

CVMC Administrative Policy & Procedure

APPROVALS	
Committee	Date
Leadership Council	04/09/2014
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Section	Patient Rights & Organizational Ethics
Policy No.	RI-20
Pages	18
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**SUBJECT: INSTITUTIONAL REVIEW BOARD**

**RI-20-I. PURPOSE & SCOPE**

Catawba Valley Medical Center (CVMC) respects its patients, their rights, and the confidentiality of their medical information in human subjects research. The Institutional Review Board (IRB) reviews research and clinical investigations/trials that are proposed to be conducted at CVMC involving subjects who are currently, have been, or could by study design become patients of CVMC or its subsidiaries and/or subjects who are currently or have been CVMC employees. The IRB acts in accordance with the ethical principles of respect for persons, beneficence, and justice in its review and monitoring of human subject research.

**RI-20-II. FUNCTIONS**

The IRB complies with the Code of Federal Regulations (CFR) as outlined in 45 CFR 46 and 21 CFR 50 & 56 in review and monitoring of proposed research and clinical investigations/trials:

- A. Approves, modifies or disapproves proposed research covered by this policy and notifies investigators of its decision(s) in writing.
- B. Requires documentation of informed consent or waives documentation of consent or waives securing subject consent.
- C. Conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.
- D. Requires that any change(s) to previously approved research be submitted by the investigator to the IRB with the stipulation that changes cannot be implemented prior to review, approval and written notification of approval of the changes.
- E. Requires unanticipated problems and unanticipated adverse events with untoward risk to the subject be reported by the investigator to the IRB Chair in a timely fashion.
- F. Exercises the right to suspend or terminate approved research that is not being conducted in accordance with IRB requirements.

**RI-20-III. STRUCTURE**

A. Board Composition

Designed to be diverse in membership and fair in execution of its duties, the IRB has a minimum of five members with varying backgrounds to promote thorough review of research commonly conducted at CVMC.

1. Membership includes:
  - a. At least one member whose primary concerns are in scientific areas.
  - b. At least one nonscientific member.
  - c. At least one member who is not otherwise affiliated with CVMC.

- d. Representation from more than one gender.
  2. The IRB may at its discretion invite individuals with competence in specialized areas to assist in the review of research, when expertise beyond that of its members is required.
  3. Alternate members may be appointed to serve in the absence of appointed members with similar expertise. The alternate serves in all capacities of IRB membership during the absence of the appointed member. An alternate's vote will not count toward the quorum if the appointed member they represent is also
- B. Convened Meetings
1. Meetings are scheduled quarterly.
  2. Additional meetings are scheduled at the discretion of the IRB Chair.
  3. Teleconferences are acceptable provided each participating IRB member has received all pertinent material prior to the call and can actively and equally participate in the discussion. Satisfaction of these conditions will be documented in the meeting minutes.
  4. In the absence of agenda items that require a vote of the IRB, scheduled meetings may be cancelled, but at least one meeting will be held annually.
  5. Investigators attend meetings upon request of the IRB Chair. However, they are dismissed prior to the IRB acting on their research which is under review.
- C. Research Review
1. Except when an expedited review procedure is used, the IRB reviews proposed research at convened meetings at which a majority of IRB members are present, including at least one nonscientific member, i.e., a quorum.
  2. In order for research to be approved, it must receive a majority vote of this quorum. Should the quorum fail during a meeting (e.g., through recusal of members with conflicting interests, early departures, etc.), the IRB cannot take further action, i.e. vote, unless the quorum is restored.
  3. No member participates in initial or continuing review of research in which the member has a conflicting interest, except to provide information as requested by the IRB.
- D. Administrative Relationships
1. The IRB reports to the organization's Patient Rights Council (PRC) any unanticipated problems and unanticipated adverse events (RI-20-V.E) of which investigators inform the IRB.
  2. Information reports to the PRC, provided upon request, include, but are not limited to, number of active research studies and board member education compliance.

#### **RI-20-IV. ROLES & RESPONSIBILITIES**

##### **A. Chair**

1. Elected every two years by majority vote of the IRB membership, the Chair may serve unlimited successive terms.
2. Duties:
  - a. Presides at meetings of the IRB;
  - b. Implements IRB policies and procedures;
  - c. Distributes the agenda and research proposal documents to IRB members in advance of scheduled meetings;
  - d. Ensures that appropriate documentation of IRB proceedings and business occurs;

- e. Appoints subcommittees as deemed appropriate;
  - f. Represents the IRB to investigators and serves as their direct IRB contact.
- B. Vice Chair
- 1. Elected every two years by majority vote of the IRB membership, the Vice Chair may serve unlimited successive terms.
  - 2. Duties:
    - a. Presides at meetings of the IRB at the request of the Chair;
    - b. Assists the Chair in conducting the business of the IRB as needed.
- C. Members
- 1. Appointed by the IRB Chair for a two-year term, members may serve unlimited reappointments.
  - 2. Duties:
    - a. Review research proposal documents in advance of IRB meetings;
    - b. Vote to approve, disapprove or modify proposed research;
    - c. Comply with competence requirements;
    - d. Attend at least 75% of convened meetings in any given year – failure to do so may serve as grounds for dismissal from the IRB.
- D. Protecting Human Research Participants (PHRP) Education
- 1. Members are required to complete basic education in human subjects protection prior to beginning service on the IRB.
  - 2. Member PHRP completion certificates are held in the permanent records of the IRB.
  - 3. IRB members complete PHRP education on a continuing basis to maintain and extend their competence at a minimum of biannually.
  - 4. PHRP education may be accomplished by participating in any of the following:
    - a. National Institutes of Health (NIH) Office of Extramural Research Protecting Human Research Participants;
    - b. Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) Human Subject Assurance Training;
    - c. Collaborative Institutional Training Initiative (CITI) courses;
    - d. Education equivalent to or exceeding a-c is required for initial PHRP training;
    - e. Continued PHRP proficiency may be fulfilled by participating in OHRP online tutorials/webinars, conferences, and/or in-service education opportunities.
- E. Orientation
- 1. The Chair or his/her designee conducts member orientation.
  - 2. Members receive and review IRB policy and procedures.
  - 3. Prior to assuming duties, members must provide evidence of completed PHRP education.
- F. Liaison
- 1. CVMC Patient Care Administration designates the Liaison.
  - 2. Duties:
    - a. Records minutes of IRB meetings as described in RI-20-VI.B.;
    - b. Provides correspondence to investigators delineating IRB actions;
    - c. Maintains the master study listing;
    - d. Informs investigators of progress reports due dates prior to the due dates;
    - e. Reserves meeting dates and locations;

- f. Maintains the permanent files of the IRB.

## **RI-20-V. PROCEDURES**

### **A. Research Review**

1. The standard application form, which is required for submission, is available at <http://irb.catawbavalleymedical.org/>. Certain supporting documents are required to constitute a complete research application, e.g., PHRP certificate. Initially, applications are submitted by the investigator to the Director for Research and Evidence-Based Practice. The Director communicates with the investigator as needed to ensure the application is complete. The investigator then submits his/her signed application to the IRB Chair or Vice Chair electronically.
2. In approving research, the IRB determines the following criteria are satisfied:
  - a. Risks to subjects are minimized:
    - (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    - (ii) Whenever appropriate, procedures already being performed on the subjects for diagnostic or treatment purposes are utilized;
  - b. Risks to subjects are reasonable in relation to anticipated benefits, if any;
  - c. Selection of subjects is equitable;
  - d. Informed consent is sought from each prospective subject or his/her legally authorized representative and the consent documented unless waiver of documentation or waiver of consent applies;
  - e. Adequate provisions are made to protect the privacy of subjects and to maintain confidentiality of the data; and
  - f. Additional safeguards are included in the research to protect the rights of subjects likely to be vulnerable to coercion or undue influence, e.g. children, prisoners, pregnant women, mentally disabled persons, etc.; when such subjects are being recruited for the research in accordance with applicable regulations.
3. HHS Decision Charts (<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>) are utilized by the IRB Chair to determine whether the proposed research qualifies as exempted from review, qualifies for expedited review, or requires full board review, and they are used by IRB members in their review of proposed research.

### **B. Review Categories**

1. Exempted from Review
  - a. Research which presents no foreseeable risks to subjects may qualify for exemption from IRB review. In order to adequately protect the rights of human subjects, the IRB shall make determinations of exemption for proposed research.
  - b. The investigator is informed in writing when his/her proposed research qualifies as exempt from IRB review noting that exemption does not necessarily negate obtaining informed consent from subjects.
2. Expedited Review
  - a. The IRB uses expedited procedures to review:
    - (i) Applicable research (<http://www.hhs.gov/ohrp/policy/expedited98.html>) involving no more than minimal risk, and
    - (ii) Minor changes in previously approved research during the period for which approval is authorized.
  - b. Expedited review is conducted by the IRB Chair or by his/her designee.

- c. Expedited reviewers exercise the authorities of the IRB except that they may not disapprove the research under review.
  - d. Documentation for initial and continuing reviews conducted under an expedited review procedure includes the specific category justifying the expedited review in the written investigator communication.
  - e. The Chair keeps all IRB members advised of research proposals, approved via expedited review.
3. Full Board Review
    - a. Proposed research, not qualifying for expedited review, is reviewed at a convened meeting of a quorum of the IRB.
    - b. The IRB designates the level of risk posed to human subjects as required by federal regulations. Research deemed to be of minimal risk is reviewed annually. Research deemed to constitute more than minimal risk to subjects is reviewed every six months at a minimum or more frequently at the discretion of the IRB. See RI-20-VIII. for risk definitions.
- C. Types of Review
1. Initial Review
    - a. Commences upon receipt of a complete research application, to include:
      - (i) full research protocol;
      - (ii) proposed informed consent document or consent waiver request;
      - (iii) recruitment materials, including advertisements intended to be seen or heard by potential subjects;
      - (iv) PHRP completion certificate(s); and
      - (v) evidence of current HIPPA compliance.
    - b. The research may be reviewed under expedited or full board procedures.
  2. Continuing Review
    - a. The IRB conducts continuing review of approved research at least annually, which provides an opportunity to reassess the totality of the study and assure that risks to subjects are being minimized and are still reasonable in relation to anticipated benefits, if any, to the subjects. More frequent continuing review occurs when dictated by the degree of risk associated with the research.
    - b. When conducting continuing review, the IRB begins with the working assumption that the research, as previously approved, satisfies the criteria for approval [RI-20-V.A.2.]. The IRB then focuses on whether any new information, provided by the investigator, alters prior determinations, particularly with respect to its prior evaluation of the potential benefits and/or risks to the subjects, and assesses whether any new information necessitates revision of the study protocol and/or the informed consent document.
    - c. Continuing IRB review is preceded by receipt of a written progress report from the investigator to include, but not limited to, the number of subjects enrolled, number of withdrawn subjects and reasons for withdrawal, results to date, current risk-benefit assessment, and any new pertinent information since the last IRB review. A copy of the consent document, currently in use by the investigator, must be appended to the progress report unless consent has been waived. The progress report form is available at <http://irb.catawbavalleymedical.org/>.
  3. Cooperative Review

- a. Cooperative research projects covered by this policy are those that involve more than one institution or organization. When CVMC participates in cooperative research, the IRB may:
    - (i) Enter into a joint review arrangement with another institution; or
    - (ii) Rely upon the review of another qualified IRB.
  - b. When relying on another IRB, the IRB ensures that the reviewing IRB's Federal wide Assurance (FWA) is active. A formal IRB Authorization Agreement will be executed between the two entities, and the signed document retained in the permanent files of the IRB.
  - c. Regardless of the IRB's arrangement decision, it recognizes it is still responsible for safeguarding the rights and welfare of CVMC human subjects.
  - d. When making cooperative research decisions, the IRB reviews a copy of the approved research application to include, but not limited to, the full protocol, informed consent document(s), and external IRB approval letter.
- D. Protocol Changes
1. Review of Protocol Changes
    - a. The investigator is responsible for submitting any amendment(s) to his/her approved study prior to implementing the desired change(s) using a standard form (<http://irb.catawbavalleymedical.org/>).
    - b. Protocol changes are to be incorporated into the approved protocol and a revised protocol submitted to the IRB with a file name indicating the revision number. This ensures there is only one complete protocol with the revision date(s) noted on the protocol itself. The same procedure is used for revised and approved informed consent documents which then supersede the previous one(s).
    - c. The IRB evaluates protocol changes submitted by the investigator using the same review criteria required at initial review. Minor changes may qualify for expedited review [RI-20-V.B.2 (ii)].
    - d. The IRB will evaluate if the protocol change(s) alters the risk to human subjects involved in the research. If the amendment increases the risk, the IRB will alter the continuing review period accordingly.
- E. Reporting of Unanticipated Adverse Events and Unanticipated Problems
1. Adverse Events

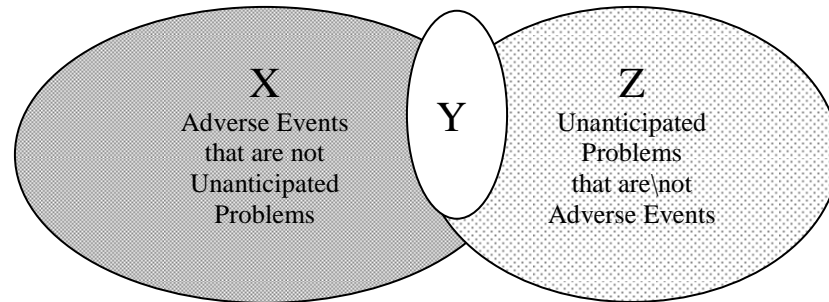
Although there is no common definition of adverse event across government and non-government entities, the following broad definition is used by the IRB.

    - a. Broadly defined, an adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.
    - b. Adverse events encompass both physical and psychological harms.
    - c. They occur most commonly in the context of biomedical and clinical research, but can occur in the context of social and behavioral research.
    - d. In the context of multicenter trials, adverse events can be categorized as either internal adverse events or external adverse events
      - (i) Internal adverse events: those experienced by subjects enrolled by the investigator at CVMC.
      - (ii) External adverse events: those experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.
  2. Unanticipated Problems

Any incident, experience, or outcome meeting all of the following criteria is defined as an unanticipated problem:

- a. Unexpected (in terms of nature, severity, or frequency) given
    - (i) the research procedures that are described in the previously approved study protocol and informed consent document; and
    - (ii) the characteristics of the subject population being studied;
  - b. Related or possibly related to a subject's participation in the research; and
  - c. Suggesting that the study places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
3. How to Determine if an Adverse Event represents an Unanticipated Problem
- a. Ask the following three questions:
    - (i) Is the adverse event unexpected?
    - (ii) Is the adverse event related or possibly related to participation in the research?
    - (iii) Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?
  - b. If the answer to **all** three questions is yes, then the adverse event is an unanticipated problem.
4. Reporting of Unanticipated Problems and Unanticipated Adverse Events
- Unanticipated problems involving risks to subjects or others and adverse events that are unanticipated must be reported by the investigator as follows:
- a. The investigator is responsible for reporting unanticipated problems and unanticipated adverse events within 24 hours to the IRB Chair or his/her designee by phone or email and in writing to the IRB within in seven days. When appropriate, the investigator reports the unanticipated problem or unanticipated adverse event to HHS and to the CVMC Compliance Officer.
  - b. The IRB reviews reports of unanticipated problems and unanticipated adverse events in accordance with guidance provided by federal agencies.

Example of an unanticipated problem not classified as an adverse event that is reportable to the IRB: An investigator conducting behavioral research collects individually identifiable sensitive information about illicit drug use and other illegal behaviors by surveying college students. The data are stored on a laptop computer without encryption, and the laptop is stolen from the investigator's car. This is an unanticipated problem that must be reported because the incident was (1) unexpected, i.e., the investigator did not anticipate the theft; (2) related to participation in the research; and (3) places the subjects at a greater risk of psychological and social harm, than was previously known or recognized, from this breach in confidentiality of the study data.
  - c. The relationship between adverse events and unanticipated problems is shown in the following figure. Investigators must report 'Z' (unanticipated problems) and 'Y' (unanticipated adverse events); however, they do not report 'X' (anticipated adverse events) to the IRB.



Y: Adverse Events that are  
Unanticipated Problems

#### F. Informed Consent

A hallmark of ethical human subject research is its voluntary nature. In most instances, voluntary participation of subjects is obtained by securing their informed consent. The IRB reviews proposed research consent documents per the following guidelines:

##### 1. General

- a. Information is conveyed in language that is understandable to the subject.
- b. Consent does not include any exculpatory language, e.g., subjects cannot be forced to give up legal rights or be given the impression that they are being asked to do so.

##### 2. Basic Elements

- a. A statement that the activity involves research.
- b. An explanation of the purposes of the research.
- c. The expected duration of the subject's participation.
- d. A description of the procedures to be followed.
- e. Identification of the procedures which are experimental.
- f. A description of any reasonably foreseeable risks or discomforts to the subject.
- g. A description of any benefits to the subject or others which may reasonably be expected from the research.
- h. Disclosure of appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the subject.
- i. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- j. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatment is available if injury occurs and if so, what it may consist of or where further information may be obtained.
- k. Who to contact for pertinent questions about the research, human subjects' rights, and in the event of a research-related injury. This human rights statement is to be included: "The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have any questions concerning your rights as a subject, email the Chair of the IRB at [irb@catawbavalleyinc.org](mailto:irb@catawbavalleyinc.org)." When subjects are being consented for registered clinical trials, include the following statement: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web



site will include a summary of the results. You can search this Web site at any time.”

1. A statement that participation is voluntary and refusal to participate will not result in penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at anytime without penalty or loss of benefits to which he/she is otherwise entitled.
3. Additional Elements (as appropriate)
  - a. A statement that the particular treatment/procedure may involve risks to the subject, or to an embryo or fetus, if the subject is pregnant or may become pregnant, that are currently unforeseeable;
  - b. Anticipated circumstances under which a subject’s participation may be terminated by the investigator without regard to the subject’s consent;
  - c. Any additional costs to the subject that may result from participation;
  - d. The consequences of the subject’s decision to withdraw from the research and the procedures of orderly termination of participation by the subject;
  - e. A statement that significant new findings developed during the course of the research, which may be related to the subject’s willingness to continue participation, will be provided to the subject;
  - f. The approved number of subjects involved in the study.
4. Consent for Children and Assent of Minors  
Parents or Guardians must consent for their children to participate in research in most cases. The IRB requires that the assent of a child subject is sought, if in its judgment the child is capable of making an informed decision about participating in the research. See RI-20-VIII. for definitions of child and minor in North Carolina.
5. Emancipated Minors  
In North Carolina, an emancipated minor may consent to medical or hospital care and/or treatment for themselves and for their children [CVMC RI-12]. The decree of emancipation must be provided to the investigator prior to consenting the emancipated minor as a subject in research except as described below. See RI-20-VIII for the definition of an emancipated minor.
6. Exceptions Involving Minors  
The General Statutes of the State [90-21.5] provide for a minor to legally consent to certain clinical services. For the proposed research, if the involvement of human subjects consists of the following interventions or interactions [CVMC RI-12], then minors may be considered adults for this purpose:
  - a. A minor may consent for treatment of sexually transmitted disease or for alcohol or drug abuse.
  - b. An unwed pregnant minor may consent to medical or surgical procedures relating to her pregnancy.
  - c. A minor mother may consent to the performance of medical or surgical care or services for her child.
- G. Consent Waiver Request  
The IRB may approve consent procedures that do not include, or which alter, some or all of the elements of informed consent, may waive the requirement to obtain written documentation of consent, or may waive obtaining informed consent from human subjects.
  1. Waiver of Documentation of Consent  
The IRB may waive the requirement for written documentation of consent in cases where:

- a. The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research and the consent document is the only record linking the subject with the research. In such cases, each subject will be asked if they want documentation to remain with them or with the research records and the subject's wishes will govern.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
2. Waiver or Alteration of Informed Consent  
Informed consent may be waived provided the IRB finds and documents that **ALL** of the following conditions have been met:
  - a. The research involves no more than minimal risk to the subjects;
  - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - c. The research could not practicably be conducted without the waiver or alteration; and
  - d. Whenever appropriate, the subjects will be debriefed, i.e., provided with additional pertinent information, after they have participated in the study.
- H. Suspension or Termination of IRB-Approved Research
  1. The IRB is authorized to suspend or terminate approval of research:
    - a. That is not being conducted in accordance with the IRB's requirements; or
    - b. That has been associated with unexpected serious harm to subjects.
  2. When suspension or termination action is taken, the IRB promptly reports its action to the investigator in writing including the reason(s) for the action.
- I. Withdrawn Research  
In the case a research application is submitted to the IRB for review and the investigator decides against conducting the study, he/she is required to inform the IRB.
  1. If the study was never approved, the IRB will document its withdrawal.
  2. If the study was approved, the IRB will document its closure.

## **RI-20-VI. DOCUMENTATION & RECORDS**

- A. Documentation of Findings
  1. Documenting Risk and Approval Period IRB determination regarding the risk associated with the proposed research and the approval period, are documented in the:
    - a. Minutes; and
    - b. Investigator correspondence.
  2. Specific findings are documented per federal regulations:
    - a. Approving a procedure which waives the requirement for obtaining a signed consent form, or alters informed consent required elements, or waives obtaining informed consent from subjects;
    - b. Approving research involving pregnant women, human fetuses, or neonates;
    - c. Approving research involving prisoners;
    - d. Approving research involving children.
  3. Method of obtaining informed consent for approved research is documented as:
    - a. Use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative; or

- b. Use of oral consent utilizing the written consent; or
  - c. Use of a short form document.
  4. IRB full board review findings and decisions are documented in the minutes and in written communication with the investigator.
  5. IRB findings and decisions regarding research reviewed under expedited review procedures are documented in the minutes and in written communication with the investigator.
  6. For proposed studies qualifying as exempt from human subjects regulations and thus IRB review, the IRB documents the justification for its decision including the specific exemption category in its written communication with the investigator.
- B. IRB Records**
1. Investigator submitted documents, e.g. research applications, , progress reports, protocol amendments, and/or reports of unanticipated problems and/or adverse events as well as statements of significant new findings that are provided to subjects by investigators become IRB records upon submission.
  2. The IRB prepares and maintains documentation of its activities, to include:
    - a. Minutes of the IRB meetings in sufficient detail to show:
      - (i) Attendance to include which members, if any, were present via conference call and that the criteria for a member's participation in this manner have been satisfied;
      - (ii) Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB to include the basis for requiring changes in or disapproving the research; and a summary of the discussion of controversial issues and their resolution;
      - (iii) The vote on all IRB actions including the number of members voting for, against, abstaining and recusal, if applicable.  
Examples of an acceptable format for documenting votes on actions taken by the IRB follow:  
Total = 15; Vote: For-14, Opposed-0, and Abstained-1  
Total = 14 (1 member rescued-provide name); Vote: For-12, Opposed-2.
    - b. IRB-investigator correspondence
    - c. Official documents of the IRB, e.g., FWA
    - d. Written IRB policy and procedures.
  3. IRB records are retained for at least three years electronically.
  4. All records are accessible for inspection and copying by authorized representatives of HHS and FDA at reasonable times and in a reasonable manner.

**RI-20-VII. INVESTIGATOR GUIDELINES**

- A. Research Application Components**
1. Full research protocol submitted utilizing the standard application form, which along with instructions and other forms are available at <http://irb.catawballeymedical.org/>;
  2. Proposed informed consent document(s) or consent waivers request form, and if applicable foreign language consent and translation certificate and/or equivalent;
  3. Relevant funding information, if existent;

4. Recruitment materials/advertisements intended to be seen or heard by potential subjects;
  5. Human subjects protection education completion certificate/record;
  6. Evidence of current Health Insurance Portability and Accountability Act (HIPAA) compliance;
  7. Additional documents as indicated on the application as appropriate for the research proposal being submitted.
- B. Investigator Responsibilities
1. Complete human subjects protection education and HIPPA education.
  2. For FDA-registered clinical trials, study sponsor training is required for investigator(s) and appropriate study personnel. Good Clinical Practice (GCP) training is desirable for clinical trial personnel.
  3. Assure the proposed consent form conveys information in language understandable to the subject, does not contain any exculpatory language, contains all the basic elements of informed consent and any additional elements (<http://www.hhs.gov/ohrp/policy/consentckls.html>) as appropriate. If waiver of informed consent or waiver of documentation of informed consent is desired, then submit an IRB consent waiver request. If the research involves children, submit a parent or guardian consent form and a child assent form if the child is capable of making an informed decision about participating in the research.
  4. Include the following human rights statement in your consent form: “The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have any questions concerning your rights as a subject, email the Chair of the IRB at [irb@catawbavalleymc.org](mailto:irb@catawbavalleymc.org).” When subjects are being consented for registered clinical trials, include the following statement: “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
  5. Submit your research application to the Director for Research and Evidence-Based Practice for review prior to submission to the IRB.
  6. Following communication from the Director for Research and Evidence-Based Practice that your research application is ready for submission to the IRB, submit a complete signed research application to the IRB Chair.
  7. Attend convened meetings of the IRB if requested by the Chair.
  8. Ensure each subjects understanding of the research and informed consent.
  9. Provide subjects with a copy of the signed, dated and witnessed consent form; when appropriate, place a copy of the signed, dated and witnessed consent form on the subject’s medical record; and keep the original signed, dated and witnessed consent form in your research records.
  10. Submit progress reports as outlined by the IRB prior to expiration of your research study approval period. A standard form is provided at <http://irb.catawbavalleymc.org/>.
  11. Ensure records related to conduction of the research are retained for at least three (3) years following completion of the research.
  12. Submit changes in the approved study protocol to the IRB Chair using a standard form provided at <http://irb.catawbavalleymc.org/>. Incorporate changes in your approved protocol and submit the revised protocol to the IRB with a file name indicating the revision number. The same procedure is used for submitting revisions to the informed consent form. Implement the changes only following written notification delineating subsequent IRB approval of the changes.

13. Report unanticipated problems and unanticipated adverse events if they occur during the course of the research to the IRB Chair by email or phone within 24 hours and in writing within 7 days. The report is to include a complete description of the problem or event, your assessment and basis for the assessment of whether the problem or event is study-related, and a statement addressing whether the research protocol or consent needs to be altered as a consequence of the problem or event. Refer to the Reporting of Unanticipated Adverse Events and Unanticipated Problems section of this policy [RI-20-V.E.] for determining what constitutes reportable unanticipated problems and unanticipated adverse events.
14. If for any reason the IRB suspends or terminates your approved research, you must abide by the IRB's decision and immediately cease research activity.
15. Should you decide against following through with research submitted to and/or approved by the IRB, you must inform the IRB of your intentions. A standard form is provided at <http://irb.catawbavalleymc.org/>.

## **RI-20-VIII. DEFINITIONS**

*Research-* systematic investigation designed to develop or contribute to generalizable knowledge

*Human Subject-*

- a. a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [OHRP definition]
- b. an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy participant or a patient. [FDA definition]

*Intervention-* physical procedures by which data are gathered and/or manipulation of the subject or subject's environment performed for research purposes

*Interaction-* communication or interpersonal contact between investigator and subject

*Private information-* information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. a medical record. *Private information must be individually identifiable*, i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information, in order for obtaining the information to constitute research involving human subjects.

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

*More Than Minimal Risk-* the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*Informed Consent-* the voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect his/her decision to participate.

*Vulnerable Populations*- subjects likely to be vulnerable to coercion or undue influence, e.g., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, incompetent adults (developmentally disabled, cognitively-impaired elderly, unconscious or inebriated individuals).

*Unanticipated Problem involving risks to subjects or others*- any incident, experience, or outcome that meets all of the following criteria:(1) unexpected, in terms of nature, severity, or frequency, given the research procedures that are described in the protocol-related documents (such as the IRB approved research protocol and informed consent document), and the characteristics of the subject population being studied; (2) related or possibly related to a subject's participation in the research; and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized. *Adverse Event*- any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

*Child*- person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted

*Emancipated Minor*- a juvenile possessing a decree of emancipation or a married juvenile has the same right to make contracts and conveyances, to sue and to be sued, and to transact business as if he/she were an adult according to Article 35 of Chapter 7B of the General Statutes of the State of North Carolina.

*Minor or Unemancipated minor* - any person under the age of 18 who has not been married or has not been emancipated [NC General Statutes – Chapter 90 Article 1A]

*Assent*- a child's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent.

*Parent*- a child's biological or adoptive parent

*Guardian*- an individual who is authorized under applicable State or local law to consent on behalf of a child to participate in research

*Clinical Investigation*- any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA

*Investigator*- an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team

*Sponsor*- a person who initiates a clinical investigation but who does not actually conduct the investigation.

*Sponsor-Investigator*- an individual who both initiates and actually conducts, alone or with others, a clinical investigation.

*Test Article*- any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Public Health Service Act.

*Legally Authorized Representative*- an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

*Family member*- any one of the following legally competent persons: spouse; parents; children (including adopted children); brothers, sisters and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

*Ward*- a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with Federal, State, or local law.

*Protocol*- detailed plan of the study.

## **REFERENCES & RESOURCES**

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>[http://www.hhs.gov/ohrp/policy/che](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)

[cklists/decisioncharts.html](http://www.hhs.gov/ohrp/policy/populations/index.html)  
<http://www.hhs.gov/ohrp/policy/populations/index.html>

<http://www.hhs.gov/ohrp/policy/consentckls.html>

<http://www.hhs.gov/ohrp/policy/expedited98.html>

<http://www.hhs.gov/ohrp/policy/exprev.html>

<http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf>.

Review Dates: 04/09/2014; 03/04/2013; 02/20/2012; 03/05/2009; 01/23/2008 (new)