3364-70-05 Protection of human subjects in research.

(A) Policy statement

The university of Toledo ("UT") assumes responsibility for safeguarding the rights and welfare of human subjects involved in all research activities conducted by its faculty, community based faculty, staff, registered students, and registered volunteers. Research involving human subjects will be conducted only in accordance with this policy, including the following activities conducted for research purposes: (1) interaction or intervention with living individuals, (2) use of human biological specimens from living individuals, or (3) review of data that can identify a living individual (directly or in combination with other data) and that is not publicly available.

UT 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 UT research will be guided by the ethical principles of the Belmont report of 1979 and conducted in compliance with applicable laws, regulations and standards of local, state, and federal government agencies (such as 45 C.F.R. 46, 45 C.F.R. parts 160 and 164, and 21 C.F.R. parts 50 and 56) concerning the protection of human subjects. The assurance between the government and university covers university faculty, community based faculty, staff, registered students, and registered volunteers who are engaged in human subject research. The institutional review board ("IRB") maintains written procedures for the protection of human research subjects.

(B) Purpose of policy

This policy enumerates the specific requirements for the performance of human research at UT in order to protect the rights and welfare of human subjects and assure that human research activities conform to the ethical codes of conduct for human experimentation, federal and state statutes, HHS and food and drug administration ("FDA") regulations, policies and guidelines; and applicable UT policies and procedures.

(C) Scope

This policy applies to all UT related research involving human subjects.

(D) Definitions

(1) The 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 C.F.R. 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 C.F.R. 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 C.F.R. 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 UT program that provides support to UT IRBs, provides educational activities, serves as a resource for faculty, staff and student researchers, recommends and implements policies 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 UT study personnel is also addressed in rule 3364-70-28 of the Administrative Code (internal auditing of

clinical research policy).

(7) "UT-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) The HRPP provides support to activities including but not limited to the following:

(1) All UT IRBs (e.g., biomedical, biomedical cancer, 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 UT-related research involving human subjects must be reviewed and approved by the appropriate UT IRB or a UT-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 by this policy without prior institutional review board approval, or to continue research beyond the specified approval dates.

(b) UT biomedical IRB and biomedical cancer IRB may approve clinical research performed at UT-affiliated practice sites or sites where the university is formally authorized to review research. A list of these sites is available from the HRPP office.

(c) Approval from non-UT 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 UT 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 UT

IRB for review before UT 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 UT IRB must review and approval all study personnel and their proposed role in the research prior to their participation in any research with human subject activity. The vice president for research must approve any exceptions to the below criteria regarding the eligibility of an individual to serve as the principal investigator of an IRB study.

(a) 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 UT IRB study. All students including graduate students conducting research must have a UT 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 study, and guide the student in compliance with university research policies and IRB procedures.

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

(c) In compliance with rule 3364-70-01 of the Administrative Code (financial conflict of interest policy for sponsored programs), 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 UT 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 UT 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) The principal investigator of an applicable IRB-approved investigator initiated clinical trial is responsible for following HHS (45 C.F.R. 46.116 (h))

and FDA (42 C.F.R. 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 UT IRB or HRPP staff may make an exempt determination after review of the proposed research study. When UT researchers are involved in collaborative research, a UT IRB may accept an exempt determination from different IRB.

(d) Provide a copy of the UT 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 UT IRB.

(e) Promptly report all proposed changes in previously approved human subject research activities to the UT IRB. The proposed changes may not be initiated without UT 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.

(f) Report progress of approved research to the UT 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 UT IRB, and any other agency required by regulation or contract, any unanticipated

problems involving human research subjects in compliance with UT IRB procedures.

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

(i) 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 UT IRB approval. A physician may provide emergency medical care to a patient without prior UT IRB review and approval to the extent permitted by law. However, such activities may not be used for research nor the data used in support of research.

(j) Advise the UT IRB, research and sponsored programs office, and the appropriate officials of other institutions of the intent to admit human subjects into another institution (e.g., into another hospital) for research purposes. When such admissions are a planned part of HHS-supported research, those institutions must possess an applicable human research federal wide assurance ("FWA") prior to involvement of such persons as human subjects in those research studies at those institutions.

(k) Provide accurate and complete information to the IRB for determination of compliance with HHS and FDA regulations, and HIPAA privacy rules. Principal Investigators will adhere to rules and regulations applicable to their research at all times.

(l) Submit final reports within thirty days following the expiration date of UT IRB approval or completion of data collection, analysis and cessation of all study activity (whichever comes first). If no expiration date is indicated, submit final reports within thirty days following the completion of data collection, analysis and cessation of all

study activity. The UT IRB may withhold approval of subsequent research applications from an investigator who has not submitted a final report from previous research.

(7) 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.

(8) Ohio law forbids experimental use or sale of any products of aborted human conception (section 2929.14 of the Revised Code). This statute extends to the use of cell lines originally derived from aborted fetal tissue received from any location.

(9) Approval for research use of autopsy or cadaveric material is not within the scope of human subjects' research.

Effective: 4/13/2020

CERTIFIED ELECTRONICALLY

Certification

04/01/2020

Date

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