IRB Glossary of Term

45 CFR 46	Title 45, Part 46 of the Code of Federal Regulations, Protection of Human Subjects. These regulations govern human subject research conducted by all federal agencies. Together, this body of regulations governs the conduct of human subjects research today.
Approval Date	The approval date is the first date that research can be performed. The approval date is reflected on Montgomery College IRB approval letter.
Assent	"Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
Assurance	A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.
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.
Bias	A point of view or preference which prevents impartial judgment in the way in which a measurement, assessment, procedure, or analysis is carried out or reported.
Children	Children, or minors, are individuals under 18 years of age.
Code of Federal Regulations (CFR)	The Code of Federal Regulations is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles representing broad areas subject to Federal regulation. Each title is divided into parts and each part is then divided into sections – the basic unit of the CFR. The purpose of the CFR is to present the official and complete text of agency regulations in one organized publication and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent Federal regulations (National Archives).

Sources:
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Coercion	The use of express or implied threats of violence, reprisal, or other intimidating behavior to compel a person to act against his or her will. Under coercion, a person has no choice.
Collaborative IRB Training Initiative (CIT)	An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the county and it is administered by the University of Miami (see: www.citiprogram.org).
Common Rule	The Common Rule, which governs research with human subjects conducted or supported by 14 federal departments and agencies including EPA, establishes a comprehensive framework for the review and conduct of proposed human research to ensure that it will be performed ethically.
Compensation	Payment for participation in research or for medical care provided to subjects as a result of being injured in research.
Confidentiality	Confidentiality refers to subjects' data and the study safeguards that will protect the data.
Conflict of Interest	The real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships. A conflict of interest occurs when individuals involved with the conduct, reporting, oversight, or review of research also have financial or other interests, from which they can benefit, depending on the results of the research.
Continuing Review	The mechanism by which the IRB periodically reviews the conduct of research. The IRB must conduct continuing review of an approved study at least once/year. Continuing Reviews do not apply to human subjects research protocols given exempt status. Continuing Reviews do not include modifications. If a modification is required it must be submitted separate from the Continuing Review.
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 has been revised several times, most recently in October, 2000.
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	Six categories of minimal risk research that are exempt from federal oversight. However, these categories of research are not exempt from review by Montgomery College Institutional Review Board, the ethical guidelines of the Belmont Report, or Montgomery College IRB policies. Exempt studies must be submitted to the IRB for an exempt determination. Investigators are not authorized to make this determination.
Expedited Review	Review of Proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review

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	for certain kinds of research involving no more than minimal risk and for minor changes in approved research.
Federal Wide Assurance (FWA)	Assurance of compliance with Department of Health and Human Services (HHS) regulations pertaining to the protection of human subjects. The federal Office for Human Research Protections (OHRP) requires that an institution/organization have an OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) if the institution/organization is engaged in human subjects research that is conducted or supported by an agency of the HHS.
FDA	Food and Drug Administration; one of the IRB regulators.
FERPA (Family Education Rights and Privacy Act)	A federal law of 1974 that protects the privacy of student education records.
Full Board Review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
Grant	Financial support provided for research study designed and proposed by the principal investigator(s).
Guardian	An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
HHS	U.S. Department of Health and Human Services, one of the IRB regulators.
Human Subjects	"Human Subject" is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information (no intervention or interaction required). Note that if research activity involves a drug, device, or biologic, other regulations and definitions may apply.
Identifiable	The identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Identifiable Private Information	Private 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). This information is considered individually identifiable if the identity of the subject is or may readily be ascertained by the investigator or associated with the information [45 CFR 46.102(f)(2)] If information includes Protected Health Information, identifiable information includes

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any of the following information for the individual, relative, employer, or household member of the individual:

- Name, street address, city, county, precinct, zip code, geocodes smaller than state
- Date of birth, ages > 89 years of age; or other dates such as diagnosis dates, procedure dates, admission or discharge dates
- Telephone numbers, fax numbers, email addresses, social security numbers, medical record number, student record number
- Health plan beneficiary numbers, account numbers, certificate/license numbers
- Vehicle identifiers and serial numbers or license numbers, device identifiers and serial numbers
- Web URLs, Internet Protocol (IP) address numbers, biometric identifiers including finger/voice prints
- Full face photographic images and any comparable images

Informed Consent — A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include an exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Informed Consent Document — A written description in lay terms of relevant study information. It is the document of study information that is communicated to the potential subject. When signed by the potential subject, it records the receipt of study related information by the subject and the subjects agreement to participate in the research study.

Institution — Any public or private entity or agency (including federal, state, and local agencies).

Institutional Official — The Institutional Official (IO) who is the signatory on the FWA filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.

Institutional Review Board (IRB) — A specially constitution review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

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Institutional Review Board (IRB) Approval	The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
Intervention	Physical procedures or manipulations of those individuals or their environment for research purposes.
IRB Application	An electronic form that includes the protocol and supporting documents (e.g., consent forms, advertisements, surveys and other attachments).
IRB Authorization Agreement (IAA)	A formal, written, agreement in which the reviewing IRB agrees to serve as the IRB of Record for another organization.
IRB Chair	The individual designated on an Institutional Review Board roster submitted to OHRP as the person assigned with leading the IRB.
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.
Knowledge	Truth, facts, information.
Lead Investigator	In multi-site studies, the lead investigator is the person who manages the research study at all sites and is responsible for the conduct of the study at all sites.
Legally Authorized Representative	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 the 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.
Minimal Risk	"Minimal risk" is defined as 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 routing physical or psychological examinations or tests.
Minors	Individuals under 18 years of age, regardless of the jurisdiction in which the research is performed.
Modification	A change to an approved study. If the modification affects the protocol, submit a modified IRB application. Modifications must not be implemented without IRB approval.
NIH (National Institutes of Health)	The National Institutes of Health is one of the world's foremost medical research centers, and the Federal focal point for medical research in the United States. The NIH, comprising 27 separate Institute of Centers is one of eight health agencies of the Public

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	Health Service which, in turn, is part of the U.S. Department of Health and Human Services.
Nonaffiliated Member	Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community.
Not Human Subjects Research	An activity that does not meet the definitions of "research" and "human subject" under either FDA or HHS regulations. If an investigator is unsure whether the proposed activity is human subjects research, the IRB recommends that the investigator e-mail a synopsis of the proposed activity (2-3 paragraphs) to the IRB.
Nuremberg Code	A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.
OHRP (Office of Human Research Protections)	The Office for Human Research Protections (OHRP), an office of the U.S. Department of Health & Human Services, provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.
Parental Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].
Principal Investigator (PI)	The PI is the person who is ultimately responsible for the conduct of the study. For student-initiated research, the student's faculty advisor serves as the PI and is ultimately Responsible for the conduct of the study.
Prisoner	"Prisoner" means 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 prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Common examples of the application of the regulatory definition of "prisoner" are as follows: Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners. Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

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Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with the Office of Human Research Protections (OHRP) when questions arise about research involving these populations.

Privacy — Privacy is about people and means respecting an individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing and circumstances of obtaining personal information from or about them. For example, individuals may not want to conduct the consent process in an open area or may not want to be seen entering a study site that might stigmatize them.

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 the individual can reasonably expect will not be made public (e.g., a medical record).

Procedures — The activities that subjects will undergo as part of their participation or investigators will follow to conduct the study. For example, in a data analysis study, the procedures would include an investigator reviewing subjects' records. In a study involving interaction or intervention with subjects, procedures would describe the nature of the intervention or interaction, such as administering surveys or questionnaires. Study procedures need to be described in detail.

Protocol — The formal design or plan of an experiment or research activity, specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Quorum — Quorum means that greater than half of the IRB members are present at an IRB meeting and the following criteria are met: at least one member whose primary concern are in scientific areas is present at the meeting; at least one member whose primary concerns are in non-scientific areas is present at the meeting; and at least one unaffiliated member is present at the meeting. A Board member may fulfill more than one criterion.

Research — A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

For example, some demonstrations and service programs may include research activities. For purposes of this part, **the following activities are deemed not to be research:**

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1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, or requested, ordered, required, or authorized by a public health authority. Such activities are limited to signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Research Misconduct

Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data or creative innovations that are nonetheless ethical, legal and meet professional standards.

Respect for Persons

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Risk

The discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. The probability, magnitude, duration, and reversibility of the risks should be described in the application. Consider physical, psychological, social, legal, and economic risks.

Serious Noncompliance

Noncompliance that materially increases risk or that results in unexpected substantial harm to subjects or others. In addition, the following instance(s) of noncompliance, as defined by OHRP, will always be determined as serious noncompliance:

- Non-Exempt human subjects research being carried out without IRB review and approval or without appropriate informed consent.
- Substantive modifications to IRB-approved research without IRB approval.

Study Measurements

The measurements used to obtain information from subjects, such as surveys, interview guides, psychological tests.

Submission

A package of information submitted to the IRB office.

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Submission Number	The protocol number followed by a dash and an incrementing numeric counter that uniquely identifies each Submission received that is associated with a protocol.
Surveys	Studies designed to obtain information form a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.
Voluntary	Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.
Waiver of Informed Consent	Occasionally, there are reasons to waive written consent or to alter the requirements of consent. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. In order to qualify for a Waiver of Consent, the following conditions should be met: 1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver of alteration the research in question could not be carried out; 4) information will be provided after participation is completed, if appropriate.

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