: _____ : 3364-70-05 : President : Vice President for Research : All University of Toledo Campuses	March 17, 2022 : March 25, 2008

	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 (UToledo) assumes responsibility for safeguarding the rights and
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(D) Definitions

(1) The “Institutional Review Board (IRB)” is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

(2) “Research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(l))

(3) “Human subject” means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e)(1))

(4) “Clinical trial” means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. (45 CFR 46.102(b))

(5) "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.

(6) “Human Research Protection Program (HRPP)” describes the UToledo program that provides support to UToledo IRBs, provides educational activities, serves as a resource for faculty, staff and student researchers, recommends and implementspolicies and regulations for the protection of human subjects in research, and ensures compliance with relevant laws, regulations, and ethical standards while addressing the needs and concerns of investigators who conduct research with human subjects. Compliance of clinical trials conducted by UToledo study personnelis also addressed in UToledo policy #3364-70-28.

(7) “UToledo-related research" means research carried out on or off campus (includingother states or countries) by university faculty, students, or other employees, andany studies conducted by any investigator using university facilities and/or university patients as subjects, including patient records or surveys.

(E) The HRPP provides support to activities including but not limited to the following:

(1) All UToledo IRBs (e.g., Biomedical and Social Behavioral and Educational). IRB members are appointed by the Vice President for Research. The university may enter into agreements with external institutional review boards, which may be authorized to review selected university research.

(a) All UToledo-related research involving human subjects must be reviewed and approved by the appropriate UToledo IRB or a UToledo-authorized external IRB prior to beginning the research, and at intervals specified by the reviewing IRB. It is a violation of federal regulations, the university assurance and university policy to commence any research covered bythis policy without prior institutional review board approval, or to continue research beyond the specified approval dates.

(b) UToledo Biomedical IRB may approve clinical research performed at UToledo-affiliated practice sites or siteswhere the university is formally authorized to review research. A list of these sites is available from the HRPP office.

(c) Approval from non-UToledo IRBs can replace approval from the university institutional review board when a formal authorization agreement is in place.

(d) Any research involving fresh samples of umbilical cord blood for research must be reviewed and approved by the UToledo IRB prior to the start of such study. If samples are to be obtained from another institution, a copy of that institution's IRB approval must be submitted to the UToledo IRB for review before UToledo IRB approval may be granted.

(e) Research covered by this policy that has been approved by an IRB 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.

(2) Study Personnel: The UToledo IRB must review and approval all study personneland their proposed role in the research prior to their participation in any research with human subject activity. The Vice President for Research mustapprove any exceptions to the below criteria regarding the eligibility of an individual to serve as the principal investigator of an IRB study.

Only university faculty, appropriately qualified salaried/contract university personnel or duly appointed community based clinical or research faculty may be a principal investigator on a UToledo IRB study. University-designated emeritus faculty may serve as principal investigator, provided they hold less than a 50 percent appointment/employment with another (non-UToledo) institution or company. 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 study, and guide personnel in compliance with university research policies and IRB procedures

(a) All students including graduate students conducting research must have a UToledo salaried faculty or appropriately qualified salaried/contracted university employee named as the principal investigator on their application.

(b) Research training is required for all study personnel interacting or intervening with human subjects. For non-UToledo 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 rolein UToledo research.

(c) In compliance with the UToledo conflict of interest policy #3364-70-01, all study personnel must apprise the IRB 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 financial interest in the technology being studied. All study personnel must disclose potential conflict-of-interests at the time of IRB application and as any new potential interests arise.

(3) The UToledo IRBs have the authority to determine the appropriate course of action with respect to study deviations and adverse events depending on the degree of risk to subjects or affected individuals and previous deviations by the investigator.

(4) The Vice President for Research is the Institutional Official (IO). The IO, or his/her designee, is responsible for communicating reports to the relevant federal agencies as required.

(5) No compensation to individuals who refer subjects for research studies (i.e., "finder's fees) is allowed, except in rare circumstances requiring prior approval of the IRB. The principal investigator must justify to the IRB the reason(s) for offering such remuneration by including a separate statement with the study application. If compensation is approved by the IRB, it must not be contingent upon the subject's acceptance into the study, agreement to participate, or completion of the study, and the subject must be informed in the consent form that the referring professional received compensation for his or her time and effort.

(6) Principal investigator responsibilities in research involving human subjects:

(a) 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 UToledo policies regarding research with human subjects. It is the responsibility of each investigator to know and understand those regulations and policies

priorto initiating any such research.

(b) The principal investigator of an applicable IRB-approved investigator initiated clinical trial is responsible for following HHS (45 CFR 46.116 (h)) and FDA (42 CFR 11) regulations which require study information to be posted on clinicaltrials.gov. Studies only defined as a clinical trial by HHS regulations may use a docket folder at http://www.regulations.gov (Docket ID: HHS-OPHS-2018-0021).

(c) Principal Investigators will not make the final determination of the category of IRB review (i.e. exempt, expedited or full board) for research involving human subjects. The UToledo IRB or HRPP staff may make an exempt determination after review of the proposed research study. When UToledo researchers are involved in collaborative research, a UToledo IRB may accept an exempt determination from different IRB.

(d) Provide a copy of the UToledo IRB-approved informed consent document (signed by the individual explaining the study and obtaining consent from the subject) to each subject at the time of consent unless the IRB has specifically waived this requirement. All signed consent documents must remain confidential and must be retained in a confidential manner approved by the UToledo IRB.

(e) Promptly report all proposed changes in previously approved human subject research activities to the UToledo IRB. The proposed changes may not be initiated without UToledo IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects in which case the IRB must be notified within ten working days. If the study uses an FDA-regulated investigational device, the IRB must be notified within 5 working days after the emergency occurred.

(f) Report progress of approved research to the UToledo IRB and submit this report for continuing review or progress report as often as and in the manner prescribed by the IRB on the basis of risks to subjects and in accordance with federal regulations. HRPP staff may review progress reports.

(g) Promptly report to the UToledo IRB, and any other agency required by regulation or contract, any unanticipated problems involving human research subjects in compliance with UToledo IRB procedures.

(h) Promptly report to the UToledo IRB, and any other agency required by regulation or contract, any deviations, violations or participant non- compliance from the UToledo IRB-approved study in compliance with UToledo IRB procedures.

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 UToledo IRB approval. A physician may provide emergency medical care to a patient without prior UToledo IRB review and approval to the extent

Approved by: /s/_____ Gregory C. Postel, M.D. President March 17, 2022_____ Date Review/Revision Completed by: Office of Research and Sponsored Programs; SLT	• *Previous 3364-70-05* Initial effective date: March 25, 2008 Review/Revision Date: July 22, 2011, September 23, 2011, August 19, 2019, March 17, 2022 Next review date: March 17, 2025