Date: August 20, 1981

From: Office of the University Counsel and Vice Chancellor for Legal Affairs

Subject: Assurances of Compliance with Human Subjects Research Regulations

Revised federal regulations issued by the Office of Protection from Research Risks (OPRR) of the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) have now taken effect making it necessary for all State University campuses engaged in human subjects research to redevelop their "assurances of compliance" in accord with these regulations.* To assist in this effort OPRR has distributed a sample assurance adaptable to the particular needs and organizational structure of individual campuses. A copy of the sample is enclosed.

The revised regulations, which were treated in some detail at a May 1981 University-wide conference on human subjects research, differ significantly from prior regulations by requiring:

-- an increase in the degree of institutional responsibility for the supervision of human subjects research;

-- the development of categories for "exempt" research and "expedited" review accompanied by precise definitions and procedures for each;

-- the establishment of detailed procedural requirements, including, e.g., commitment of space and administrative support for the campus Institutional Review Board (IRB), and specific requisites for recording IRB proceedings; and

-- the elimination of all distinction between general and special assurances.

*The regulations, which become effective July 27, 1981, are codified in the Code of Federal Regulations, Title 45, Part 46 (OPRR) and Title 21, Parts 50 and 51 (FDA). Although the regulations have been sent directly to most campuses, additional copies are available from University Counsel or the federal agencies.
Although the revised federal regulations technically apply only to HHS-funded research, OPRR expects the same protections be afforded all human subjects research regardless of funding source. Furthermore, the New York State Department of Health is empowered by Article 24-A of the Public Health Law to monitor human subjects research of a different definition from that employed by the federal agencies. (Memorandum to Presidents, Vol. 77, No. 18, October 17, 1977, treats this topic.) State requirements may be satisfied, however, by meeting the federally-recommended standards. Consequently, we advise that procedures and review mechanisms established to satisfy federal rules be complied with for all human subjects research.

We recommend therefore that each campus engaged in human subjects research take the necessary steps to revise, or prepare for the first time, an assurance of compliance with the provisions of the federal regulations for submission to OPRR. As described in the enclosure, OPRR has advised that it expects to complete negotiation of assurances "within the next year."

Please note that the sample assurance was drafted in the abstract for a hypothetical university involved in medical, behavioral, life science and social science research, and therefore the sample incorporates four separate IRBs. The assurance of compliance for each affected SUNY campus must of course be developed in accord with the needs and structure of the particular campus.

For further assistance you may wish to contact Erica Michaels, Assistant Counsel, at (518) 473-7591, or OPRR directly at the National Institute of Health, Bethesda, Maryland 20205, (301) 496-7041.

Sanford H. Levine

Enclosure

cc: Chairpersons, Institutional Review Boards

This Memorandum addressed to:

Presidents, State-operated Campuses

Copies for information to:

President, Community Colleges
Deans, Statutory Colleges
Dr. Odle
Vice Provost Spencer
Dear Colleague:

Your institution currently has on file a general assurance with the Department of Health and Human Services (HHS) in compliance with the Department’s regulations for the protection of human research subjects (45 CFR 46).

The regulations under which your assurance was developed and approved have recently been revised. Therefore, it is necessary to develop a new assurance of compliance in accord with the revised regulations which were published in the Federal Register on January 26, 1981. You were mailed a copy of these regulations in February.

The Office for Protection from Research Risks (OPRR) is responsible for the negotiation of these assurances, and has prepared a sample to assist institutions in developing the assurances required by the revised regulations. A copy of the sample is enclosed. In preparing this sample assurance we have attempted to include all of the elements necessary for compliance with the new regulations. We invite you to view this sample assurance as an aid in developing your assurance and would appreciate your comments as to its adequacy in assisting you in that development.

The enclosed sample assurance is for a hypothetical institution (XYZ University) which conducts or sponsors a relatively large amount of research involving human subjects. Our hypothetical case also assumes that the institution has developed its assurance to incorporate the required sections of 45 CFR 46 and to establish procedures within the institution for the efficient review and processing of research protocols. A principal component of our hypothetical institution’s organization is its Office of Research Administration (ORA). The ORA provides a central focus for researchers, Institutional Review Boards (IRBs) and administrators for processing protocols and communicating other information concerning research involving human subjects. This sample assurance will, of course, have to be adapted to the organizational structure of your institution.

Beginning July 27, 1981, your institution will be responsible for moving as rapidly as possible toward full compliance with the provisions of the new regulations. In the near future OPRR staff will be in contact with you regarding your progress in developing your new assurance. We expect to complete negotiation of assurances within the next year.

If you have any questions, please do not hesitate to contact this office.

Charles R. McCarthy, Ph.D.
Director, OPRR
National Institutes of Health
Bethesda, Maryland 20205
(301) 496-7041

Enclosure
THIS IS A SAMPLE ASSURANCE FOR A MAJOR INSTITUTION CONDUCTING RESEARCH IN A NUMBER OF SCIENTIFIC FIELDS. THIS SAMPLE SHOULD BE USED ONLY AS A GUIDE IN DEVELOPING AN ASSURANCE SPECIFICALLY TAILORED TO THE NEEDS OF THE INDIVIDUAL INSTITUTION.

The XYZ University

Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects

The XYZ University and XYZ University Hospital, hereinafter referred to as "institution," hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended) as specified below.

I. Statement of Applicability, Principles and General Policies.

A. Applicability.

1. Except as noted in 2 below, this assurance is applicable to all activities which, in whole or in part involve research with human subjects if:

   a. the research is sponsored by this institution, or

   b. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or

   c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

   d. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

2. Only provisions II.A.1-6; II.B.1.a,b,d,e,f; and III. of this assurance are applicable to the activities listed above if the only involvement of human subjects will be in one or more of the categories exempted or waived under 45 CFR 46.101(b)(1-5) or 46.101(e).

B. Ethical Principles.

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as

2. In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all applicable HHS-funded research and, except for the requirements for reporting information to HHS, all other research without regard to source of funding.1/

C. Institutional Policy.

1. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this assurance.

2. It is the policy of this institution that, except for those categories specifically exempted by 45 CFR 46, all research covered by this assurance will be reviewed and approved by an institutional review board (IRB) which has been established under an assurance of compliance negotiated with HHS. The involvement of human subjects in research covered by this policy will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained in accord with and to the extent required by 45 CFR 46.116. Certification of the IRB's review and approval for all HHS-funded research involving human subjects will be submitted to HHS with the application or proposal for funding.2/ Furthermore, the IRB's review of research on a continuing basis will be conducted at appropriate intervals but not less than once per year.

1/ NOTE: The hypothetical XYZ University has chosen to require that research covered by its assurance be conducted in accord with the requirements of 45 CFR 46, regardless of the source of funding. Institutions may, at their option select some other mechanism for insuring that human research subject protections are provided for those participating in research not funded by HHS.

2/ NOTE: The hypothetical XYZ University, for reasons of administrative simplicity, has chosen to require that HHS-funded research covered by its assurance receive IRB review and approval and that certification to that effect be submitted to HHS with the application or proposal for funding. This exceeds the requirement of the HHS regulations which permit institutions to submit the certification as late as 60 days following the submission of an application or proposal to HHS.
3. It is the policy of this institution that unless informed consent has been specifically waived by the IRB in accordance with 45 CFR 46.116, no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this assurance.

5. This institution bears full responsibility for complying with federal, state or local laws as they may relate to research covered by this assurance.

6. This institution has established and will maintain four IRBs each in accordance with 45 CFR 46.3. These IRBs have the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities involving human subjects.

7. This institution has provided and will continue to provide both meeting space for the IRBs and sufficient staff to support the IRBs' review and recordkeeping duties.

8. This institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, IRBs, other institutional officials and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

9. This institution will maintain documentation of IRB activities as prescribed by 45 CFR 46.115.

10. This institution will exercise appropriate administrative overview carried out at least annually to insure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46 and this assurance.

NOTE: The hypothetical XYZ University has chosen to establish four IRBs to provide review appropriate for this institution's volume and variety of research activities. Institutions may, at their option, establish more or fewer IRBs to meet their specific needs.
11. This institution will comply with the policies set forth in 45 CFR 46 Subpart B, which provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova.

12. This institution will comply with the policies set forth in 45 CFR 46 Subpart C, which provide additional protections for prisoners involved in research.

13. This institution, in addition to complying with the requirements of 45 CFR 46, will consider additional safeguards in research when that research involves children, individuals institutionalized as mentally disabled and other potentially vulnerable groups.

14. This institution will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects. When research covered by this assurance is conducted at or in cooperation with another entity, all provisions of this assurance remain in effect for that research. This institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another assurance of compliance with HHS. Such acceptance must be in writing, approved and signed by this institution's Office of Research Administration (ORA), approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed agreement must be forwarded to the Office for Protection from Research Risks (OPRR), HHS.

15. This institution shall provide each individual at the institution conducting or reviewing human subject research (e.g., PIs, department heads, clinical care staff, research administrators, IRB members) with a copy of this institutional assurance of compliance and copies of any future modifications which may be made to this assurance, with the exception of changes in IRB membership.

II. Implementation.

A. Responsibilities of Research Investigators and Department Heads.

NOTE: The hypothetical XYZ University has chosen to involve its individual department heads in the review process. Traditionally, many large institutions employ this review requirement as an adjunct to IRB review. This review requirement may not be appropriate for some institutions. HHS regulations do not designate this specific review as a required method for maintaining institutional oversight of human subject research.
1. Determination of human subject involvement.
   a. Research investigators and department heads shall make a
determination as to whether research will involve human
subjects as defined in 45 CFR 46.102.
   b. When it is not clear whether the research involves human
subjects as defined in 45 CFR 46.102, research
investigators should seek assistance from the ORA and
and the IRB in making this determination.

2. Preliminary determination of exemption eligibility.
   a. Research investigators and department heads shall make
the preliminary determination of whether such research which
does involve human subjects is exempted from coverage under
45 CFR 46.101.

3. Preparation of protocol.
   a. Research investigators shall prepare a protocol giving a
complete description of the proposed research. In the
protocol, research investigators shall make provisions
for the adequate protection of the rights and welfare of
prospective research subjects and insure that pertinent
laws and regulations are observed. This requirement is
applicable even in cases where the research is exempt
under 45 CFR 46.101.
   b. Research investigators shall include samples of proposed
informed consent forms with the protocol.

4. Scientific merit and ethical consideration review.
   a. Department heads, through appropriate procedures
established within their respective departments, are
responsible for reviewing research protocols for ethical
considerations and scientific merit.

5. Submission of protocol to the ORA.
   a. Research investigators and department heads shall be
responsible for insuring that all research involving
human subjects is submitted to the ORA.

6. Submission of a supplement to an original protocol
to the ORA.
   a. Research investigators shall be responsible for
submitting a supplement and the original protocol to
the ORA when:
   (1) it is proposed to involve human subjects, and the
activity previously had only indefinite plans for
the involvement of human subjects, or
it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or

(3) it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

7. Complying with IRB decisions.

a. Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.

8. Obtaining informed consent.

a. Research investigators are responsible for obtaining informed consent in accordance with 45 CFR 46.116, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent.

b. Unless otherwise authorized by the IRB, research investigators are responsible for insuring that legally effective informed consent shall:

(1) be obtained from the subject or the subject's legally authorized representative;
(2) be in language understandable to the subject or the representative;
(3) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
(4) not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

9. Providing basic elements of informed consent.

a. Unless otherwise authorized by the IRB, research investigators at a minimum shall provide the following information to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which 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;

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(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous 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 are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) 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. Providing additional elements of informed consent.

a. When required by the IRB, the research investigator shall provide one or more of the following additional elements of information to each subject:

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

(2) Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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; and

(6) The approximate number of subjects involved in the study.

11. Documentation of informed consent.

a. Research investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB.
b. Research investigators shall insure that each person signing the written consent form is given a copy of that form.

c. Research investigators may use a consent form which is either:

(1) A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it, or;

(2) A "short form" written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, research investigators shall insure that:

(a) a witness is present at the oral presentation,  
(b) the short form is signed by the subject or the representative,  
(c) the witness signs both the short form and a copy of the written summary of the oral presentation,  
(d) the person obtaining consent signs a copy of the summary,  
(e) a copy of both the short form and summary is given to the subject or the representative, and  
(f) the written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

12. Retention of signed consent documents.

a. Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the ORA.

13. Submission of progress reports on the research.

a. Research investigators are responsible for reporting the progress of the research to the ORA, as often as and in the manner prescribed by the IRB but no less than once per year.

14. Submission of injury reports and reports of unanticipated problems involving risks.

a. Research investigators are responsible for reporting promptly through their department heads to the ORA any injuries to human subjects.

b. Research investigators are responsible for reporting promptly through their department heads to the ORA any
unanticipated problems which involve risks to the human research subjects or others.

15. Reporting changes in the research.
   a. Research investigators are responsible for reporting promptly through their department heads to the ORA proposed changes in a research activity.
   b. Changes in research during the period for which IRB approval has already been given, shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

16. Reporting of noncompliance.
   a. Research investigators and department heads are responsible for reporting promptly to the ORA and the IRB any serious or continuing noncompliance with the requirements of this assurance or the determinations of the IRB.

17. Attending IRB meetings.
   a. To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators and department heads are encouraged to attend IRB meetings when invited by the IRB.

18. Notifying the ORA concerning investigational new drugs.
   a. The research investigators shall be responsible for notifying the Food and Drug Administration (FDA) and the ORA whenever it is anticipated that an investigational new drug or device exemption will be required.

B. Responsibilities of the Office of Research Administration (ORA).

1. Institutional determinations concerning exemptions, sponsorship, and certification.

NOTE: The hypothetical XYZ University has chosen to establish an Office of Research Administration to provide a central focus for researchers, IRBs and administrators for processing protocols and communicating other information concerning research involving human subjects. The establishment of such an office will not be appropriate for some institutions and is not required by the HHS regulations. Institutions may, at their option, employ other methods for achieving efficient processing and oversight of activities covered by their assurance.
a. The ORA shall receive from the research investigators through their department heads all research protocols which involve human subjects.

b. The ORA is responsible for reviewing the preliminary determinations of research investigators and department heads and for making final institutional determination whether research protocols qualify for exemption from coverage under 45 CFR 46.101.

c. The ORA shall forward all nonexempt research protocols to the appropriate IRB for review.

d. The ORA shall review all exempted research as well as all nonexempt research which has been reviewed and approved by an IRB to determine whether this institution shall support or sponsor such research.

e. All exempted research protocols and all protocols approved by an IRB which are being submitted for HHS funding shall be forwarded to HHS by the ORA. When an IRB approves a protocol on condition that the research investigator make modifications to the protocol, the ORA shall not forward the protocol to HHS until the ORA has determined that such modifications are made. As appropriate, the IRB or the ORA may negotiate protocol modifications with the research investigator. Each protocol submitted to HHS by the ORA must include:

   (1) certification that the research was reviewed and approved by an IRB, established under this assurance (The identification numbers of this assurance and the IRB must be included in the certification.); or
   (2) certification that the research was reviewed and approved by an IRB established under another assurance (The identification numbers of the approving IRB and the assurance under which it was established along with a copy of the signed agreement stipulated at I.A.15. above must be included with the certification.); or
   (3) notification that the research was determined to be exempt from coverage under 45 CFR 46 or that coverage was waived.

f. The ORA shall keep research investigators aware of decisions and administrative processing affecting their respective protocols and shall return all disapproved protocols to the research investigators.

2. Receive appeal requests.

   a. The ORA shall receive all requested appeals of IRB decisions with attached protocols from the research investigators and forward those protocols to the Appeal IRB.
3. Comply with the Investigational New Drug or Device Certification Requirement.

a. The ORA shall identify the test article (i.e., drug biologic or device) in the certification to HHS when the proposal involves a test article and state whether the 30-day interval required for test articles has elapsed or was waived by the FDA.

b. If the 30-day interval has expired, the ORA shall state in the certification to HHS whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human subjects.

c. If the 30-day interval has not expired and a waiver has not been issued, the ORA shall send a statement to HHS upon expiration of the interval.

4. Certification requirement in cases of supplements to HHS funded protocols.

a. The ORA is responsible for submitting a certification to HHS, and when otherwise required by HHS, a supplement to an original protocol, when:

(1) it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects, or

(2) it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or

(3) it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

In addition, the ORA shall insure that no human subjects are involved in research projects for which the filing of a supplement is required by HHS, prior to review of the submitted supplement and approval by appropriate HHS officials.

5. Retention of signed consent documents.

a. The ORA shall designate procedures for the retention of the signed consent documents. These documents shall be retained for at least three years after termination of the last IRB approval period.

6. Reporting requirements.

a. The ORA shall be responsible for promptly reporting information, as appropriate, to the IRBs, the OPRR, and research investigators and department heads on a variety of issues. Information may flow from sources such as human subjects, research investigators, IRBs or other institutional staff. Specifically, the ORA shall:
(1) Report promptly to the OPRR any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;
(2) Report to the appropriate IRB information received concerning noncompliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;
(3) Maintain information concerning the IRB's reasons for the termination or suspension of IRB approval; and
(4) Report promptly any changes in IRB membership to the OPRR.

C. IRB Structure.

1. Institutional establishment of the IRBs. (See footnote 3/, page 3)

a. IRB number 01 (known as the Medical School IRB) is established within the medical school to review biomedical research. The IRB membership is appointed by the Dean of the Medical School and is subject to approval by the University President. Of the original members one third of the members are appointed for one year, one third for two years and one third for three years. All future appointments and reappointments will be for terms of three years.

b. IRB number 02 (known as the Behavioral and Life Sciences IRB) is established to review behavioral and life sciences research. The IRB membership is appointed by the Provost of the University and is subject to approval by the University President. Of the original members one third of the members are appointed for one year, one third for two years and one third for three years. All future appointments and reappointments will be for terms of three years.

c. IRB number 03 (known as the Social Science IRB) is established to review social science research. The IRB membership is appointed by the Provost of the University and is subject to approval by the University President. Of the original members, one third of the members are appointed for one year, one third for two years and one third for three years. All future appointments and reappointments will be for terms of three years.

d. IRB number 99 (known as the Appeal IRB) is established to act as an appeal body when a research investigator chooses to appeal a decision made by another IRB. The membership is composed of the chairpersons and the five senior members of the existing IRBs. If the composition of the IRB should at any time, because of varying circumstances not meet the membership criteria established by 45 CFR 46.107, additional members will be appointed through special negotiations with the OPRR.
2. IRB membership requirements.

a. Each IRB is comprised of members from diverse backgrounds to promote complete and adequate review of research activities covered by this assurance, and has the professional competence necessary to review the specific research activities which will be assigned to it.

b. Each IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

c. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, institutionalized as mentally disabled), each IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.

d. Each IRB includes both male and female members.

e. Each IRB includes members representing a variety of professions.

f. Each IRB includes at least one member whose primary expertise is in a non-scientific area.

g. Each IRB includes at least one member who is not otherwise affiliated with the institution and who is not a part of the immediate family of a person affiliated with the institution.

3. IRBs membership lists and qualifications.

a. The names and qualifications of the members of each IRB are enclosed in accordance with 45 CFR 46.103(b)(3).

D. IRB authorities and responsibilities.

1. IRB review and approval of research.

a. The IRBs shall have the responsibility to review and the authority to approve, require modification in or disapprove all activities or proposed changes in previously approved activities covered by this assurance.

\[\text{NOTE: For the purposes of this sample assurance only a blank format is enclosed.}\]
b. The IRBs shall approve research based on the IRBs' determinations that the following requirements are satisfied:

1. Risks to subjects are minimized:
   (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   (b) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Documentation of informed consent.

a. In accord with 45 CFR 46.117, the IRBs shall require documentation of informed consent by use of a written consent form, or may waive the requirement for the research investigator to obtain a signed consent form for some or all subjects if the IRB determines that:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; or
(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

b. When the documentation requirement is waived, the IRB may require the research investigator to provide subjects with a written statement regarding the research.

3. Waiver or alteration of informed consent.

a. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(a) & (b), or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research is to be conducted for the purpose of demonstrating or evaluating:
   (a) federal, state or local benefit or service programs which are not themselves research programs.
   (b) procedures for obtaining benefits or services under these programs, or
   (c) possible changes in or alternatives to these programs or procedures; and
(2) The research could not practically be carried out without the waiver or alteration.

b. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(a) & (b), or waive the requirements to obtain informed consent provided the IRB finds and documents 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 practically be carried out without the waiver or alteration; and
(4) Whenever appropriate the subjects will be provided with additional pertinent information after participation.

4. Observation of the consent process and the research.

a. Each IRB shall have the authority to observe or have a third party observe the consent process and the research.

5. Frequency of review.

a. Each IRB shall determine, in its review of research protocols, which projects will require IRB review more often than annually.
b. Except as may be otherwise provided in this assurance, all convened IRB meetings shall be conducted under and pursuant to Robert's Rules of Order.7/

c. Convened meetings of each IRB shall occur:

(1) On the third Wednesday of each month; and
(2) at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous; and
(3) at the call of the chairperson upon the receipt of a joint written request of three or more members.8/

6. Continuing review.

a. Each IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

7. Verification of change.

a. Each IRB shall determine which projects need verification from sources other than the research investigators that no material changes have occurred since previous IRB review.

8. Authority to suspend or terminate approval of research.

a. Each IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions and requirements or that has been associated with unexpected serious harm to subjects.

9. Information dissemination and reporting requirements.

a. The IRBs shall have the authority and be responsible for promptly reporting information to the ORA, the OPRR or both on a variety of issues. In conjunction with this requirement the IRBs must be prepared to receive and act on information received from a variety of sources, such

7/ NOTE: The hypothetical XYZ University has chosen to conduct its IRB meetings in accordance with Robert's Rules of Order. Institutions may choose other procedural guidelines for the conduct of IRB meetings.

8/ NOTE: The hypothetical XYZ University has chosen to conduct monthly IRB meetings and to provide a mechanism for convening meetings when certain other circumstances exist. Institutions may choose other procedural guidelines for the frequency of IRB meetings.
as human subjects, research investigators, the ORA or other institutional staff. For reporting purposes, the IRB will follow the procedures described below:

(1) Any serious or continuing noncompliance by research investigators with the requirements of the IRB - This information shall be reported promptly to the ORA and the OPRR.

(2) Injuries to human subjects - Information received by the IRB concerning injuries to subjects shall be reported promptly to the ORA. (The ORA is responsible for reporting to the OPRR.)

(3) Unanticipated problems - Information received by the IRB concerning unanticipated problems involving risks to subjects or others shall be reported promptly to the ORA. (The ORA is responsible for reporting to the OPRR.)

(4) Suspension or termination of IRB approval - Each IRB suspending or terminating approval of research protocols shall include a statement of the reasons for the IRB's action and shall report the action promptly to the research investigator, the ORA and the OPRR.

10. IRB records.

a. Each IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

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

(2) Minutes of IRB meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the research investigators.

(5) A list of IRB members as required by 45 CFR 46.103(b)(3).

(6) Written procedures for the IRB as required by 45 CFR 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5).
b. Each IRB shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity.

c. IRB records shall be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner, or shall be copied and forwarded to HHS when requested by authorized HHS representatives.

E. IRB Procedures.

1. IRB receives protocol.

   a. The IRB chairperson shall receive all nonexempt research protocols from the ORA.

2. Determination of review procedure.

   a. The IRB chairperson shall determine whether the research protocol meets the criteria necessary for an expedited review process.

   b. The IRB chairperson refers all research protocols to either full committee review or expedited review.

3. Expedited review.

   a. The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46.

   b. An IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

   c. The only other research for which an IRB may use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories:

      (1) Collection of: hair and nail clippings, in a nondisfiguring manner, deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

      (2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

      (3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the
use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electoretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6) Voice recordings made for research purposes such as investigations of speech defects.

7) Moderate exercise by healthy volunteers.

8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

11) Any other category specifically added to this list by HHS and published in the Federal Register.

d. Expedited review shall be conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson to conduct the review.

e. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.

f. When the expedited review procedure is used, the IRB chairperson or member(s) conducting the review shall
inform IRB members of research protocols which have been approved under the procedure.

g. At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.21

4. Full committee review.

a. Research protocols scheduled for review shall be distributed to all members of the IRB prior to the meeting.

b. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

c. All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.

d. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

e. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research.

f. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting.

g. No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

h. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions

21 NOTE: The hypothetical XYZ University has chosen to establish a procedure by which a convened IRB may overrule decisions made when an activity has been approved using expedited procedures. The HHS regulations do not specifically require that an institution establish this procedure.
reached at the convened meeting shall supercede any decisions made through the expedited review.

5. IRB notification to research investigators and the ORA of decision(s).

a. The IRBs shall notify the research investigators and the ORA in writing of the IRBs' decisions, conditions and requirements.

b. The IRBs shall also provide to the research investigator reasons for the IRB's decision to disapprove a research protocol and an opportunity for the research investigator to respond. Reasons for disapproval shall also be transmitted to the ORA by the IRB.

6. Appeal board review.

a. The appeal IRB shall serve only in the capacity of an appellate body.

10/ NOTE: The hypothetical XYZ University has chosen to establish a procedure by which a convened IRB may overrule decisions made when an activity has been approved using expedited procedures. The HHS regulations do not specifically require that an institution establish this procedure.
III. Institutional Endorsement and HHS Approval

A. Authorized Institutional Official (primary contact).

Signature: ____________________________ date: _______
Name: ________________________________
Title: ________________________________
Address: ____________________________________________
                                            ____________________________________________
                                            ____________________________________________
Phone: ______________________________________

B. HHS Approving Official.

Signature: ____________________________ date: _______
Name: ________________________________
Title: ________________________________
Address: ____________________________________________
                                            ____________________________________________
                                            ____________________________________________
Phone: ______________________________________

C. Effective date of assurance ____________________________

D. Expiration date of assurance ____________________________
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<th>LAST NAME</th>
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<th>AFFILIATION WITH INSTITUTION</th>
<th>ADDRESS AND PHONE NUMBER - CHAIRPERSON ONLY</th>
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X Denotes Chairperson  
XX Denotes Alternates  
HV Denotes Non-voting Members  

JULY 3, 1981