IRB Frequently Used Definitions

1. ***Adverse event:*** An untoward or undesirable experience associated with the use of a medical product, such as a drug, device or biologic, in a patient or research subject.
2. ***Advocate:*** An individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.
3. ***Anonymous data:*** Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA, and no code is assigned that would allow data to be traced to an individual.
4. ***Assent:*** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
5. ***Belmont Report:*** Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research identifying the basic ethical principles underlying the conduct of research involving human subjects, that is, respect for persons, beneficence and justice.
6. ***Beneficence:*** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as expressions of beneficent actions (Belmont Report, 1978):
    a. Do no harm, and
    b. Maximize possible benefits and minimize possible harms.
7. ***Children:*** People 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.
8. ***Coercion:*** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.
9. ***Confidentiality:*** means respecting a potential or current participant's right to be free from unauthorized release of information that the individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. In the context of a research protocol, "confidentiality" refers to the understanding between the participant and investigator (e.g., as set forth in the consent and authorization documents) as to how participant information will be handled, managed, and disseminated (e.g., shared with others) as part of the research.
10. ***Continuing review:*** Periodic review of research activities at intervals appropriate to the degree of risk, but not less than once per year. The criteria for approval are defined by federal regulations.
11. ***De-identified health information:*** Health information that has been stripped of all 18 identifiers as defined by HIPAA so that the information cannot be traced back to an individual. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:
    a. The code is not derived from or related to the information about the individual;
    b. The code could not be translated to identify the individual; and
    c. The covered entity does not use or disclose the code for other purposes or disclose the mechanism for re-identification.
12. ***Exempt review:*** Studies determined by the IRB to meet the exempt criteria as defined by the federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.

13. ***Expedited review:*** A review of research involving human subjects by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
14. ***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 consent document. No activities can occur after the expiration date.
15. ***Federal wide assurance (FWA):*** A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects.
16. ***Full committee review:*** Studies reviewed by the full, convened IRB committee with a recorded vote and corresponding minutes to document the discussion.
17. ***Human subject:*** means a living individual about whom an investigator (whether professional or student) conducting research obtains
    a. Data through intervention or interaction with the individual, or
        i. Interaction includes communication or interpersonal contact between investigator and subject.
    b. Identifiable private information.
18. ***Informed Consent*****:** Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.
19. ***Intervention*****:** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
20. ***IRB*****:** means an institutional review board established in accord with and for the purposes expressed in this policy.
21. ***IRB approval:*** means 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.
22. ***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 procedures involved in the research.
23. ***Minimal risk:*** means 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.
24. ***Noncompliance:*** An act or omission in the conduct or oversight of human subject research that represents a failure to follow:
    a. Federal, state or local regulations
    b. Institutional policies relevant to human subject research
    c. The approved research plan
    d. The determinations of the IRB
25. ***Oral (verbal) consent:*** A spoken presentation of the elements of informed consent to the prospective subject or their legally authorized representative. The presentation may be based on information contained within an oral consent script or the written consent document. Oral consent is often associated with waiving the documentation of consent. Oral consent is usually recorded in the research project files.
26. ***Principal investigator (PI):*** Adheres to federal regulations, state and local laws, institutional policies, IRB policies and procedures regarding the safety and protection of human subjects, and good clinical practice (GCP) guidelines.

27. ***Privacy versus confidentiality:***
    a. *Privacy* is about people and their choice to share personal information. It is a right in health care and research.
    b. *Confidentiality* is about data. It is the investigator's obligation to protect subjects' information.
28. ***Protocol violation:*** Problems that violate the terms of a study but do not meet the criteria for an UPIRTSO. See unanticipated problem involving risk to subjects or others (UPIRTSO).
29. ***Recruitment:*** Recruitment, a component of the consent process, is the process of distributing or presenting information that describes the research project and eligibility criteria so that a prospective subject may consider enrollment.
30. ***Reportable event:*** A process (with an associated IRB form) used by an investigator to report any problem or event or other act or omission to the IRB that in their opinion is a UPIRTSO.
31. ***Research:*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
32. ***Serious noncompliance*:** Any noncompliance that results in or has the potential to: a) substantially compromise the rights and welfare of subjects; b) substantially impact the integrity and validity of the study data; and c) compromise the integrity and effectiveness of the Mayo Clinic Human Research Protection Program.
33. ***Surrogate consent:*** Consent obtained from the participant's legally authorized representative (LAR).
34. ***Suspension for cause:*** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the investigator or his or her personnel.
35. ***Unanticipated problem involving risk to subjects or others (UPIRTSO):*** Any unanticipated problem or adverse event that meets these three criteria:
    a. ***Serious:*** Serious problems or events that result in significant harm (which may be physical, psychological, financial, social, economic or legal) or increased risk for the subject or others (including individuals who are not research subjects).
    b. ***Unanticipated:*** Unexpected problems or events are those that are not already described as potential risks in the protocol consent document, not listed in the investigator's brochure or not part of an underlying disease. A problem or event is unanticipated when it was unforeseeable at the time of its occurrence. A problem or event is unanticipated when it occurs at an increased frequency or at an increased severity than expected.
    c. ***Related:*** A problem or event is related if it is possibly related to the research procedures.
36. ***Undue influence:*** occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.
37. ***Vulnerable populations in research:*** Vulnerable populations may include (but are not limited to): individuals who are pregnant; prisoners; individuals who have been involuntarily committed to a medical facility; children; subordinates such as students, trainees and employees; individuals who are economically or educationally disadvantaged; individuals who have a language barrier; individuals with a cognitive disability; and individuals with an illness for which all standard treatment options have been exhausted.
38. ***Voluntariness:*** An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence.

39. ***Withdrawals:*** Subjects who signed the consent form, but later withdrew from the study, either before or after receiving a study drug, device or intervention. This does not include screen failures.

References

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https://humansubjects.nih.gov/walkthrough-investigator#tabpanel11
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