INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING PROCEDURES
FAIRFIELD UNIVERSITY

Institutional Review Board's Mandate to Protect Human Subjects.

The University shall establish and maintain an Institutional Review Board (IRB) to ensure the protection of the rights and welfare of human research subjects pursuant to the federal regulations (45CFR Part 46 and 21CFR Part 56). The IRB performs prospective and continuing review of protocols, the informed consent process and the procedures utilized to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the *Belmont Report*, and with applicable federal, state, local and institutional requirements.

The Fairfield University IRB will apply only those standards contained within the federal regulations which reflect the principles articulated in the Belmont Report. The IRB will not apply any more stringent standards to the review of research involving human subjects unless specifically directed to do so by University policy approved by the appropriate faculty governance bodies.

Consistent with the federal regulations, decisions by the IRB to not approve research may not be appealed to any authority outside the IRB. In all instances, to the best of its abilities, the IRB will work with investigators to revise protocols that are not approved so as to meet the standards set forth in the regulations. On the other hand, approval of research by the IRB does not guarantee permission to conduct any particular research project. IRB approval does not override other University policies or authorities.

All research involving human subjects conducted by University employees or students at Fairfield University or outside of the University in their capacity as an employee/student is subject to prospective review and approval by the IRB and may not proceed without it, unless specifically exempted by the IRB from review.

IRB Administration.

The IRB will report to the Chief Academic Officer. The Chief Academic Officer will provide sufficient resources for the efficient conduct of IRB business, including an administrative staff person to serve as Administrative Liaison. The Administrative Liaison's duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IRB records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records and the progress of all studies; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrative Liaison will attend all IRB meetings, and reports to the IRB Chairperson.

IRB Membership.

The IRB will have sufficient expertise to review the broad variety of research in which the University becomes involved, will be knowledgeable about all relevant regulatory requirements and will make every effort to be impartial and objective in its review (45 CFR 46.107(a) and 21 CFR 56.107(a)).

Appointment of IRB Chairperson, Length of Service and Duties.

The IRB Chairperson shall be appointed by the President. In addition to the responsibilities of IRB membership, the Chairperson has primary responsibility for conducting IRB

meetings and directing the IRB staff to ensure operation of the IRB within all applicable regulatory requirements. The IRB Chairperson works with IRB members and investigators to ensure that the rights and welfare of research subjects are adequately protected. The Chairperson shall sign all official IRB correspondence, unless otherwise indicated, and shall report directly to the Chief Academic Officer.

Appointment of IRB Members, Length of Service and Duties.

The President will appoint members to the IRB, typically in consultation with current and past members. Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or table protocols. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their expertise, and serve as general reviewers on all research discussed at convened meetings. The IRB Chair may designate members of the IRB to review non-research, exempt, and expedited review protocols.

IRB Membership Requirements.

In accordance with the compositional requirements of section 46.107 of 45 CFR 46, the membership is composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Fairfield. The Board shall include at least one member whose primary concerns are in nonscientific areas, and one person who is not currently affiliated with Fairfield University and is not part of the immediate family of a person who is currently affiliated with Fairfield University. Members will be drawn from diverse backgrounds including consideration of their racial 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. When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.

Specific Duties.

The IRB is responsible for developing procedures for submitting research protocols for review, determining if research protocols are in conformity with the federal regulations with regard to use of human subjects in research, reviewing approved research projects on a continuing basis (at a minimum of once a year), reporting to the Chief Academic Officer of the University any serious or continuing noncompliance by University investigators with the conditions outlined in the project as approved, and reporting to the Secretary of Health and Human Services any serious or continuing noncompliance by University investigators who are funded by the Department of Health and Human Services.

Conflict of Interest.

No IRB member may participate 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. For example, when an IRB member is a Principal Investigator for a study being

reviewed by the IRB, the member cannot vote on or otherwise participate in the IRB's review of his or her study.

Initial Training, Continuing Education, and Professional Development of IRB Members.

IRB members shall receive a copy of these IRB standard operating procedures to review research from an ethical and regulatory perspective. In addition, all IRB members must complete the initial educational module on human subject's research that is available through the National Institutes of Health. Specific information on these resources will be made available by the Administrative Liaison. Members are expected to become familiar with the Federal regulations and Belmont Report.

Compensation of IRB Members.

IRB members are not provided monetary compensation for their service on the IRB.

IRB Meetings

Schedule.

Meetings will be convened at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous, or upon the receipt of a joint written request of three or more members. The IRB committee should meet no less than four times per year. It is within the discretion of the IRB Chairperson to cancel or add a meeting in the event there is no business or additional business to conduct.

Quorum.

A majority of the membership, including at least one member whose primary concerns are in nonscientific areas, and one person who is not currently affiliated with the institution, shall constitute a quorum and is required in order to convene a meeting for the review of research protocols. Members may be present in person or audio (telephone) or interactive teleconference. Members present via teleconference shall be noted as such in the meeting minutes, which shall also indicate that the members received all pertinent information prior to the meeting and were able to actively and equally participate in all discussions.

Procedure.

All convened IRB meetings shall be conducted under and pursuant of Robert's Rules of Order. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. At a convened IRB meeting, any member may request that an activity that 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. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

Substance of IRB Review

Principal Investigators' Submission to IRB.

All research studies involving human subjects should be submitted for IRB review by the Principal Investigator. Submissions should be made through the online system using the IRB submission template form. This form includes all submission requirements (see Appendix A for submission requirements). The Principal Investigator must request either exemption from IRB review, expedited review, or full board review.

IRB Review and Approval of Research.

Initial Review and Categorization of Study: The Chair or the Chair's designee will review the submitted protocol and determine its status for IRB review (non-research, exempt, expedited review or full board review). Unless the protocol is categorized as exempt from IRB review under 45 CFR 46.101(b) (and described in Appendix C), or does not meet the criteria for human subjects research (45 CFR 46.102(d) and (f)), all human subjects research must be prospectively reviewed and approved by the IRB. For those studies that qualify as exempt or do not meet the criteria for human subject's research, the Chair will designate the study as such and notify the PI. The IRB Chair may deem a protocol exempt after obtaining enough information from the investigator to determine whether the claimed exemption applies. The members of the IRB are given a list of all recently verified exempt protocols before the next scheduled meeting. No action is required on their part, though they can read exempt proposals and raise concerns. (No continuing reviews or renewals are required for exempt or non-research protocols.)

Expedited Review Procedure: For studies determined to be eligible for expedited review, the Chair or the Chair's designee from the IRB membership will review the proposed research and determine if the criteria for expedited review as described in the federal regulations ([56 FR 28012, 28022 June 18, 1991, as amended at 70 FR36328, June 23, 2005] and included in Appendix D) have been met. If so, the Administrative Liaison will ensure that the Principal Investigator has submitted all the required materials and the Chair will then review the proposed research and assess whether the study should be approved by expedited review according to the criteria for IRB approval of research (section V-C). The decision is communicated to the PI and to the IRB committee members. IRB members are then expected to review the protocol and approval decision and alert the Chair if there is a question or potential issue of concern before or at the next scheduled meeting. Approved protocols are approved for a period of up to one year as determined by the IRB at the time of approval. Approved protocols will also require submission of a continuing review report at the completion of the study or within one year of approval date, whichever comes first (described in Appendix B, and reviewed in section V-B4).

Full Review Procedure: For non-exempt studies that do not meet the criteria for Expedited Review, full board review is required. The Administrative Liaison will ensure that the Principal Investigator has submitted all the required materials, and will add this protocol to the agenda of the next meeting. The IRB committee members will review the proposed research in preparation for discussion at the next meeting. The proposal is discussed at the meeting, and a majority vote from all present members is required for approval. The PI is notified by the Chair of approval, conditional approval pending minor changes, need for major changes before review, tabling, or disapproval (with explanation).

Approved protocols are approved for a period of up to one year as determined by the IRB. Approved protocols will also require submission of continuing review at the completion of the study or within one year of approval date, whichever comes first (described in Appendix B, and reviewed in section V-B4*).*

Continuing Review: The IRB is required to conduct substantive and meaningful continuing review of research. Such reviews shall be conducted at intervals appropriate to the degree of risk of the project, but not less than once per year. (See Appendix B.) The IRB requires that the PI submit a continuing review report within the time period approved. The IRB Chair shall review the protocol file at the time of the continuing review. The PI indicates on the continuing review report if he or she is requesting continuation of the proposal for up to one more year or is terminating the protocol. This must be done before approval has expired. The Chair can approve continuation of research originally approved by expedited review. Approval is discussed at the next meeting and can be affirmed or rescinded. All other continuing reviews must be reviewed by the full board.

Criteria for IRB Approval of Research.

In order to approve any proposed research to be conducted at the University, the IRB shall determine that all of the following requirements (46.111(a) (1-7)) are satisfied, as quoted below.

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

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

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research, and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Informed consent shall 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. The following information will be provided to each subject:

- A statement that the study involves research, an explanation of the purposes of the research the expected duration of the subject's participation, a description of

the procedures to be followed and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- 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
- 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.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- 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;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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
- The approximate number of subjects involved in the study.

The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent set forth in this section. The IRB may waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and

- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Informed consent will be appropriately documented in accordance with and to the extent required by 45 CFR 46.117. The consent form may be either of the following:

- A written consent document that embodies the elements of informed consent stated above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read the document before it is signed.
- A short form written consent document stating that the elements of informed consent as noted above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

- That 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
- That 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. A general description of the data and safety-monitoring plan shall be submitted to the IRB as part of the research proposal. The plan must include procedures for reporting adverse events.

When appropriate, the research study provides adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence (i.e. children, prisoners, pregnant women, mentally disabled persons, or economically or

educationally disadvantaged persons), additional safeguards should be included in the study to protect the rights and welfare of these subjects.

Actions Taken at Convened Meeting.

IRB actions for initial or continuing review of research will include the following:

- *Approved* with no changes or no additional changes. The research may proceed.
- *Approved with minor changes* that are clearly delineated by the IRB so the investigator may simply concur with the IRB's revisions. The research may proceed **after** the required changes are made and verified by the IRB Chair.
- *Tabled.* Tabled research applications are approvable but require substantive changes or additional substantive information that must be reviewed at a subsequent convened subsequent meeting of the IRB. The research may proceed only **after** the convened IRB meeting has reviewed and approved the required changes to the research or the information provided.
- *Disapproved.* The IRB has determined that the research, as submitted, may not be conducted by the investigator(s). If the IRB disapproves a research protocol, it shall include in its written notification a statement of the reasons for its decision and afford the investigator an opportunity to respond in person or in writing.

IRB Record Keeping and Required Documentation.

IRB Records.

Federal regulations require that the IRB retain records for at least three years after the termination of the research protocol. All IRB records shall be kept in a secure place. Access to IRB records shall be limited to the Chairperson of the IRB, the administrative staff of the IRB, the IRB members, and officials of federal and state agencies. IRB records will include the following:

- IRB Standard Operating Procedures (SOP)
- IRB membership roster
- Curriculum Vitae for IRB members
- Record of certification of *human subjects training* for IRB members and Principal Investigators when required by Federal Grant or IRB.
- IRB research application files for all submitted protocols, including all required documentation, continuing review reports, and correspondence.
- Minutes of the convened IRB meetings

The Administrative Liaison shall ensure that a current IRB membership roster is maintained pursuant to 45 CFR 46.103(b) (3).

Contents of Minutes.

The minutes of IRB meetings shall be compiled by the Administrative Liaison and approved by the IRB. The following specific information shall be included in the minutes:

Attendees by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests, and whether

quorum requirements have been met. Members present via teleconference shall be noted as such in the meeting minutes.

Actions taken by the IRB on new and continuation applications; review of protocol and informed consent modifications or amendments; protocol deviations; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions. Votes on these actions are categorized as "for", "against" and "abstain". The basis for requiring changes in or disapproving research.

A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol, as well as a list of exempt and non-research protocols.

Report of other business.

Members, who absented themselves by name, name of protocol and reason for the conflict.

Additional Considerations.

Certificates of Confidentiality.

The IRB may determine that special protections are needed to protect subjects from the risks of investigative or judicial processes in research projects that include the collection of highly sensitive information about individually identifiable subjects necessary to achieve the research objectives. Research will be considered sensitive if it involves the collection of information in any of the following categories:

- Information relating to sexual attitudes, preferences or practices;
- Information relating to the use of alcohol, drugs or other addictive products;
- Information relating to illegal conduct;
- Information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community;
- Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to an individual's psychological well-being or mental health.

For such sensitive information the IRB may require that the investigator obtain a Certificate of Confidentiality from the Department of Health and Human Services. Federal funding is not a prerequisite to such a determination that a Certificate of Confidentiality is necessary. The purpose of the Certificate of Confidentiality is to protect against any involuntary release of sensitive information about individual subjects for use in federal, state or local civil, criminal, administrative or other legal proceedings. The Certificate does not prohibit the disclosure of information by an investigator including, but not limited to, child abuse or a communicable disease. The investigator must detail in the informed consent document what information will and will not be protected by the Certificate of Confidentiality.

Reporting Unanticipated Problems and Adverse Events.

Any adverse events or unanticipated problems involving subjects of any IRB-approved study must be reported to the IRB as soon as possible, but no later than thirty days from the event's occurrence. Deaths or other serious adverse events should be reported to the IRB as soon as possible, but no later than five days after the event's occurrence. If an adverse event occurs at a study site other than the University, the Principal Investigator must promptly notify all IRBs governing the protocol.

Review of Standard Operating Procedures (SOP).

The IRB shall review the IRB SOP at a minimum of every five years. Recommended revisions to the SOP will be discussed and decided on by the full IRB.

Protocol Amendments:

If a Principal Investigator would like to make a change to an already approved protocol or exempt protocol, he or she can submit an amendment to the protocol through the online system. Minor changes can be reviewed and approved by the Chair, and discussed at the next meeting. Major changes are typically referred to the full IRB committee for discussion and action at the next meeting.

APPENDIX A – Protocol Submission Requirements

The online system provides a template for protocol submission, HIPAA regulations and forms, Conflict of Interest Form, the IRB Membership List, Federal Regulations and Mandatory Education information. Requested information includes the following:

- Name of P.I. and co-P.I.s
- Project title
- Purpose of study
- Background
- Location of study
- Duration of project
- Research plan
- Statistical considerations
- Incentives for subjects
- Subject population
- Potential risks & benefits to subjects
- Description of informed consent
- confidentiality and data security
- funding source
- requested review type
- If applicable, copies of all data collection tools, questionnaires, interview/survey forms, assessment materials, and descriptions of materials that subjects will encounter.
- If applicable, advertisement(s) for subject recruitment. If the forms of advertisement for recruitment contains more than the title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information, they must be submitted to and approved by the IRB prior to distribution or publication of the material.
- If applicable, documentation of training in the protection of human research subjects, and curriculum vitae for each investigator listed on the application.
- If applicable, a Conflict of Interest form for each investigator listed on the application.
- If applicable, a Request for Access to Protected Health Information for a Research Purpose and/or Research Authorization Form

APPENDIX B – Continuing Review Submission Requirements (Request for Termination or Continuation)

All protocols approved by Expedited or Full IRB review are required to have a continuing review submitted by the PI four weeks prior to the end of the one-year approval period. The PI will be prompted for this information through the online system, and the continuing review information can be submitted through this system. Requested information includes:

- Total # Subjects Enrolled Since Last Continuing Review
- Total # Subjects Enrolled in Study to Date
- Total # Subjects Who Have Died
- Total # Subjects Who Have Completed Study
- Total # Subjects Still Active
- Request for permission to continue and reason, or termination
- Unforeseen/Adverse Events (and describe)

APPENDIX C – Criteria for Exemption Status

Exemption Criteria: All research that is potentially exempt from IRB review shall be submitted to the IRB Chairperson with a request for exemption status. Research activities in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from IRB review pursuant as quoted from 45 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 conducted by or subject to the approval of department or agency heads 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 below the level 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.

APPENDIX D – Criteria for Expedited Review

Expedited Approval: Federal regulations permit the IRB Chairperson to review and approve proposed research through an expedited procedure if the proposed research activities (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the categories in 45 CFR 46.110 and 21 CFR 56.110 (as quoted below).

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, nonpregnant 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[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring 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 unstimulated fashion or stimulated by chewing gumbase 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 subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive 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 nonresearch 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.