

## Abbreviations, Acronyms, and Definitions

1571, 1572	Application for an IND (FDA). <i>See also IND. See Form 1572</i>
21 CFR 50	Protection of Human Subjects (FDA)
21 CFR 56	Institutional Review Boards (FDA)
45 CFR 46	Protection of Human Subjects (Common Rule). <i>See also the Common Rule</i>
404, 405, 406, 407	Categories of pediatric research under the Common Rule
510(k)	Premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective that is substantially equivalent to a legally marketed device.

### A

AAC	Asthma and Allergy Center (on the Bayview Campus)
Abuse-labile	Pharmacological substances that have the potential for creating abusive dependency. Abuse-labile substances can include both illicit drugs ( <i>e.g.</i> , heroine) and licit drugs ( <i>e.g.</i> , methamphetamines).
ACCM	Anesthesia and Critical Care Medicine
ACRP	Association of Clinical Research Professionals
ACTG	AIDS Clinical Trials Group (NIAID)
ACTU	AIDS Clinical Trials Unit (NIH)
ADR	adverse drug reaction
AE	Adverse Event – An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention ( <i>e.g.</i> , headache following spinal tap or intestinal bleeding associated with aspirin therapy)
AHHRPP	Association for the Accreditation of Human Research Protection Programs. ( <i>Pronounced a-harp</i> )
Anonymity	Having no identifying information, codes; de-identified
Anonymous	<i>See also anonymity</i>
ARENA	Applied Research Ethics National Association
Assent	Agreement by an individual not competent to give legally valid informed consent ( <i>e.g.</i> , a child or cognitively impaired person) to participate in research.
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.
Autonomy	Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

## B

BA	Bioavailability
BE	Bioequivalence
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. <i>See also NCPHSBBR.</i>
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.
Biologic	Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, or cure of diseases or injuries.
BIMO	Bioresearch Monitoring
Blinded	Study design comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. <i>See also Double Blind</i>
BPRU	Behavioral Pharmacology Research Unit ( <i>on the Bayview Campus</i> ) part of the JHUSOM Department of Psychiatry
BSPH	Bloomberg School of Public Health

## C

CAM	Complementary and Alternative Medicine
CAP	Center for Addition and Pregnancy ( <i>on the Bayview Campus</i> )
CBER	Center for Biologics Evaluation and Research
CCOI	Committee on Conflict of Interest
CCRA	Certified Clinical Research Associate
CCRP	Certified Clinical Research Professional
CDC	Center for Disease Control and Prevention (Atlanta, GA), an agency within the Public Health Service, DHHS ( <a href="http://www.cdc.gov">www.cdc.gov</a> )
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health
CE	covered entity
Certificate of Confidentiality	Advance grant of confidentiality that will provide protection against a subpoena or research data.
CF	Consent Form
CFR	Code of Federal Regulations

CFS	Consent Form Specialist
CFR	Code of Federal Regulations
CHR	Committee on Human Research (School of Public Health)
CIRB	The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI) in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The CIRB reviews adult and pediatric national multi-center cancer treatment trials. JHU SOM has amended the FWAs on file with OHRP to include CIRB as a designated review board for collaborative oncology projects.
CIM	Certified IRB Manager
CIP	Certified IRB Professional
CIR	Center for Immunization Research
CITI	Collaborative Institutional Training Initiative
Class I, II, III Devices	Classification by the Food and Drug Administration of medical devices according to potential risks or hazards.
CLIA	Clinical Laboratory Improvements Amendments
CLIA approved laboratory	Laboratory that has voluntarily applied for and have been accredited by a private, nonprofit accreditation organization approved by CMS.
COC	Certificate of Confidentiality. <i>See also <b>Certificate of Confidentiality.</b></i>
Cognitively impaired	Having either a psychiatric disorder or a development disorder that affects cognitive or emotional functions to the extent that judgement and reasoning is significantly diminished.
COI	Conflict of Interest Committee on Outside Interests
Common Rule	45 CFR 46, applies to all research involving human subjects conducted, otherwise subject to regulation by any federal department or agency that has adopted this Federal policy (total of 16 agencies).
Compensation	Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. <i>JHM IRBs use the word <b>compensation for payment for participation in research.</b></i>
Competence	A legal term, used to denote capacity to act in one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) and to make a choice.
Confidentiality	Pertains to the treatment of information that an 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
Continuing Review	Reevaluation of approved research at intervals that are appropriate to the degree of risk; all research must be reviewed at least annually.

Contraindicated	Disadvantageous, perhaps dangerous, a treatment that should not be used in certain individuals or conditions due to risk
Convened 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.
CPA	Cooperative project assurance. <i>See also assurance.</i>
CR	Common Rule. <i>See also common rule.</i>
CR	Continuing Review. <i>See also continuing review.</i>
CRBO	Clinical Research Billing Orientation. The course must be completed by the Principle Investigator and his/her study team who will bill for services provided to participants enrolled in clinical trials
CRC	Clinical Research Committee (SKCCC)
CRF	case review form Case Report Form
CRMS	Clinical Research Management System
CRO	clinical research organization or contract research organization, also Clinical Research Office of SKCCC Contract Research Organization
CRO (JHM only)	Clinical Research Office (Oncology)
CRRC	Clinical Radiation Research Committee
CRRMC	Clinical Research and Review and Monitoring Committee (SKCCC)
CRSS	Clinical Research Support Services
CSO	Consumer Safety Officer (FDA)
CTEP	Clinical Therapeutics Evaluation Program (NCI) <a href="http://ctep.cancer.gov">http://ctep.cancer.gov</a>
CTU	Clinical Trials Unit
<b>D</b>	
DDS	Drug Data Sheet
Declaration of Helsinki	A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.
DEXA	Dual Energy X-ray Absorptiometry. <i>See also DEXA Scan.</i>
DEXA Scan	A procedure to measure fat mass, lean body mass, and/or body mass
DHEW	Department of Health, Education and Welfare, now replaced by DHHS and DOE
DHHS	Department of Health and Human Services (US Federal)
DMC	Data monitoring committee. <i>See also DSMB.</i>

DOD	Department of Defense (US Federal)
Double Blind	Study design comparing two or more interventions in which both the investigators and the subjects do not know the treatment group assignments of individual subjects. <i>See also <b>Blind</b></i>
DQ	Disqualification
Drug	Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.
DSMB	Data and Safety Monitoring Board – A committee of scientists, physicians, statisticians and others that collects and analyzes data during the course of a clinical trial to monitor for adverse events and other trends.
DSMP	Data and Safety Monitoring Plan
<b>E</b>	
Education Research	Scholarly inquiry with the ultimate goal of improving the educational process or learning environment
EI	Establishment Inspection (FDA)
EIR	EIR – Establishment Inspection Report (FDA)
eIRB	Electronic Institutional Review Board, the Johns Hopkins Medicine electronic protocol submission and tracking system.
eOPC	Electronic submission system for the Office of Policy Coordination
Emancipated minor	Legal status confirmed upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.
Equitable	Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.
ESCRO	Embryonic Stem Cell Research Organization Committee
Exempt Research	Certain categories of research involving human subjects that are not subject to federal regulation.
Expedited Review	Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor change in approved research. This type of review is done by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB.
Experimental	Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered “experimental” without necessarily being part of a formal study (research to evaluate its usefulness).

## F

FAQ	frequently asked questions
FDA	Food and Drug Administration (US Federal) <a href="http://www.fda.gov">www.fda.gov</a>
Form FDA 482	“Notice of Inspection”
Form FDA 483	“Inspectional Observations”
Form FDA 1572	Form FDA 1572 – Statement of Investigator
FSA	Further Study Action (in eIRB)
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.
FWA	Federal-Wide Assurance. <i>See also assurance.</i>

## G

GCP	Good Clinical Practice
GCRC	General Clinical Research Center (now ICTR)
GCRC-CRU	General Clinical Research Center-Clinical Research Unit (now ICTR-CRU)
GCRP	Good Clinical Research Practice
Gene therapy	The treatment of genetic disease accomplished by altering the genetic structure of either somatic (nonreproductive) or germline (reproductive) cells
Genotype	The genetic constitution of an individual
GMP	Good Manufacturing Practice
Grant	Financial support provided for research study designed and proposed by the principal investigators(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.
GRC	Gerontology Research Center, NIA ( <i>on the Bayview Campus</i> )

## H

HCGH	Howard County General Hospital
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health Maintenance Organization
HUD	Humanitarian Use Device

Human Subjects Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

## I

IACUC Institutional Animal Care and Use Committee  
IBC Institutional Biosafety Committee  
IDB Investigator's Drug Brochure  
IC Informed Consent  
ICF Informed Consent Form  
ICH International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use International Conference on Harmonization  
  
ICTR Institute for Clinical and Translational Research (formerly GCRC)  
ICTR-CRU Institute for Clinical and Translational Research-Clinical research Unit (formerly GCRC-CRU)  
IDE Investigational Device Exemption (FDA) – Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in Clinical investigations [21 CFR 812.20]  
IND Investigational New Drug / Device application (FDA)  
Investigator's Brochure Material from a pharmaceutical company about a new drug under and IND. [http://irb.jhmi.edu/Guidelines/invest\\_broch.html](http://irb.jhmi.edu/Guidelines/invest_broch.html)  
IRB Institutional Review Board  
IT Information Technology  
IVD In Vitro Device; In Vitro Diagnostics  
IVF In Vitro Fertilization

## J

JCAHO Joint Commission on Accreditation of Healthcare Organizations  
JCCI Joint Committee on Clinical Investigations (predecessor to OHSR)  
JHBMC Johns Hopkins Bayview Medical Center  
JHGC Johns Hopkins Geriatric Center  
JHH Johns Hopkins Hospital

JHM	Johns Hopkins Medicine
JHMI	Johns Hopkins Medical Institutions
JHSOM	Johns Hopkins School of Medicine
JHCCC CRO	Johns Hopkins Comprehensive Cancer Center Clinical Research Office (predecessor to SKCCC)
JHOC CRC	Johns Hopkins Oncology Center Clinical Research Committee
JHSPH	Johns Hopkins School of Public Health
Justice	An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons or similar circumstances or characteristics similarity.

## K

KKI	Kennedy Krieger Institute
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## L

Legally authorized representative	A person authorized either by statute or by court appointment representative make decisions on behalf of another person. In human subjects research, 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. ( <i>Maryland state law does <u>not</u> specify who may be a legally authorized representative for <u>research</u>.</i> )
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## M

Mature minor	Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes ( <i>e.g.</i> , consenting to medical care). NOTE: A mature minor is not necessarily an emancipated minor. <i>See also <b>emancipated minor</b>.</i>
MedDRA	Medical Dictionary for Regulatory Activities
Medical device	A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.
MFRC	Maternal Fetal Research Committee
Minimal risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research

purposes is no greater than the risk of doing so as part of routine physical examination.

MPA Multiple project assurance. *See also* **assurance**.

MTD Maximum Tolerated Dose

## N

NAI No Action Indicated (FDA inspection classification)

NBAC National Bioethics Advisory Commission <http://bioethics.gov>

NCI National Cancer Institute (NIH) [www.cancer.gov](http://www.cancer.gov)

NCPHSBRR National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research – An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations. *See also Belmont Report.*

NCRR National Center for Research Resources (NIH) [www.ncrr.nih.gov](http://www.ncrr.nih.gov)

NDA New Drug Application – Request for FDA approval to market a new drug.

NEI National Eye Institute (NIH) [www.nei.nih.gov](http://www.nei.nih.gov)

NHLBI National Heart, Lung, and Blood Institute (NIH) [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)

NIA National Institute on Aging (NIH) (*the Gerontology Research Center is on the Bayview Campus*) <http://nia.nih.gov>

NIAAA National Institute on Alcohol Abuse and Alcoholism (NIH) [www.niaaa.nih.gov](http://www.niaaa.nih.gov)

NIAID National Institute of Allergies and Infectious Diseases (NIH) [www.niaid.nih.gov](http://www.niaid.nih.gov)

NIAMS National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH) [www.niams.nih.gov](http://www.niams.nih.gov)

NIDA National Institute on Drug Abuse (NIH) (*the Intramural Research Program is on the Bayview Campus*) [www.nida.nih.gov](http://www.nida.nih.gov)

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases (NIH) [www.niddk.nih.gov](http://www.niddk.nih.gov)

NIDPOE Notice of Initiation of Disqualification Proceeding and Opportunity to Explain

NIH National Institute of Health – A federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research. [www.nih.gov](http://www.nih.gov)

NIMH National Institute of Mental Health (NIH) [www.nimh.nih.gov](http://www.nimh.nih.gov)

NINDS National Institute of Neurological Disorders & Stroke (NIH) [www.ninds.nih.gov](http://www.ninds.nih.gov)

NINR National Institute of Nursing Research (NIH) <http://ninr.nih.gov/ninr/>

Nonaffiliated Member	Member of an Institutional Review Board (IRB) who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).
Nonsignificant risk device	An investigational medical device that does not present significant risk to the patient
Nontherapeutic research	Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future
Normal volunteers	Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as a comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.
NSR	non significant risk (device)
Null hypothesis	The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.
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.
<b>O</b>	
OAI	Official Action Indicated (FDA inspection classification)
OHRP	Office for Human Research Protections (US Federal) <a href="http://www.hhs.gov/ohrp">www.hhs.gov/ohrp</a>
OHSR	Office of Human Subjects Research (JHSOM)
OPC	Office of Policy Coordination
OPRR	Office for Protection from Research Risks (predecessor to OHRP) – The office within the NIH, agency of the Public Health Service, DHHS, responsible for implementing DHHS regulations (45 CFR 46) governing research involving human subjects.
ORA	Office of Regulatory Affairs (FDA) <a href="http://www.fda.gov/ora">www.fda.gov/ora</a>
ORA	Office of Research Administration (JHSOM)
ORCA	Office of Research Compliance and Assurance; Veteran's Administration <a href="http://www.va.gov/orca/">www.va.gov/orca/</a>
ORI	Office of Research Integrity (PHS, DHHS) <a href="http://ori.dhhs.gov">http://ori.dhhs.gov</a>

ORRCS	Office of Recruitment and Retention Consulting Service
OSHA	Occupational Safety and Health Administration (Department of Labor)
OTC	Over-The-Counter (refers to nonprescription drugs)
<b>P</b>	
Permission	The agreement of parent(s) or guardian to the participation of their child or ward in research
PDF	Portable Document Format (refers to computer file)
PE	Protocol Event
Phase I, 2, 3, 4 Drug Trials	Different stages of testing drugs in humans, from first application in humans (Phase I) through limited and broad clinical tests (Phase 3), to post marketing studies (Phase 4). <i>See also FDA section</i>
Phenotype	The physical manifestation of a gene function.
PHI	Protected Health Information. <i>See also HIPAA</i>
PHS	Public Health Service (US Federal) – Part of the DHHS, includes the FDA, NIH, CDC, SAMHSA, and HRSA.
PI	Principal Investigator
Placebo	A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual power of a drug.
PMA	Pre-Market Approval application (FDA)
PRA	Prospective Reimbursement Analysis. This analysis is required for all studies that could have participant or study sponsor billing.
PRIM&R	Public Responsibility in Medicine and Research <a href="http://www.primr.org">www.primr.org</a>
Privacy	Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
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 design 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.
P&T	Pharmacy and Therapeutics Committee
Purity	The relative absence of extraneous matter in a drug or vaccine that may or may not be harmful to the recipient or deleterious to the product.

**Q**

QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement

## R

R&D	Research and Development
Radioactive drug	Any substance defined as a drug in 201(b)(1) of the Federal Food, Drug and Cosmetic Act that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons [21 CFR 310.3(n)]. Included are any non-radioactive reagent kit or nuclide generator that is intended to be used in the preparation of a radioactive drug and “radioactive biological products,” as defined in 21 CFR 600.3(ee). Drugs such as carbon-containing compounds or potassium-containing salts containing trace quantities of naturally occurring radionuclides are not considered radioactive drugs.
Radiopaque contrast agents	Materials that stop or attenuate radiation that is passed through the body, creating an outline on film of the organ(s) being examined. Contrast agents, sometimes called “dyes”
Radiopharmaceuticals	Drugs (compounds or materials) that may be labeled with a radioisotope. These materials are largely physiological or sub-pharmacological in action, and, in many cases, function much like materials found in the body. The principal risk associated with these materials is the consequent radiation exposure to the body or to specific organ systems when they are injected into the body.
Random	Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically ( <i>e.g.</i> , as dictated by the standards or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research, because it makes more likely the probability that difference observed between subject groups are the result of the experiment intervention.
Randomization	<i>See also random.</i>
Randomized	<i>See also random.</i>
RDRC	Radioactive Drug Research Committee
REM	Roentgen Equivalent in Man – The unit of measurement for a dose of an ionizing radiation that produces that same biological effect as a unit of absorbed dose (1 rad) of ordinary X-rays. One millirem is equal to 1/1000 of a rem.
Research	A systematic investigation ( <i>i.e.</i> , the gathering and analysis of information) designed to develop or contribute to generalized knowledge.
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 probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk”. <i>See also <b>minimal risk</b>.</i>
RPMS	Research Protocol Management System
RPN	Research Protocol Number ( <i>no longer used</i> )
RSS	Research Subjects Specialist
<b>S</b>	
SAE	Serious Adverse Event
SC	Study Coordinator
Significant risk device	An investigational medical devices that presents a potential for serious risk to the health, safety, or welfare of the subject.
SKCCC	Sidney Kimmel Comprehensive Cancer Center
SKCCC CRO	Sidney Kimmel Comprehensive Cancer Center Clinical Research Office
SKCCC CRRMC	Sidney Kimmel Comprehensive Cancer Center Clinical Research Review and Monitoring Committee
SoCRA	Society of Clinical Research Associates
SOM	School of Medicine
SON	School of Nursing
SOPs	Standard Operating Procedures
Sponsor	A person or entity that initiates a clinical investigation of a drug – usually the drug manufacturer or research institution that developed the drug. The sponsor does not actually conduct the investigation, but rather distributes the new drug to investigation and physicians for clinical trials. The drug is administered to subjects under the immediate direction of an investigator who is not also a sponsor. A clinical investigator may, however, serve as a sponsor-investigator. The sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable laws and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.
SR	Significant Risk
Statistical significance	Determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion.
Sterility	The absence of viable contaminating microorganisms, aseptic state.
Student	An individual who has registered within any academic division of Johns Hopkins University, regardless of whether s/he is enrolled in courses or on authorized leave.

Study Section A group of high regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of application for research grants and contracts. Scientific review groups are also required to review the ethical agents of proposed involvement of human subjects. Various kinds of scientific review group exist, and are known by different names in different institutes of the NIH (*e.g.*, Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).

## V

VA Veterans Administration (US Federal)

VAI Voluntary Action Indicated (FDA inspection classification)

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.

Vulnerable subjects Prisoners, pregnant women and fetuses, children as defined in 45 CFR 46. *JHM IRBs also consider other vulnerabilities such as economic, employees of JHMI, and subjects unable to give consent.*

## W

WHO World Health Organization

WIRB Western IRB - Organization, contracted by JHUSOM, that reviews multicenter, commercially funded protocols Western Institutional Review Board

WL Warning Letter

WMA World Medical Association – Issues and updates the Declaration of Helsinki

WWW World Wide Web