The Smith-Kettlewell Eye Research Institute

Policies and Procedures

for

Human Subjects Protections

and

Operation of the Institutional Review Board

March 9, 2007
I. Introduction
As required by 45 CFR 46, this document describes the Policies and Procedures governing the Program of Human Subjects Protection and the operations of the Institutional Review Board of The Smith-Kettlewell Eye Research Institute (SKERI). This document will be updated and revised as necessary and will be periodically reviewed in its entirety. SKERI will establish all procedures necessary to implement these policies.

II. Institutional Authority
Federal-Wide Assurance [46.103(a)]
SKERI will provide written assurance to the Department of Health and Human Services (DHHS), in the form of the federal-wide assurance (FWA), that it will comply with the requirements set forth in 45 CFR 46. Such assurance will be reviewed yearly and updated as necessary. SKERI’s FWA is 00002436, which expires January 21, 2009. This assurance is executed by the Chief Operating Officer (COO) who is legally authorized to act for SKERI as the Signatory Official (SO), and to assume on behalf of SKERI the obligations imposed by this policy.

Institutional Review Boards (IRB) linked to this assurance
The IRBs linked to this assurance are established in accordance with the requirements of 45 CFR 46, and are administered and/or supported by the SKERI Administration:

1. IRB00005252, known as Smith-Kettlewell Eye Research Institute IRB #1 (SKERI IRB), is responsible for overseeing research conducted within SKERI.

2. IRB00000239, known as California Pacific Med Center IRB # 1 (CPMC IRB), is a cooperative activity of SKERI and the California Pacific Medical Center (CPMC) and is responsible for overseeing research carried out at both institutions. It is formally registered with the Office for Human Research Protections of the US Department of Health and Human Services as an Institutional Review Board of SKERI.

Operation of the Human Subject Protection Program
1. SKERI’s SO will have ultimate responsibility for ensuring ethical conduct of research involving human subjects.

2. This SO will appoint a Human Subjects Coordinator (HSC) to oversee the administration and daily operations of human subject protection matters. The HSC shall have demonstrated experience in human subjects protections, federal
regulations and, when possible, research with human subjects. The HSC shall report to the SO for matters related to the protection of human subjects.

III. Statement of Principles [46.103(b1)]

The Smith-Kettlewell Eye Research Institute (SKERI) supports the advancement of scientific knowledge through clinical research. SKERI is grateful to individuals who choose to participate in such research, and is committed to the highest standards of clinical research and to protecting the rights and welfare of participants in clinical research conducted by its staff or at its facility.

The Institutional Review Boards are charged with the responsibility for reviewing and overseeing all research involving human participants conducted by SKERI.

All of SKERI’s human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Specifically, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of justice requires that subjects be fairly selected (FWA).

SKERI will enact all policies and procedures necessary to carry out its responsibilities and ensure ethical conduct of research.

All human subject research conducted by SKERI will receive IRB approval before being initiated. SKERI’s assurance applies federal human research subject regulations at Code of Federal Regulations Title 45, Part 46 (45 CFR 46) to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance (FWA).

Where appropriate, SKERI will require adequate additional protections for fetuses, pregnant women, prisoners and children as required under 45 CFR 46, subparts B, C and D.

Where appropriate, SKERI will require adequate additional protections for other classes of special populations, including but not limited to, decisionally-impaired individuals, HIV-positive individuals, non-English-speaking individuals, or employees and students of the institution who may participate as research subjects,
in accordance with the criteria found at 45 CFR 46.111 and the federal guidelines for involvement of such individuals in research.

Procedures to protect human subjects normally followed in foreign countries may differ from those set forth in this policy. In these circumstances, where research takes place in foreign countries, if the SO in consultation with the Institutional Review Board (IRB) and, if necessary, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), determines that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in this policy, the SO may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. [46.101(h)]

IV. Authority of IRB(s)
1. All human subject research conducted by SKERI will be in accordance with the decisions of the IRB(s) that review SKERI’s human subject research as well as that IRB’s policies and procedures.

2. The designated IRB(s) that review SKERI’s research have the authority to a) approve, b) require modifications to secure approval, c) disapprove, and d) terminate or suspend all such research. All IRB decisions will be accepted as binding on SKERI and no human subject research will take place without documented IRB approval.

3. In addition, the designated IRB(s) have the authority to a) require research progress reports, b) audit and/or monitor the research, and c) report suspensions, terminations and non-compliance to IRB officials, SKERI and the federal government.

V. IRB Membership
The SKERI IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by SKERI. The SKERI IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. [46.107(a)]
Every nondiscriminatory effort will be made to ensure that the SKERI IRB does not consist entirely of one gender, so long as no selection is made to the IRB on the basis of gender. [46.107(b)]

The SKERI IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. [46.107(c)] At least one member whose primary concerns are in nonscientific areas must be present to meet quorum for full regular review. [46.108(b)]

The SKERI IRB shall include at least one member who is not otherwise affiliated with SKERI, and who is not part of the immediate family of a person who is affiliated with SKERI. [46.107(d)]

No member shall participate in the SKERI IRB’s initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB. [46.107(e)]

The SKERI IRB shall at its discretion, invite individuals with competence in special areas to assist in the review of research that requires expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. [46.107(f)]

Where research involves prisoners as subjects, a majority of the IRB shall have no association with the prison(s) involved and at least one member of the IRB shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

SKERI shall maintain a list of IRB 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 IRB deliberations; and any employment or other relationship between each member and the Institution. Changes in IRB membership shall be reported to OHRP. [FWA]

Review of Research
Non-expedited initial and continuing review of research will occur at convened meetings of the Smith-Kettlewell IRB at which 51% of the members are present, including at least one non-scientific member. Approval of research is by a majority vote of the quorum. Loss of quorum due to recusal or early departure prohibits the taking of action until the quorum is restored. [46.108(b)]

Initial Review
In accordance with 45 CFR 46.111 criteria for IRB approval of research (risks are minimized and reasonable in relation to anticipated benefits, subject selection is equitable, informed consent is sought and documented, safeguards for human subjects include data management, protection of privacy, protection of vulnerable subjects, etc.), the IRB shall require the submission of the following documents for initial review:

1. Full protocol
2. Proposed consent and/or assent forms
3. Relevant grant materials*
4. Any brochures, advertisements, etc.

When protocol applications are received by the IRB, the Human Subjects Coordinator (HSC) performs a preliminary review of all materials for completeness and provision of the relevant information for the particular type of protocol, applicable laws, and applicable SKERI policies. Additionally, the HSC initiates the review process as Exempt, Expedited, or Regular based on the investigator’s request.

For full committee convened review, all IRB members shall receive all materials one week prior to the scheduled meeting. If the review qualifies as expedited (see below), all members shall be given access to all materials including any decision. A primary reviewer shall be assigned to do an in-depth review of all materials. As part of the in-depth review, the primary reviewer shall ensure and document that the IRB protocol is entirely consistent with the research described in any HHS proposal. A copy of the *grant materials shall be retained with the IRB records and made available to all IRB members. In reviewing grant materials, attention shall be paid to the qualifications of collaborating investigators and other members.
of the research team, cooperating institutions or other performance sites, and the Protection of Human Subjects section.

The IRB may rely on a summary or checklist that addresses the above concerns, with a certification by the investigator that the IRB protocol is entirely consistent with the grant application it applies to.

The IRB will provide the investigator and the institution with written notification of all decisions to approve or disapprove research and of any modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, written notification will include the reasons for the decision, and the investigator will be given an opportunity to respond in person or in writing. Documentation shall include the requirements for continuing review. [46.109(d)]

IRB-approved research may be subject to further appropriate review and approval or disapproval by Institute officials. However, under no circumstances shall those officials approve research that has not been approved by the IRB. [46.112]

**Expedited Review**
In accordance with 45 CFR 46.110(b)(1), categories of research listed in the Federal Register of November 9, 1998, may be reviewed under an expedited review procedure by the IRB chairperson, or by one or more experienced reviewers designated by the Chairperson from the IRB membership.

In addition, expedited review may be used to review minor changes in previously approved research during the period of one year or less. See below under Modifications.

In accordance with 45 CFR 46.110 (b)(2), in executing the review, the reviewers will have all authorities of the IRB except that the reviewers may *not* disapprove the research. A research activity may be disapproved only after full committee review. [46.108]

If the reviewer does not find that the requirements for expedited review are satisfied, the protocol or protocol amendment is assigned for review at a convened meeting of the IRB.

When an expedited review is conducted, all IRB members shall be notified of the research proposal that has been reviewed and approved under the expedited procedure, and given access to all materials including the decision.
Documentation of initial expedited review shall include the specific permissible category justifying the expedited review.

**Conditional Review**
When the IRB review recommends substantive modifications or clarifications, the research shall be deferred pending subsequent review of the requested materials by the convened IRB. When the IRB review stipulates minor specific revisions concurred by the investigator, the IRB chair may subsequently review and approve the revisions under expedited review procedures.

**Exempt Status**
An investigator may request Exempt Status, which must be approved by the Chair or designated IRB member(s). Protocols categorized as Exempt must satisfy the requirements set forth in 45 CFR 46.101 (b), or 21 CFR 56.104, and not be protocols involving prisoners as specified in 45 CFR Subpart C nor be protocols involving Stem Cells under the California Health and Safety Code Section 125119. The protocol must meet SKERI ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations as outlined in 46.116).

**Continuing Review**
Continuing review of research must be substantive and meaningful. The Smith-Kettlewell IRB will conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year. Continuing review includes the authority to observe the consent process and the research, and review records. [46.109(e)]

Continuing review shall ensure compliance with the criteria set forth in 45 CFR 46.111.

The Principal Investigator (PI) is responsible for ensuring continuing approval of research protocols at the time intervals deemed appropriate by the IRB. The HSC will notify the PI in a timely manner that continuing review is due. Should the protocol approval expire, the HSC shall notify the PI immediately and document the reason. No human subjects shall be seen unless the protocol is approved.

Continuing review by the convened IRB, shall include a status report (Continuing Review Form), a copy of the complete protocol and current consent form, as well
as any newly proposed consent forms or modifications. The status report shall report on the progress of the research including:

1. The number of subjects accrued.
2. A summary of adverse events and any unanticipated problems involving risks to subjects or others, and any withdrawal of subjects from research or complaints about the research since the last IRB review.
3. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review.
4. Any relevant multi-center trial reports.
5. Any other relevant information, especially information about risks associated with the research.

In conducting continuing review of all research not eligible for expedited review, all IRB members shall receive all materials at least one week prior to the scheduled meeting. In addition, all IRB members shall have access to the complete research study protocol file including IRB minutes.

When reviewing continued research under an expedited review procedure, the IRB Chair (or designated IRB member(s)) shall receive and review the above materials.

The minutes of the IRB shall document separate deliberations, actions, and votes for each protocol undergoing continuing review by the IRB. The votes shall be recorded in the minutes by protocol using the following format recommend by OHRP: Total= 15; vote: for-14; opposed-0; abstained-1. [46.115]

**Modifications to Previously Approved Protocols**
Investigators must submit proposed modifications to IRB-approved protocols and consent documents prior to initiating their use, except where necessary to eliminate apparent immediate hazards to subjects. In such rare cases, when modification or deviation of the approved protocol is necessary, it shall be reported to the IRB and HSC within 48 hours of occurrence. The IRB will determine whether the change was consistent with ensuring the participants’ continued welfare.

If the modifications are major, a regular review at a convened IRB meeting is conducted; if the modifications are minor, an expedited review is conducted.

A major modification is one in which there is an increase in the level of risks to participants or a greater than minor modification in any of the following:

1. The consent form
2. Research design or methodology
3. The subject population enrolled in the research
4. The qualifications of the research team
5. The facilities available to support safe conduct of the research
6. Any other factor which would warrant review of the proposed
changes by the convened IRB.

A minor modification eligible for expedited review is one in which all of the
following are true in the judgment of the IRB reviewer:
1. Any increment in risk is less than minimal risk.
2. All modifications would have been eligible for expedited review
had they been part of the initial protocol review.
3. Either the research is minimal risk or the proposed changes do not
alter the study design.

The modification shall be submitted with the changes tracked. A final document
will be generated when the modification is approved, indicating the approval date.

For any approved modification, the IRB or designated reviewer (in the event of
Expedited Review) may require investigators to re-consent subjects (in the case of
major changes or if such information reasonably may affect their willingness to
continue in the research), or give participants information relating to the change via
an informational sheet.

The IRB shall notify the investigator of findings and actions taken on proposed
modifications, including any further modifications or clarifications required to
secure approval.

Approval of the revision does not alter the expiration date on the consent form.
The expiration of the original protocol or the last approved continuing review does
not change with a revision.

**Pregnant Women, Human Fetuses and Neonates**
When the protocol involves pregnant women, human fetuses and neonates, the IRB
considers the investigator’s response to the items in regulation 45 CFR 46.204, as
well as the IRB’s review of the items, and makes a finding under 45 CFR §46.204,
45 CFR §46.205, 45 CFR §46.206, and 45 CFR §46.207.

**Prisoners**
When the protocol involves prisoners as participants, the investigator’s rationale

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and the risks of involving prisoners are considered by the IRB as it makes any finding required by 45 CFR §46.305 and 45 CFR §46.306.

Children
When the protocol involves children as participants, the IRB considers all of the regulations of 45 CFR §46.404, 45 CFR §46.405, 45 CFR §46.406, 45 CFR §46.407, 45 CFR §46.408 and if appropriate, FDA 21 CFR §50.51, FDA 21 CFR §50.52, FDA 21 CFR §50.53, FDA 21 CFR §50.54, and FDA 21 CFR §50.55 to make the appropriate finding(s) under which the children may be included.

Children Who Are Wards
When the protocol involves children who are wards of the state the IRB considers all of the regulations of 45 CFR §46.406, 45 CFR §46.407 and if appropriate, FDA 21 CFR §50.53, FDA 21 CFR §50.54 and 45 CFR §46.409(a) and FDA 21 CFR §50.56(a) to make the appropriate finding(s) under which the wards of the state may be included.

Emergency Review
Nothing in 45 CFR 46 is intended to limit the authority of a physician to provide emergency medical care, to the extent permitted under Federal, State or local laws. Any emergency medical care that is provided without prior IRB approval shall not be considered human subject research, the patient may not be considered a research subject, nor can the data be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices or biologics, US Food and Drug Administration (FDA) requirements must be satisfied. The physician or investigator shall notify the IRB immediately when emergency medical care is provided.

Additional Review by Institution
Research approved by the IRB may be subject to further review and approval or disapproval by the Institution. However, research that has been disapproved by the IRB may not be approved by the Institution. [46.112]

Record keeping
All records shall be kept in accordance with 45 CFR 46.115 and shall include the research proposal reviewed, scientific evaluation, consent documents, progress reports, interim reports, and reports of injuries to subjects.

Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions, the basis for
requiring changes in or disapproving research, and a written summary of the any discussion of controverted issues and their resolution. The votes shall be recorded in the minutes by protocol using the following format recommend by OHRP: Total= 15; vote: for-14; opposed-0; abstained-1. [46.115]

If the IRB determines that a protocol requires continuing review more often than annually due to the degree of risk, this shall be documented in the minutes and conveyed to the investigator. The minutes shall clearly reflect the determination regarding risk and review interval.

The IRB shall maintain adequate documentation of continuing review, copies of all correspondence between investigators and the IRB, a list of IRB members as detailed above and in 46.103(b)(3), written procedures for the IRB, copies of statements of new findings provided to subjects (see Informed Consent below).

In accordance with 45 CFR 46.115, IRB records shall be retained for 3 years following the completion of the research, and all records shall be accessible for inspection by authorized representatives of the department or agency at reasonable times and in a reasonable manner. HIPAA-related documentation such as HIPAA authorizations, waiver of authorization, or accounting for disclosure logs, must be maintained for six years from the completion of the study.

Informed Consent
No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall minimize the possibility of coercion or undue influence in obtaining informed consent. The information shall be given to the subject in language understandable to the subject or his/her representative. No informed consent may include any exculpatory language through which the subject or representative appears to waive any of the subject’s legal rights or release the investigator, the sponsor or the Institution from liability for negligence. [46.116]

In accordance with California State Law [24172- 24173], subjects or their representative, shall be given the Experimental Subject’s Bill of Rights prior to consenting to participate in any experiment, as well as a copy of the signed and dated written consent form [24173].

In accordance with 46.116 and 24.173, informed consent shall include the following:

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1. A statement that the study involves research, an explanation of the purpose of the research, expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be available to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments will be made available if injury occurs, and if so, what they consist of.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject.

8. The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment [24.173].

9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

10. Informed consent shall when appropriate include all other considerations outlined in 46.116:

   a) Risks to subject or embryo or fetus if the subject is or becomes pregnant;

   b) Anticipated circumstances under which the 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 by the subject;

   d) 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 subject;
e) The approximate number of subjects involved in the study.

The IRB may approve a consent form which does not include or which alters some or all of the elements of informed consent provided that the research meets the requirements of 46.116 (c) and (d).

In such cases, or when consent is waived, HHS regulations at 45 CFR 46.116(d) require that the IRB document that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved in advance by the IRB [46.117] and signed by the subject or the subject’s legally authorized representative, unless waived by the IRB as provided in 46.117(c). In cases where the IRB has waived the documentation of written consent, the IRB may require the investigator to provide subjects with an approved written description of the research.

The consent form may be read to the subject or the subject’s legally authorized representative, but the investigator must give the subject adequate opportunity to read the consent form prior to signing.

A short form written consent document may be approved by the IRB which states that the elements of informed consent listed above and in 46.116 have been presented orally to the subject or subject’s legally authorized representative. When this method is used, there must be a witness to the oral presentation, and the IRB must approve a written summary of what will be said to the subject or representative. The subject needs only to sign the short form, however the witness must sign both the short form and the summary, and the person obtaining consent shall also sign the summary. A copy of the summary and the short form consent shall be given to the subject or representative.
Adverse Events
Any unanticipated problems involving risks to subjects or others must be reported to the HSC and IRB Chair immediately, and must include the event and how it was handled, including any follow-up needed.

If the IRB determines that suspension or termination of the project is warranted, the investigator will be notified immediately and the decision will be documented in sufficient detail.

Training and Education
1. All researchers and pertinent staff will receive initial and ongoing education in the general concepts of ethical conduct of research and the protection of human subjects.

   The core curriculum of human subject protection training for all researchers and pertinent staff will include:
   a. The terms and conditions of SKERI’s Federal Wide Assurance (FWA).
   b. The Belmont Report basic ethical principles and their application.
   c. SKERI’s policies and procedures for the protection of human subjects.
   d. The HIPAA Privacy Rule.
   e. Other applicable State and Federal regulations.

2. Only those researchers and study personnel who have completed all necessary training and who are qualified to perform the specific research interventions identified in the protocol will participate in the conduct of human subject research.


4. When possible, the SO and HSC will attend human subject protections training initiatives offered by appropriate sponsors.

5. The HSC will monitor federal regulatory websites and other research-related resources to stay current with regulatory changes in human subject protection guidelines and policies. The HSC will ensure that regulatory changes or other pertinent information is communicated to institute officials, investigators and IRB members in a timely manner.
6. Completion of all training requirements will be documented and recorded for each individual. Copies of all such documents will be available for review by cognizant IRB personnel when necessary.

Research Compliance and Oversight
1. SKERI will maintain and manage an oversight system to ensure that research by its staff or within its facility complies with the terms of the approved protocol, federal regulations and state law, IRB decisions and IRB policies and procedures.

2. SKERI will conduct procedural and record keeping audits for the purpose of detecting, correcting and reporting (as required) administrative and/or material breaches in protecting the rights and welfare of human subjects.

3. A climate free of fear of sanction is required to foster appropriate reports and ensure a fair review of allegations; therefore, any individual who reports an incident of non-compliance will remain confidential and be protected from retaliation. Retaliation against good faith "whistle blowers" is illegal and will not be tolerated at SKERI.

Non-compliance
Non-compliance means conducting research involving human subjects in a manner that disregards or violates regulations governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects, inadequate or non-existent procedures for informed consent, inadequate supervision in research involving novel interventions or procedures, failure to follow recommendations made by the IRB or Institution to ensure the safety of subjects and failure to report appropriate adverse events or proposed protocol changes to the IRB and the Institution.

In the event of non-compliance
1. SKERI will review all allegations of non-compliance with human subject regulations. Any individual or organization may submit a written complaint or allegation of non-compliance to the SO and IRB. The Institution may also initiate a complaint based on information available to the Institution (e.g., deficiencies noted in IRB files, media or scholarly reports of research activity subject to committee jurisdiction).

2. SKERI will review the allegation of non-compliance, the response from the researcher and any other information necessary to conduct its investigation.
3. Based on its investigation, SKERI will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The report will be reviewed by the IRB and SO.

4. SKERI is required to report to the appropriate Federal Department or Agency any “serious or continuing noncompliance” with the regulations governing the protection of human subjects or the requirements or determinations of the IRB Committee. Whenever possible, the Institution will coordinate with the IRB before submitting such reports.

5. When the IRB or SKERI makes a decision to suspend or terminate approval of research for any reason, the following individuals, in addition to the investigators listed on the protocol and the departments/Institutions involved in the research, will be notified, where applicable:
   a. SO
   b. IRB Chair(s) of Institutions participating in the research under a Cooperative Agreement or Inter-Institutional Agreement to the FWA
   c. Appropriate federal departments or agencies
   d. Food and Drug Administration
   e. The funding agency

Conflict of Interest
SKERI will take steps to identify actual or potential sources of conflict of interest in human subject research and either eliminate, reduce or manage such conflict. Investigators are required to disclose actual or potential research related conflicts of interest.

The IRB will evaluate such conflicts and, if necessary, determine (1) whether the conflict is permissible in the context of the protocol, and, if so, (2) whether the conflict warrants disclosure to potential subjects as part of the informed consent process or (3) warrants further management to reduce or eliminate the interest.