A	
Adverse Effect	Unanticipated problem or unfavorable symptom or disease occurring during a clinical study, though not necessarily caused by the study treatment, which harms subjects or others, for example, a loss of research records, drug overdose, serious symptoms, or death
Adverse Event	Occurrence of an adverse effect occurring during a clinical study. 45 CFR part 46, subpart A
AE	Adverse Event - Adverse event means an undesirable experience associated with research activities. Examples in a mammography study Adverse events include but are not limited to: (1) Poor image quality (2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and (3) Use of personnel that do not meet the applicable requirements
Amendment	Any changes to previously approved research
Approve	The study has been reviewed and approved to continue without revisions
Approve Pending	The study has been approved pending minor revisions to the protocol or consent
Assent	Child's agreement to participate in research, which is not just a failure to object. 45 CFR 46.402, CFR 46.116
Assurance	Written, binding commitment an institution submits to a federal agency promising to comply with human subjects or research animal regulations and stating procedures for achieving compliance.
Authorization	Legislation enacted by Congress that sets up or continues the legal operation of a federal program or agency either indefinitely or for a specific time or sanctions an expenditure. An authorization is normally a prerequisite for an appropriation or other kind of budget authority.
Autonomy	**1 :** the quality or state of being self-governing; *especially* **:** the right of self-government **2 :** self-directing freedom and especially moral independence **3 :** a self-governing state
B	
Belmont Report	Statement of ethical principles for human subject research issued by the National Commission for the Protection of Human Subjects in 1978 http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
Beneficence	Ethical principle stated in the Belmont Report stating an obligation to protect people from hard by not doing harm and by maximizing benefits and minimizing risks
Biosafety Level	Guidelines for microbiological and biomedical laboratories that provide increasing levels of protection for workers based on known risks of manipulating transmissible agents, using engineering controls, management policies, work practices, and occasionally, medical interventions
C	
CFR	Code of Federal Regulations
Clarification	Act by an offeror to clarify aspects of a proposal or resolve minor or clerical errors. Either an offeror or the government may initiate a clarification
Class I, II, III devices	FDA classifications for medical devices by potential risks. 21 CFR 812
Clinical Investigation	Research in which an experimental drug is given to human subjects. 21 CFR 312
Clinical research	Human subjects term indicating research conducted on human subjects or on material of human origin identifiable with the source person. Policy covers large and small-scale, exploratory, and observational studies. There are three types: 1. Patient-oriented research 2. Epidemiologic and behavioral studies 3. Outcomes and health services research

Clinical trial	Human subjects term indicating a prospective study of human subjects designed to answer questions about biomedical or behavioral interventions, e.g., drugs, treatments, devices, or new ways of using known treatments to determine whether they are safe and effective. • Phase I tests a new intervention in 20-80 people for an initial evaluation of its safety, e.g., to determine a safe dosage range and identify side effects. • Phase II studies an intervention in a larger group of people, usually several hundred, to determine efficacy and further evaluate safety. • Phase III studies the efficacy of an intervention in large groups of several hundred to several thousand subjects by comparing it to other standard or experimental interventions, while monitoring adverse events and collecting information that will allow safe use. • NIH-defined phase III clinical trial is a broadly based, prospective investigation, including community and other population-based trials, usually involving several hundred or more people, to evaluate an experimental intervention in comparison with a standard or control, or to compare two or more existing treatments. Often, the aim is to provide evidence for changing policy or standard of care. It includes pharmacologic, non-pharmacologic, and behavioral interventions for disease prevention, prophylaxis, diagnosis, or therapy. • Phase IV is a study done after an intervention has been marketed to monitor its effectiveness in the general population, and collect information about adverse effects associated with widespread use.
Clinical Trial Agreement	Agreement governing the safety and efficacy of outside collaborator's proprietary biologics or pharmaceutical compounds in clinical studies
Clinical trial monitoring	Collection and analysis of data as a projected progress to ensure appropriateness of the research a projects design, and the protection of human subjects
Code of Federal Regulations	Annually revised codification of general and permanent rules published in the Federal Register.
Coded private information	Identifiable private information such as a subjects name or social security number, that is replaced with a code, e.g. number, letter or symbol. Investigators are considered to be conducting human subjects research only if thy can identify subjects by linking the information to them directly or through a coding system.
Co-Investigator	Any individual member of the clinical team designated and supervised by the principle investigator at a trial site to perform critical trial-related procedures and/or to make important trail-related decisions (e.g. associates, N.P.'s)
Common rule	Subpart A of 45 CFR 46, Protection of Human Subjects
Compassionate Use Investigation New Drug	FDA procedure for making available to a patient a non-investigational new drug, based on a physician's request
Confidential disclosure agreement	Agreement ensuring government employees do not publicly disclose a company's proprietary information and that a company does not publicly disclose the governments scientific findings before publication and before the government secures patent rights
Confidentiality	Act of not divulging information disclosed in a relationship of trust without permission, including fulfilling the expectation that it will remain private
Conflict of interest	Financial, career, or other such interest, including interests of family members, that could be advanced by participation on an NIH Advisory Council, IRB or other advisory board 45 CRF 73 and 42 CFR 50
Continuing review	The IRB will determine based on the amount of risk involved an appropriate review period for a research study not to exceed one year from the initial approval date
Continuing review	Institutional Review Boards (IRBs) are responsible for continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected. The Food and Drug Administration (FDA) regulations regarding continuing review require an IRB to develop and follow written procedures for:

	conducting continuing review of research at intervals appropriate to the degree of risk, but not less than once per year • determining which studies need verification from sources other than the investigator that no material changes in the research have occurred since the previous IRB review [21 CFR 56.108(a)(2)]; • ensuring that changes in approved research are promptly reported to, and approved by, the IRB [21 CFR 56.108(a)(3-4)]; and • suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements [21 CFR 56.108(b)(2) and 56.113].
Consent	See informed consent
Consultation	Expert brought into provide advice
Core	A resource that provides services or facilities to at least two research projects
Cost analysis	Analysis performed by a contracting officer to determine whether an offeror's proposed costs are fair and reasonable.
D	
Data and safety monitoring board	Independent committees that reviews clinical trial progress and safety, and advises advisory boards whether to continue, modify, or terminate a trial. One of several types of clinical trial monitoring options.
Deferred	There is a serious concern or the required changes are extensive enough that the study will require another full board review once the changes are made and resubmitted. (Tabled)
Department of Health and Human Services	Federal government department whose mission is to protect the health of Americans and provide essential human services DHHS http://www.hhs.gov/
Drug discovery	Identification of a new drug targets and leads for treatments or preventions either by identifying molecules with desired biological effects or by screening agents using an indicator system to show efficacy
E	
Earmark	Requirements by Congress that a federal agency set aside funds within an appropriation for a stated recipient or purpose, for example, to establish a research center grant program or conduct a clinical trial
Equitable	State in which investigators fairly distribute research benefits and burdens when selecting human subjects
Exempt	If research in which the only involvement of human subjects fits into one of the 6 categories of CFR 46.101, that research may be exempt from IRB review.
Exemption	FDA term for an IND application filed usually by a sponsor with the FDA. It includes a detailed description of the planned investigation including phase I, II, III studies and names of investigators and IRB. FDA has 30 days to review and IND. 21 CFR 312
Exemption categories	Human subjects term indicating six research categories exempt from human subjects regulations: 1. Research conducted in educational setting involving normal educational practices, such as research on instructional strategies, techniques, curricula, or classroom management methods 2. Research using cognitive diagnostic, aptitude, and educational achievement tests, or surveys, interviews, or observations of public behavior, unless human subjects are identifiable, and disclosure of response could put them at risk of liability or damage to their reputations or financial standing. 3. Research using cognitive diagnostic, aptitude, and educational achievement tests, or surveys, interviews, or observations of public behavior, unless subjects are public officials or candidates for public office, or federal statutes require that the confidentiality of identifiable information will be maintained. 4. Research involving the collection or study of existing data, documents,

	records, pathological specimens, or diagnostic specimens, if the sources are publicly available, or the information is recorded so subjects cannot be identified. 5. Research and demonstration projects conducted or approved by agency heads to study public benefit or service programs, procedures for obtaining benefits or services, or other changes to those programs. 6. Taste and food quality evaluation and consumer acceptance studies in a) wholesome foods without additives or b) food containing a food ingredient at or below a level and use found to be safe, or an agricultural chemical or environmental contaminant at or below a level deemed safe by the following agencies: FDA, EPA and Us. Department of Agriculture
Expected Adverse Events	Adverse events described in package labels, brochures, protocols, and consent forms.
Expedited IRB Review	Review of research project by a designated voting member or members rather than an entire IRB is allowed for some minimal risk research and minor changes in approved research
Expedited Review	Research that poses no more than minimal risk and minor changes to previously approved research may be approved by the chair or designee in accordance with CFR 46.110
Experimental	Therapy unproven or not yet scientifically validated for safety and efficacy. A procedure may be considered "experimental" without necessarily being part of formal research
F	
FDA	See Food and Drug Administration http://www.fda.gov/
Federalwide assurance	Online form every institution conducting human subject research must file with the Office of Human Research Protections HHS, to establish policies and procedures for the protection of human subjects as required by HHS regulations 45 CFR 46. It applies to award recipients and collaborating institutions.
Food and Drug Administration	Food and Drug Administration – Since 1971, FDA regulations have required that studies involving investigational new drugs and biologics performed on human subjects in institutions (including hospitals, nursing homes, mental institutions, and prisons) receive review and approval by an Institutional Review Board (IRB). Medical devices have required IRB review since 1976. FDA developed the Bioresearch Monitoring Program and began an expanded review of IRB operations in April 1977. The Bioresearch Monitoring Program, which encompasses not only IRBs, but also clinical investigators, research sponsors, monitors, and non-clinical (animal) laboratories, is primarily intended to ensure the quality and integrity of data submitted to FDA for regulatory decisions, as well as to protect human subjects of research. For this reason, the IRB regulations note that FDA may inspect IRBs and review and copy IRB records [21 CFR 56.115(b)]. The FDA inspects the IRB once every three years. We are asked to pull for review: 1. all our meeting binders, agenda, minutes, documentation for the past three years. 2. All studies will IND's 3. All correspondence sent to FDA regarding those INDs 4. IRB registration / updates to OHRP
Food and Drug Administration	HHS agency that reviews clinical research to regulate the marketing of food, drugs, devices and cosmetics
Full board review	Review meeting of a majority of IRB members, including at least one non-scientific member. To gain IRB approval, a majority of members present at a meeting must agree.
Full board review	Review of research by a fully constituted IRB (fully constituted board requirements see CFR 46.107) Criteria for full board review can be found under CFR 43.109
FWA	See Federal wide assurance
G	
Gender	Human subjects term indicating a classification of research subjects into women

	and men. In some cases, gender cannot be accurately determined, e.g. for pooled blood samples
Gene therapy	Treatment of genetic disease by altering the genetic structure of either somatic or germline cells
Genome	Organism's chromosomes containing genes and other DNA
Germline cell	Cell that becomes egg or sperm
GLP	Good laboratory practices http://www.fda.gov/ora/compliance_ref/bimo/7348_808A/Default.htm
GMP	Good manufacturing practice
Grant	Financial assistance from NIAID for approved activities. Performances responsibility rests primarily with a grantee with little or no government involvement in the research; term covers grants and cooperative agreements
Grants.gov	Site through which applicants find and apply for grants for over 1,000 grant programs from 26 federal grant-make agencies www.grants.gov
H	
Health Insurance Portability and Accountability Act	Law from 1996 that amends the Internal Revenue Code to improve portability of health insurance coverage, promote medical savings accounts, improve access to long-term services and coverage, and simplify administration of health insurance http://thomas.loc.gov/cgi-bin/query/z?c104:H.R.3103.enr:
HHS	See Department of Health and Human Services http://www.hhs.gov/
Human Subject	Legally defined term indicating a living personal with whom an investigator directly interacts or intervenes or obtains identifiable, private information. Regulations apply to human organs, tissues, body fluids, and recorded information from identifiable people. Seed 45 CFR 46
Human Subject	As defined by 45 CFR 46.102(f) Human subject means a living individual about whom an investigator whether professional or student conducting research obtains: 1. data through intervention or interaction with the individual or 2. identifiable private information
Human subject code	Number a scientific review group places on a summary statement during initial peer review, reflecting the application of human subject regulations to a project, and inclusion of women, children, and racial and ethnic populations. Some codes indicate a human subjects concern that would result in a bar to award.
Human subject concern	Human subject term indicating any actual or potential unacceptable risk or inadequate protection against risk to human subjects.
I	
IACUC	See Institutional animal care and use committee
IBC	See Institutional biosafety committee
IDE	See Investigational Device Exemption
IND	See Investigational new drug
Individually identifiable	Describes private information associated with a subjects identity or through which an investigator may ascertain identity, directly or through a coding system. See definitions 45 CFR 46.102 (f). If identity is knowable, the study is human subjects research. OHRP Guidance on Research involving coded private information or biological specimens. http://www.hhs.gov/ohrp/policy/index.html#biol
Informed Consent	Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in research or under a medical procedure. In giving informed consent, human subjects may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence. 21 CFR 50.20 and 50.25
Initial submission	The first time a study is submitted for approval. Your institute will have policies and procedures for submission requirements.
Institutional animal care and use committee	Committee established by a research institution to ensure that the care and use of animals in research is appropriate and humane. IACUCs independently

	determine that an institution is meeting requirements to ensure humane care and use of animals and is complying with regulations. They also review and approve protocols.
Institutional animal care and use committee certification	Approval by an IACUC of a project involving research animals. Grant applications and contracted proposals must include verification of IACUC certification before award.
Institutional assurance of protections for human subjects	Human subjects term indicating a document filed with the Office for Human Research Protections, HHS formalizing a research institutions commitment to protect human subjects.
Institutional Biosafety Committee	Committee set up by a research institution under the NIH Guidelines for Research Involving Recombinant DNA Molecules to review recombinant DNA research and ensure its legal use. IBC may also review other biohazardous research, including biodefense select agents. http://www4.od.nih.gov/oba/Rdna.htm
Institutional official for animal welfare	Senior official who signs an institutions animal welfare assurance, making a commitment on behalf of the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.
Institutional official for human subjects	Senior official who signs and institutions human subjects assurance, making a commitment on behalf of the institution to comply with 45 CFR part 46
Institutional Review Board	Committee set up or used by a research institution to ensure the protection of human subjects by independently approving, modifying, or disapproving research protocols. They can be domestic or foreign and must follow federal regulations and local institutional policy. IRBs must register with the Office for Human Research Protections HHS
Institutional review board certification of approval	Human subjects term indicating that an institutional review board has approved a clinical research protocol, consent form (if applicable), monitoring and reporting procedures and plans for analyzing intervention differences among different groups of human subjects (for example, women and minorities, ethnic and racial subgroups, and children). IRBs also approve research annually and any time there are major changes in a research protocol or other procedures.
Institutional review board documentation	Method of documenting and IRBs assessment of proposed or active research
Intensity or severity of adverse events	Grade of adverse events or side-effects of interventions.
Investigator	See principal investigator.
Investigational device	Device, including a transitional device, under investigation. 21 CFR 812
Investigational device exemption	Similar to an IND allows an unapproved medical device to be used for investigational purposes
Investigational drug	Substance in any clinical stage of evaluation not released by FDA for general use or cleared for sale in interstate commerce; also used for commercially available drugs that are proposed for a new use, contain a new component, have a new dosage or mode of administration, or are in a new combination or combined in new proportions
Investigational medical device	Healthcare product that dose no work by chemical action or by being metabolized and is not yet approved for marketing by FDA.
Investigational new drug	Status given by the FDA to a new drug or biological product to be used in a clinical investigation.
Investigational new drug application	Under regulation 21 CFR 21, applications filed by a drug sponsor with the FDA on form FDA 1571 to conduct clinical trials, included detail descriptions of all trial phases, protocols, IRB members and investigators. Once clinical evaluation is completed, a new drug application must be submitted to FDA to obtain approval to market the drug. Often used interchangeable with IND.
Investigational new drug, compassionate use	Procedure that makes a non FDA approved drug that does not have an IND available to patients with a life-threatening disease
Investigation new drug, treatment	Procedure that makes a new investigational drug available outside a clinical trial to patient with a life-threatening disease 21 CFR 312
Investigators for human subjects research	Any person involved in conducting human subjects research, excluding those who only provide coded private information or specimens, e.g. through a tissue

	repository, unless also research consultants or collaborators. Investigators who do not have access to subjects' identifiers are exempt form human subjects requirements
J	
Justice	Term describing equal distribution between who ought to receive the benefits or research and bear its burdens
L	
Legally Authorized Representative	An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participants participation in the procedure(s) involved in the research.
M	
Minimal risk	Human subjects term indicating that the probability and magnitude of harm or discomfort anticipated in research are not greater than those encountered in daily life or routine tests.
Minority group	Human subjects term indicating a subset of the population distinguished by either racial, ethnic, or cultural heritage. Categories re American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian or other Pacific Islander.
Misconduct in science	Fabrication, falsification or plagiarism in proposing, performing, reviewing, or reporting research. Fabrication is making up data or results; falsification is manipulating research resources or processes, or changing or omitting data or results to render the research record inaccurate; plagiarism is appropriating another person's ideas, processes, results or words without giving credit. Research misconduct does not include honest effort or differences or opinion.
Monitor	Person designated by a sponsor or contract research organization to oversee an investigation. A monitor may be an employee or a consultant to a sponsor or a contractor. Monitor also means to oversee an investigation.
N	
National Institute of Health	Federal government agency that conducts and supports biomedical and behavioral research to create fundamental knowledge of living systems, and reduce the burden of illness and disability.
National Science Advisory Board for Biosecurity	Body that advises federal agencies on ways to minimize the possibility that biological research knowledge and technologies will be used to threaten public health or national security.
Normal volunteer	Volunteer human subject who either does not have the condition being researched or is being studied for normal physiology or behavior
Nuremberg Code	The modern story of human subjects protections begins with the *Nuremberg Code,* developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. http://ohrp.osophs.dhhs.gov/irb/irb_appendicies.htm
O	
Obtain	Human subjects term meaning to receive or access individually identifiable human data or specimens including those already in investigator's possession
Offer	Response to a contract solicitation that would bind an offeror to fulfill a contract
Offeror	Contracting term denoting an applicant responding to a request for proposals
Office for Human Research Protections	NIH office that oversees human subjects protections for HHS supported research http://www.hhs.gov/ohrp/
Office of Laboratory Animal Welfare	NIH office that oversees compliance with the PHS Policy of Humane Care and Use of Laboratory Animals. http://grants.nih.gov/grants/olaw/olaw.htm
Office of Research Integrity	HHS office that promotes integrity in biomedical and behavioral research supported by the Public Health Service by monitoring institutional investigations of scientific misconduct, and facilitating the responsible conduct of research http://ori.dhhs.gov/

OLAW	See Office of Laboratory Animal Welfare
ORI	See Office of Research Integrity
P	
Patent	Document issued by the U.S. Patent and Trademark Office containing a description, specification, and claims that describe the subject matter in detail and giving its owner a right to exclude other from making, using, or selling it. Only the inventor can obtain a patent; however, employers often require employees to hand over patent rights.
Preclinical	Research conducted in animals after the discovery of a compound t to analyze its biological effects, including pharmacokinetics, toxicology, and mutagenisis
Primary Reviewer	An IRB member assigned to familiarized themselves with a submission and present the objectives to the board. The person acts as the expert in helping the board answer any concerns.
Principal Investigator	An individual who actually conducts a clinical 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 the responsible leader of that team.
Privacy Act	Law protecting citizens against needless collection or release of personal data
Private information	Information for which a person can expect that observations or recordings are not taking place, and the information will not be made public. Information must be individually identifiable to constitute humans subjects research
Procurement	Acquisition of property or services for the benefit or use of the government, generally through a contract
Protocol	Formal design for research involving human subjects or research animals an investigator submits to an IRB or IACUC for review. A protocol generally has an objective, rationale, design, eligibility requirements, treatment given and a description of research and data analysis methods
Provisional	The study is approved minor revisions to the protocol or consent (approve pending)
Public Health Service	Umbrella organization consisting of eight HHS health agencies, the Office of Public Health and Science, and the Commissioned Corps, a uniformed service or more than 6, 000 health professionals. http://phs.os.dhhs.gov/ophs/
R	
Racial and ethnic categories	Human subjects terms defined by the Office of Management and Budget and used by NIH to allow comparison to national database
Recombinant DNA	Recombinant DNA molecules are either 1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or 2) DNA molecules that result from the replication of those described in 1)
Research	Systematic investigation, including research development, testing and evaluation to develop generalizable knowledge.
Research	As defined by the Belmont Report – an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop a contribute to generalizable knowledge (expressed, for example in theories, principals, and statements of relationships). Research is usually described in formal protocol that sets forth an objective and a set of procedures designed to reach that objective
Risk	Probability of harm or physical, psychological, social, or economic injury resulting from participation in a research study
S	
SAE	Serious adverse event means an adverse event that may significant compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.
Safety reports for INDs and	Written reports from sponsors notifying FDA and investigators of drug associated

IDEs	serious and unexpected adverse events
Scope	Scientific parameters of a funded research project. A grantee cannot change the scope of a project on his or her own because doing so would significantly alter the project Council approved.
Serious adverse event	Adverse event that results in death, life-threatening experience, hospitalization, or prolongation of hospitalization, significant disability or birth defect. Investigators must file serious adverse event reports with the sponsor and IRB which reports them to them to the FDA. IND sponsors must notify FDA and NIAID with 24 hours. If applicable, investigators must also fine and FDA adverse event report
Subject	Healthy person or patient who participates in a clinical investigation, either as a recipient of an investigations drug or as a control. 21 CFR 312
T	
Tabled	There is a serious concern or the required changes are extensive enough that the study will require another full board review once the changes are made and resubmitted. (Deferred)
Termination	Discontinuance of a clinical investigation before completion by sponsor or by withdrawal of IRB or FDA approval
U	
Undue influence	Concept that investigators may not use unfair measures to enroll persons in research. (see general requirements of informed consent 45 CFR 46.116
Unexpected adverse event	Adverse events not described in labels, brochures, published medical literature, protocol or consent documents.
USDA	US Department of Agriculture http://www.usda.gov/wps/portal/usdahome