20 Definitions

A –

Access –The mechanism of obtaining or using information electronically, on paper, or other medium for the purpose of performing an official function.

Adverse Event – Any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article.

Agent – Any person performing institutionally-designated activities or exercising institutionally delegated authority or responsibility.

Anonymized means that data or biospecimens do not contain any identifying information and they cannot be linked to any identifiable person.

Authorization – A detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.

C –

Children – persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. According to Michigan state law, minors are persons under the age of 18. The general rule is that a person may consent for his/her own medical care at the age of 18. Therefore, the CMU IRB generally defines children as persons under 18 years of age. Certain statutes and case law, however, provide minors with "majority" status in some circumstances, giving them the right to consent to their own medical care. For example, for emancipated minors, Michigan law enumerates certain categories of individuals who, although under the age of 18, have the right to make medical decisions on their own behalf, such as minors who are married, widowed, or divorced; minors who are parents; etc.; for mature minors, Michigan law recognizes that some minors may be sufficiently "mature" to give consent to medical treatment, even though they do not qualify as "emancipated"; or certain minors seeking care for drug addiction, sexually transmitted diseases, emotional disorders, or abortion or mental health treatment. Because Michigan law does not specifically address consent of children with majority status to research, the CMU IRB will review issues of consent related to enrollment of these children in research on a case-by-case basis.

Note: For research conducted in jurisdictions other than Michigan, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The CMU General Counsel's Office will provide assistance with regard to the laws in other jurisdictions.

Clinical Investigation (per FDA) - Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Clinical Trial (per NIH) - 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.

Common Rule –The Common Rule refers to the "Federal Policy for the Protection of Human Subjects" adopted by a number of federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in 45 CFR 46 Subpart A. For the purposes of this document, references to the Common Rule will cite the DHHS regulations.

Community. The term "community" encompasses any group that is identified or self-identifies as a community (including ethnic, religious, occupational, social, or special interest group or group defined by a disease or physical condition), local community organizations and advisory boards, and/or formalized community partnerships.

Covered entity –The term applied to institutions that must comply with the Privacy Rule. These include health plans and health care clearinghouses.

Health care providers who conduct certain financial and administrative transactions electronically. These electronic transactions are those for which standards have been adopted by the Secretary under HIPAA, such as electronic billing and fund transfers.D –

Dead fetus – A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery – Complete separation of the fetus from the woman by expulsion, extraction, or any other means.

De-identified means that identifiers have been removed from data biospecimens; a code may link individual records or specimens to identifiable persons. The requirement for IRB review depends on who deidentified the data/biospecimens and who has access to the linking code.

De-Identified Information – Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. If information is de-identified, it no longer is subject to the Privacy Rule and is exempt from HIPAA.

Deletion – The removal, erasing, or expunging of information or data from a record.

Disclosure –The release, transfer, provision of access to, or divulging in any other manner information outside of the covered entity.

E –

Engagement – Institutions are considered "engaged" in a research project when the involvement of their employees or agents in that project includes any of the following:

1. Intervention for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
2. Intervention for research purposes with any human subject of the research by manipulating the environment.
3. Interaction for research purposes with any human subject of the research.
4. Obtaining the informed consent of human subjects for the research.
5. Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to

   a. observing or recording private behavior;

   b. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and

   c. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

F –

Fetus – The product of conception from implantation until delivery.

Equivalent Protections – {define}

G –

Guardian – An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. In Michigan, a "guardian" of a minor means someone with the duty and authority to act in the best interests of the minor, subject to residual parental rights and responsibilities, to make important decisions in matters having a permanent effect on the life and development of the minor and to be concerned with his/her general welfare [See MCL 330.1100(b)(6)].

Note: For research conducted in jurisdictions other than Michigan, the research must comply with the laws regarding guardianship in all relevant jurisdictions. The CMU General Counsel's Office will provide assistance with regard to the laws in other jurisdictions.

H –

Health Information –Any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual.

Human subject means a living individual about whom an investigator (whether professional or student) is 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.

For research covered by FDA regulations (21 CFR 50 and 56), "human subject" means an individual who is or becomes a participant in a clinical investigation (as defined below), either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject/participant also includes any individual on whose tissue specimen an investigational device is used or tested.

Note: The terms "subject" and "participant" are used interchangeably in this document and have the same meaning.

Human Subjects Research –This means any activity that meets the definition of "research" and involves "human subjects" as defined by either the Common Rule or FDA regulations.

I –

IDE – An investigational device exemption in accordance with 21 CFR 812.

Identifiable Health Information –A subset of health information including demographic information collected from an individual.

IND – An investigational new drug application in accordance with 21 CFR Part 312.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Investigational Device – A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. As further stated, a device is any healthcare product that does not achieve its primary intended purpose by chemical action or by being metabolized.

Investigational Drug – An investigational drug for clinical research use is one for which the PI or a sponsor has filed an IND application (21 CFR Part 312) or an approved drug that is being studied for an unapproved or approved use in a controlled, randomized, or blinded clinical trial.

Interaction includes communication or interpersonal contact between investigator and subject.

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Institutional Review Board (IRB) – An IRB is a board designated by Central Michigan University to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects in research. The IRB may be assigned other review functions as deemed appropriate by the VPR/DGS or the Provost of the University Central Michigan University.

Note: In the sections that follow, the singular form "IRB" will be used to mean all IRBs registered to CMU.

Institutional Official (IO) – The IO is responsible for ensuring that the HRPP at Central Michigan University has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance.

L –

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Limited Data Set –Protected health information that excludes specific direct identifiers of the individual or of relatives, employees, or household members of an individual. A limited data set can only be used for the purposes of research, public health, or healthcare operations, and disclosed for the purpose of research.

M –

Minimum Necessary –The principle that any access should be limited to the minimum amount of information needed to accomplish the intended purpose of the use or disclosure.

Minimal risk means that that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

N –

Neonate – A newborn.

Non-Significant Risk (NSR) – An investigational device other than a significant risk device.

Nonviable neonate – A neonate after delivery that, although living, is not viable.

P –

Pregnancy – The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Preparatory Research – The method applied to developing or designing a research study.

Prisoner – Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures that provide