GENERAL GUIDELINES

Institutional Review Board

I. OVERVIEW

This set of guidelines supplements the university policy on Institutional Review Board of Human Subjects Research that was issued on 12.01.2010. Both the policy and the guidelines govern the procedures for any research activities conducted at, supported by, or affiliated with Abu Dhabi University that involve human subjects. Based on the level of risk for human subjects, research projects may be eligible to be exempted from being reviewed or may be eligible for an expedited review as detailed in Part (3) of these guidelines.

II. APPLICABILITY OF THE GUIDELINES

(1) Except as provided in paragraph (2) of this section, these guidelines apply to all research activities involving human subjects that are conducted at, supported by, or affiliated with Abu Dhabi University.

(2) These guidelines do not apply to student research activities that are conducted as part of course work requirements that meet all of the following requirements:

(a) No sharing of the collected data or the results beyond registered students and assigned faculty or supervisors of the course.

(b) Human subjects cannot be identified, directly or through identifiers linked to the subjects.

(c) The research conducted does not violate any of the requirements stated in any part of these guidelines

(3) These guidelines do not affect any applicable national or international laws or regulations that may provide additional protections for human subjects.

(4) For cooperative research projects that involve researchers from other institution(s), these guidelines apply along with any other policies or guidelines from the other institution(s).

جامعة أبوظبي
ABU DHABI UNIVERSITY

III. CATEGORIES OF REVIEW

The IRB classifies research into three categories based on the level of risk for human subjects. These categories are:

(1) Exemption from review: a request for exemption from review may be submitted to the IRB by the researchers when the research satisfies one or more of the following criteria:

(a) Research 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.

(b) 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.

(c) 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.

(d) 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 and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe based on the current national regulations and laws.

(2) Expedited review: a request for expedited review may be submitted to the IRB by the researchers in a case where the research involves minimal risk to human subjects but involves procedures with potential impact on human subjects, such as the collection of body samples or physiological data, video or voice recordings, or studies involving vulnerable populations or sensitive issues. Some examples of research activities that may qualify for expedited review include:

(a) Research on medical devices for which the medical device is cleared/ approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(i) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children (pending informed consent from their parents or legal guardians), appropriate for 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.

(c) Prospective collection of biological specimens for research purposes by noninvasive means; with examples of (i) hair and nail clippings in a nondisfiguring manner; (ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (iii) permanent teeth if routine patient care indicates a need for extraction; (iv) excreta and external secretions (including sweat); (v) 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;(vi) placenta removed at delivery; (vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (viii) 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; (ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (x) sputum collected after saline mist nebulization.

(d) 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 and used by qualified personnel. (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.); with examples of (i) 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; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(e) Collection of data from voice, video, digital, or image recordings made for research purposes; provided all necessary precautions are taken to ensure the safety of the data and given that the data will be permanently erased once it has been aggregated and

analyzed and provided the human subjects cannot be identified, directly or through identifiers.

(f) 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 groups, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: The research objective should not be sensitive to the study group and should not have any potential to be used for stereotyping such as the superiority of certain groups based on their color, gender, religion, or ethnic classification).

When a request for expedited review is received by IRB, at least two members of the IRB, designated by the chairperson, should review the proposal and independently indicate their approval or disapproval. Researchers are not required to meet with the reviewers; however, reviewers frequently give written comments advising the researchers on methods to enhance the protection of human subjects. Reviewers may request more information or require changes in procedures to enhance the provisions for informed consent, confidentiality and risk/benefit balance.

(3) Full review: When a research proposal does not meet the requirements to be exempted from review or for expedited review, it must be fully reviewed by IRB. A full review occurs when the IRB reviews the proposed research and meets with the researchers to discuss and evaluate the impact on human subjects.

IV. APPROVAL CRITERIA

(1) In order to approve research covered by these guidelines, the IRB shall determine that all of the following requirements are satisfied:

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

(b) Risks to subjects are reasonable in comparison 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 risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(c) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting(s) in which the research will be conducted and 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.

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(e) The research plan makes adequate provision for monitoring the data collected to ensure the safety and confidentiality of subjects. The research plan should provide explicit provisions for the methods used to securely store the data and the anticipated period the data should be available for analysis and the anticipated date the data will be permanently erased once the analysis is completed and verified.

(f) If the human subjects are offered monetary reparation for their participation, they should be clearly informed of the exact amount they will receive and whether the amount is a lump sum or based on the actual time spent by the participant. The participant should always be given the right to abandon the experiment at any time and in this case, he/she should receive prorated compensation for the time spent in the incomplete experiment.

(g) Under no circumstances should the human participants be subject to physical, emotional, sexual, or any other form of abuse.

(h) The research subject and objective should not be offensive to the human subjects and should not have any potential to be used for stereotyping such as the superiority of certain groups based on their color, gender, religion, or ethnic classification.

(2) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

V. INFORMED CONSENT OF PARTICIPANTS

(1) Except as provided elsewhere in these guidelines, investigators involved in all research projects that need a review (not exempted) should obtain legally effective informed consent of any human subject (or the subject's legally authorized representative) prior to the subject's participation in the research. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Informed consent may still enable the subject or his/her representative to seek redress in case of misapplication or negligence.

(2) Except as provided in paragraph (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(a) 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;

(b) A description of any reasonably foreseeable risks or discomforts to the subject;

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(f) 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;

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

(h) 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.

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

(a) 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;

(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 in the research;

(d) The medical, social or any other consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) 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

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

(4) 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 this section, or waive the requirements to obtain informed consent if the research could not practicably be carried out without the waiver or alteration provided all the following conditions are met:

(a) The research involves no more than minimal risk to the subjects;

(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(5) Informed consent shall be 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. A copy shall be given to the person signing the form.

(6) The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds 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. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

VI. SUSPENSION OR TERMINATION OF A RESEARCH APPROVAL

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be promptly reported to the applicant principal investigator(s) with copies sent to the Provost and the Director of the Research Center