Name of Policy: Protection of human subjects in research.

Policy Number: 3364-70-05

Approving Officer: President

Responsible Agent: Vice President for Research

Scope: All University of Toledo Campuses

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☐ New policy proposal  ☒ Minor/technical revision of existing policy

☐ Major revision of existing policy  ☐ Reaffirmation of existing policy

(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. University of Toledo research involving human subjects shall be conducted only in accordance with this policy. This includes any of the following activities conducted for research purposes: interaction or intervention with living individuals, use of human biological specimens from living individuals, or review of data that can identify a living individual (directly or in combination with other data) and that is not publicly available. The university is guided 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 (ICH), 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.

(B) Purpose of Policy

The purpose of this policy is to enumerate the specific requirements, roles and responsibilities for the performance of human research at the University of Toledo. This policy is intended to protect the rights and welfare of human subjects and to assure that human research activities conform to the ethical codes of conduct for human experimentation, federal and state statutes, Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations, policies and guidelines; and applicable University policies and procedures that are referenced in this policy.

(C) Policy

(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 university’s promise that university research will be guided by the ethical principles of The Belmont Report,
conducted in compliance with the Common Rule (45 CFR 46 Part A), reviewed by an authorized IRB, provide educational training to investigators and guided by written procedures for the protection of human research subjects. The document also assures HHS that the university will provide education in human research ethics and protections.

(2) The university has established two institutional review boards. The biomedical institutional review board is appointed by the chancellor and executive vice president for biosciences and health affairs 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 university research. The university department for human research protections works in an administrative capacity with the institutional review boards to review, process and track research and serve as a resource for university faculty, staff and student researchers. 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) All university-related research involving human subjects must be reviewed by the appropriate university institutional review board or an authorized university institutional review board (a) prior to beginning the research, and (b) at intervals specified by the reviewing IRB which will be no less than annually. It is a violation of federal regulations, the university assurance and university policy to commence any research covered by this policy without prior institutional review board approval, or to continue research beyond the specified approval dates. 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.

(4) The university biomedical institutional review board only can approve clinical research performed at university-affiliated practice sites or sites where the university is formally authorized to review research. A list of these sites is available from the department for human research protections office.

(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, approved IRB applications, and approved consent forms from associated institutional review boards must be submitted for inclusion in university IRB records. Consistent with federal regulations, university officials reserve the right to not approve any research approved by any associated institutional review board.

(6) Approval for research use of autopsy or cadaveric material is covered by another university policy and is not within the scope of human subject research.
(7) The assurance between the government and university covers only university faculty, community based faculty, staff, registered students, and registered volunteers who are engaged in human subject research. Only university faculty, community based 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. For non-university personnel covered by an assurance at another institution, the principal investigator is responsible for providing to the university institutional review board written proof of current institutional review board approval throughout the duration of the research from the institutional review board that covers that non-university personnel’s human subject research activities, unless the university is authorized by a registered agreement to approve research for the individual(s) institution.

(8) Only university salaried faculty, appropriately qualified salaried/contract university personnel or duly appointed community based clinical or research faculty may be a principal investigator on a university institutional review board application. All students including graduate students 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 human subject protections guidance, provide direct, personal, day-to-day oversight of activities and personnel associated with the institutional review board protocol, and guide the student in compliance with university and institutional review board research policies. 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.

(9) All study personnel must submit their qualifications to participate in research to the university institutional review board. Research training is required for all research team members interacting or intervening with human subjects. The university institutional review board must review and approve all study personnel and their proposed role in the research prior to their participation in any research activity. For non-university personnel, the principal investigator is responsible for providing written assurance to the university, of the non-university personnel’s qualifications and expertise to serve in the proposed role in university research.

(10) Types of institutional review board review

There are three types of institutional review board review for research involving human subjects: convened board, expedited, and designation of exempt. Each type of review is specifically defined in the federal regulations (45 C.F.R. 46 and 21 C.F.R 56) and the department for human research protections’ policies and procedures. The university institutional review board must follow these
specifications for-designating the-review type-to remain in compliance-with our Assurance. Each review type requires a designated application form for submission to the university institutional review board. These forms may be obtained from the university department for human research protections website: http://www.utoledo.edu/research/RC/HumanSubs_Menu.html. All reviews also involve a determination by the university institutional review board or university compliance staff as to compliance with 45 C.F.R. parts 160 and 164 (Health Information Portability and Accountability Act (HIPAA Privacy Rule).

(a) Convened board review

Research that requires convened review includes:

i. All human subject research involving more than minimal risk
ii. Human subject research involving minimal risk that does not fit into an expedited or exempt category
iii. Human subject research with a genetic component (with some exceptions)

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.

The convened IRB meets on a monthly basis according to a schedule posted on the corresponding IRB’s web page which can be found at http://utoledo.edu/research/RC/HumanSubs_Menu.html.

Convened research applications require submission of an application form, a proposed informed consent form, an assent form for research involving minors, 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 instructions posted on the department for human research protections web page which can be found at http://utoledo.edu/research/RC/HumanSubs_Menu.html. Applications that are incomplete as of the submission deadline may be delayed for review until the next submission period during which the application is complete.

If the convened institutional review board requests minor modifications as a condition of approval, investigators are required to have all modifications to the research materials reviewed and approved by the university institutional review board (chair or chair designee) prior to instituting them. If the convened institutional review board requests more
than minor modifications or clarifications, the application is deferred and investigators must resubmit the amended application packet to the convened board according the submission schedule for the monthly IRB meetings.

Following initial review and approval by the university institutional review board, investigators conducting convened category research are required to have all modifications to the research protocol, application responses, new or revised recruitment materials, or other study materials 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, investigators must also report adverse events to the university institutional review board in a timely manner as set forth in the department for human research protections’ adverse event reporting policy.

Investigators are responsible for maintaining institutional review board approval until data collection and analysis of identifiable data is complete and all human subject research activity has ceased. They must submit all 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. Failure to file requested reports with the institutional review board may result a suspension of approval for the investigator’s other research until compliance is obtained.

(b) Expedited review

A research study that involves no more than minimal risk, as defined in this policy, or no physical risk to living subjects (e.g., existing record review or use of existing pathology specimens) and which is 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). Refer to the web site at the end of this policy for the list of types of research that might receive expedited review.

Expedited category protocols are reviewed by an experienced volunteer institutional review board member or the institutional review board chair and reported to the convened institutional review board. An expedited reviewer may request minor changes or clarifications, approve, or refer to the full board. Approval of expedited applications is generally within three weeks, but approval time is dependent upon institutional review
board receipt of a complete 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 and recruitment materials) which can be approved "as is". Approval time is sometimes affected by availability of board members who volunteer time to review expedited applications. The time needed for responses from the principal investigator to any questions from the institutional review board reviewer will affect the total time required for review and approval.

Following initial review and approval by the university institutional review board, investigators conducting expedited category research are required to have all modifications to the research protocol, application responses, recruitment materials, or other study materials 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 investigators must also report adverse events to the university institutional review board in a timely manner as set forth in the department for human research protections’ adverse event policy.

Investigators are responsible for maintaining institutional review board approval until data collection and analysis of identifiable data is complete and all human subject research activity has ceased. They must submit all reports and information that the university institutional review board requests. 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. Failure to file requested reports with the institutional review board may result a suspension of approval for the investigator’s other research until compliance is obtained.

(c) Exempt research

Research that meets certain criteria set forth in 46 C.F.R. 45. 101(b) may be designated as exempt. Only the institutional review board chairperson or designated DHRP 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 do not have the authority to make an independent determination that research involving human subjects is exempt from the review process.

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.
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” category.

(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. Only the most current form versions will be accepted for review.

(11) Ohio law forbids experimental use or sale of any products of aborted human conception (Ohio Revised Code section 2919.14). 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.

(14) In compliance with the university conflict of interest policy #3364-70-01, 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 disclose potential conflict-of-interests at the time of the IRB application and as any new potential interests arise. 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 Vice President for Research Administration 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 to the study participants or their private information, unless they are in a position to influence the study's results.

(15) Patient confidentiality, human research subject confidentiality, and the absolutely voluntary nature of participation in research protocols must be considered and maintained when recruiting potential subjects.

(a) 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, publication or broadcasting. They should be part of the original protocol application whenever possible. Adding or modifying advertisements after initial approval requires a protocol application amendment and approval prior to the release of the new or revised advertising. Investigators must allow enough time for review and approval of amendments prior to publication, broadcasting or use of the advertisement. In general, advertisements submitted after initial protocol approval, are reviewed under the expedited amendment review method.

(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, or receipt of permission from the institutional review board to review data preparatory to research. 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. The investigator must obtain a partial waiver of authorization to use and disclose protected health information (see institutional review board application) prior to using this recruitment method.

(16) 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. The IRB has the authority to determine the appropriate course of action with respect to the protection of human research subjects depending on the degree of risk (including an increase in risk) to subjects or affected individuals and previous deviations by the investigator. Appropriate courses of action include but are not limited to: a letter to the investigator that will be kept on record with the IRB or additional required human subjects protection education.

(17) It is university policy not to allow any compensation to individuals 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.

(18) 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). The institutional review board may withhold approval of subsequent research applications from an investigator who has not submitted a final report from previous research.
(19) 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 be reviewed for compliance with the HIPAA privacy rule. This requires a HIPAA authorization from the patient/subject or a waiver of authorization from the IRB. 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 pre-determined 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 and authorization 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” genetic 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 samples 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 and authorization of the subject. Through the informed consent and authorization process, the subject must be given an 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, even when consent to store the samples for future research was obtained from the subject. Information accompanying 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.
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. 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.

(b) 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 and therefore the institutional review board will not approve this activity.

(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 as not IRB regulated research.

Research using only existing specimens where the investigator does not record any identifying information can generally be designated exempt category research.

Research that requires existing specimens, as described above, but which have patient identifiers associated, can normally be reviewed via the expedited review mechanism.
After proposed procedures are reviewed and approved by the institutional review board, a statement of approval, or determination of exempt or not regulated 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) Research involving cadavers and cadaveric material is not within the oversight responsibilities of the institutional review board. Researchers interested in such research should review the University policy applicable to such research.

(20) 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 or not human subject research. The university institutional review board makes an exempt 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 confidential manner approved by the university institutional review board.

(d) Principal investigators must promptly report all proposed changes in previously approved human subject research activities to the university institutional review board. The proposed changes shall 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 and submitting for continuing 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.

(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. However, such activities may 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 federalwide assurance (“FWA”) 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 DHHS regulations, FDA regulations, and the HIPAA privacy rule and for adhering rule and regulations applicable to their research at all times.

(21) All individually identifiable protected health information, as defined by the HIPAA privacy rule, must be removed or redacted from medical records and
research records prior to such records being removed from the University for research purposes. This does not limit the ability of sponsors and their research monitors to review or copy medical or research records as necessary to monitor the research, however, such copied materials must be stripped of protected health information prior to leaving the University.

An exception to this redaction policy can be approved by the IRB if the consent and HIPAA authorization clearly explain the scope of the disclosure and the subject agrees to such disclosure. The Principal Investigator is responsible for ensuring compliance with subject’s authorization.

(22) Further information regarding approval of research protocols, application requirements, and submission deadlines may be obtained from the department for human research protections.

(23) Review by institution.
Research covered by this policy that has been approved by a University institutional review board may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

(D) Definitions

(1) 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 obtained must be individually identifiable in order for 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.

(c) “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.

(d) "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.

(E) World wide web sites for regulations and documents:

(1) Declaration of Helsinki (1964, as revised in 1989) <http://www.fda.gov/oc/health/helsinki89.html>
(3) CIOMS International Ethical Guidelines <http://www.cioms.ch/>
(4) PHS/OHRP Regulations (45 CFR 46) <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>
(21 CFR 56) [http://www.fda.gov/ohrt/irbs/appendixc.html]
(21 CFR 312)
(21 CFR 812)

(6) Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164)
[http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html]

(7) University federal wide assurance
[http://hsc.utoledo.edu/research/human_assurance/mco_fwa.pdf]

(8) University institutional review board forms and guidance
[http://www.utoledo.edu/research/RC/HumanSubs_Menu.html]

(9) Medical Research Council of Canada Tri-Council Policy Statement:
Ethical Conduct for Research Involving Humans
[http://www.sshrc.ca/english/programinfo/policies/ethics.htm]

(10) NIH Primer: Research and Privacy
http://hsc.utoledo.edu/research/nih_privacy_primer.pdf

(11) Research which may be eligible for EXPEDITED REVIEW
[http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm]

(12) 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/hsdc95-02.htm]

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| /s/ laj  
Lloyd A. Jacobs, M.D.  
President  
September 23, 2011  
Date | *Previous 3364-70-05* |

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