



## Mercy University IRB Glossary

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### A

**Adverse Event (AE):**

An adverse event is defined broadly to include any untoward or unfavorable occurrence (physical or psychological) in a human participant, including any abnormal sign, symptom, or disease, temporally associated with the participant's time in a research study, whether considered related to their participation. These events can occur in the context of biomedical or social/behavioral research.

**Advertisement:**

A public announcement that is intended to be seen or heard by a prospective participant to solicit that person's enrollment in a research study.

*Note: This can include newspaper, radio, TV, bulletin boards, posters, and flyers in electronic advertising or in print.*

**Age of Consent:**

The age of consent is the legally defined age at which a person has the capacity to voluntarily agree to sexual activity, and in some cases, may no longer be required to obtain parental consent to marry. The age of consent must not be confused with the age of majority.

**Age of Majority:**

The age of majority is the threshold of adulthood as recognized or declared in law. It is the moment when a person is no longer considered a child and can assume legal control over their person, actions, and decisions, thus terminating the control and legal responsibilities of their parents or guardians over them. The age of majority must not be confused with the age of consent.

**Allegation:**

A report that noncompliance may have occurred, and requires further investigation to determine if noncompliance has, in fact, occurred.

**Amendment:**

An Amendment is a change to an approved research study (Expedited or Full Board) that is subject to IRB review and approval before implementation, unless the immediate change is necessary to eliminate an apparent hazard to participants. Currently enrolled and active participants must be informed of the change if it could affect their willingness to continue participation in the study. The Amendment review process is required by federal regulations.

**Anonymous Data:**

Unidentified data (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information or materials (e.g., data) that cannot be linked directly or indirectly by anyone to their source(s).

**Appeal:**

Request for reconsideration of an IRB determination in research involving human subjects, including (but not limited to) decisions regarding approval status, conditions for approval, or noncompliance.

*Note: An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal.*

**Approval Date:**

The first date that research can be performed (following notification from the IRB), consistent with federal regulations, state and local laws, and College policy. The approval date is the date that the research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that modifications/conditions are met by the investigator.

**Approval Period:**

For initial review, the interval that begins on the day research is approved by convened or expedited review, or if modifications are required (to secure approval), the date that modifications/conditions are met by the investigator. For continuing review, the interval that begins on the day research is re-approved (by convened or expedited review) or modifications are required.

*Note: An approval period for initial or continuing review may not be approved for a maximum period of one year from the date of approval or for a shorter period, as determined by the IRB.*

**Approved:**

An IRB action taken when the required determinations are made that allow research involving human subjects to proceed consistent with federal regulations, state and local laws, and College policy.

**Assent:**

Affirmative agreement to participate in research expressed by an individual (child or adult). Failure to object is not assent.

**Assurance:**

A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP). It promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**Authorized Signatory:**

An individual authorized by an institution or organization to approve a specific action or binding document by virtue of their signature.

**Autonomy:**

Personal capacity to consider alternatives, make choice, and act without undue influence or interferences of others.

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## B

**Bank (Repository):**

Collection of data obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes.

**Belmont Report:**

A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

**Beneficence:**

An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules:

1. do not harm; and
2. protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**Benefit:**

A valued or desired outcome; an advantage.

**Blinding:**

The process by which investigators and/or participants do not know to which study group they are assigned. There are single blind studies (in which the participant is blinded) and double-blind studies (in which both the participant and the investigator are blinded).

**Broad Consent:**

In the revised Common Rule, "broad consent" is an alternative consent process only for the storage, maintenance, and secondary use of identifiable private information for future, yet-to-be-specified research. The use of broad consent requires that the investigator maintain a sophisticated tracking system. For this reason, and because the regulations permit the secondary research use of identifiable data through study-specific consent, IRB waiver of consent, or removal of identifiers, Mercy College does not plan to implement the broad consent option at this time. Limited exceptions will be considered.

For full details about broad consent including the requirements (in addition to tracking), limitations, and considerations for use, see [SACHRP's Recommendations for Broad Consent Guidance](#).

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## C

**Cede Review:**

The act of transferring IRB review and oversight.

**Certificate of Confidentiality (CoC):**

A Certificate of Confidentiality (CoC) helps researchers protect the confidentiality of participants enrolled in sensitive human subjects research studies. Certificates protect against compulsory legal demands, such as U.S. court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Any researcher can apply for a [CoC](#) to protect their participants, however a CoC is issued automatically for applicable NIH awards as part of the award terms and conditions.

**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.

*Note: For most studies, this means individuals under 18 years of age, however not all U.S. states and foreign countries recognize 18 as the age of majority. There are locations that consider adulthood as young as 9 and as old as 21.*

**Clinical Trial:**

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.

*Note: This definition is shared by the Common Rule and the National Institutes of Health.*

**Coded Information:**

(1) Identifying information (such as name or social security number) in which the identifying information has been replaced with a code (such as a number, letter, or combination thereof), so that the investigator is unable to readily ascertain the identity of the individual to whom the private information pertains; and (2) there is a key to decipher the code, enabling linkage of the identifying information to the private information.

**Coercion:**

Overt or implicit threat of harm intentionally presented by one person to another to obtain compliance.

*Note: This could be a physician telling a patient that they will lose access to their health services if they do not enroll in clinic's research.*

**Cognitively Impaired:**

Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

**Cohort:**

A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

**Collaborating Institution:**

An institution working with Mercy College on a multi-site human subjects research study that is either (a) the institution to whom we will relinquish IRB oversight or (b) the institution(s) ceding review to Mercy's IRB.

**Compensation:**

Payment, merchandise, class credit, or other gift or service provided to research participants or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation.

*Note: Compensation is sometimes distinguished from an **incentive** or **inducement**, which is generally thought of as a payment or other offering that is "over and above" reimbursement and intended to encourage research participation.*

**Competence:**

Used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Conditionally Approved:**

An IRB action that specifies conditions under which research can be approved. Comments by IRB members must be directive requesting simple concurrences or specific, non-substantive changes.

Upon receipt of the required changes, the IRB Chair or another member designated by the Chair will verify that the appropriate additions/corrections were made and will either approve the study or return it to the Full Board for further review at a convened meeting.

**Confidentiality:**

Refers to how a researcher has agreed to handle, manage, and disseminate the information disclosed by or data regarding a participant. There is a relationship of trust between these parties and the expectation that confidential information or data will not be divulged to others by the researcher without the participant's permission in ways that are inconsistent with the agreement regarding disclosure of the information or data.

**Conflict of Interest:**

A Financial Conflict of Interest, a Non-Financial Conflict of Interest, or an opportunity for personal benefit of an IRB member or Immediate Family member that exerts, could exert, or could be perceived to exert an influence on the individual's professional judgment in exercising the individual's role as an IRB member.

**Continuing:**

Category of review of human subjects research, and subject to IRB review and approval to assure the continued protection of the rights and welfare of the participants in that research. To re-approve the research, the IRB must assess the study based on the federal requirements for approval: minimized risks to participants, equitable selection of participants, informed consent process, appropriate data management and security, appropriate participant privacy and confidentiality of data, and safeguards for vulnerable populations. The continuing review process is defined by federal regulations.

**Continuing Noncompliance:**

A pattern of noncompliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that noncompliance will continue without intervention, or involves frequent instances of minor noncompliance. Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

**Convened IRB:**

A meeting of the IRB at which a majority of IRB members are present.

**Corrective Actions:**

Suggestions for corrections or improvements to be made to assure regulatory agency inspection readiness and alignment with regulations and standards and a listing of current good practices.

**Cultural Consultant:**

A cultural consultant assesses research that will take place in a foreign country or in the U.S. that involves a unique population (for example, Kiryas Joel in Orange County, NY). The cultural consultant will examine the awareness of and the sensitivity to the particularities of the national, cultural, and/or linguistic group of the study site and population.

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## D

**Data and Safety Monitoring:**

The process for reviewing data collected as research progresses to ensure the continued safety of current and future participants as well as the scientific validity and integrity of the research.

**Data Repository:**

A place that holds research data and makes that data available for future use by the broader research community. Data repositories may have specific requirements concerning the research topic, data re-use and access, file format and data structure, and the types of metadata that can be used. Many data repositories have restrictions on who can deposit and access data.

*Note: Data repositories may also be called registries, banks, or libraries*

**Data Use Agreement (DUA):**

A written agreement between two (or more) parties to ensure that research data will only be used for specific uses and disclosures. DUAs can be incoming (data coming to Mercy College ) or outgoing (data being sent outside of Mercy College ) or involve sharing across multiple parties. Investigators are not permitted to sign DUAs on behalf of the College.

**Debriefing:**

Information about the research that is provided to participants after study completion. A debriefing session is used to provide important information about the nature of the research, additional information for educational purposes, or additional resources that may be appropriate for, or useful to, participants. Debriefing is often required when the research involves deception or incomplete disclosure. In general, this type of debriefing explains any deception or incomplete disclosure, provides information about why it was necessary to use deception or incomplete disclosure to conduct the research, and provides other options available to participants (e.g., the ability to withdraw their data).

**Deception:**

Occurs when an investigator gives false information to, or otherwise intentionally misleads, a research participant about some key aspect of the research to avoid biased responses. If participants are given false information or are otherwise misled during a study, then the participants are not provided with all the required elements of informed consent: in these instances, approval for a waiver or alteration of informed consent is required.

**Decisional Capacity:**

Decisional Capacity refers to a prospective participant's ability to make a meaningful decision about whether to participate in a research study. The four elements of decisional capacity are a participant's ability to Understand the information presented to them, Appreciate the risk and benefits involved, Reason and engage with the research personnel about the information presented to them, and Express a choice about whether or not to participate.

**Declaration of Helsinki:**

A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

**Deferred:**

An IRB action taken when the convened IRB cannot fully evaluate the research under review and make the determinations required for IRB approval without (i) modifications to the Application and/or informed consent document(s), or (ii) submission of clarifications or additional materials prior to reconsideration of the research.

*Note: Deferring a submission requires that the entire study with the additional information or modifications be reviewed by the Full Board at a convened meeting.*

**De-Identified:**

All direct personal identifiers are *permanently* removed (e.g., from data), no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s).

*Note: For purposes of Mercy College IRB policy, health information is de-identified when it does not contain any of the 18 identifiers specified by the HIPAA Privacy Rule at 45 CFR Part 164 (or has been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule). Other demographic information, such as gender, race, ethnicity, and marital status are not included in the list of identifiers that must be removed.*

**Department of Health and Human Services:**

The U.S. Department of Health and Human Services is a federal agency charged with enhancing and protecting the health and well-being of all Americans by providing for effective health and human services and fostering advances in medicine, public health, and social services.

**Deviations:**

A protocol deviation is not defined by DHHS or the FDA. Broadly, a protocol deviation is an unapproved departure from the procedures described in the IRB-approved materials. Deviations may occur for a variety of reasons, maybe anticipated and/or intentional, may be known or identified before they occur or discovered after the fact.

**Diminished Decision-Making Capacity:**

Refers to a prospective participant's ability to make a meaningful decision about whether to participate in research (e.g., because of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia).

*Note: Diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating.*

**Disapproved:**

An IRB action taken when the determinations required for approval of research cannot be made, even with substantive clarifications or modifications to the Application and/or informed consent process/document(s).

*Note: Only the Full Board may disapprove a study.*

**Disclosure:**

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

**Durable Power of Attorney for Health Care:**

A type of advance medical directive in which legal documents provide the power of attorney to another person in the case of an incapacitating medical condition.

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## E

**Emancipated Minors:**

For purposes of Mercy College IRB policy, the following persons under the legal age of 18, who because of their unique circumstances have the legal rights of adults, including the right to consent to treatments or procedures involved in research:

- Persons under the age of 18 on active duty in the military
- Married persons under 18 years of age

**Encryption:**

The process of converting information, particularly information such as social security number and name that identifies individuals, into a code.

**Engagement:**

Involved in human subjects research in such a way (or to the extent) that the ethical and regulatory requirements for human subjects protection are applicable. An individual (or organization) becomes engaged in human subjects research when the individual (or organization's employee or agent):

- Receives a direct federal award to support research,
- Obtains information about research participants through intervention or interaction,
- Obtains, uses, studies, analyzes, or generates identifiable private information about research participants, or
- Obtains informed consent of research participants.

*Note: Mercy College applies this definition to all Exempt and non-Exempt research.*

**Equitable:**

Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**Exempt:**

Category of review of human subjects research that is minimal risk, and not subject to review and approval by an IRB. Categories of Exempt research activities are defined by federal regulations.

*Note: Researchers conducting Exempt research must comply with the requirements of the IRB and Mercy College.*

**Exempt Modification:**

A change to an Exempt research study that is subject to Mercy College IRB review and approval before implementation, unless the immediate change is necessary to eliminate an apparent hazard to participants. Currently enrolled and active participants must be informed of the change if it could affect their willingness to continue participation in the study. The Exempt Modification review process is required by Mercy College policy.

**Existing:**

Available or "on the shelf" (e.g., data) at the time the research is submitted for a determination of whether the research is exempt.

**Expedited:**

Category of review of human subjects research that is minimal risk, and subject to IRB review and approval. Categories of Expedited research activities are defined by federal regulations.

**Expiration Date:**

The date that the IRB's approval of research has lapsed and research can no longer be performed.

*Note: An expiration date may not be longer than one year from the date the approval period begins.*

**Expired Study:**

When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the informed consent document. No activities can occur after the expiration date.

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## F

**Faculty Advisor:**

An active mentor to a student researcher who shares the responsibility for the ethical conduct of the research with the student. The Faculty Advisor is expected to discuss the general principles of research ethics prior to the initiation of any project involving human subjects, help the student determine whether the project requires Institutional Review Board (IRB) review, and guide the student through the IRB application process. Faculty Advisors on undergraduate research studies must serve as the PI of the study and will take on the role and responsibility of the PI.

**Federal Policy for Protection of Human Research Subjects (45 CFR 46):**

The basic Department of Health and Human Services policy on the protection of human participants in research. This policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research.

**Federalwide Assurance (FWA):**

The Federalwide Assurance (FWA) is granted by the Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP). It is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-Exempt human subjects research conducted or supported by DHHS. Under an FWA, an institution commits to DHHS that it will comply with the requirements set forth in 45 CFR Part 46, as well as the Terms of Assurance.

*Note: Mercy College FWA #00010496*

**Financial Conflict of Interest:**

An interest of an IRB member or Immediate Family member of monetary value (a) that is, could be, or could be perceived to be impacted by the research under review, including an IRB member or Immediate Family member's interest in or relationship to an entity that the research impacts, may impact, or could be perceived to impact; or (b) that influences, could influence, or could be perceived to influence the IRB member's professional judgment in exercising his/her role as an IRB member. Financial interests may include, but are not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

**Food and Drug Administration (FDA):**

The FDA is the federal oversight agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the U.S. food supply, cosmetics, and products that emit radiation. The FDA is also responsible for regulating the manufacturing, marketing, and distribution of tobacco products, and for advancing the public health by helping to speed innovations that make medical products and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medical products and foods to improve their health.

*Note: Mercy College does not review/approve research falling under oversight of the FDA.*

**Full Board:**

Category of review of human subjects research that is greater than minimal risk, and subject to IRB review and approval.

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## G

**Generalizable Knowledge:**

Knowledge from which conclusions will be drawn that can be applied to populations beyond the specific population from which it was collected.

**Good Clinical Practice (GCP):**

A standard established by the International Conference on Harmonisation for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

*Note: In the United States, FDA has adopted GCP as guidance for the ethical conduct of clinical trials.*

**Grant:**

Financial support provided for research study designed and proposed by the Principal Investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

**Greater than Minimal Risk:**

The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Guardian for Adults:**

An individual who is authorized under applicable state or local law to make personal, health, and financial decisions for their ward (an adult with impaired decision-making capacity).

**Guardian for Children:**

An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

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## H

**Human Subject (as defined by DHHS):**

A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information.

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## I

**Identifiable Private Information:**

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

**Immediate Family member:**

Spouse, domestic partner, or child.

**Incapacity (Incompetence):**

Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Incentive:**

Financial payments and/or other inducements to investigators, research staff, or referring physicians to promote enrollment of subjects in research study. These do not include payments to subjects themselves. Examples include:

- the sponsor provides financial reimbursement to the research and/or study staff that exceeds the fair market value of the services provided.
- the sponsor provides payment or services outside the scope of the research study requirement, such as, unrestricted educational grants.

**Incomplete Disclosure:**

Occurs when an investigator withholds or conceals information from a participant about the specific purpose of, or activities involved in, the research. If material information or activities are withheld that could potentially influence the decision of prospective participants to take part in the research, then the participants are not provided with all the required elements of informed consent: in these instances, approval for a waiver or alteration of informed consent is required.

**Individually Identifiable:**

The identity of the participant is or may readily be ascertained by the investigator or the investigator's staff or is associated with the information.

*Note: Individually identifiable for the purposes of Mercy College IRB policy may be similar to, but is not the same as, protected health information as defined by the HIPAA Privacy Rule at 45 CFR Part 160. Limited data sets released from data repositories with IRB approval to release such data sets are not considered to be individually identifiable.*

**Informed Consent:**

Prospective agreement to participate in research expressed by an individual (or their legally authorized representative) giving them the opportunity to choose what may or may not happen to them during the research study based on the elements of information, comprehension, and voluntariness.

**Institutional Official (IO):**

The individual identified on Mercy College's Federalwide Assurance with the Office for Human Research Protections who is legally authorized to act for Mercy College, on behalf of Mercy College, and obligates the College to the Terms of the Assurance. At Mercy College, the IO is the College President.

**Institutional Review Board (IRB or MCIRB):**

The Mercy College Institutional Review Board (IRB) exists to promote high quality, ethical research. It does this by serving as the advocate for the rights and welfare of persons who participate in research programs conducted by faculty, staff, students, and researchers at Mercy College. The MCIRB has responsibility for review of research involving human subjects conducted at Mercy College and assists researchers in complying with federal, state and Mercy College policies regarding experimentation involving human subjects.

**Interaction:**

Communication or interpersonal contact between an investigator (or research team) and participant. For example, interviews, observations, or physical measurements. Interactions may be in person, online, or by phone.

**Intervention:**

Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participants' environment that are performed for research purposes.

**Investigator:**

The project director or principal investigator and any other persons, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is responsible for the design, conduct, or reporting of sponsored research.

**IRB Authorization Agreement (IAA):**

A written agreement between two or more institutions that is used to document the delegation of IRB review responsibilities. This agreement may also be referred to as a reliance agreement or cede review agreement.

**IRB of Record:**

The IRB that has been designated through an IRB Authorization Agreement (IAA) to provide ethical oversight of a study in which more than one organization is engaged in the research.

**IRB Registration Number:**

The Health and Human Services (HHS) registration number for an IRB that reviews human subjects research conducted or supported by HHS.

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## J

**Justice:**

An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

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## K

**Key Informant:**

Any individual who provides information on topics other than themselves with respect to a specific research study.

*Note: Examples may be describing a clinic's intake policy or demographics of a local community. When conducting surveys or interviews, a key informant is not considered a human subject since they do not share personal information or opinions, therefore this activity does not require IRB review.*

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## L

**Legally Authorized Representative:**

An individual, judicial, or other body authorized under applicable law to consent to research participation on behalf of a designated person.

*Note: If there is no applicable state law addressing a legally authorized representative, this term is defined as a person acceptable for providing consent in the non-research context on behalf of the prospective participant's enrollment in research.*

**Licensed Medical Provider:**

A person conducting clinical assessments or making a clinical judgment who has the independent authority to treat patients. The licensed medical provider should have appropriate expertise in research inquiry.

**Limited Data Set:**

Protected Health Information (PHI) that does NOT include any of the following 16 categories of direct identifiers, but that may include city, state, ZIP code, or elements of dates, concerning an individual or an individual's relatives, employers, or household members:

1. Names; or
2. Postal address information, other than town or city, state, and ZIP Code; or
3. Telephone numbers; or
4. Fax numbers; or
5. Electronic mail addresses; or
6. Social security numbers; or
7. Medical record numbers; or
8. Health plan beneficiary numbers; or
9. Account numbers; or
10. Certificate/license numbers; or
11. Vehicle identifiers and serial numbers, including license plate numbers; or
12. Device identifiers and serial numbers; or
13. Web universal resource locators (URLs); or
14. Internet protocol (IP) address numbers; or
15. Biometric identifiers, including fingerprints and voiceprints; or
16. Full-face photographic images and any comparable images.

**Limited Guardian:**

An individual appointed by the court whose responsibilities for the personal affairs of their ward (an adult with impaired decision-making capacity) are limited only to those areas where the ward lacks capacity.

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## M

**Memorandum of Understanding (MOU):**

A formal agreement between Mercy College and another institution that identifies the Mercy College Institutional Review Board as the IRB of record for that institution.

**Minimal Risk:**

The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.

*Note: The regulatory definition of “minimal risk” for research involving prisoners differs from the definition of minimal risk for research involving participants who are not prisoners.*

**Minor Changes:**

Changes to research that in the judgment of the IRB do not affect assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, participant population, qualifications of the research team, or the facilities available to support the safe conduct of the research.

*Note: A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited initial review.*

**Minor Non-Compliance:**

Any non-compliance that is not serious or continuing noncompliance. For example, minor noncompliance might include the following violations:

- missing an original signed and dated research consent form;
- missing pages executed research consent forms;
- inappropriate documentation of informed consent (e.g., missing one or more signatures or date);

- obtaining informed consent using an invalid/outdated research consent form that contains all the information required by the IRB;
- failure to submit continuing review forms/documents prior to expiration of IRB approval;
- unplanned deviation from the approved protocol where the deviation does not impact the rights and welfare of subjects or the integrity of the research.

**Minor Protocol Deviations:**

Minor Protocol Deviations are deviations from IRB-approved procedures that (i) do not cause harm and have no potential to cause harm to the research subject or others, and (ii) do not impact the integrity of research data. Minor protocol deviations include over-enrollment of participants in a minimal risk study; follow-up visits occurring outside the protocol required time frame because of the participant’s schedule; blood samples obtained at times close to, but not precisely at, the time points specified in the protocol.

**Modifications Required:**

An IRB action that specifies conditions under which research can be approved, pending the following: confirmation of specific understandings by the IRB about how the research will be conducted, submission of additional documentation, precise language changes to the protocol and/or informed consent document(s), and/or substantive changes to documents with specific parameters the changes must satisfy.

*Note: Verification that the investigator’s response(s) satisfies the conditions for approval set by the IRB may be performed by the IRB Chair and/or other designated individual(s).*

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**N**

**Noncompliance:**

Noncompliance is defined broadly to include (i) a failure to comply with any federal, state, or local regulation that governs human subjects research; or (ii) a violation of any Mercy College policy on human subjects research; or (iii) any unapproved deviation from an IRB-approved protocol or stipulations imposed by the IRB as a condition of approval, unless such deviation is necessary to preserve the life or health of a subject and the IRB is notified following such deviation as soon as possible after the deviation occurs.

**Non-Financial Conflict of Interest:**

An interest, other than monetary, of an IRB member or Immediate Family member in the design, conduct, or reporting of the research under review, or other interest that compromises, could compromise, or could be perceived to compromise the individual’s professional judgment in exercising the individual’s role as an IRB member.

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**O**

**The Office for Human Research Protections (OHRP):**

The Office for Human Research Protections provides leadership in the protection of the rights, welfare, and wellbeing of participants involved in research conducted or supported by the U.S. Department of Health and Human Services by providing clarification and guidance, developing education programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social / behavioral research.

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**P**

**Parent:**

A child’s biological or adoptive mother or biological or adoptive father.

**Participant Population:**

A research methodology involving participation, observation, and analysis of the daily life of the people being studied.

**Pass-Through Funding:**

Funds issued by a federal agency that are then transferred to other eligible groups per the award eligibility terms. The "prime awardee" issues the subawards as competitive or noncompetitive as dictated by the prime award terms and authorizing legislation. Prime awardee institutions on a pass-through funding grant are considered engaged by the Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP) and must ensure ethical oversight for their role in the research.

**Permission:**

The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research.

**Personally Identifiable Information (PII):**

Refers to information that can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth or mother's maiden name.

**Power Differential:**

Relationship in which a person has a role that is perceived to have or actually has more authority, agency, or knowledge over another.

**Pre-Review:**

The process performed by MCIRB staff to determine that a submission for IRB review is complete, including the required materials, copies, and signatures, and that institutional requirements, such as completion of human subjects' protection education and conflict of interest disclosure, have been met.

**Prime Awardee:**

The lead institution or organization that is the recipient of a federal award.

**Principal Investigator (PI):**

An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, and who provides technical and administrative oversight of the research and makes important study-related decisions. For purposes of MCIRB policy, only one individual is designated as the Principal Investigator of a human research study.

**Prisoner:**

An individual (whether convicted felon or untried person) involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility) with restricted ability to leave the institution encompassing:

- individuals sentenced to such an institution under a criminal or civil statute
- individuals detained in other facilities (including psychiatric units, hospitals, and drug treatment facilities) by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution
- individuals detained pending arraignment, trial, or sentencing. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners.

*Note: Consult with the MCIRB when planning to work with this population, as your study may require an analysis of the population's particular circumstances.*

**Privacy:**

Refers to a participant's right to control who has access to them, their location, and their space. It is the recognition that a participant has the right to determine the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with researchers.

**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 and that individual can reasonably expect will not be made public (e.g., medical record, employee, or student records).

**Procedure:**

A series of actions conducted in a certain order or manner; operational method by which policy is put into practice.

**Program Evaluation:**

An activity conducted to evaluate a specific program to provide information for and about that program regardless of any professional benefit to the investigator.

**Prospective:**

Research utilizing human participants' data that will be collected after the research is approved by the IRB.

**Protected Health Information (PHI):**

Under the Health Insurance Portability and Accountability Act (HIPAA), "protected health information" is considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, or transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations (PHI healthcare business uses).

*Note: PHI is only considered PHI when an individual could be identified from the information.*

PHI includes one or more of the following 18 identifiers. If these identifiers are removed the information is considered de-identified protected health information, which is not subject to the restrictions of the HIPAA Privacy Rule.

1. Names; or
2. All geographic subdivisions smaller than a state, including street address, city, or county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
  - a. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
  - b. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000; or
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; or  
All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older; or
4. Telephone numbers; or
5. Fax numbers; or
6. Email addresses; or
7. Social security numbers; or
8. Medical record numbers; or
9. Health plan beneficiary numbers; or
10. Account numbers; or
11. Certificate/license numbers; or
12. Vehicle identifiers and serial numbers, including license plate numbers; or
13. Device identifiers and serial numbers; or
14. Web Universal Resource Locators (URLs); or
15. Internet Protocol (IP) addresses; or
16. Biometric identifiers, including finger and voice prints; or
17. Full-face photographs and any comparable images; or

18. Any other unique identifying number, characteristic, or code, including any code that includes or is derived from any of the identifiers on this list.

**Protocol:**

Documentation of study objective, design, methods, statistical methods and organization. This term also includes amendments made to the original document.

**Publicly available:**

Refers to data and when used for human subjects research that are accessible to anyone in the general public, without the need for special permissions or privileges.

*Note: Examples include data available for purchase, searchable online, or available at a library. Researchers may be subject to an agreement with the entity releasing the data prior to receipt and use (such as a Data Use Agreement). However, not all information online is publicly available. Public Twitter posts are publicly available, while posts from a closed Facebook group are not.*

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## Q

**Quality Assessment/Improvement (QA/QI):**

An activity conducted to assess, analyze, critique, and improve current practice or process in an institutional setting or ensure it conforms to expected norms, involving data-guided, systematic activities designed to bring about prompt improvements regardless of any professional benefit to the investigator.

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## R

**Randomization:**

The process by which participants are assigned to a group of study procedures by chance rather than by choice.

**Recruitment:**

The process of identifying and reaching potential participants to enroll in a research study. It is considered the beginning of the participant selection and informed consent/assent processes.

**Recruitment Materials:**

May include (but are not limited to) printed materials, newsletters, recruitment lists, phone scripts, e-mails, electronic advertisements, and video/audio scripts. Recruitment materials must contain enough information to provide potential participants a sense of the study and the ability to decide if they may be eligible to participate.

**Reimbursement:**

Payment provided to research participants or their legally authorized representatives that reflects their out-of-pocket expenses associated with participating in a research study. These expenses could be parking, transportation, childcare costs, lost wages, accommodations, food, etc.

**Relying Institution:**

The entity that agrees to rely upon the reviewing IRB when entered into an IAA or reliance agreement. The relying institution agrees to depend on the IRB of Record for review of human subjects research and ensuring compliance with all relevant mandates and reporting requirements.

**Reportable Event:**

A type of unanticipated event or occurrence related to a human subjects research study that requires review by the IRB as defined in the IRB Reportable Events Policy.

**Research:**

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

*Note: A systematic investigation is the use of a predetermined method (i.e., eligibility criteria, surveys, blood draws, etc.) to gain information by collecting and analyzing data. Generalizable knowledge is conclusions that can be applied to a larger population beyond the specific site of data collection or the participants who provided the information.*

**Research Data:**

Any information (identifiable or anonymous) obtained through intervention or interaction with human subjects, or any identifiable private information obtained, used, studied, received, or accessed by a member of a research team for the purposes of conducting human subjects research.

**Research Misconduct:**

Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion.

**Research Performance Site:**

Location/site at which human subjects research may be performed because of an understanding of the local research context and appropriate oversight mechanisms that ensure protection of research participants.

**Research Personnel (or Researchers/Key Personnel):**

Persons who have direct contact with participants, contribute to the research in a substantive way, have contact with a participant's identifiable data, or use a participant's personal information for research purposes.

**Retrospective:**

Research utilizing human participants' data that were previously collected (e.g., on the shelf) before the research was submitted to the IRB.

**Reviewing IRB:**

The IRB of record performing review on behalf of one or more institutions, also referred to as the single IRB, central IRB, and/or IRB of record.

**Risk:**

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

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## S

**Secondary Participants:**

Participants in human subjects research about whom an investigator indirectly collects identifiable private information through interactions with primary participants (those who have enrolled in the study through a consent process).

**Secondary Research:**

Study of existing information or materials (e.g., data) that have been previously collected for a purpose (including non-research purposes) other than the currently proposed activity.

**Sensitive information:**

Information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.

**Serious Noncompliance:**

Noncompliance that (i) significantly increases risks, or significantly decreases potential benefits, to participants; (ii) adversely affects the rights, welfare and safety of participants; (iii) adversely affects the scientific integrity of a study; or (iv) is the result of a willful violation of any federal, state, or local regulation that governs human research, or (v) is a willful violation of any Mercy College policy on human subjects research.

**Signatory Official:**

The individual authorized to represent and commit the entire institution and all its components to a legally-binding agreement.

**Significant Financial Interest (SFI):**

A "Significant Financial Interest" (SFI) is the receipt by you, your spouse, or your dependent children of any of the following, if related to your college responsibilities or professional expertise:

- Income that exceeds \$5,000 from any outside entity, measured on a rolling 12-month basis. This may be one payment from a particular company of more than \$5,000, or multiple payments from the same company that, in the aggregate, exceed \$5,000.
- Acquisition of equity in a public company that exceeds \$5,000 in value;
- Aggregated income and equity/ownership interest from a public company that exceeds \$5,000, as measured on a rolling 12-month basis;
- Any equity/ownership interest in a privately-held company;
- Any income received from rights in intellectual property, as measured on a rolling 12-month basis.

**Source Data:**

Data or other information necessary to perform the research received from a party external to Mercy College via a properly executed agreement. Source Data does not include original data generated by Mercy College researchers or the results of analyses conducted using Source Data.

**Sponsored Funding:**

External or internal funding of research through formal application, competitive award, or an achievement/recognition award where the sponsor is legally obligated to commit funds and/or facilities to the principal investigator (PI) to conduct research.

**Sub-Award:**

An award provided by a prime awardee to a sub-recipient for the sub-recipient to carry out a portion of the research or substantive effort of a federal award received by the prime awardee.

**Subject Pool:**

A group of individuals who identified themselves as being willing to participate in research. Signing up to join a subject pool does not enroll a person in a research study or make that person a research participant.

**Substantive Action:**

An action taken by an IRB that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the AE in research.

**Suspension:**

An action taken by the convened IRB or the IRB Chair to temporarily stop some or all approved research activities to protect participants pending completion of an investigation. Suspended studies remain open until the convened IRB determines to (i) lift the suspension or (ii) terminate the study or some activities of the study.

**Systematic Investigation:**

A planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.

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**T****Tabled:**

An IRB action that indicates that review was not initiated or was not completed, resulting in postponement of IRB review, usually due to loss of quorum or other administrative issue. Research tabled by the IRB will be reviewed at the next convened IRB meeting.

**Termination:**

An action taken by the convened IRB or the IRB Chair to permanently stop all research activities in an approved research study.

**Therapeutic Misconception:**

An ethical problem in human subjects research when a participant mistakenly believes that the primary purpose of the study in which they are enrolled is to directly benefit the individual participants, rather than to produce generalizable knowledge.

**Third-Party:**

In terms of recruitment, any person or vendor (outside of the research team) who recruits on behalf of that team.

*Note: This may be physicians or school administrators who provide information to their patients or students, respectively, about a research study, or commercial entities hired to aid in recruitment.*

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## U

**Unanticipated Problems Involving Risk to Participants or Others:**

Any incident, experience, or outcome during human research that is (i) unexpected (in terms of nature, severity, or frequency), (ii) related or possibly related to participation in research, and (iii) suggests that the research places participants or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Undue Influence:**

Excessive or inappropriate reward or other overture to persuade a person to act against that person's own interests or without adequate consideration of the consequences to obtain compliance.

*Note: Influence is contextual, so undue influence will likely depend on an individual's unique situation. This could be a professor promising their students extra credit for participating in the professor's research or a patient feeling obligated to enroll in their healthcare provider's study.*

**Unexpected Death:**

The death of a research participant in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, or sponsor brochure. This definition does not include deaths associated with a terminal condition unless the research intervention clearly hastened the participant's death. A participant's death that is determined to be clearly not associated with the research is also not an "unexpected death" for purposes of the reporting requirements of these procedures.

**Unexpected Adverse Event (UAE):**

An adverse event occurring in one or more participants in a research study, the nature, severity, or frequency of which is not considered consistent with either the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol-related documents, investigator brochure, informed consent document, or other relevant sources of information regarding the research, such as product or device labeling and package inserts; or is not considered consistent the expected natural progression of any underlying disease, disorder, or condition of the participant(s) experiencing the adverse event and the participant's predisposing risk factor profile for the adverse event.

**Unrelated:**

Unassociated or without a timely relationship; evidence exists that an outcome is related to a cause other than the event in question. This definition should be considered in the context of determining whether an adverse event is related or possibly related to participation in research for purposes of determining whether it qualifies as a Reportable Event.

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## V

### Vulnerable Population

A group of participants that may have insufficient power or resources to protect their own interests, which may make them susceptible to undue influence and/or coercion depending on the situation, their condition, or the research. A population's vulnerability may change depending on the nature of the research and may fluctuate over time. Investigators must take special care and consideration when recruiting, consenting, and conducting research activities with these populations.

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## W

### Whistleblower:

An individual who makes a report in good faith to the Mercy College IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.

### Waiver of Documentation of Informed Consent:

An allowance in the Federal Policy for the Protection of Human Research Subjects (45 CFR Part 46) for an IRB to waive the requirement for the investigator obtain a signed consent document from participants when specific conditions are met.

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## X, Y, Z

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### MCIRB Acronyms

<a href="#">AE</a>	Adverse Event
<a href="#">CoC</a>	Certificate of Confidentiality
<a href="#">COI</a>	Conflict of Interest
<a href="#">DHHS</a>	U.S. Department of Health and Human Services
<a href="#">FDA</a>	Food and Drug Administration
<a href="#">FERPA</a>	The Family Education Rights and Privacy Act
<a href="#">FWA</a>	Federalwide Assurance
<a href="#">GCP</a>	Good Clinical Practice
<a href="#">HIPAA</a>	Health Insurance Portability and Accountability Act
<a href="#">IAA</a>	Institutional Authorization Agreement
<a href="#">IO</a>	Institutional Official
<a href="#">IRB</a>	Institutional Review Board
<a href="#">MOU</a>	Memorandum of Understanding
<a href="#">NIH</a>	National Institute of Health

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<b>NSF</b>	National Science Foundation
<b><u>OHRP</u></b>	Office for Human Research Protections (under DHHS)
<b>ORI</b>	Office of Research Integrity
<b><u>PHI</u></b>	Protected Health Information
<b><u>PI</u></b>	Principal Investigator
<b><u>QA/QI</u></b>	Quality Assurance/Quality Improvement
<b><u>UAE</u></b>	Unexpected Adverse Event
<b><u>UP</u></b>	Unanticipated Problem Involving Risk to Participants or Others