UNIVERSITY OF TEXAS ARLINGTON

Policy RA-PO4

Statement of Principles and Policies Regarding Human Subjects in Research

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Statement of Principles and Policies Regarding Human Subjects in Research

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A. Statement of Principles

The University of Texas at Arlington is committed to the principle that research, teaching, and public service activities should contribute to the acquisition of knowledge and should benefit humanity. Safeguarding the rights and welfare of human subjects in research, development and related activities is of prime concern to The University of Texas at Arlington and shall be a responsibility of all persons at all levels, including, staff, faculty, and students. All activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles in The Belmont Report. It is the policy of this University to maintain such reviews as necessary to minimize the risks of injury to human subjects and to insure maximum protection for the rights and welfare of subjects.

B. Scope

This policy applies to all individuals who employ human subjects in research. It is applicable to activities that occur in University facilities as well as other locations whenever projects involve University funding, faculty scholarship, or any faculty/staff/student effort as part of University activities.

C. Policy Statement

1. It is the policy of The University of Texas at Arlington to assure that the use of human subjects in all research activities conducted at University

facilities or any other location, by any faculty, staff or students of the University will be done in accordance with applicable federal and state laws and regulations and the Rules and Regulations of the UT System Board of Regents.

2. An Institutional Review Board for the Protection of Human Subjects (IRB) will be maintained to review research projects and activities that involve human subjects **[as defined in** Section III., Definitions]. The IRB shall consist of qualified representatives charged with the major responsibility of assuring the protection of human subjects against undue risk in accord with the Code of Federal Regulations, Basic Health and Human Services Policy for Protection of Human Subjects, IRB Membership.

3. The jurisdiction of the UT Arlington IRB is defined by its Federal-wide Assurance document (FWA #FWA00001762) with the Office for Human Research Protections (OHRP) under the Department of Health and Human Services and by UT Arlington's institutional policies. The FWA is an agreement between DHHS and the University to review and approve research involving human subjects in accordance with the ethical principles outlined in the Belmont Report and the DHHS regulations 45 CFR Part 46. An institution must have an FWA in order to receive HHS support for research involving human subjects. Each FWA must designate at least one IRB registered with OHRP and comply with the terms of an Assurance in accord with the terms of Federal wide Assurance (FWA) for the Protection of Human Subjects.

4. No research activity involving human subjects shall be undertaken unless the Institutional Review Board has reviewed and preapproved such activity. Although federal guidelines require Institutional Review Board approval specifically for activities funded by federal grants, the University extends the review procedure to all such projects under its jurisdiction, whether privately or publicly funded, or unfunded. Since the participation of human subjects in research and related activities may raise fundamental ethical and civil rights questions, no distinction in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty or other University employees, on or off campus.

5. The conduct of any research involving human subjects shall be reviewed by the IRB before it is begun and at timely intervals thereafter in accord with the IRB Review of Research section of the Code of Federal Regulations Basic Health and Human Services Policy for Protection of Human Research Subjects. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the Institution (for example, certain projects may expose the institution to risk or liability or involve other procedures that may require administrative review and approval). *However, those officials may not approve the research if it has not been approved by the IRB.*

6. Reviews by the Institutional Review Board for the Protection of Human Subjects will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from review of projects or activities in which they have an active role or conflict of interest, in accord with the Department of Health and Human Services Final Guidance Document, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection.

7. The Institution and the IRB will consider the ethical implications and potential risk(s) to human subjects. The core principles that drive such considerations include:

    a. The risks to the subjects are so outweighed by the sum of the benefits to the subject from the research and the importance of the knowledge to be gained by the researcher and therefore, society, as to warrant a decision to allow the subjects to accept these risks.

    b. The rights and welfare of all subjects (including unborn fetuses) will be adequately protected.

    c. Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provision of federal law and institutional practices as found in Standard Operating Procedures for Regulatory Services.

8. The IRB will promote continuing constructive communication between Board members and the principal investigator(s) as a means of safeguarding the rights and welfare of the human subjects.

9. The University of Texas at Arlington acknowledges that it has responsibility for the proper performance of work and services including the use of human subjects under any grant or contract covered by this policy, including continuing compliance with pertinent federal, state, or local laws, particularly those concerned with informed consent.

10. The IRB will accept responsibility for maintaining appropriate and informative records of the Board's review or other documentation that may pertain to the selection, participation, and protection of subjects and to the review of circumstances that affect the rights or welfare of individual subjects.

11. The IRB will at least annually evaluate the practices and procedures designed for the protection of the rights of human subjects.

12. In cooperative research projects (those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to UT Arlington), each Institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the DHHS Regulations on Protection of Human Subjects (45 CFR Part 46, as amended). When research is conducted at or in cooperation with another entity, the investigator must obtain either

approval from the UT Arlington IRB, or written acknowledgement from the UT Arlington IRB of its acceptance of a collaborating institution's IRB approval for the project. If the cooperating institution does not have an IRB, a letter of acceptance of UT Arlington's IRB review and approval for the research to be conducted must be submitted by the CEO/signatory official of the cooperating institution. In instances where UT Arlington's IRB acknowledges approval of a cooperating institution's IRB approval in accordance with the Cooperative Research section of the Code of Federal Regulations, Basic Health and Human Services Policy for Protection of Human Research Subjects 45 CFR 46.114, the protocol of the IRB of record must have a Principal Investigator that is employed by the cooperating institution. Whenever UT Arlington relies upon an IRB operated by another institution or organization for review of research covered by its Federalwide Assurance (FWA), UT Arlington will ensure that this arrangement is documented by a written agreement between the institution and the other organization or institution operating the IRB. This agreement must be kept on file at both institutions/organizations and made available to DHHS or any U.S. federal department or agency conducting or supporting research covered by the FWA upon request.

13. The IRB and Institution will take action to mitigate or eliminate financial conflicts of interest that have the potential to affect the rights and welfare of human subjects in research as described in the Department of Health and Human Services Grants Policy regarding Financial Conflict of Interest.

III. Definitions

Human Subject Research: any activity that either: (1) meets the Department of Health and Human Services (DHHS) definition of "Research" and involves "Human Subjects" as defined by the DHHS; or (2) meets the Food and Drug Administration (FDA) definition of "Research" and involves "Human Subjects" as defined by the FDA.

DHHS Definition of Human Subject Research: Research is defined by DHHS as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A **Human Subject** is defined by DHHS as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

- **Intervention** is defined by DHHS as both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- **Interaction** is defined by DHHS as communication or interpersonal contact between investigator and subject.

- **Identifiable Private Information** is defined by DHHS as information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

FDA Definition of Human Subject Research: Research is defined by FDA to include all clinical investigations of a test article regulated by the Federal Food, Drug, and Cosmetic Act under sections 505 ["New Drugs" - any use of a drug other than the use of an approved drug in the course of medical practice] and 520 ["Devices Intended for Human Use" - any activity that evaluates the safety or effectiveness of a device], as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. A **Human Subject** is defined by FDA as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. A human subject according to the FDA includes an individual on whose specimen a medical device is used.

- **Medical Device** is defined by FDA as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; **or** (c) intended to affect the structure or any function of the body of man or other animals, **and** does not achieve its primary intended purposes through chemical action within or on the human body or in animals and is not dependent upon being metabolized for the achievement of its primary intended purposes.

IV. Relevant Federal and State Statutes and Rules

The University of Texas at Arlington will comply with federal, state, and local rules and regulations pertaining to human research:

- Department of Health and Human Services (DHHS) 45 CFR 46, "Protection of Human Subjects"
- Food and Drug Administration (FDA) 21 CFR 50, "Protection of Human Subjects"
- Food and Drug Administration (FDA) 21 CFR 56, "Institutional Review Boards"
- Department of Health and Human Services (DHHS) 42 CFR 50, "Responsibility of Applicants for Promoting Objectivity in Research"

V. Relevant UT System Policies, Procedures and Forms

- UT Arlington's Institutional Review Board for the Protection of Human Subjects: Standard Operating Procedures

- UT Arlington's SMART IRB Online Submission System

VI. Who Should Know

This policy impacts all UT Arlington employees and students engaging in research.

VII. UT Arlington Office(s) Responsible for Policy

The Vice President for Research is the Institutional Official for the human research protection program at The University of Texas at Arlington. The Institutional Official is responsible for ensuring compliance with federal and state regulations pertaining to human research, and is responsible for the delegation of authority for the establishment and enforcement of relevant University policies and procedures.

VIII. Dates Approved or Amended

March 23, 2012

IX. Contact Information

All questions concerning this policy should be directed to Research Administration - Office of Regulatory Services at regulatoryservices@uta.eduor www.uta.edu/uta/research, 817-272-3723.