally authorized representative using a document meeting the informed consent requirements detailed below.
- E. A signed copy of the informed consent will be provided to the person signing the form.
- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the participant.
- G. Where appropriate, there are adequate provisions to protect the privacy of the participant and to maintain the confidentiality of data. While the FDA has access to medical records is a regulatory requirement, participant's names are not usually requested by the FDA unless the records of particular individuals require a more detailed study of the cases, or unless there is a reason to believe that the records do not represent actual cases studied or actual results obtained. The FDA understands the need to protect the privacy of research participants. When an individually identifiable medical record is copied and reviewed by the Agency, the FDA safeguards the information and disseminates the information only under conditions that

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protect the individual's privacy to the fullest possible extent consistent with laws relating to public disclosure and the agency's law enforcement responsibilities.

- H. The Committee's primary responsibility with respect to protecting confidentiality is to the research participant. The Committee should, however, respect the sponsor's need to maintain confidentiality of certain information about products under development. The Committee members and staff should be aware that information submitted for review may be confidential, trade secret, and of commercial interest and recognize the need for maintaining the confidentiality of the review materials and records.
- I. Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards shall be included in the study to protect the rights and welfare of these participants.
- J. An assessment is made on whether there is an alternative research design or interventions that should be recommended to the investigator to reduce risks associated with the study.

Rochester Regional Health and the Rochester Regional Health Human Research Protection Program Policy and Procedures Manual have safeguards in-place to ensure appropriate procedures for obtaining informed consent.

- If a patient is unable to provide consent to participate in a protocol due to being acutely or chronically incapacitated, the investigator may identify an appropriate surrogate to provide consent from a "Patient Representative". Selection of the appropriate surrogate must be consistent with hospital policy relative to consent for other clinical issues (e.g. DNR orders, consent for treatments and procedures). At the time of the initial approval, there must be approval for the use of a surrogate consent for that study from the Clinical Investigations Committee.
- Any questions regarding the rights of a research participant should be directed to the IRB Administrator.

VI. Informed Consent

A. Basic Elements of Informed Consent:

Informed consent document must meet all of the requirements detailed in CFR Title 21, Part 50 as well as Rochester Regional Health CIC local requirements detailed below.

- 1) The first page of the consent form must be printed on letterhead appropriate for the Rochester Regional Health affiliate or practice site of the principal investigator.
- 2) The local number of participants anticipated to be enrolled in the study must be listed in consent form. **7/11**
- 3) The informed consent document must be written at an educational level that is reasonably expected to be understood by the participant.

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- 4) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and the identification of any procedures which are experimental.
- 5) Conflict of Interest Statement – Rochester Regional Health and the investigator are receiving payment from (Sponsor) for conducting this research. If Applicable also add – In addition, the Principal Investigator has a consulting relationship with (Sponsor) unrelated to this study. The investigator and Rochester Regional Health may receive part of the profits, if any, from patents resulting from this research. If you would like more information, please ask the researchers or the study coordinator.
- 6) A description of any reasonably foreseeable risks or discomforts to the participant. Risks should be presented as a range of occurrence, for example: “Likely (occurring in 10% or greater of the study population)”, “Less Likely (occurring in 5 – 10% of the study population)” and “Rare (occurring in 0 – 5 % of the study population)”, or similar gradation of risks. Exceptions will be made on a per case basis.
- 7) A description of any benefits to the participant or to others which may reasonably be expected from the research.
- 8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- 9) Confidentiality of Records: HIPPA – Health Insurance Portability and Accountability Act Data Privacy Statement, (DPS) see section XXX.
- 10) For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

In addition the following paragraph shall be included for research being done completely or in part at RRHS:

“Rochester Regional Health, in fulfilling its public responsibility, has provided professional liability insurance coverage and will be responsible for any injury only in the event such injury is caused by the negligence of Rochester Regional Health.”

- 11) The “**Pt. Int. ____**” notation (as previously required in the footer of each page of the consent document) is no longer required for approval. Existing protocols are not included in this change unless amended. If the PI wishes to retain the notation or the protocol sponsor requires the notation, it may remain.

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- 12) Under contact information, www.clinicaltrials.gov needs to be inserted for patients who wish to look up information pertaining to the study they are participating in or other studies.

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- 13) An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant.

Contact Persons

The consent form must address three (3) areas for participant's questions namely, questions about the research itself, questions about research related injury and questions about the participant's rights. Examples of acceptable wording for this section:

“For more information concerning this research you should contact (specify name) at (telephone number) (Note: this person is usually the principal investigator).”

“If you believe that you may have suffered a research related injury, contact (specify name) at (telephone number) who will give you further instructions. (Note: this person is usually the PI, or, if the PI is not a physician, some pre arranged medical contact).”

“If you have any questions about your rights as a research participant, you may contact the IRB Administrator of the Rochester Regional Health Clinical Investigation Committee at (585)-922-5640.”

- 14) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- 15) When non-English speaking participants are expected to be entered into a study, the CIC board must approve a consent document written in the language in which the information is to be presented to the participants. A consultant may be utilized to assure that the translation is correct. A copy of the translated consent document must be given to each appropriate participant. While a translator may be used to facilitate conversation with such subjects, routine ad hoc translation of the consent form may not be substituted for a written translation.
- 16) The following formatting requirements for consent forms must be met: (a) except for the first page, each page of the consent form must contain a header that includes the title (complete or abbreviated) of the study; and; (b) each page of the document must include a page of page number style and version date in the footer.

B. Additional Elements of Informed Consent (As Appropriate)

A statement that the particular treatment or procedure may involve risks to the participant, (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the subject's consent. A statement that the study

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doctor, sponsor (if applicable), and the Rochester Regional Health Clinical Investigation Committee have the right to terminate the protocol at this site.

Any additional costs to the participant that may result from participation in the research.

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the participant's.

A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the participant.

C. Signature Page Requirements

The Rochester Regional Health Clinical Investigations Committee requires that a consent form provide a place for the printed name and signature of the person obtaining consent, the patient/participant, and a witness. The requirement of a witness is not required by federal regulations; however the Rochester Regional Health CIC requires this signature for all research with greater than minimal risk to study participants. The intent of the witness is to acknowledge that the participant is giving their consent freely and without reservation, the witness does not need to be present for the entire informed consent process. The witness must be an individual not directly involved in the conduct of the study. For studies meeting the definition of minimal risk, the requirement of a witness signature is waived. If a sponsor or funding agency has more stringent requirements for the participation of the witness during the informed consent process, that will be acceptable to the Clinical Investigations Committee. This policy does not apply to consent forms reviewed and approved prior to October 1, 2000. For these studies, changes will be required at renewal. The following wording is recommended for the signature portion of the consent form:

Person Obtaining Consent

I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

_____	_____	_____
Print Name	Signature	Date

Participant/Patient Representative

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I will receive a signed copy of this form for my records and future reference.

_____	_____	_____
Patient Name (Print)	Signature	Date

_____	_____	_____
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Patient Representative (Print) Signature Date

Relationship if other than the participant: _____

Witness

The participant has indicated to me that the research has been explained to the participant, that the participant has read (or had read to the participant) this consent form, and that all of the participant's questions have been answered. In my judgment, the participant is voluntarily signing this consent form. *****Note – the witness can't be anyone involved in the study*****

Witness Name (Print)

Signature

Date

D. Exceptions (21CFR 50.23)

The obtaining of informed consent shall be deemed feasible unless, both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

The human participant is confronted by a life-threatening situation necessitating the use of the test article.

Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from the participant.

Time is not sufficient to obtain consent from the participant's legal representative.

There is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.

If the Investigator believes that immediate use of the test article is required to preserve the participant's life and it is not possible to obtain timely certification from a physician, who is not participating in the study, the Clinical Investigator may proceed with its use. Following such emergency test article use, a physician who is not otherwise participating in the study must review and evaluate the use in writing.

When an emergency use without informed consent has occurred, the Investigator must submit the certification or the evaluation to the CIC within 5 working days after the test article's use. The CIC Chair must review the documentation and, at the next convened meeting, the full Board should be made aware of the use.

E. Waiver of Informed Consent Requirements

1. The Committee may approve a waiver of some or all of the consent requirements provided that:
 - The research involves no more than minimal risk to the participant;

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- The waiver will not adversely affect the rights and welfare of the participant;
 - The research could not practically be carried out without the waiver; and
 - Whenever appropriate, the participant will be debriefed - provided with additional pertinent information after they have participated in the study
2. The Committee may waive the requirement for written documentation of consent in cases where:
- The principal risks are those associated with a breach of confidentiality concerning the participant's participation in the research, and
 - The consent document is the only record linking the participant with the research,
- OR**
- The research presents no more than minimal risk, and
 - The research involves procedures that do not require written consent when performed outside of a research setting.

VII. Serious Adverse Event Reporting

Non fatal, serious adverse events, which occur during participation in a study protocol under the approval of a Rochester Regional Health CIC (i.e. local adverse events), are to be reported to the CIC within 48 hours of the investigator's knowledge of the event. Fatal serious adverse events are to be reported within 24 hours.

Serious adverse events (occurring at other study sites and reported to the PI by the sponsor) are to be reported within 30 working days of the investigator's knowledge of the event. This includes all sponsor generated safety reports, and amendments/addendums to safety reports.

A CIC Serious Adverse Event Report cover sheet (See Attached) which is completely filled out and signed by the investigator must accompany all internal serious adverse events reported to the CIC.

All serious adverse event reports are reviewed by the CIC Chairperson or by the Acting Chairperson if a conflict of interest exists. Serious Adverse event reports may prompt a request for revision of the informed consent document, a request for protocol amendment, or suspension or revocation of the approval of the study. Suspension or revocation of approval will only occur after review and voting by the responsible board, unless an eminent danger to participants warrants quicker action by the Chairperson.

11/16 Major Protocol deviations are to be submitted to the CIC within 48 hours of investigator becoming aware of event. Other Type of deviation/violations are to be submitted to the CIC within 7 days of investigator becoming aware of event.

See Major Deviation form and policy for further guidelines

Noncompliance Guidelines

See Serious Adverse Event Reporting Requirements for Clinical Trials Letter dated 12/1/14

VIII. Urgent and Emergent CIC Board Approval

If it is urgent to begin a study before the next scheduled CIC board meeting, a board meeting will be called on an emergency basis. The clinical investigator will not be given permission to initiate a study prior to the time the study has been approved at a convened meeting by a CIC board unless one of the following conditions applies:

the study involves no more than minimal risk as defined in 21 CFR 56.110(b) and is eligible for expedited review,

the condition is life-threatening, as described in 21 CFR 56.102(d) of the regulations and the procedures outlined in 21 CFR 56.104(c) are followed, or

the requirements for CIC review and approval have been waived by the FDA

IX. Administrative Review

Research that has been approved by a Committee IRB may be subject to review by the Medical Board and/or the Board of Directors. Although these administrative bodies may disapprove a research protocol, these bodies may not approve the research if a CIC board has not approved it.

X. Suspension of Research

The Committee shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to participants.

Any suspension or termination of approval shall include a statement of the reasons for the Committee's action and shall be reported promptly to the investigator, appropriate institutional officials, the sponsor if applicable, and the Food and Drug Administration.

XI. Records

The records of the Committee shall be retained for at least 3 years following completion of the research. Records shall be accessible to authorized representatives of the Food and Drug Administration at reasonable times in a reasonable manner.

The Research Office shall prepare and maintain the following:

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.

Minutes of Committee meetings which shall be in sufficient detail to show attendance at the meetings, actions taken by the Committee, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

Records of continuing review activities.

a. Copies of all correspondence between the Committee and the Investigator.

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- b. A list of Committee members identified by name, earned degrees; representative capacity, indications of experience (such as board certifications, licenses, etc.) sufficient to describe each member's chief anticipated contributions to Committee deliberations, and any employment or other relationship between each member and the institution.

Statements of significant new findings provided to participants.

XII. Research Involving Medical Devices

Investigational devices are medical devices which are the object of clinical research to determine their safety or effectiveness. Studies undertaken to develop safety and effectiveness data for medical devices involving human participants must be conducted according to the requirements of the Investigational Device Exemption (IDE) regulations (21 CFR 812).

Investigational devices are classified as either significant risk or non-significant risk devices. Examples of non-significant risk devices are: most daily wear contact lenses, lens solutions, heel cups, antibacterial surgical garments, incontinence devices, oral training splints, and ultrasonic tooth cleaners. Unless otherwise notified by FDA, an investigation of a non-significant risk device is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements of the IDE regulations. These regulations require, in part, that IRB approval be obtained and maintained throughout the investigation and that informed consent be obtained and documented.

A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of the participants. Such a device is intended as an implant; is to be used in supporting or sustaining human life; or is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health. Examples of significant risk devices are, TMJ prostheses, stents, lithotripters, sutures and absorbable bandages/materials, ECT devices, extended wear contact lenses, pacemakers, contraceptive devices, most laser systems, and most hemodialysis systems. Investigations involving significant risk devices must meet the full IDE requirements including the submission of an IDE application to the FDA. As with non-significant risk devices, Clinical Investigation Committee board approval is required prior to conducting clinical trials of the investigational device.

In addition to determining whether a study should be approved, the CIC board will also determine whether the device presents significant or non-significant risk.

In deciding if a device presents significant risk or non-significant risks, the CIC board will consider the device's total risk, and not compare these with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the CIC board will consider the risks of the procedure in conjunction with the risks of the device.

Once a decision on the degree of risk is reached, the Rochester Regional Health CIC Board will consider whether the study should be approved or not. Some studies involving non-significant risk devices may also be considered minimal risk studies and thus may be reviewed through the expedited review procedure established by the Rochester Regional Health Clinical Investigation Committee. The FDA considers studies of all significant risk devices to present more than minimal risk; therefore full board review at a convened meeting is required for all studies involving significant risk devices. In considering whether a study should be approved, the

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Rochester Regional Health Clinical Investigation Committee will use the same criteria it would use in considering approval of any research involving FDA-regulated product.

1/15 If a Principal Investigator submits a device study as non significant and the CIC determines the risk is significant, the meeting discussion will be recorded in the minutes and the Principal Investigator will be made aware of the decision.

XIII. Conflict of Interest:

Any CIC member with a real or potential conflict of interest relative to any business being considered by the CIC must make this conflict of interest immediately known and abstain from the final discussion and voting. The member may provide information requested by the committee, but may not attempt to influence or otherwise affect the committee's final deliberations or decision. A conflict of interest may include, but is not limited to the member being an investigator, co-investigator, study coordinator, supervisor or family member of staff conducting a study, or having a direct financial interest in the performance of the study. The financial interest includes equity interests, consulting fees/salary support or intellectual property rights.

This conflict of interest policy extends to all CIC business including board meetings, CIC subcommittee meetings, CIC study audits and inquiries or investigations of misconduct in science.

It is the responsibility of the CIC member to bring any conflict of interest to the immediate attention of the CIC Chairman or Acting Chairman before or during the progress of any board meeting, subcommittee meeting, audit, inquiry or investigation.

XIV. Communication Outside of Board Meetings

On occasion, communication to CIC members will be conducted outside of regularly scheduled board meetings. Any communication sent to CIC members will be noted during the next scheduled meeting and a copy of the communication will be appended to the minutes. If the communication concerns issues that require discussion and approval of the CIC members, this business will be conducted during the meeting and the outcome properly recorded in the meeting minutes.

XV. Assurance of Member/Alternate Status

The IRB Administrator shall assure that each individual voting on CIC business is either a full board member or an alternate member attending in place of a full member. This will be accomplished by bringing the CIC roster to each board meeting to verify the status of each attendee.

XVI. Approvals Pending Revisions

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This policy describes the procedures to be followed for verifying that all revisions and additional information requested by the CIC are submitted by the investigator prior to the issuance of a final approval. This policy applies to studies which receive board approval pending revisions.

The IRB Administrator or CIC Chairman will assure all revisions to study submissions have been complied with prior to granting final approval. This assurance shall be documented by the reviewer checking off each item on a copy of the pending approval letter that had been sent to the investigator. This checked copy of the letter shall then be retained in the study file.

Once a Protocol has been given “pending approval”, the PI/Research Staff has three (3) months time to complete the requested changes, unless the IRB Administrator has granted an extension to this time in writing.

If the requested changes cannot be completed within the specified time frame the PI/Research Staff should contact the Research Protections Office for guidance, (most protocols will be required to be resubmitted as new protocols and will be subject to re-review).

XVII. Annual Review of CIC Guidelines

The IRB Administrator and CIC Chairman shall complete annual review of the CIC Guidelines during the fourth quarter of each year. The guidelines shall be updated to reflect any changes or modifications in policies and procedures or regulations since the last review and approval. A revised copy of the guidelines shall be discussed and approved by the CIC Membership at the annual CIC meeting held in December. If no revisions to the guidelines are indicated, this shall be reported to the CIC and approved by a vote of the members. The guidelines may be revised as needed by a vote of the members at any time between Annual Reviews.

Annual Report

Annually, at the end of each calendar year, the IRB Administrator shall prepare a report reviewing the status of protocols that have been considered by the Committee in the past year. A copy of this report will be sent to the Committee members and Medical Staff Offices.

XVIII. Quality Assurance Audit

The Quality Assurance Audit, (QAA) Policy provides a process for the CIC to audit investigators and studies being conducted under the approval and oversight of the CIC.

The Audit process is intended to evaluate the compliance of the investigator with Good Clinical Practices and other applicable regulations governing the conduct of the research project.

This policy is also intended to provide investigators with feedback concerning their compliance so that identified deficiencies can be corrected and the investigator achieve voluntary compliance with the requirements of the CIC.

See the CIC QAA Policy for details of procedures to be followed.

XIX. Permission by Parents or Guardians and Assent by Children

The Rochester Regional Health CIC shall determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the CIC children are capable of providing assent. In determining whether children are capable of assenting, the CIC shall take into account the ages, maturity, and psychological state of the children involved.

The judgment may be made for all children to be involved in the research under a particular protocol, or for each child, as the CIC deems appropriate. If the CIC determines that the capability of some or all children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the children and is available only in the context of the research, the assent of children is not a necessary condition for proceeding with the research. Even where the CIC determines that the subjects are capable of assenting, the CIC may still waive the requirement under circumstances in which consent may be waived.

When parental permission is to be obtained, the CIC may find that the permission of one parent is sufficient for research to be conducted or that 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.

Children who are wards of the State or any other agency, institution, or entity can be included in research under 45 CFR 46 section 46.409.

For studies with minor participants who can give their assent, include both of the following signature lines:

Patient/Child Assent (for children 7 years of age or older)

It has been explained to me that I am going to be in a study. Information about me will be collected as part of the study. My parent or guardian is giving permission for me to be in this study. I have been allowed to ask questions about being in the study. My questions have been answered in a way I understand. I agree to be in this study.

Patient Print Name

Signature

Date

Parent/Guardian

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give permission for my child to

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participate in this study. I will receive a signed copy of this form for my records and future reference

Parent/Guardian Print Name	Signature	Date
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XX. Audit Inspection

The Rochester Regional Health Clinical Investigation Committee requires that research investigators provide the Committee with a copy of any audit or inspection reports of findings issued to them by regulatory agencies, cooperative groups, contract research organizations, the sponsor or the funding agency. This does not include reports from routine monitor visits unless required by the sponsor.

XXI. Administrative Meetings

The IRB Administrator meets on a frequent basis with the Medical Director to provide an update on research activities. Resource needs for the CIC that include staff, computer equipment, materials, space, and managing communication to and from investigators relating to CIC questions and requests are also discussed. On an annual basis the budget of the CIC is reviewed.

XXII. Decisionally Impaired Participants

In the case of participants with decisional impairments the CIC may require the following:

1. Investigators use specific instruments or techniques to assess and confirm the potential participant understands the nature and elements of consent.
2. Investigators use monitors as appropriate to oversee the progress of the research.
3. Investigators to have a waiting period for consent
4. Establish, or require the availability of an ombudsman or research participant advocates
5. The assent of adults who lack capacity to consent.

These issues will be discussed and if deemed necessary, implemented on a case by case basis when reviewing protocols that will involve decisionally impaired participants.

XXIII. Consent Monitors

Where appropriate, the CIC may require the use of consent monitors. This may include the use of CIC staff or a third party to observe the consent process and the research for protocols approved by the CIC. The CIC may also require an appropriate individual to monitor the health status of incapacitated participants and be authorized to withdraw a participant from research, if necessary to protect his/her welfare.

XXIV. Drug Records in Pharmacy

When applicable, the Pharmacy Department will have the most updated version of the investigator brochures. These brochures will be given to the Pharmacy Department by the investigator/coordinator when a new research application is submitted to the CIC Office. The investigator/coordinator is responsible for providing the Pharmacy Department with any revisions/updates to the brochure.

XXV. Investigator Appeals

Appeals regarding Rochester Regional Health CIC decisions can be submitted, in writing to the CIC by a principal investigator. This process allows the investigator to bring concerns about their individual protocol review to the CIC for reconsideration without compromising the integrity of the CIC review process. If the investigator is not satisfied with the re-review of the Committee an ad-hoc committee may be assembled. A copy of the appeal will be given to the Medical Director who will choose the members to conduct the review. The outcomes of the appeals are reported to the investigator appealing. If the investigator appealing is not satisfied with this outcome, he/she can submit a further appeal to the Institutional Official. The Institutional Official may not approve research that has not been approved by the CIC.

XXVI. Input from Investigators/Coordinators

Annually, the CIC conducts a meeting with investigators, coordinators, pertinent administrators and committee members. This meeting allows dialogue between the group to discuss issues that have occurred during the year and to review any revised or new guidelines. The CIC also encourages research staff to discuss any concerns they may have with the CIC Office Staff, the Chairman, and the Committee and to make constructive suggestions without compromising the integrity of the CIC process.

XXVII. Guidance on Recruitment of Human Participants through Advertising

Direct advertising for research participants, i.e. advertising that is intended to be seen or heard by prospective participants, are considered part of the informed consent and subject selection process. The aim of the Rochester Regional Health CIC is to ensure that the information is not misleading to participants.

This is especially important when a study may involve participants who are likely to be vulnerable to undue influence, for example financially constrained participants.

When direct advertising is to be used, the Rochester Regional Health CIC must review both the information contained in the advertisement and the mode of its communication. This is to determine that the procedure for recruiting participants is not coercive and that the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

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Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as “new treatment” or “new medicine” without explaining that the test article is investigational. A phrase such as “you will receive new treatments” incorrectly implies that all study participants will be receiving newly approved products of a 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.

If an investigator decides to begin advertising for participants after the study has received Rochester Regional Health CIC approval, the advertising may be considered as an amendment to the ongoing study. When such advertisements are easily compared to the consent, the Rochester Regional Health CIC will review and approve the advertisement using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

Generally, advertisements should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.

1. the name and address of the investigator and/or research facility (e.g. Rochester Regional Health) and the person or office to contact for further information;
2. The purpose of the research (e.g. the condition under study or goal of the project);
3. In summary form, the criteria that will be used to determine eligibility for the study;
4. The time or other commitments required of the participants; and
5. A brief list of participation benefits, if any (e.g. a no-cost health examination). Note, payments to participants for participation are not benefits, they are inducements. Advertisements may state that participants will be paid, but they should not emphasize the payment or the amount to be paid.

XXVIII. Data Safety and Monitoring Plan

Given the diversity of research protocols conducted at Rochester Regional Health, it is recognized that a Data Safety Monitoring Plan (DSMP) may not be applicable to all investigators and studies. The DSMP submitted with appropriate protocols will be written by the investigator and must answer the following questions:

1. What procedures will you use to monitor the participant’s safety throughout the study?
 - specify whether or not your study involves vulnerable participants
 - specify the name and contact information of the individual responsible for monitoring the safety environment of the participant (e.g. PI, Medical Monitor, Safety Officer, Independent Committee)
 - List the screening and interim procedures, tests, exams, questionnaires, etc. that will be used to screen out ineligible participants and/or monitor clinical performance.
 - Describe the QA procedure for monitoring toxicities, AEs, early drop outs or risky procedures
2. What are your methods of data collection and storage?

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- Indicate who is responsible for the collection and storage of data, where it will be stored, and any security measures needed to properly protect data from inadvertent loss or inappropriate use.
 - Describe the informed consent process and measures to ensure the privacy and confidentiality of study participants
3. Who will verify data accuracy and compliance with the protocol and how often will it be done?
 4. Who will monitor the occurrence of adverse events and where will they be documented?
 - Indicate the name and contact information of the individual responsible for monitoring the occurrence of adverse events throughout the study, whether they are anticipated, unanticipated, or serious.
 - Describe the frequency of monitoring procedures
 5. To whom and with what frequency will adverse events be reported?
 - include a description of the individual and/or entities to which expected and unexpected events will be reported and with what frequency
 - indicate that you will follow Rochester Regional Health Adverse Event Policy on mandatory reporting of SAE's
 - If a DSMB is required, describe the composition of the board, what role the board will play, and the frequency of the meetings. Confirm that the CIC, principal investigator and other appropriate entities will receive all reports of DSMB meetings and other aggregate data analyses that may be indicated
 6. What are the criteria for stopping the study all together?
 - include a description of how often interim data will be reviewed and by whom
 - specify any conditions that would necessitate early termination
 - indicate who will perform aggregate analyses

XXX: Confidentiality of Records HIPPA - Health Insurance Portability and Accountability Act (Data Privacy Statement)

As referenced from the OCR HIPPA Privacy TA 164.512I.001 dated 12/03/2002 (as applicable to research.)

Background

The HIPPA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. The Privacy Rule defines the means by which individuals will be informed of the uses and disclosures of their medical information for research purposes, and their rights to access information about them held by the covered entities. The Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensures that researchers continue to have access to medical information necessary to conduct vital research.

Protected Health Information (includes any of the following)

Names

Social Security Numbers

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Street address
Medical Records Numbers
Health Plan Numbers
Telephone/Fax numbers
E-mail address
Account Numbers
Vehicle identifier/Serial numbers
Certificate/License Numbers
Device identifier/Serial Numbers
IP address- (internet protocol address numbers)
URL's (web address)
DNA. Tissue Samples or any other materials that may contain identifiable characteristics
Full Face Photos
Biometric identifiers including finger and voice prints

Facilities can include any patient related dates or geographic subdivisions, such as zip codes, as part of the limited data set.

What does not require HIPPA accountability

- Screening charts for number of patients to get a sponsor to approve site
- Data Analysis part of research
- Patients consented prior to 4/14/2003

What does require HIPPA accountability

- Screen charts to enroll participants – charts need to have a signed authorization from a Department Chief to be reviewed
- Consents signed on or after April 14, 2003

For all Principal Investigators who are the first contact with the patient, the ‘Notice of Privacy Practices Acknowledgement’ form must be signed and included in the patients medical records. A copy of the Notice is available through the Rochester Regional Health Clinical Investigations Committee Office or through the Rochester Regional Health Intranet. A copy of the Privacy Practices statement is available through the Rochester Regional Health Hospital Admissions Department.

The following statement must be included in all consent forms either as part of the Confidentiality Section or as an Addendum to the Consent Form.

A. For all Sponsor supported research:

**Confidentiality of Records and HIPAA Authorization
(Data Privacy Statement)**

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A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to (“disclosed”) for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing the consent document for this study, you will give permission (“authorization”) for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you may not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor/investigator and staff will use your medical records and information created or collected during the study to conduct the study.
- The study doctor/investigator and staff will send your study-related health information (“study data”) to the sponsor of the study and its representatives (“sponsor”). Because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will represent the terms of this Data Privacy Statement in all countries.
- The study data sent by the study doctor/investigator to the sponsor does not include your name, address, social security number, or other information that directly identifies you. Instead, the study doctor/investigator assigns a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (e.g. date of birth). If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor/investigator.
- The investigator or sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs.

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- The investigator or sponsor may add your study data to data from other studies in research databases so that the investigator or sponsor can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the Rochester Regional Health Clinical Investigations Committee overseeing this study at Rochester Regional Health.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the Rochester Regional Health Clinical Investigations Committee overseeing this study at Rochester Regional Health, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.
- The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your study data in the same way as the sponsor.
- The investigator or sponsor will not disclose personal health information to insurance companies unless required to do so by the law, or unless you provide separate written consent to do so.
- Your medical records and study data may be held and processed on computers.
- **11/14** If research related procedures are performed within the Rochester Regional Health (RGH) (i.e. laboratory tests, imaging studies and clinical procedures), the results will be placed in your Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RGHS staff who are not part of the research team.

Your personal health information may no longer be protected by HIPAA privacy rule once it is disclosed by your study doctor/investigator to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor/investigator or Rochester Regional Health. However, to ensure the scientific integrity of the study, you

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will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing written notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. [The sponsor will still use study data that was collected before you cancelled your authorization.] If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

Your authorization for the use and disclosures described in this Data Privacy Statement does not have an expiration date.

Note: Any change to the statement, whether requested by the sponsor or as modified by the Principal Investigator must be reviewed and approved by the IRB Administrator prior to use.

B. For all Non-Sponsor supported research:

HIPAA Language for Non Sponsored Studies

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to (“disclosed”) for this research study. It also describes your privacy rights, including your right to see you personal health information.

By signing the consent document for this study, you will give permission (“authorization”) for the uses and disclosures of your personal health information that are described in the Data Privacy Statement. If you do not want to allow these uses, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor/investigator and staff will use your medical records and information created or collected during the study to conduct the study.

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- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities (e.g. the Food and Drug Administration) [list any other groups or organizations that may have access to PHI] and the Rochester Regional Health Clinical Investigation Committee overseeing this study at Rochester Regional Health.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by regulatory authorities and the Rochester Regional Health Clinical Investigation Committee overseeing this study at Rochester Regional Health. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.
- Your medical records and study data may be held and processed on computers.
- **11/14** If research related procedures are performed within the Rochester Regional Health (RGH) (ie laboratory tests, imaging studies and clinical procedures) the results will be placed in your Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RGHS staff who are not part of the research team.

Your personal health information may no longer be protected by the HIPAA privacy rule once it is disclosed by your study doctor/investigator to other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor/investigator or Rochester Regional Health. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed.

You may cancel your authorization at any time by providing notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

Your authorization for the use and disclosures described in this Data Privacy Statement does not have an expiration date.

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Note: Any change to the statement, whether requested by the sponsor or as modified by the Principal Investigator must be reviewed and approved by the IRB Administrator prior to use. Any questions regarding HIPPA requirements may be directed to the IRB Administrator.

XXXI. External Institutional Review Board

National Cancer Institute Central IRB

Rochester Regional Health has an agreement to utilize the National Cancer Institute Central Institutional Review Board for Phase III Oncology Studies.

The CIC Chairman has the authority to approve additions to the protocol or word substitutions in the informed consent. The CIC has the option to accept the CIRB approval as written, accept it with minor modifications or decide not to accept the CIRB review and require that the investigator submit the protocol for full board review. If the CIC Chairman accepts the protocol it will be reported to the Committee as an Administrative Approval.

As part of this review by the CIRB, the CIC may add stipulations or local requirements to protocols, particularly to increase participant's safety, to clarify procedures, etc., but may not delete or contradict any protocol contents.

The CIRB will setup a database both for record keeping and notification purposes. The CIRB will notify the CIC when there are any actions taken on the protocol, e.g. an SAE report requiring a change in the consent form, an approved protocol amendment, a change in the protocol/informed consent resulting from the continuing review, etc. For studies approved by the CIRB process, the IRB of record is the CIRB of the NCI and not the Rochester Regional Health CIC.

5/17 Central IRB

Rochester Regional Health may utilize Central IRB when reviewing sponsor research. Reference standard operating procedures on minimal and greater than minimal risk when utilizing an external IRB

Staff involved in the conduct of the study must complete human subject protection training.

As part of this review by CIRB, the CIC may add stipulations or local requirements to protocols, particularly to increase participant's safety, to clarify procedures, etc but may not delete or contradict any protocol contents. Boilerplate language must be inserted into the consent forms.

Boilerplate language is in bold and italic

From Basic Elements of the Informed Consent

1) The first page of the consent form must be printed on letterhead appropriate for the Rochester Regional Health affiliate or practice site of the principal investigator.

2) Number of participants anticipated to be enrolled locally

The number of participants anticipated to be enrolled locally in the study must be listed in the consent form.

3) Conflict of Interest Statement

The investigators at Rochester Regional Health do not receive any direct payment from the sponsor for the conduct of this study. However, a per patient payment is received by Rochester Regional Health to cover research expenses.

4) HIPPA Statement

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Data Privacy Statement explains how your personal health information will be used and who it will be given to (“disclosed”) for this research study. It also describes your privacy rights, including your right to see your personal health information. By signing the consent document for this study, you will give permission (“authorization”) for the uses and disclosures of your personal health information that are described in this Data Privacy Statement. If you do not want to allow these uses, you may not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- ***The study doctor/investigator and staff will use your medical records and information created or collected during the study to conduct the study.***
- ***The study doctor/investigator and staff will send your study-related health information (“study data”) to the sponsor of the study and its representatives (“sponsor”). Because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will represent the terms of this Data Privacy Statement in all countries.***
- ***The study data sent by the study doctor/investigator to the sponsor does not include your name, address, social security number, or other information that directly identifies you. Instead, the study doctor/investigator assigns a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (e.g. date of birth). If***

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you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor/investigator.

- *The investigator or sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs.*
- *The investigator or sponsor may add your study data to data from other studies in research databases so that the investigator or sponsor can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.*
- *Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, doctors at other institutions participating in the study, and the Rochester Regional Health Clinical Investigations Committee overseeing this study at Rochester Regional Health.*
- *Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions.*
- *Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the Rochester Regional Health Clinical Investigations Committee overseeing this study at Rochester Regional Health. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law.*
- *The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners signs a contract that requires it to protect your study data in the same way as the sponsor.*
- *The investigator or sponsor will not disclose personal health information to insurance companies unless required to do so by the law, or unless you provide separate written consent to do so.*
- *Your medical records and study data may be held and processed on computers.*
- *If research related procedures are performed within the Rochester Regional Health (RRH) (i.e. laboratory tests, research imaging studies and clinical procedures), the results will be placed in your Electronic Medical Record (EMR). Once placed in your EMR, results are accessible to appropriate RRH staff who are not part of the research team.*

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor/investigator or Rochester Regional Health. However, to ensure the scientific integrity of the study, you will not be able to review some of the study information until after the study has been completed. You may cancel your authorization at any time by providing written notice to the study doctor/investigator. If you cancel your authorization, the study doctor/investigator and staff will no longer use or disclose your personal health information in connection with this study, unless the study doctor/investigator or staff needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. [The sponsor will still use study data that was collected before you cancelled your authorization.] If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any

benefits to which you are otherwise entitled. Your authorization for the use and disclosures described in this Data Privacy Statement does not have an expiration date.

5) For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained. In addition the following paragraph shall be included for research being done completely or in part at RRHS:

“Rochester Regional Health, in fulfilling its public responsibility, has provided professional liability insurance coverage and will be responsible for any injury only in the event such injury is caused by the negligence of Rochester Regional Health.”

6) Contact Persons

An explanation of whom to contact for answers to pertinent questions about the research and research participant’s rights, and whom to contact in the event of a research-related injury to the participant. The consent form must address three (3) areas for participant’s questions namely, questions about the research itself, questions about research related injury and questions about the participant’s rights. Examples of acceptable wording for this section:

“For more information concerning this research you should contact (Principal Investigator’s name) at (telephone number).”

“If you believe that you may have suffered a research related injury, contact (Principal Investigator’s name) at (telephone number) who will give you further instructions.”

“If you have any questions about your rights as a research participant, you may contact the IRB Administrator of the Rochester Regional Health Clinical Investigation Committee at (585)-922-5640.”

7) Signature Page Requirements

The Rochester Regional Health Clinical Investigations Committee requires that a consent form provide a place for the printed name and signature of the person obtaining consent, the patient/participant, and a witness. The requirement of a witness is not required by federal regulations; however the Rochester Regional Health CIC requires this signature for all research with greater than minimal risk to study participants. The intent of the witness is to acknowledge that the participant is giving their consent freely and without reservation, the witness does not need to be present for the entire informed consent process. The witness must be an individual not directly involved in the conduct of the study. For studies meeting the definition of minimal risk, the requirement of a witness signature is waived. If a sponsor or funding agency has more stringent requirements for the participation of the witness during the informed consent process, that will be acceptable to the Clinical Investigations Committee

The following wording is recommended for the signature portion of the consent form:

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Person Obtaining Consent

I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Print Name

Signature

Date

Participant/Patient Representative

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I will receive a signed copy of this form for my records and future reference.

Patient Name (Print)

Signature

Date

Patient Representative (Print)

Signature

Date

Relationship if other than the participant: _____

If the study is greater than minimal risk, a witness must sign the consent form

Witness

The participant has indicated to me that the research has been explained to the participant, that the participant has read (or had read to the participant) this consent form, and that all of the participant's questions have been answered. In my judgment, the participant is voluntarily signing this consent form. ***Note – the witness can't be anyone involved in the study***

Witness Name (Print)

Signature

Date

XXXII. Reference: Section IV Committee Review: A) Full Board Review: Primary Reviewer Form

If a PR feels that an item “needs discussion” or has a specific issue related to their review (other than minor typographical errors), these items must be brought to the attention of the committee during the review.

Even if these issues are noted on the PR Form, if these issues are not presented to the committee, the Principal Investigator cannot be requested to address the issue or make changes to the consent/protocol.

If there is discovery of a significant issue requiring re-review and vote by the committee, the PI would be required to address the issue prior to final approval. If this occurs, the three month window for completing requested changes would start from the latest review.

Requested changes or notes made by the PR directly pertaining to the review, including any typographical errors for formatting modifications should be noted on the PR’s copy of the ICF (or if more convenient in a document addressed to the CIC) which should be returned with the PR Form to the CIC office for reference and filing.

XXXIII. Rochester Regional Health Human Research Protection Program Website

To access to the website from within Rochester Regional Health, log on to the RGHS intranet home page then click on the Rochester Regional Health.org, then go to clinical trials

From outside of Rochester Regional Health, go to www.Rochester Regional Health.org and follow the above prompts

Any questions concerning the site should be directed to the Rochester Regional Health Research Protection Office at (585) 922-5640.

Specific content areas of the website include:

- Contact Information
- Updates and Information
- Application for New Protocol Review
- Continuing Review Forms
- Other Forms/Templates
- Certifications
- References

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Beginning 12/2004, all submissions should only be on forms downloaded from the website or those sent by the Research Protection Office.

XXXIV. Incentives and Paying Research Subjects

The CIC will not approve research projects involving chances such as raffles or drawings for prizes.

Incentives (such as gift cards) must be equal and provided to all subjects. Incentives may not be given if the subjects perceive the incentive as a reward for the quality of performance.

Subjects may be paid for inconvenience, time spent, and as reimbursement for expenses. Subjects may not be paid relative to the potential risks of study participation, nor for the amount or nature of a biological material that may be collected as part of the research procedures. Payments should not be judged to be so large as to potentially induce prospective subjects to consent to participate in the research against their better judgment regarding the clinical benefits and risks of participation.

XXXV. Roswell Park Cancer Institute Institutional Review Board

Rochester Regional Health has an agreement to utilize the Roswell Park Cancer Institute Institutional Review Board for Investigator Initiated Oncology Studies.

Rochester Regional Health has designated 2 staff members to be part of the Roswell Park Cancer Institute Institutional Review Board. This RGHS member has input into the scientific and informed consent approval and is a voting member of the RPCI IRB. If the study is approved by RPCI IRB and the RGHS designee accepts the protocol, it will be reported to the CIC Committee as an Administrative Approval. If the RGHS designee has reservations about the study despite approval by the RPCI IRB, the designee will recommend the RRHS investigator involved in the RPCI follow the procedure for investigator appeals process.

As part of this review by the Roswell Park Cancer Institute, the CIC may add stipulations or local requirements to consents, particularly to increase participant's safety, to clarify procedures, etc., but may not delete or contradict any protocol contents.

For studies approved by the Roswell Park Cancer Institute process, the IRB of record is Roswell Park Cancer Institute Institutional Review Board of the NCI and not the Rochester Regional Health CIC.

Rev. 09/2002, 02/2003, 11/2003, 01/2004, 01/2005, 12/2005, 12/2006, 12/2007, 12/2008
12/2009, 7/2011, 1/2012, 1/2013, 1/2014, 1/2015, 1/2016, 1/2017

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XXXVI. Signature Page

Print	Signature	Date
James R. Cronmiller, MA Chair Rochester Regional Health Clinical Investigation Committee		

By signing below, I indicate that I have read these Policies and Procedures for the Rochester Regional Health Human Research Protection Program which defines the activities and responsibilities of the Clinical Investigations Committee. I have been provided a copy of these Policies and Procedures for my records.

Name of Committee Member or Alternate

Print	Signature	Date
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Board: _____