African-Caribbean Cancer Consortium

RESEARCH AND ETHICS REVIEW COMMITTEE (RERC) GUIDELINES AND PROCEDURES

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Mission

The mission of African-Caribbean Cancer Consortium (AC3) Research and Ethics Review Committee (RERC) is to protect the rights and welfare of all research participants as well as to provide clear and unambiguous guidelines for investigators conducting human subject research. It serves as the Consortium's Institutional Review Board (IRB).

AC3 relies on the principles identified in the Belmont Report and the Declaration of Helsinki in their review of Human Subjects as well as The Code of Federal Regulations for the protection of human subjects. These include CFR 16 and 20, CFR 50 and 56 as well as CFR 45 and 46. AC3 is cognizant of the International Committee **on** Harmonization (ICH) and of course good global practice as outlined by the US Food and Drug Administration.

Role

The AC3 research review committee will review and approve all proposals for collaborative projects that will be conducted under the umbrella of the AC3 (i.e. a study that would use information from AC3 research subjects, that would involve specimens, new data collection, or creation of new data in any investigation that is executed through collaboration within the AC3 network and infrastructure). Study proposals may be submitted by AC3 members (as an AC3 study) as well as interested non-members (as an ancillary study).

Definitions of an AC3 Study vs. an Ancillary Study

An AC3 study is one that is led by an AC3 member investigator and meets at least one of the following criteria -

- A study that would be covered by specific aims of an AC3 Project (i.e. projects conducted and funded as AC3 multi-centered collaborations between at least two of the three AC3 networks, AC3-Africa, AC3-Caribbean and AC3-USA or within one of the three AC3 networks).

- A study that would involve <u>existing</u> AC3 data <u>only.</u>

An Ancillary Study is one that is led by an AC3 non-member investigator and meets at least one of the following criteria -

- A study that would use information from AC3 research subjects in an investigation that is not described as an AC3 multi-center project.

- A study that would involve specimens, new data collection, or creation of new data (i.e. creating new derived variables) that are not included as part of the routine AC3 data set or data analyses.

The AC3-RERC will review and approve study proposals based on feasibility and will identify appropriate AC3 investigators if needed based on their research focus and expertise. The principles of this *RERC policy* are to provide research subject protection (ensure use of data does not exceed informed consent), coordinate efforts to avoid duplication of work, evaluate impact on the inventory of biological material and minimize barriers to publication of AC3 Studies.

Definitions of AC3 Resources

AC3 resources include the infrastructure (i.e. coordinating personnel and/or research study staff) and network (including member network as well as organizations, institutions and/or collaborator with whom AC3 has formal agreements).

REQUIREMENTS FOR APPROVAL OF AN ANCILLARY STUDY

Approval requires that the Ancillary Study has scientific merit and does not –
:

(a) Interfere with the completion of or compete with the main objective of the AC3;

(b) Adversely affect research subject cooperation and compliance with AC3;

(c) Divert study resources (personnel, equipment or study samples), either locally or centrally;

(d) Jeopardize the public image of AC3; and

(e) Use AC3 study contract resources without acknowledgement e.g. manuscript, poster and presentations etc.

The Ancillary Study must also –

(a) Review the AC3 Data Sharing Policy prior to ancillary study proposal submission; and

(b) Receive approval from the AC3-Research and Ethics Review Committee before a grant to support it is submitted or before execution (if the grant is already funded).

RESEARCH AND ETHICS REVIEW COMMIITTEE (RERC) PROCESS

A Letter of Intent (LOI) must be submitted to the AC3-RERC for review and possible approval. The LOI should be no more than 5 pages in length and should include the following –

(i) Date of LOI Submission;
(ii) Planned funding submission date (if applicable);
(iii) Title of Project;
(iv) Bio sketches of Principal and Co-Investigators;
(v) Brief Background;
(vi) Proposed Study (include samples/data required; if genotyping, provide genetic info (see Appendix A));
(vii) Any conflicts with other approved AC3 ancillary studies; and
(viii) References.

The key criteria for approval of proposals are scientific merit and impact on the main AC3 study. While proposal approval can be provided to the Ancillary Study PI to allow grant submission, implementation of any ancillary study will depend on a number of factors **including an adequate plan for reimbursing all ancillary study costs.** Ancillary study proposals submitted by investigators from the primary AC3 institutions will be given priority.

The AC3-RERC will provide initial review and approve, reject or request modification of ancillary study proposals in a timely manner (generally 2-4 weeks). The Ancillary Study Principal Investigator (PI) initiating the ancillary study proposal will receive email notification of the proposal status following AC3-RERC review. **Note:** Prior to approval, the AC3-RERC may ask for the development of a more comprehensive scientific proposal in response to questions or requested revisions. *Please allow approximately 2 months for the entire proposal approval process.*

Studies Requiring External Funding

In general, ancillary studies require external funding. Funding must cover the cost incurred by the AC3 collaborators (e.g., to process or ship samples), and to the AC3 Data management Core (for tasks such as sample selection, preparing and documenting analysis files, participating in statistical analysis, and integrating the new ancillary data back into the AC3 database). No funds for these purposes are available within AC3.

Once the AC3 Ancillary Study Proposal is approved, the Ancillary Study PI may develop a grant proposal requesting external funding for the study. The grant proposal must be developed with AC3-RERC input/review and should include a budget for specimen release, use of the AC3 Data management core, and other support. Once the grant proposal has been approved by the AC3-RERC, the Committee will provide a Letter of Support and the grant proposal may be submitted for funding. Once funding has been secured, the Ancillary Study PI should provide AC3 with a copy of IRB approval. *Please allow approximately 4 months for the grant development and AC3-RERC approval process.*

Pilot Studies or Funding Not Required

If the proposed study is a pilot study or does not require funding, after receiving notification of concept approval for the LOI from the AC3-RERC, the Ancillary Study PI may complete and submit the more detailed *Ancillary Study Proposal Form (pilot studies or funding not required)*, in lieu of a grant proposal that would require AC3-RERC approval. This form has a typical grant application format [including specific aims, background, preliminary data, materials/methods (including statistical analyses and power calculations), description of any conflicts with other approved AC3 ancillary studies, and references]. The *Ancillary Study Proposal Form (pilot studies or funding not required)* is designed to provide the essential information required to assess the "AC3 Requirements for Ancillary Study Approval" (listed in section above). Upon approval by the AC3-RERC of the *Ancillary Study Proposal Form (pilot studies or funding not required)*, the Ancillary Study PI should provide AC3 with a copy of IRB approval.

Amendments to Ancillary Study Proposals

Amendments to ancillary study proposals (e.g., change in PI, adding analyses to be measured or additional interviews or other data to be analyzed)) require AC3-RERC approval via submission of a revised proposal (with revisions highlighted in yellow) and a cover memo summarizing the changes. Approval notification via email and hardcopy will be provided within 2-4 weeks.

DATA/SPECIMEN SHARING AND AUTHORSHIP AGREEMENTS

AC3 Studies

AC3 has an interest in sharing data and bio specimens with the entire AC3 member investigators who may wish to contribute analyses for the benefit of the scientific and health care communities, in the best interests of the study participants from whom these data are

derived. To further enrich the AC3 resource, all AC3 member investigators are required to reserve and aliquot of all bio specimens collected during the study for the AC3 Bio specimen inventory. In addition, all AC3 collaborators are required to supply their research data to the AC3 coordinating center after publication, and/or 12 months after completion of their project. Both data and bio specimens will remain in the AC3 inventory for access to other AC3 members and/or non-members subsequent to the submission of an AC3-RERC approved proposal to access specimens and/or data.

Ancillary Studies

For non-member AC3 collaborators, the AC3 Data/Bio specimen Sharing Agreement and Authorship agreements must be completed AFTER the ancillary study proposal has been approved by the AC3-RERC, but BEFORE external funding has been secured (if applicable), IRB approval has been received by AC3-RERC, and the ancillary study begins. These agreements only needed to be signed once and will remain on file for documentation for any future collaboration.

The collaborative agreement will also include an assessment made by AC3 for recovery of costs associated with delivery of the data and/or bio specimens, including costs of preparation of any ethical or regulatory reviews that may be required in any locality, and the requesting organization must commit to cover these costs. AC3 will provide applicant organizations with an estimate of costs for use in such proposals, or in other funding deliberations. Given that these conditions are met, approval is given contingent upon continuation of necessary support, and on submission of annual progress reports.

To further enrich the AC3 resource, the Non-member AC3 collaborators are required to reserve and aliquot of all bio specimens collected during the study for the AC3 Bio specimen inventory. In addition, Non-member AC3 collaborators are required to supply of their research data to AC3 after publication, and/or 12 months after completion of their project. In addition, data sharing requests will be tracked over time by the AC3-RERC and described in the progress and final grant reports.

Secondary Analyses

AC3 has an interest in sharing data with other interested and qualified research groups or individual researchers who may wish to contribute analyses for the benefit of the scientific and health care communities, in the best interests of the study participants from whom these data are derived. In general, data that are still in the process of analysis and not yet published may be considered by some or all of the AC3 membership to be not yet ready for sharing, and this will apply especially to data that have not yet been fully reviewed, cleaned and subjected to sufficient analysis to ensure that they are reliable and appropriate.

Especially in the case of complex datasets, a plan for data sharing will often of necessity include collaborative agreements and authorship agreements with AC3 working groups that have generated all or some of the data to be shared. No warranty condition is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of the data that is transferred by AC3 to other researchers. The recipient researchers shall therefore in any event be entirely responsible for any use whatsoever of such data.

The collaborative agreement will also include an assessment made by AC3 for recovery of costs associated with delivery of the data, including costs of preparation of any ethical or regulatory reviews that may be required in any locality, and the requesting organization must commit to cover these costs. AC3 will provide applicant organizations with an estimate of costs for use in such proposals, or in other funding deliberations.

Given that these conditions are met, approval is given contingent upon continuation of necessary support, and on submission of annual progress reports.

Following the appropriate data transfer agreements, data may be shared by direct transfer of data files or, especially in circumstances in which there is risk of subject identification or when security or other legal restrictions apply to the data, a data enclave may be provided as a physical location where the user may go to access shared data under controlled conditions (e.g., supervision by the PI or designated agent).

Data will be provided with necessary documentation, including explanations regarding complex shared data, assuming that costs are covered and that appropriate collaborative agreements are reached regarding for example the level of involvement of the appropriate AC3 working group in the proposed analyses.

To further enrich the AC3 resource, the researchers are required to supply their research data to AC3 after publication, and/or 12 months after completion of their project. In addition, data sharing requests will be tracked over time by the AC3-RERC and described in the progress and final grant reports.

Completion, Submission and Approval of the Manuscript Proposal Form

Ancillary studies must complete and submit a manuscript proposal form prior to submitting a manuscript for publication. The AC3-RERC will suggest co-authors; all co-authors, the AC3-RERC and the AC3 Data management Core must approve the final draft. If revisions are requested, these must be completed and resubmitted for final approval prior to submitting the manuscript for publication.

Yearly Status on Progress of Ancillary Studies

The AC3-RERC monitors the development of the ancillary studies, receipt of funding, initiation dates, and progress. The Ancillary Study PI must provide a written progress report on the status of the ancillary study to the AC3-RERC each year (by November 1 of each study year, and at the completion of the ancillary study). The reports should include a list of data collected and/or analyses measured.

THE MANUSCRIPT PROPOSAL PROCESS (ANCILLARY STUDY)

The Ancillary Study PI should be cognizant that the AC3 requires acknowledgement in all manuscripts and abstracts associated with the AC3-RERC approved project.

Notification of Results of Ancillary Studies to the Community

It is the AC3's policy that the aggregate results from all AC3 studies be reported to the community in which the research was conducted.

Confidentiality and Conflict of Interest

All applications and review materials submitted to AC3 are confidential and review committee members who feel that they may have a conflict of interest in objectively reviewing a proposal should immediately inform the chair of the committee immediately so that an alternative person may be selected in good time so as not to disrupt the scheduling of review dates and times

Scoring an Application

Suggested Scoring Form - in order to provide adequate feedback to applicants the following is a suggested scoring procedure –

Impact	Score		Strengths	Weaknesses
High Impact	1	Exceptional	Exceptionally strong	Essentially no weaknesses
	2	Outstanding	Extremely strong	Negligible weaknesses
	3	Excellent	Very strong	Only some minor weaknesses
Moderate Impact	4	Very Good	Strong	Numerous minor weaknesses
	5	Good	Strong	At least one moderate weakness
	6	Satisfactory	Some strengths	Some moderate weaknesses
Low Impact	7	Fair	Some strengths	At least one major weakness
	8	Marginal	A few strengths	A few major weaknesses
	9	Poor	Very few strengths	Numerous major weaknesses

Action by RERC

The RERC can take one of four actions: approve, approve with modifications (conditional) or deny or return the application to the investigator for more information before making a decision (incomplete).

Investigators will receive written documentation regarding the decision made about their application. Any conditions or modifications required will be sent to investigators by email within 3-4 week after submission of the application. The time between submission to approval is typically 4 - 6 weeks. Approval letters will be sent by e-mail and in hard copy. Approval may be for up to one year. Projects for longer than one year will require progress review and renewal. .

1 Exempt

Research that involves human subjects may be determined to meet one of the six categories for exemption. RERC policy requires a consent process even if the research falls under one of the exemption categories and the IRB may require changes to a protocol even though it may fall under one of the exemption categories.

Exempt categories as outlined in 45 of the Code of Federal Regulations (CFR) 46.101*)*

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 subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably

place the subjects at risk of criminal or civil liability or be damaging to the subjects' 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 paragraph (b)(2) of this section, if:

    (i) the human subjects 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

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.

6. Taste and food quality evaluation and consumer acceptance studies -

    (i) if wholesome foods without additives are consumed; or

    (ii) if a food is consumed that contains a food ingredient at or 6 below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Reviews

Research activity that involves no greater than minimal risk to subjects may be eligible for expedited review.

Expedited reviews are conducted by the RERC Chairperson or his designate and one or more members of the RERC who have knowledge in the area of research to be reviewed.

The expedited review process can be applied to new applications with minimal risk or minor changes in previously approved research (also called amendments).

Under the expedited review procedure, the Chairperson or his/her designee examines the

expedited review reports and has the authority as the RERC to make a determination to approve or request modifications. Nevertheless, a research application cannot be disapproved through the expedited process as a majority of members must vote to disapprove an application.

Upon evaluation of the application, the reviewers may request review by a full RERC Committee.

Expedited categories (as outlined in 45 CFR 46.110)

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. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 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, the frequency with which it will be collected.

   For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in a week period and collection may not occur more frequently than two times per week.

3. 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 external secretions (including sweat);

(e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylatic 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; and

(j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (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:

(a) physical sensors that are applied either to 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 testing#, 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). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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.

Information required in all application submitted to RERC

The initial application requires submitting information on each of the following -

- Study Title and Prospectus;
- Exemption Category (if seeking a exempt review);
- Description of the informed consent process and informed consent form to be used;
- Description of subject recruitment;
- First person scenario;
- Description of any potential risks and safeguards;
- Description of potential benefits;
- Information on records storage and distribution; and
- All study instruments, consent forms and recruitment materials to be used (survey, interview questions, recruitment scripts, focus group outlines, etcetera).

Special Populations

Children (with modification from 45 CFR 46, subpart D)

Invariably children will be included in all research involving human subjects unless there is a scientific reason to exclude them, such as the following –

- research topic to be studied is irrelevant to children;
- there are laws or regulations barring the inclusion of children in the research; and
- insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment).

The researcher should contact the Research Integrity Officer if assistance is needed in determining scientific inclusion and exclusion justifications.

The RERC will review projects in which no greater than minimal risk to children is presented, only if adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

The RERC will review projects in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if –

- The risk is justified by the anticipated benefit to the subjects;

- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

The RERC will review projects in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if:

- The risk represents a minor increase over minimal risk;

- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

- The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

- Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Research which is not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children will only be reviewed if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Unless permission to forgo obtaining either assent by the child or permission from his or her parents or guardian is explicitly granted by the IRB, both are required in research that will involve children.

The RERC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. If the IRB determines that the capability of some or all of the 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 the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, we may still waive the assent requirement under circumstances in which consent may be waived in accordance with general informed consent provisions. When the IRB determines that assent is required, it shall also determine how assent must be documented.

In addition, the RERC shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from both parents, 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.

If the RERC determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects--for example, neglected or abused children--it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law.

Prisoners (Modified from 45 CFR 46, subpart C)

Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary decision regarding whether or not to participate as subjects in research.

The RERC shall review research only if it finds that:

- The research is in a permissible category (see below);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the RERC finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentence, and for informing participants of this fact.

Permitted Research Involving Prisoners

Biomedical and behavioral research may involve prisoners as subjects only if the proposed research involves the following:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk or inconvenience to the subjects;

- Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk or inconvenience to the subjects;

- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only (when DHHS funding is sought) after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register of the intent to approve such research; or

- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners (in a manner consistent with protocols approved by the RERC) to control groups which may not benefit from the research, the study may proceed only (when DHHS funding is sought) after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.