

**The glossary that is used at IRC is below. But first, there are a number of words that are commonly confused, conflated and mixed together.**

<p>Sponsor, CRO Funding agency, Client Cooperative group</p>	<p><b>Sponsor</b> is a word used only in connection with FDA regulated studies.</p> <p><b>Funding agency</b> is generally used for federal agencies. Some people (especially in oncology) mistakenly use sponsor and cooperative group inter-changeably.</p> <p><b>CRO</b> – A contract research organization can contract to manage some or all of the work involved in a clinical investigation.</p> <p><b>Cooperative Groups</b> are organized under a group like the NCI to manage protocols and data for oncology trials.</p> <p><b>Client</b> – Any of these can contract with us and will fulfill both roles.</p>
<p>PI, Director Co-PI, Sub-PI, Sub I,</p>	<p>An <b>investigator</b> is a person who searches for information or data. Could be FDA, a detective, or a journalist. Could be a person doing one study task but not doing the design or management.</p> <p><b>Principal Investigator</b> is the person responsible for the conduct of the study generally at the site. This is the person with ultimate responsibility for conduct and who may delegate some or all of the duties.</p> <p><b>Director</b> may be the sponsor’s medical or clinical director in charge of the principal investigators.</p> <p><b>Co-PI</b> – No such thing as there cannot be two people on top of the pyramid (This is in direct conflict with community based participatory research needs,)</p> <p><b>Sub-PI</b> This is a person to whom the Principal Investigator can delegate major responsibilities such as when the PI is gone.</p> <p><b>Sub-I:</b> This is a person involved gathering information but not in a position of authority.</p> <p><b>PROBLEM:</b> In clinical investigations it is easy to identify an independent site and the investigator at that site. It is much more difficult in other realms.</p>
<p>Study Trial Investigation Research Experiment A Clinical</p>	<p><b>Study</b> may be a less scary word but is also used in too many other contexts such as to study for a test, or a blood study.</p> <p><b>Investigation or Clinical Investigation:</b> An FDA-defined term equated with research. See below</p> <p><b>Research:</b> A Common Rule defined term that includes many styles of investigations including clinical investigations, evaluation studies, or, in fact, could include animal or laboratory research.</p> <p><b>A Clinical</b> is shorthand for a clinical investigation.</p> <p><b>Experiment:</b> This term is rarely used as it is scary. It may not have the rigorous design found in research.</p> <p><b>Trial:</b> that which happens in a courtroom? Or a clinical trial</p>

<p>Violation Deviation Exception Anomaly</p>	<p>These three terms are almost indistinguishable. They are used differently by others in this field. The protocol or a requirement of the IRB was violated in some way.</p> <p><b>Anomaly:</b> Something was out of sync, wrong or off somehow. Seen as being much less perjorative</p> <p><b>Violation</b> is a broader term that includes violations of IRB requirements, of ethical requirements, of the protocol or of something else.</p> <p><b>Deviations</b> and <b>exceptions</b> pertain to not following the protocol to the letter. At IRC we interpret this as an <b>exception</b> being something pre-approved by the sponsor but not necessarily the IRB. A <b>deviation</b> is something done already without prior permission.</p> <p><b>A violation may also be non-compliance</b></p>
<p>Authority Responsibility</p>	<p><b>Authority</b> is associated with power. A person has legitimate authority through command lines such as the CEO or chancellor or Institutional officer. Authority can be assumed at any level through charisma, expertise, or dominance.</p> <p><b>Responsibility</b> implies a burden or duty to perform or follow-through on an act. Responsibility is the basis for the “the buck stops here” concept. One can delegate the authority in a chain of command to give the lower level person the power to get something done. One cannot delegate the responsibility to make sure it is finished well.</p>

## **Glossary of words as used at IRC**

**ABBREVIATED IDE:**

A device term used to designate an investigational device that does not need an IDE issued by the FDA and is not exempt from the IDE requirements.

21 812.2(b)

**ABSTAIN:** A category of voting in which a person chooses not to vote. The minutes need not reflect the person’s identity. The person is included in the quorum count.

See Recusal

**ADVERSE EVENT:** An untoward physical or psychological occurrence in a human subject participating in research. It can be an unfavorable or unintended event including an abnormal laboratory finding, symptom or disease. An AE is described in terms of seriousness, causality and expectation

21 CFR 312

ISO does not imply a relationship

**ADVERTISEMENT:** An advertisement is recruitment material using the media, or other means, in a pre-planned way with the intent of informing potential subjects that a trial exists. Under this definition, any print, mailed, radio, television or computer advertisement targeting subjects is an advertisement. Patient brochures, videos, letters, directories, or mailers intended for other professionals are not considered subject advertising for purposes of this definition (Revised 9/1/98 in response to FDA letter).

**ALLEGATION:** an unproven claim, written or oral.

**ANONYMOUS/ANONYMIZED:** Without any identifiers or way to link the information to its owner.

**ANTICIPATED:** planned for within the protocol, mentioned on the consent form, or included within a description of the test article (e.g., the Investigator's Brochure) as a greater than rare event.

**APPROVAL:** See IRB Approval

21 CFR 56.102(m)

**APPROVAL DATE:** Date decision was made to approve.

Full Board: Date of IRB meeting at which approval was given. If approval was granted contingent upon changes being made, it is the date of the most recent full board meeting.

Expedited: Date reviewer signed last review page.

**APPROVAL ISSUANCE DATE:** Date on approval letter or date on which approval letter is received, whichever comes first. There may be a gap between approval date and issuance date but no work should start before the approval letter is received.

**APPROVAL PERIOD:** The time between the Approval Date and the date set for the expiration date.

45 CFR 46.402(b)

**ASSENT:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent

**ASSURANCE:** See Federal-Wide Assurance

**CAPACITY:** Capacity refers to legal status. An under-age person lacks legal capacity to consent. A person with a guardian may have definite opinions to be considered but no legal ability to sign the form.

See Competence

**CERTIFICATE OF CONFIDENTIALITY** A document provided by a federal agency to investigators upon application and approval, which allows records to be safeguarded from subpoena. Certificates are provided only for research, funded by any federal agency, which involves drug abuse, illegal activity or conditions which might place the subject with some legal jeopardy.

**CERTIFICATION** The official notification by the institution to the supporting agency in accordance with the requirements of 45 CFR 46 (subpart A) that a research project or activity involving human subjects has been reviewed and approved by the IRB in accordance with their approved assurance.

FORM

**CHILDREN:** Persons who have not attained the age of consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (A minor is a legal

45 CFR 46.402(a)

concept described within state law.)

**CLINICAL INVESTIGATION:** Any experiment that involves a test article and one or more human subjects, and that either: (a) must meet the requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or (b) as study of a test article the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of Part 58, regarding non-clinical laboratory studies. The terms "research," "clinical research," "clinical study," "study," and "clinical investigation" are deemed to be synonymous for purposes of this part (The NIH equivalent is defined as "research.").

21 CFR 56.101( )

**CLINICAL TRIAL:** See Clinical Investigation

**CLINICAL TRIAL REGISTRY:** A central, accessible, listing of clinical trials.

FDAAA2007 Sec  
801  
Clintrials.org

**CODED:** A link between a sample or information that could permit the recipient to link it to its owner.

**COMMON RULE:** Regulations found in Title 45 Code of Federal Regulations, Part 46, Subpart A. Called the Common Rule as subpart A was accepted in 1990 by 16 federal agencies.

**COMPASSIONATE USE:** This term has several uses although this term is not defined in any regulation:

- a. Use of a marketed drug for an unapproved use.  
This falls within the physician's discretion and requires no prior approval.
- b. Use of a marketed drug for an investigational use.  
This is research and requires an IND and IRB approval.
- c. Use of an investigational drug for a single patient with no emergency.
- d. Use of an investigational drug for a single patient in an emergency.  
This data may not be used in any DHHS funded study; it may be used in the safety evaluation for FDA but is not likely to be accepted for efficacy.
- e. Use of an investigational drug in a "late Phase III" protocol.

**COMPETENCE:** Competence refers to abilities. A person with Alzheimer's may progress through a range of competence; having once been competent and losing it. An underage person may be gaining competence.

See capacity

**CONFIDENTIAL:** Information that should be maintained as if it is secret. Records about people and studies are often confidential. Prevention of disclosure to other than authorized individuals of a sponsor's or subjects

See Privacy

private information.

**CONFLICT (of Interest):** A convergence of an investigator’s private interests with his or her research interests such that an independent observer might reasonably question whether the investigator’s professional actions or decisions were improperly influenced by considerations of personal gain.

An individual or a group with interests that conflict in such a way that a study could be biased or an inappropriate subject could be enrolled.

The test applies to the person and to the family.

See Interests  
See Family

**CONSENT:** the knowing agreement of an individual given without coercion or undue influence.

**COUNSELING MATERIALS:** Written materials that resemble recruitment materials that are to be used solely as explanation during the consent process.

**CONSEQUENTIAL:** causing greater than trivial physical or other harm to subjects or the study.

**DEVIATION:** An unplanned exception from a protocol made for an individual subject.

See Violation

**DEVICE ADVERSE EFFECT:** any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other *unanticipated* serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

21 CFR 812.3(s)  
UADE is an unanticipated

**ETHICAL REVIEW BOARD:** the European counterpart to IRBs.

**EMERGENCY USE:** The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

21 CFR 56.102(d)

**ENGAGED IN:** A term used to describe institutions covered by the Common Rule and who should be submitting an FWA.

OHRP guide

**EXCEPTION:** A planned violation of a protocol made for an individual subject.

**EXEMPT Research:** An activity that is research involving human subjects but that is not required to have IRB review.

**EXPEDITED Process:** The IRB review process involving 1 or more experienced reviewers instead of the convened board.

**EXCULPATORY:** Language implying that the investigator or sponsor will be absolved of responsibility.

**EXPERIENCED:** Any person who has served on any IRB for greater than six

IRC

months and who has been determined by the members to be capable of conducting expedited review. Used in conjunction with who can be an expedited reviewer.

**FAMILY:** *As used in conflict of interest:* includes at a minimum the investigator and the immediate family. Immediate includes spouse or domestic partner and dependent children. There is no requirement to include those who are dependent on the PI or on whom he or she are dependent.

**FEDERAL-WIDE ASSURANCE:** An agreement between a federal agency (generally OHRP) and an institution receiving federal contract or grant money assuring that the institution has appropriate plans and mechanisms to protect human subjects.

**FDA** Food and Drug Administration, a regulatory agency in the Public Health Service

**FETUS:** The product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

[45 CFR 46.203(c)].

**FETUS, DEAD:** Means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord, if still attached (NOTE: This is a regulatory definition. I did not make this up!)

[45 CFR 46.203(f)].

**FETUS, VIABLE:** As it pertains to the fetus, means being able (capable?), after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery it is an infant.

[45 CFR 46.203(d)].  
As it is after delivery, the fetus becomes the infant.

**GOOD CLINICAL PRACTICE (GCP):** A standard for the design, review, conduct, performance, monitoring, auditing, recording, analyzing 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 subjects are protected.

**GUARDIAN.** An individual who is authorized under applicable state or local law to perform specific activities on behalf of another. For research the guardian must have been appointed to be able to consent on behalf of a child or on behalf of adults unable to care for themselves for like activities.

**HARM:** actual (as opposed to potential) damage to the health, safety or welfare of a person or to society

See also Risk

**HUMAN RESEARCH PROTECTION PROGRAM:** A systematic and

comprehensive approach by an organization to ensure human subject protection in all research at that organization.

**HUMAN SUBJECT:**

- (1) A living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.
- (2) An individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human being or a patient.
- (3) A human who participates in an investigation, either as an individual on whom *or on whose specimen* an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease

45 CFR 46.102(f).  
[21 CFR 56.102(e)]

21 CFR 812.3(p)

*NOTE: IRC policy is to call a subject a subject rather than to use the euphemism participant. Participant may be used when the subject and investigator are at equivalent positions of power.*

**IDE (INVESTIGATIONAL DEVICE EXEMPTION):** No device may be placed in interstate commerce for use in medical diagnosis or treatment unless it has been granted marketing approval by the FDA. An exemption may be granted for an investigational device to be shipped for use in an approved investigation (21 CFR 812). The IDE may be granted by an IRB if the IRB agrees with the sponsor's contention that the device involved poses a non-significant risk to the health, safety or welfare of the subjects. If the sponsor does not put forward such a contention or if the IRB disagrees with it, it is presumed to be a significant risk device which must receive its IDE from the FDA.

21 CFR 812

**IND (INVESTIGATIONAL NEW DRUG):** No drug may be placed in interstate commerce for use in medical diagnosis or treatment unless it has been granted a New Drug Approval (NDA) or Abbreviated New Drug Approval (ANDA) by the FDA. An exemption is granted by the FDA only for use of a drug in the context of an investigational protocol approved by an IRB.

21 CFR 312

**INFLICTED KNOWLEDGE:** Information given to a person who had not requested it or who does not have the means to do anything with it when that knowledge might presage future problems

**INSTITUTION:** Any public or private entity or agency (including Federal, State, and other agencies). The word "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for purposes of this part.

See also:  
Organization

**INSTITUTIONAL REVIEW BOARD (IRB):** Any board, committee, or other group formally designated by an institution to review biomedical research involving human beings as subjects, to approve the initiation of and conduct periodic review of such research. The primary purpose of

45 CFR 46.102(g).

such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase "institutional review committee" as used in section 520(b) of the act.

An institutional review board established in accord with and for the purposes expressed in this policy

### **INTERESTS (Conflict of)**

These tests apply to the aggregate holdings of the person and the family (see family).

The interests are in companies that are involved in development of the test article, or the conduct or the analysis of the study and to direct competitors of those companies.

#### **FINANCIAL**

- a. financial support or grants from the same institute or corporation or from a competing corporation, in an amount that its loss would significantly impact the member,
- b. a "significant" equity position in the sponsor company or a direct competitor of that company. Ownership interest, stock options, or other financial interest
  - greater than \$10,000 or greater than 5% of any single entity.
  - Whose value cannot be referenced to publicly traded prices
  - Whose value will be affected by the outcome of the research.
  - Whose value cannot be readily determined.
- c. expectation of receiving compensation, salary, royalties or other payments
  - with value that may be affected by the outcome of the study or
  - greater than \$10,000 per year.
- e. FDA limits. For investigators: any holdings that would generate need for a Form 3455.
- f. NSF – Equity interests that, when aggregated, represent \$10,000 or more than a 5% ownership interest (by reference to public prices or other reasonable measures of fair market value) in any entity that would reasonably appear to be affected by the funded project.
- g. Does NOT include funds over which person has no control such as mutual funds.

**NON-FINANCIAL:** personal, non-financial relations (both positive or negative) with the investigator or the company.

- a. Any intellectual property rights
- b. Publication rights
- c. Proprietary interest in the research (patent, trademark, copyright or licensing agreement).

Link

21 CFR 54

See also Conflict (of interest)

- d. Being an officer or a director of the company or agency sponsoring the study.

**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. Interaction includes communication or interpersonal contact between investigator and subject.

**INVESTIGATOR:** an individual who actually conducts some part of an investigation, i.e., getting consent, doing surveys being a member of a team led by the principal investigator. *Clinical investigator* means only a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects.

The Principal Investigator is the person with authority to make final decisions about the conduct of the study at a particular site.

**IRB APPROVAL:** The determination of the IRB that the clinical investigation 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.

**KEY PERSONNEL:** Those who are responsible for design, consent, subject interaction, data management and reporting. Those people listed on the grant or on the 1572.

**LEGALLY AUTHORIZED REPRESENTATIVE:** An individual or juridical or other body authorized under applicable state law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

**MEDICAL EXPERIMENT:**

- a) The severance or penetration of damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
- b) The investigational use of a drug or device as provided in Sections 111590 and 111595.
- c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

**MINIMAL RISK:** 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.

*2/13/07 Board discussed use of the term and agreed that it should be interpreted to apply to the risks ordinarily encountered in the*

Sub-investigator” includes any other individual member of that team.

CALIF Health & Safety Code, Div 20, Section 24170

46.303d

*daily life of that subject population. Thus, something low risk done in a high-risk population could be minimal risk.*

**MINIMAL RISK (Prisoner)** 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.

**MONITOR** A person external to the research site and team assigned to review research data for validity and integrity. Most often a person hired by a Contract Research Organization.

**NON-COMPLIANCE** Any action, activity or omission associated with the conduct of research involving human subjects that fails to comply with the study protocol, the federal regulations or institutional policies governing such research.

Acts of non-compliance can range from minor and sporadic problems, such as turning in a report a day late or failing to obtain a monitoring test as required by the protocol, to serious or continuing non-compliance, such as failing to obtain consent or repeated failure to conduct mandated safety monitoring.

1. Failure to obtain IRB approval for non-exempt research or continuing to conduct a study while study approval has lapsed;
2. Inadequate or non-existent procedures for the informed consent process; enrollment of inappropriate or non-eligible subjects.
3. Inadequate supervision;
4. Failure to follow recommendations made by the IRB;
5. Failure to report adverse events or protocol changes;
6. Failure to provide ongoing progress reports;
7. Protocol deviations.

**NON-COMPLIANCE - CONTINUING** A pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that non-compliance will continue without intervention, or frequent instances of minor non-compliance. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

**NON-COMPLIANCE - SERIOUS** One or more actions of non-compliance that increases risks to participants, decreases potential benefits or compromises the integrity or validity of the research or is in direct conflict with IRB or agency determinations Serious protocol deviations that may place subjects at risk from the research.

**NON- SIGNIFICANT RISK DEVICE:** Undefined but taken to be the obverse of a Significant Risk Device.

**NON- SIGNIFICANT RISK DEVICE STUDY:** A study of any risk level that includes use of a device deemed to be NSR. Note that studies are described as having greater than or less than minimal risk

**OTHER(s);** A person two or three degrees removed from the study subject

**PARTICIPANT:** This is another word to describe a person participating in a study. It is considered to be more politically correct than subject although it seems to imply the relationship that is ideal rather than the relationship that is likely to exist in fact.

**PREGNANCY:** Encompasses the period of time from implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until expulsion or extraction of the fetus or birth.

46.202f

**PRINCIPAL INVESTIGATOR:** An individual who actually conducts an investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject or, in the event of an investigation conducted by a team of individuals, is responsible leader of that team.

21 CFR 56. 101  
not defined in 45  
CFR 46

An individual who is the responsible person (the buck stops there) at a given site AND who is responsible for the rights, welfare or safety of subjects (as opposed to clients or patients) at that site. Thus, for instance, a site director who allows recruitment for or conduct of research or facilitates the conduct by an external investigator is not a principal investigator. An evaluator who is the project director is not the PI; the site director is. A PI conducts the study as opposed to simply recruiting for others.

**PRISONER:** Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, with arraignment, trial or sentencing.

46.303c

This term includes non-institutional restraint such as house arrest, prisoner-patients in the hospital or other restraints on movement.

**PRIVATE:** A person's sense of what is secret to that person. This could include private space (the distance between individuals) or secrets. 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 and which the individual can reasonably expect will not be made public.

**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 which has been provided for specific purposes by an individual and which the individual

45 CFR 46.102(f)

can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertainable by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**PROBLEM:** a negative event that is of a physical, social, economic, financial or legal nature

1. A question to be considered, solved, or answered
2. A situation, matter, or person that presents perplexity or difficulty,
3. A misgiving, objection, or complaint

**PROBLEM INVOLVING RISK TO SUBJECTS OR OTHERS:** An event that involves a serious harm to the individual subject or that indicates a potential for serious harm to future subjects or others. Relatedness is implied

**PROGRAM EVALUATION:** A formalized, systematic activity that objectively assesses the success of an established program in achieving its objectives; it may also assess efficiency, timeliness, and cost effectiveness. The information is generally used to improve the program rather than be generalized.

May be determined to be “research” by some agencies.

**PROTECTED HEALTH INFORMATION:** A HIPAA term for information that is individually identifiable and is about health but is protected under the HIPAA rules. See HIPAA

**PROTOCOL:** A stand-alone document that describes the background and rationale, objective(s), design, methodology, statistical considerations and procedures of a study.

**PUBLISH:** to issue printed or otherwise reproduced textual or graphic material for sale or distribution to the public. To make publicly or generally known. Publication is often as one determinate of whether an activity is generalizable.

(Q: Is data kept confidential for a patent published? Probably not)

**QUALITY:** The totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance  
Ability of a set of inherent characteristics of a product, process or system to fulfill requirements of customers and other interested parties.

**QUALITY ASSURANCE:** A systematic process to compare performance against a standard

**QUALITY IMPROVEMENT:** a systematic, data-guided project intended to

Distinguish  
from Research

21 CFR 820(s)

ISO 9000.2000

Distinguish from  
Research

Distinguish from

improve the way in which care or service is provided for clients, patients or students.

**RECUSE:** A decision to be absent from the discussion and vote. Distinguished from abstention by the absence from the room. A recused person will be named if recusal is for conflict of interest. This person cannot be counted toward the quorum.

**REGULATORY DETERMINATIONS:** These are the review criteria to be met to make a given decision. Often also called the “review criteria.”

**RELATED TO THE RESEARCH PROCEDURE:** An adverse event is related to the research procedure if, in the opinion of the principal investigator, it is more likely than not to have been caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

**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 these regulations whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities

**RESEARCH SUBJECT TO REGULATION:** and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

**RESPONDENT** the person(s) responding. Typically of which an allegation of an act(s) of serious and or continuing non-compliance, or scientific misconduct is directed, or the person(s) whose actions are the subject of inquiry or investigation.

**RISK** A statement of the probability of a future harm.

**SAFETY REPORT:** Report generated by a sponsor to inform all sites about a serious adverse event from another site. Also known as an external report

**SCIENTIFIC MISCONDUCT:** Serious deviation from accepted practice in carrying out research or in reporting the results of research or material failure to comply with accepted standards of conduct. This may include plagiarism, misrepresentation of authorship, fabrication, falsification or destruction of data, violation of confidentiality, intentional deception, omission, dishonesty or obstruction of another's' work.

Research

Contrast this with related to participation in a study

45 CFR 46.102(e)  
See also Clinical Investigation

45 CFR 46.102(e)

21 CFR 312.

**SCIENTIST:** A person who self-identifies as a scientist and has the training or professional experience to make that claim.

A “**non-scientist**” is a person who does not self-identify as a scientist although he or she may have once done so and have had scientific training.

For IRC, a hiatus of 10 years between activity as a scientist and board membership plus interim activity in a non-scientific field is required.

**SERIOUS:** Flagrant, Any act of non-compliance that increases risks to participants more than minimally, decreases potential benefits or compromises the integrity or validity of the research or our trust in the site. FDA defines some events as serious regardless, such as being in the hospital *for any reason* whether study related or not. Any of the following must, by definition, be described as serious:

- Death,
- a life-threatening adverse drug experience,
- in-patient hospitalization or prolongation of existing hospitalization,
- a persistent or significant disability/incapacity,
- or a congenital anomaly/birth defect.

**SIGNIFICANT RISK DEVICE** An FDA definition of an investigational device as it is used within the context of a particular study. The device’s risk, in that context, has the potential for serious harm to the health, safety or welfare of the subject.

**SOURCE DOCUMENT:** The original document showing a piece of data regardless of what or where the information is. Auditors have the right to inspect source documents.

**SPONSOR:** A person, corporation, or agency who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator) and the employees are considered to be investigators.

**SPONSOR-INVESTIGATOR:** An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to or used involving, a subject. The term does not include any person other than an individual, (e.g., corporation or agency).

**STUDY:** A word that is discouraged as it could imply a blood study, to study as for a test, or research.

There is no generally accepted regulatory definition. For IRC, a hiatus of 10 years between activity as a scientist and board membership plus interim activity in a non-scientific field is required.

See also IDE  
21 CFR 812.3(m)

**SUBSTANTIVE:** As used in approval contingent, substantive means unanticipated responses not envisioned during discussion.

As used in a minor modification or a violation that is or is not substantive and therefore reportable, it is something that alters the outcome, validity or design of the study or that increases subject risk.

**SUSPENSION:** A temporary hiatus in some or all study activity requested by the IRB or a representative of the IRB. If required by the IRB it must be reported to the appropriate federal authority, if any.

**TERMINATE:** An action taken by the Full Board to stop a study or a part of a study permanently. If required by the IRB it must be reported to the appropriate federal authority, if any.

This is distinguished from simple closure at the end of a study.

**TEST ARTICLE:** Any drug (including a biological product for human use), medical device for human use, food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act [42 U.S.C. 262 and 263 (b-n)]

**UNANTICIPATED:** An occurrence that was not considered - at least to the magnitude and frequency presented - and for which no preparation was made. It often means an event not addressed in the investigator's brochure, protocol or informed consent document.

Often used synonymously with unexpected.

**UNEXPECTED:** An occurrence that was considered but that, with the preparations made, was not expected to occur within the realm of the study.

An adverse event is "unexpected" when its specificity and severity are not accurately reflected in the protocol or consent document.

Often used synonymously with unanticipated.

**UNINTENDED CONSEQUENCE:** An unanticipated outcome from an action. The primary example is from receipt of un-requested information that can alter an approach to life.

**VIOLATION:** A failure to follow the protocol and the agreements reached with the IRB concerning its implementation.

Exceptions are planned for an individual subject.

Deviations are surprises by an individual subject

A violation of a regulatory part of the protocol (e.g., failure to get consent) is also non-compliance.

**VULNERABLE Subjects:** Individuals whose willingness to volunteer in a study may be unduly influenced by circumstances beyond their control or whose ability to understand the information and assess it is compromised.

AAHRPP 1.3.J.

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