


<p><b>Name of Policy:</b> <u>Protection of human subjects in research.</u></p> <p><b>Policy Number:</b> 3364-70-05</p> <p><b>Approving Officer:</b> President</p> <p><b>Responsible Agent:</b> Vice President for Research Administration</p> <p><b>Scope:</b> All University of Toledo Campuses</p>	 <p><b>Effective date:</b> March 25, 2008</p>
<p><input type="checkbox"/> New policy proposal</p> <p><input checked="" type="checkbox"/> Major revision of existing policy</p>	<p><input type="checkbox"/> Minor/technical revision of existing policy</p> <p><input type="checkbox"/> Reaffirmation of existing policy</p>

(A) Policy statement

The University of Toledo assumes responsibility for safeguarding the rights and welfare of human subjects at risk in all research activities conducted under the auspices of this institution. The university is guided in that respect by the statement of principles in the declaration of Helsinki (1964, as last revised), the ethical guidelines for clinical investigation adopted by the American medical association in 1966, the Belmont report of 1979, the international conference on harmonization of technical requirements for registration of pharmaceuticals for human use guidance, the 1993 council for international organizations of medical sciences (CIOMS) international ethical guidelines for biomedical research involving human subjects, the 1998 medical research council of Canada tri-council policy statement on ethical conduct for research involving humans, and applicable laws, regulations and standards of local, state, and federal government agencies (including 45 C.F.R. 46 [subpart A – the “Common Rule” – and subparts B to D], 45 C.F.R. parts 160 and 164, and 21 C.F.R. 50) concerning the protection of human subjects.

- (1) The university has a federal wide assurance (“Assurance”) on file with the United States department of health and human services (HHS) office for human research protections (OHRP). This assurance sets forth the policies for the protection of human subjects and includes the duties and procedures of the institutional review board.
- (2) The university has established two institutional review boards. The biomedical institutional review board is appointed by the executive vice president and provost of the health science campus and the social behavioral and educational institutional review board is appointed by the provost of the main campus. The university also has agreements with several other institutional review boards that may review selected research at the university. The university department for human research protections works in an administrative capacity with the institutional review boards to review and track research. It is the responsibility of the department for human research protections, working with the institutional review boards, to recommend and implement policies and regulations for the protection of human subjects in research.
- (3) "University-related research" means research carried out on or off campus (including other states or countries) by university faculty, students, or other employees, and any studies conducted by any investigator using university facilities

and/or university patients as subjects, including patient records or surveys. All university-related research that involves human subjects directly or through the use of records, tissues, or other indirect means must receive prior university institutional review board review and approval before any project can begin (university office for human research protections assurance and university medical staff bylaws, rules and regulations). It is a violation of federal regulations, university assurance and university policy to commence any research covered by this policy without prior institutional review board approval. This requirement will, at times, entail review of projects by the institutional review board of two or more institutions, for example, when a university faculty member is involved, as a co-investigator, in studies involving human subjects at another institution or wishes to access records at or obtain materials from another institution. The university institutional review board only can approve clinical research performed at university-affiliated practice sites. A list of these sites, provided by the University of Toledo physicians group, is available from the research and sponsored programs administration office.

- (4) All university-related research involving human subjects must be reviewed by the appropriate university institutional review board or university affiliated institutional review board.
- (5) Approval from non- university institutional review boards can replace approval from the university institutional review board when a formal agreement is in place. Those institutional review boards with formal agreements with the university are named in the university assurance. All approval letters from associated institutional review boards must be submitted for inclusion in department for human research protections records. Consistent with federal regulations university officials reserve the right to disapprove any research approved by any associated institutional review board.
- (6) Although approval for research use of autopsy or cadaveric material is not required by federal regulations, university has established a policy that such research must be reviewed by the cadaveric tissue research committee prior to initiation of a project.
- (7) The assurance between the government and university covers only university faculty, volunteer faculty, staff, registered students, and registered volunteers who are engaged in human subject research. Only university faculty, volunteer faculty, staff, registered students, and registered volunteers (“university affiliates”) may be listed as study personnel on a university institutional review board application unless it is documented that these individuals who are not university affiliates are either (a) not engaged in research (their role must be defined) or, (b) they have an approved individual investigator’s agreement on file with the university institutional review board. Moreover, only university salaried faculty or appropriately qualified salaried/contract university personnel can be principal investigator on a university institutional review board application. A graduate

student conducting research must have a university salaried faculty or appropriately qualified salaried/contracted university employee named as the principal investigator on their application. The principal investigator must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the institutional review board protocol. The vice president for research administration must approve any exceptions to the above criteria regarding the eligibility of an individual to serve as the principal investigator of an institutional review board protocol.

- (8) All study personnel must submit their qualifications to participate in research to the university institutional review board. The university institutional review board must review and approve all study personnel prior to their participation in any research activity. For non-university personnel included on an university institutional review board application, the principal investigator is responsible for providing to the university institutional review board written proof (current institutional review board approval letter signed and dated by the appropriate institutional review board designee) of current institutional review board approval (throughout the duration of the research) from the institutional review board that covers that individual's required human subject research training and conduct.
- (9) Definition of research involving human subjects:
  - (a) Research is defined by federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 C.F.R. 46.102[d]). [Note: In a recent document entitled "NIH Primer: Research and Privacy," (Jan. 4, 2000) NIH has clarified the meaning of the term "generalizable knowledge." In this publication NIH defines the term as follows: "generalizable knowledge {for health care facilities} is knowledge related to health that can be applied to populations outside the population served by the covered entity."]
  - (b) A human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains:
    - (i) data through interventions or interactions with the individual or
    - (ii) identifiable private information.Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Distinction must be made between interventions or procedures being done as part of the individual's clinical care and those that are "protocol -induced". Protocol-induced interventions or procedures (including lab tests, drugs, radiation exposure, or devices) means interventions or procedures that the study subject would not have been exposed to had he or she not volunteered to participate in the research. Interaction includes communication or

interpersonal contact between investigator and subject. Private information includes 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 that has been provided for specific purposes by an individual, which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects" (45 C.F.R. 46.102[f]). For research involving human subjects, an institutional review board approval is required not only during the period when patients are being entered into the study, but for the entire time that private information about study subjects is being collected or analyzed for research purposes.

(10) Types of institutional review board review

There are three types of institutional review board review and associated approval for research involving human subjects: convened board, expedited, and exempt. Each type of review and approval is specifically defined in the federal regulations (45 C.F.R. 46). The university institutional review board must follow these specifications for designating the review type to remain in compliance with our Assurance. All reviews also involve a determination by the university institutional review board as to compliance with 45 C.F.R. parts 160 and 164 (Health Information Portability and Accountability Act (HIPAA Privacy Rule)). [NOTE: Each review type requires a designated application form for submission to the university institutional review board. These forms may be obtained from the university research website <<http://www.UT.edu/research>>.

(a) Convened board review

All projects involving human subjects exposed to more than minimal risks must be submitted for review by the convened institutional review board, which meets on a monthly basis. Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life [of the population or class of research subjects involved] or during the performance of routine physical or psychological examinations or tests.

Such projects require submission of an application form, a proposed informed consent (with or without an assent form(s)), and other supporting documents (e.g., protocol documents, recruitment material, questionnaires or surveys, investigator brochures (for sponsored pharmaceutical research) and grant or contract proposals (if applicable) as noted on the schedules posted on the department for human research protections web page which can be found at [http://utoledo.edu/research/RC/HumanSubs\\_Menu.html](http://utoledo.edu/research/RC/HumanSubs_Menu.html).

Review by the convened board is also generally required for studies that could (or may appear to) potentially expose a participant to additional risk because of a physician's dual role as physician and researcher. An example would be when a physician removing tissues for non-research (medical treatment or diagnosis) purposes as part of his/her clinical duties is also a researcher who might use some of the excess material left over after pathological evaluation for his/her own research.

Following initial review and approval by the university institutional review board, investigators conducting research designated by the institutional review board as convened review are required to have all modifications to the research protocol reviewed and approved by the university institutional review board prior to instituting them. In addition to reporting adverse events to the sponsor and required regulatory agencies they must also report adverse events to the university institutional review board in a timely manner. Investigators are responsible for maintaining institutional review board approval until data collection and analysis is complete and all research activity has ceased. They must submit all other reports and information that the university institutional review board has requested, such as safety notifications from sponsors or reports by a data safety monitoring board (DSMB). Upon completion of the data collection and analysis or after other termination of a protocol, all principal investigators must submit a final report to the institutional review board.

(b) Expedited review

Those studies, which must involve no more than minimal risk, as defined above, or no physical risk to living subjects (e.g., existing record review or use of existing pathology specimens) and which are included on the list of types of research designated by federal regulations as qualifying for expedited review may be approved through the expedited review process (45 C.F.R. 46.110, as revised 11/98). See web site at the end of this policy for the list of types of research that might receive expedited review. Such protocols do not have to wait for a convened meeting of the institutional review board, but may be reviewed and approved by the institutional review board chair or his or her designee and reported to the convened institutional review board. Approval of expedited applications is generally within two weeks, but approval time in that period of time is dependent upon institutional review board receipt of a completed application form (including all required (original) signatures) a well written protocol and informed consent document (if required), and receipt of all required supporting documents to be used in the research (including questionnaires/surveys) which can be approved "as is". Approval time also is dependent upon the institutional review board receiving responses from the principal investigator to any questions that the institutional review board reviewer may have.

Following initial review and approval by the university institutional review board, investigators conducting research designated by the institutional review board as convened review are required to have all modifications to the research protocol reviewed and approved by the university institutional review board prior to instituting them. In addition to reporting adverse events to the sponsor and required regulatory agencies they must also report adverse events to the university institutional review board in a timely manner. Investigators are responsible for maintaining institutional review board approval until data collection and analysis is complete and all research activity has ceased. They must submit all other reports and information that the university institutional review board has requested, such as safety notifications from sponsors or reports by a data safety monitoring board (DSMB). Upon completion of the data collection and analysis or after other termination of a protocol, all principal investigators must submit a final report to the institutional review board.

(c) Exempt research

Research that meets certain criteria set forth in 46 C.F.R. 45. 101(b) may be designated as exempt. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt from the review process. Only the institutional review board chairperson or the DHRP administrative staff has the authority to designate a research protocol as "exempt," and this can be done only after review of the research protocol and procedures.

Investigators conducting research designated exempt by the institutional review board are required to have all modifications to the exempt research protocols reviewed and approved by the university institutional review board prior to instituting them. Investigators must also submit status updates to the university institutional review board every two years, and a final report to the institutional review board upon completion of the data collection and analysis.

Note: For the purposes of exempt status, the OHRP defines "existing material" to mean that all material to be used in the study must be in existence, i.e., "on the shelf" at the time of institutional review board review of the protocol. If any study material is to be obtained prospectively, the study is not eligible for exempt status under the "existing data" criterion.

(d) IRB applications

The most current versions of the application forms (exempt, expedited, and convened review) and all related forms are available on the department for human research protections web page located at [http://www.utoledo.edu/research/RC/HumanSubs\\_Menu.html](http://www.utoledo.edu/research/RC/HumanSubs_Menu.html). Only the most current form versions will be accepted for review.

- (11) Section 2919.14 of the Ohio Revised Code forbids experimental use or sale of any products of aborted human conception. Legal opinions obtained by the university indicate that this statute extends to the use of cell lines originally derived from aborted fetal tissue, even if an Ohio investigator brought them from another state or received them from a colleague at an out-of-state institution.
- (12) University institutional review board approval is required for any research involving fresh samples of umbilical cord blood for research prior to the start of such projects. If samples are to be obtained from other hospitals, a copy of that institution's institutional review board approval must be submitted to the university institutional review board before university institutional review board approval can be granted.
- (13) Financial information, such as study budget, schedule of payments to investigators and enrollees, and monetary or other enrollment incentive/bonus payments, if offered, must be submitted with the application for institutional review board review. If, as the study progresses, there are changes in financial arrangements or a sponsor decides to institute incentive/bonus offers, these new arrangements must be submitted for the institutional review board and university research administration review and approval prior to instituting these changes. It is the policy of the university that neither it, nor its investigators, subunits or other study personnel, will accept incentives or bonuses tied to the rate of recruitment of study subjects or to early enrollment of subjects in clinical trials, whether such incentives or bonuses are offered as a part of a research agreement or at any other time. For the purposes of this policy, the terms incentives and bonuses include anything of value.
- (14) In compliance with the university conflict of interest policy (# 03-005), all study personnel must apprise the institutional review board of any financial or other interest (including, but not limited to, consulting agreements) that they, or any member of their family, have in a sponsoring company or any interest in the technology being studied. For this reason, all study personnel must complete a disclosure of potential conflict-of-interest form to provide the institutional review board information necessary to assess the potential for conflict-of-interest. When human subject research is associated with a grant or research agreement, the institutional review board will receive a copy of the disclosure form submitted to the research administration office with the grant proposal or research agreement. For unsponsored research, an institutional review board-specific disclosure form is required. The institutional review board may request that the provost refer to the university conflict of interest review committee any issues that it considers to have a potential for representing a conflict-of-interest, or the appearance thereof. Final institutional review board approval for any study will be withheld pending resolution of any conflict-of-interest issues to the satisfaction of the institutional review board.

Note: For the purposes of this item, "study personnel" includes, but is not limited to, the principal investigator, co-investigators, study coordinators, research collaborators and all other individuals interacting with subjects for research purposes. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of research with human subjects, to the study participants or their private information, unless they are in a position to influence the study's results or have privileged information as to the outcome.

- (15) Patient-physician confidentiality, patient-employee/volunteer confidentiality and the absolutely voluntary nature of participation in research protocols must be considered and maintained when recruiting potential subjects.
- (a) Publicly placed flyers, posters, brochures, and advertisements in newspapers and other such publications are good means for recruitment that avoid any possibility of coercion and promote voluntary participation. See below for further details on such instruments.
  - (b) Review of departmental log books, medical charts, and databases for potential subjects is not an acceptable practice prior to institutional review board review and approval. It is acceptable to request information on the number of cases that might fit the criteria an investigator wants to study in order to determine whether there is an adequate population size to support a research study. Such a request must not include patient identifiers. Persons with access to patient names and diagnoses should not, nor should they be asked to, provide such lists for an investigator to use to contact potential participants, who could view such an unexpected communication to be an invasion of privacy and a breach of doctor-patient confidentiality.
  - (c) If an investigator plans to recruit subjects that are not his/her own patients, he or she should enlist the assistance of the potential participants' own physicians to introduce the study. An invitational, informational letter from the personal physician or clinic doctor to the potential participants should be used to explain that there is a research study being conducted and state by whom, what the study is designed to investigate, why they are being asked to participate (medical diagnosis, age/sex criteria, caregiver to someone with a specific condition, and such), and whom to contact if interested in learning more details. In the letter, the potential participants may also be asked to give permission for the investigator(s) to make direct contact. The personal physician would then relay the names of the "positive" responders to the investigator. A draft of this letter must be submitted to the institutional review board with the remainder of the application materials.

- (16) All forms of advertisement to recruit human subjects for research studies (including, but not limited to, newspaper ads, flyers, posters, announcements disseminated by e-mail, web pages, phone scripts or other announcements) must be submitted to the university institutional review board for review and approval prior to use or publication. They should be part of the original protocol application whenever possible
- (17) All deviations from the university institutional review board approved protocol including, but not limited to over-enrollment, violation of inclusion or exclusion criteria, use of non-institutional review board approved personnel or facilities engaged in research, must be reported to the university institutional review board by the principal investigator as soon as he or she becomes aware of it.
- (18) It is university policy not to allow any compensation to professionals who refer subjects for research studies (i.e., “finder’s fees), except in rare circumstances. The principal investigator must justify to the institutional review board the reason(s) for offering such remuneration by including a separate statement with the protocol application. If compensation is approved by the institutional review board, it must not be contingent upon the subject’s acceptance into the protocol, agreement to participate, or completion of the protocol, and the subject must be informed in the consent form that the referring professional received compensation for his or her time and effort.
- (19) Investigators are required to submit final reports within thirty days following the expiration date of university institutional review board approval or within thirty days of the completion of data collection, analysis and cessation of all study activity (whichever date occurs first).
- (20) University procedures for specific types of research
  - (a) Procedures for the use of medical records

Any review or use of medical records information for the purpose of research at the University of Toledo Medical Center hospitals and clinics must receive prior approval of the university institutional review board and authorization by the health information management department and be reviewed for compliance with the HIPAA privacy rule. In addition to the appropriate institutional review board application form, a separate institutional review board form for waiver of informed consent will be required if informed consent is requested. The statement of institutional review board approval will be communicated to the principal investigator, who should take a copy of the institutional review board approval document to the health information management department, which can then release the requested materials.
  - (b) Procedures for genetic testing and other markers

- (i) Any request for genetic testing or testing of other markers at any time during, or at the conclusion of a clinical trial or other research project must be specifically submitted to the university institutional review board for review and approval and determination of compliance with the HIPAA privacy rule. Approval for “routine blood tests” should not be construed to include pharmacogenomics, genotyping or any other type(s) of genetic study.
- (ii) Protocols seeking approval for “hypothesis-driven” research involving genetic testing or testing for other markers must have a demonstrated specific goal. The university institutional review board will determine whether a study meets the standards of “hypothesis-driven” research.
- (iii) The disposition of samples at the completion a study involving genetic testing must be determined. Where possible, provisions in the study agreement should provide for proper disposition of the samples once the study is complete.
  - (a) For company sponsored studies, samples should be returned to the university to be destroyed, destroyed by the sponsor, or maintained without identifiers with prior institutional review board approval and the explicit informed consent of the subject.
  - (b) For university investigators, the samples should be destroyed or maintained with prior institutional review board approval and the explicit informed consent of the subject.
  - (c) The length of time that a specimen is maintained must be the minimal determined necessary to maintain the integrity of the research.
- (iv) Regarding protocols that contain requests for samples for future, unspecified “non-hypothesis-driven” research:
  - (a) For company sponsored studies involving genetic testing or testing for other markers, the samples collected must be used only for the research proposed in the institutional review board-approved protocol, unless additional collection and use is specified in the company protocol and reviewed and approved by the institutional review board. If the sponsor requests collection of additional sample for future, unspecified “non-hypothesis-driven” research, information associated with those samples must be stripped

of identifiers. The subject must be given the option whether or not to participate in the additional collection of samples. An explanation of intended use and potential risks of genetic testing should be clearly explained in the consent form and a separate statement of consent, specific to the genetic testing, must be signed or initialed by the subject (this may be contained within the study consent form).

- (b) For university investigators, identified and/or unidentified samples may be maintained with prior institutional review board approval and the consent of the subject. Through the informed consent process, the subject must be given option whether or not to participate and as much information as possible about the future use of the samples. Additional research projects with the stored samples must be approved by the institutional review board. Information sent with samples sent outside the institution must be stripped of identifiers.
  - (c) It is recognized that with current technology, no genetic material can be totally anonymous if there is another identified sample in another repository, such as the department of defense. It is therefore critical that those who hold genetic material that has been collected for research have strict criteria for use and protection of confidentiality with respect to that genetic material.
- (v) Research protocols that involve genetic testing or testing for other markers should not include minors or those who are mentally incapacitated unless there is specific scientific justification for including that particular vulnerable population.
- (a) The institutional review board believes that the risks of genetic testing or testing for other markers in children are potentially greater than the risks for adults, because a minor cannot give his or her own consent, and information gained from genetic testing or testing for other markers of disease susceptibility could potentially follow the individual throughout his or her life.
  - (b) The institutional review board concluded that the long-term risks of genetic testing, even when it is related to therapy, may be greater for children than for adults, owing to the unknown consequences of future discoveries.

- (c) In studies where the outcome of genetic testing or testing for other markers is not related to therapy or potential therapy, the institutional review board believes that risks outweigh benefits to the minor.

- (c) Procedures for the use of tissues and/or hardware removed during surgery:

The University of Toledo Medical Center (UTMC) medical staff bylaws, rules and regulations require that all tissues and hardware removed during surgery be submitted to the department of pathology. Investigators requiring the use of human tissues from the university hospital's surgical procedures should contact the director of clinical laboratories or the chairman of pathology prior to submission of a protocol to the institutional review board in order to ensure availability of required material. Research which requires only existing specimens (i.e., archived "on-the-shelf" specimens), all of which are in existence at the time of institutional review board review and none of which have patient identifiers associated with the specimen, can normally be designated by the institutional review board chair as exempt research. Research that requires existing specimens, as described above, but which have patient identifiers associated, can normally be reviewed by the institutional review board chair via the expedited review mechanism. The determination of "exempt" designation or "expedited" review can only be made by the institutional review board chairperson or his/her designee. After proposed procedures are reviewed and approved by the institutional review board, a statement of approval or determination of exempt status will be forwarded to the principal investigator, who should take a copy of the institutional review board approval document to the department of pathology, which can then release the requested material(s). All such research must be reviewed for compliance with the HIPAA privacy rule.

- (d) Procedures for the use of autopsy material, cadavers and cadaveric material:

Research involving cadavers and cadaveric material must be reviewed by the cadaveric tissue research committee prior to initiation of a project. Investigators requesting the use of cadavers should contact the chairman of anatomy and neurobiology or his or her designee. Investigators requesting the use of autopsy material should contact the chairman of pathology, prior to submission of a protocol to the cadaveric tissue research committee in order to ensure availability of required material. After proposed procedures are reviewed by the cadaveric tissue research committee, approval will be forwarded to the principal investigator, who should take a copy of the approval document to the department of pathology, which can then release the requested material(s). All use of

autopsy material must be reviewed for compliance with the HIPAA privacy rule.

- (21) Principal investigator responsibilities in research involving human subjects:
- (a) Principal investigators must acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable Federal Regulations, as well as university policies regarding research with human subjects. It is the responsibility of each investigator to know and understand those regulations and policies prior to initiating any such research.
  - (b) Principal investigators will not make the final determination of the category of institutional review board review (i.e. exempt, expedited or convened board) for research involving human subjects. Federal regulations apply to all university-related research unless reviewed by the university institutional review board and determined (stated in writing) to be exempt. The university institutional review board makes that determination after review of the proposed research protocol.
  - (c) Principal investigators are responsible for providing a copy of the university institutional review board-approved informed consent document (signed by the individual explaining the protocol and obtaining consent from the subject) to each subject at the time of consent; unless the institutional review board has specifically waived this requirement. All signed consent documents must remain confidential and must be retained in a manner approved by the university institutional review board.
  - (d) Principal investigators will promptly report all proposed changes in previously approved human subject research activities to the university institutional review board. The proposed changes will not be initiated without university institutional review board review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
  - (e) Principal investigators are responsible for reporting progress of approved research to the university institutional review board for review, as often as and in the manner prescribed by the institutional review board on the basis of risks to subjects and in accordance with federal regulations. For protocols requiring convened board and expedited review this must occur at least once per year and for protocols determined by the university institutional review board to be exempt this must occur at least every two years.
  - (f) Principal investigators will promptly report to the university institutional review board (and any other agency required by regulation or contract) any injuries or other unanticipated problems involving risks to subjects or

others. This includes instances when the subject outcome is death, life threatening event, disability, congenital anomaly and/or requires or prolongs hospitalization and/or requires intervention to prevent permanent impairment or damage.

- (g) Principal investigators will promptly report to the university institutional review board (and any other agency required by regulation or contract) any deviations, violations or participant non-compliance from the university institutional review board approved protocol in compliance with the guidance stated in the non-compliance reporting form for university institutional review board approved protocols).
  - (h) No principal investigator or any member of his/her research team will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior university institutional review board approval. A physician may provide emergency medical care to a patient without prior university institutional review board review and approval to the extent permitted by law (see section 116[f] of the Ohio Revised Code). However, such activities will not be counted as research nor the data used in support of research.
  - (i) Principal investigators will advise the university institutional review board, research administration and the appropriate officials of other institutions of the intent to admit human subjects into another institution (e.g., into another hospital) who are involved in research protocols. When such admissions are a planned part of DHHS-supported research, those institutions must possess an applicable human research assurance prior to involvement of such persons as human subjects in those research protocols at those institutions.
  - (j) Principal investigators are responsible for providing accurate information to the institutional review board for determination of compliance with the HIPAA privacy rule and for adhering to the rule at all times.
- (21) Further information regarding approval of research protocols, application requirements, and submission deadlines may be obtained from the department for human research protections.
- (22) World wide web urls for regulations and documents:
- (a) Declaration of Helsinki (1964, as revised in 1989)  
<<http://www.fda.gov/oc/health/helsinki89.html> >
  - (b) Belmont Report of 1979  
<<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm> >

- (c) CIOMS International Ethical Guidelines <<http://www.cioms.ch/>>
- (d) PHS/OHRP Regulations  
(45 CFR 46)  
<<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm> >
- (f) FDA Regulations  
(21 CFR 50) <<http://www.fda.gov/oc/ohrt/irbs/appendixb.html>>  
(21 CFR 56) <<http://www.fda.gov/oc/ohrt/irbs/appendixc.html> >
- (g) Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164)  
<<http://www.hhs.gov/ocr/hipaa/finalreg.html> >
- (h) University federal wide assurance  
<[http://hsc.utoledo.edu/research/human\\_assurance/mco\\_fwa.pdf](http://hsc.utoledo.edu/research/human_assurance/mco_fwa.pdf)>
- (i) University institutional review board forms and guidance  
<[http://www.utoledo.edu/research/RC/HumanSubs\\_Menu.html](http://www.utoledo.edu/research/RC/HumanSubs_Menu.html)>
- (j) Medical Research Council of Canada Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans  
<<http://www.sshrc.ca/english/programinfo/policies/ethics.htm>>
- (k) NIH Primer: Research and Privacy  
[http://hsc.utoledo.edu/research/nih\\_privacy\\_primer.pdf](http://hsc.utoledo.edu/research/nih_privacy_primer.pdf)
- (l) Research which may be eligible for EXPEDITED REVIEW  
<<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm> >
- (m) Research that may EXEMPT from the requirement for IRB approval:  
<<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/basics.htm#Exempt>  
<<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hcdc95-02.htm> >

<p>Approved by:</p> <p><u>/s/ laj</u> Lloyd A. Jacobs, M.D. President</p> <p><u>May 20, 2008</u> Date</p> <p><i>Review Revision completed by: Senior Leadership; Research Council</i></p>	<p><b>Policies Superseded by This Policy:</b></p> <ul style="list-style-type: none"> <li>• 02-001 <i>Protection of Human Subjects in Research, former Health Science Campus policy, 07-01-03</i></li> <li>• III-2-2, Article II, <i>Compliance with External and Internal Policies, Section 3 and Section 4, Main Campus policy, approved February 10, 1999</i></li> </ul> <p>Initial effective date: March 25, 2008 Review/Revision Date: Next review date: March 25, 2011</p>
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