Essential Elements of Ethics Glossary

Term	Definition
Active Comparator	An active comparator is an existing known medication or intervention for a condition or process that is used for one arm of a clinical study or trial. An active comparator contrasts with other types of comparators such as a placebo, for example, which is inactive but simply a means of comparison for the intervention. https://globalhealthreviewers.tghn.org/resources/glossary/
Active Control	An active control (positive control) trial is one in which an investigational drug is compared with a known active drug. ICH Harmonised Tripartite Guideline E10 http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E10/Step4/E10_Guideline.pdf
Adaptive trials designs	A study design that aims to learn from the data as it is being collected, enabling the study to be modified as the research progresses without undermining the integrity of the trial and allowing what is learned to be applied as quickly as possible. Gallo et al Phrma (2006) J.Biopharm Stat 16(3) 275 -283) http://www.tandfonline.com/toc/lbps20/16/3#.VFou_2N40nN
Adverse event (AE)	In the context of a clinical trial, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Anonymization	To make anonymous. Research records or biological samples from which all direct or indirect identifiers have been removed such that no link is possible between the records or samples and the identity of the person who was the source of the record or sample (CIOMS - http://www.cioms.ch/)

Arm	In a clinical trial, an 'arm' is an assigned group, for example a trial may include a placebo arm and an investigational intervention arm. Some types of trial design include more than two arms. Participants are usually randomly assigned to these groups. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Assay sensitivity	Assay sensitivity is achieved in a clinical trial when a distinction between effective and ineffective treatment has been made. Hey SP, Weijer C Perspect Biol Med 2013 Winter 56(1):1-17 http://www.ncbi.nlm.nih.gov/pubmed/23748523
Assent	A variation on consent wherein a person who does not possess full competence to give informed consent gives affirmative agreement to participate in research. For instance, a child or person with dementia should give assent before being enrolled in research. However, it is important to note that assent does not eliminate the need for obtaining the permission of a parent or other legally authorized decision-maker. http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
Autonomy	Respecting a participant's autonomy involves respecting their capacity to make decisions about research participation, either on an individual basis, or following discussion with others, such as family members. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Baseline data	Data or measurements collected at the outset of implementation of a surveillance system or of strengthening activities, or a set of indicators that have been identified to monitor and evaluate the performance of a surveillance and response system. For example, the baseline mortality rate (or non-crisis mortality rate) is mortality rate before the crisis.

Benefit	A favourable consequence arising from a study, for example the demonstration that a vaccine is effective in a randomized controlled trial or the identification of a workplace hazard in an observational study. Benefits are often contrasted to 'risks' (as in a 'risk/benefit ratio') but the term 'risk' is ambiguous because it connotes both an adverse consequence and the probability of its occurrence (i.e., risk in the formal epidemiological meaning). To avoid this ambiguity, the term 'risk' is better replaced by 'harm' when the consequence is certain or has already occurred, or 'potential harm' when it remains a possibility. In the context of planned research, the balance to be struck is thus between potential benefits (to society and possibly to the subjects) and potential harms (principally to research participants but can also include their communities more broadly), paying attention both to the type and magnitude of these benefits and harms and the probability that they will occur. Potential benefits and harms to participants may not be restricted to them, but may extend to their family members or, more generally, to a group to which they belong. For instance, findings of a higher than average prevalence of certain genetic traits or diseases among study subjects may offer a means of early assessment and prevention (a benefit for the group of which they are a part) but may also stigmatize the family or the group in the eyes of others (a harm for the group). http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf
Biobanking	Biobanks store a wide range of human biological samples and specimans accessible to researchers for future study. Edwards T et al (2014) Clin. Biochem 47(4-5) 245-51 http://www.pubfacts.com/detail/24345347/Biobanks-containing-clinical-specimens:-defining-characteristics-policies-and-practices.
Blinding/Masking	A procedure in which one or more parties to the trial are kept unaware of the treatment assignments(s). Single-blinding usually refers to the subject(s) being unaware and double-blinding usually refers to the trial participant(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). See blinded trial or masked trial. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
CABs/CAMs	Community Advisory Boards/Mechanisms. see Community Advisory Boards
CIOMS	Council for International Organizations of Medical Sciences

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects	The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization in official relations with the World Health Organization (WHO). It was founded under the auspices of WHO and the United Nations Educational, Scientific and Cultural and Organization (UNESCO) in 1949 with among its mandates that of maintaining collaborative relations with the United Nations and its specialized agencies, particularly with UNESCO and WHO. The CIOMS (Council for International Organizations of Medical Science) Guidelines, are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms. A particular aim is to reflect the conditions and the needs of low-resource countries, and the implications for multinational or transnational research in which they may be partners. Like the *Declaration of Helsinki* (see below), the CIOMS Guidelines provide important guidance on the ethical conduct of health research. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
CIOMS International Ethical Guidelines for Epidemiological Studies	CIOMS (Council for International Organizations of Medical Science) Guidelines for Epidemiological Studies provide ethical guidance for epidemiologists, as well as those who sponsor, review, or participate in epidemiological studies, on identifying and responding to the ethical issues that are raised by the process of producing this knowledge. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Clinical Research	Clinical research is research that is based around the patient (whether that's the individual or isolated tissues). In clinical research the investigator, or a colleague, interacts directly with a human participant. A clinical trial (e.g. of a new drug or vaccine, for example, or new way of using an existing drug) is one type of clinical research; other types include developing new technologies and studying the mechanisms of human diseases. https://globalhealthreviewers.tghn.org/resources/glossary/
Clinical trial	Any research study that prospectively assigns individual research participants, or groups of research participants, to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, and preventive care. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf

Coercion	A threat designed to force someone to take part in research, whether or not they want to. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Community	May be defined as groups of people who can be identified by one or more of the following: place of residence (location or neighbourhood), activity (for example, employment), or who identify around an identity, activity or function. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Community advisory boards (CABS)	Boards or groups composed of individuals or stakeholder representatives that act as an independent advisory voice and facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise in specific trials. From UNAIDS/AVAC Good Participatory Practices 2011.
Community Engagement	The inclusive participation of relevant partners working collaboratively towards common goals. Tindana et al (2007) Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. PLoS Med 4(9): e273. doi:10.1371/journal.pmed.0040273 http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040273
Compensation	Money, vouchers or other forms of recompense given to participants in research to compensate for their time and participation. http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf
Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Confidentiality	The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities. https://globalhealthtrainingcentre.tghn.org/elearning/education/research-ethics/research-ethics-introduction-course-overview/1281/

Consent	The process whereby potential participants in a clinical trial are informed about the potential risks and benefits of participating in the trial. They should also be informed of all procedures to be carried out and what would be required of them, as well as their rights to decline or withdraw from the study at any time. The completion of the process is frequently documented on a signed consent form. Special ethical concerns exist for those not able to consent for themselves (e.g. minors or unconscious adults). In studies for emergency conditions it may be appropriate to have an initial basic consent process with further information later. In very rare cases it may be appropriate for professional representatives (e.g. doctors or judges) to consent on behalf of an individual. https://globalhealthreviewers.tghn.org/resources/glossary/
Control group	The control group consists of research participants who are not given the intervention which is being tested in the research and compared with a group who are given the intervention. In clinical trials, the intervention would normally be a novel treatment, such as a medicine or vaccine but interventions may also be social and behavioural in nature, for example, safe sex campaigns. https://globalhealthtrainingcentre.tghn.org/elearning/education/research-ethics/research-ethics-introduction-course-overview/1281/
Controlled	In a controlled trial, one intervention is measured against another– e.g. a new drug might be tested against a placebo or an existing medication for the condition, or a new vaccine tested against an existing vaccine (the existing vaccine being the control). In this trial design, subjects are usually randomly assigned to either the control arm of the trial or the investigational arm(s). Commonly these trials are single or double blinded (see blinding, double blinded). https://globalhealthreviewers.tghn.org/resources/glossary/
DoH	Declaration of Helsinki (see The Declaration of Helsinki)
Effectiveness	The degree to which an intervention has a definite or desired effect in a specific context. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf

Efficacy	The extent to which an intervention can have a desired effect under ideal or controlled circumstances, such as in a clinical trial. Efficacy can be compared to 'effectiveness', which refers to the desired effect in real life circumstances. http://www.news-medical.net/health/Efficacy-What-Does-Efficacy-Mean.aspx
Endpoint	The point in a trial or other type of research at which the predetermined target or goal has been reached. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Epidemiology	The study of the distribution and determinants of health-related states or events in specified population, and the application of this study to control of health problems. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Ethical guidelines	Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
Ethical Review	Based on certain set of criteria, a proposal is submitted for review. See also: Exempt from review, Expedited review and Full Committee review
Ethnicity	The collective identity shared by a group of people of common descent or origin. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Exclusion criteria (see also 'Inclusion criteria)	The criteria used to determine whether a person may or may not be allowed to participate in a clinical trial. The most important criteria used to determine appropriateness for clinical trial participation include age, sex, the type and stage of a disease, treatment history, and other medical conditions. See *Inclusion criteria*. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
First in Human Study	A clinical trial conducted after the development of a drug or medical procedure has undergone laboratory / animal testing and further assessments, and is now to be tested on humans for the first time. http://www.takeda.us/research_development/pdf/clinicaltrialsglossary.pdf

Futility	"The inability of a clinical trial to achieve one or more of its objectives. This determination may be suggested, for example, during an interim analysis of a trial by a data safety monitoring board." UNAIDS (2011) Good participatory practice: Guidelines for biomedical HIV prevention trials, UNAIDS)
GCP	see Good Clinical Practice
Gender	Gender refers to the *socially constructed* roles, behaviours, activities, and attributes that a given society *considers appropriate* for men and women (as opposed to 'sex', which refers to those which are biologically determined). To put it another way: "Male" and "female" are sex categories, while "masculine" and "feminine" are gender categories. Aspects of sex will not vary substantially between different human societies, while aspects of gender may vary greatly. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Genomic Research	The study of how genes function and interact and the effects this combination has on the body http://www.who.int/genomics/geneticsVSgenomics/en/
Good Clinical Practice (GCP)	Good Clinical Practice (GCP) is an ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects, that has its origin in the International Conference on Harmonization (ICH). Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. Although it concerns good *research* practices, the term *clinical* is used to distinguish these standards from those that apply to good *laboratory* and good *manufacturing* practices for pharmaceuticals. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Guidelines (Ethical guidelines)	Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/

Hypothesis	An unproved theory which can be scientifically investigated and tested http://www.cochrane.org/glossary/5#letterh
IC	Informed consent
ICF	Informed consent form
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
Immunity	The body's ability to protect itself against infection and disease or other unwanted biological invasion, and is related to the function of the immune system. Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
In vitro	The technique of carrying out an experiment in an artificial environment outside a living organism. Generally, it is performed in glass or plastic vessels in a laboratory. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Inactive intervention	Inactive interventions include e.g. placebos (see Placebo), Washout periods (see washout periods), and treatment withdrawals http://www.research.ucsf.edu/chr/guide/chrPlacebos.asp
Incidental Findings (IF)	An unexpected finding that could potentially impact on the participant's health discovered during, but unrelated to the purpose and aims of the research being conducted. Report by Representatives of Research Imaging Centres http://www.rcr.ac.uk/docs/radiology/pdf/BFCR%2811%298_Ethics.pdf
Inducement	Something offered to prospective participants in return for taking part in research; common examples include money and food. Inducements are common in research and appropriate so long as they are not undue. Potential inducements and other benefits of research should be considered on a case by case basis by research ethics committees who can take account of the individual nature of each study and geographical area. From Global Health Reviewers Glossary (http://globalhealthreviewers.tghn.org/resources/glossary/)

Intervention	A defined set of research activities that are implemented to achieve specified outcomes in a target population http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
IRB	Institutional review board
Justice	Refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both burdens and the benefits of participation in research. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Minimal risk	In this expression 'risk' is taken in its common meaning of a possible but not certain adverse effect (on health). Minimizing risk implies reducing to the feasible minimum the number and magnitude of such possible effects as well as the probability that they will occur. A study is often said to involve “minimal risk” when the potential harms involved are comparable to those as experienced in “ordinary life” by a person of a given age and gender or by an apparently healthy person undergoing routine medical surveillance. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Monitoring	In the context of a clinical trial, monitoring is the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Non Inferiority Trial	Non-inferiority trials compare new treatments to existing treatments in order to test that they are not clinically worse than the treatment in current use. NHS - National Institute for Health Research http://www.rds-sc.nihr.ac.uk/planning-a-study/study-design/quantitative-studies/clinical-trials/non-inferiority-trials/

Pharmacodynamics	An area of research which focuses on the study of how drugs produce their effects on the body Boston University School of Medicine Pharmacology & Experimental Therapeutics http://www.bumc.bu.edu/busm-pm/academics/resources/glossary/#p
Pharmacokinetics	Studies the course, process and interaction with the body a drug takes from initial administration to the point the drug is eliminated from the body. http://www.merriam-webster.com/medlineplus/pharmacokinetics
Pharmacology	Studies the interaction between the drug and the body and how the effects of the drug changes the body's function. http://www.takeda.us/research_development/pdf/clinicaltrialsglossary.pdf
Phase I, II, III, and IV trials	The CIOMS Guidelines (see above) provide the following useful classification of the phases of clinical trials for vaccine development and for drug development. **Vaccine development: Phase I**: refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration, and usually involves fewer than 100 volunteers. **Phase II** refers to the initial trials examining effectiveness in a limited number of volunteers (usually between 200 and 500); the focus of this phase is immunogenicity. **Phase III** trials are intended for a more complete assessment of safety and effectiveness in the prevention of disease, involving a larger number of volunteers in a multicentre adequately controlled study. **Drug development: Phase I** refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studies to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness. **Phase II** investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients. **Phase III** trials are performed after a reasonable probability of effectiveness of a drug has been established and are intended to gather additional evidence of effectiveness for specific indications and more

	precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies. **Phase IV** trials are conducted after the national drug registration authority has approved a drug for distribution or marketing. These trials may include research designed to explore a specific pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug. **Phase IV** trials may also be designed to evaluate a drug in a population not studied adequately in the pre-marketing phase (such as children or the elderly) or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need not be reviewed by ethical review committees. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Placebo	In the context of research, placebo is a substance or procedure which a patient accepts as a medicine or therapy but which actually has no specific therapeutic activity for his condition. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Placebo-control study	see Research design
Placebo-control study	A research design in which the use of a "dummy" or inert intervention is used as a comparator in a control arm of the study in order to eliminate bias. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Protocol	The protocol for clinical research is the plan on which the study is based. It manifests as a document particular to that piece of research, which details the study design and organisation, methodology (including exclusion/inclusion criteria for patients, dosing requirements, length of study etc), objectives and endpoints. It may also detail the rationale and background of the trial. The protocol should be designed so as to safeguard the rights of participants and to answer the study questions. https://globalhealthreviewers.tghn.org/resources/glossary/

Public Health	Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases. Thus, public health is concerned with the total system and not only the eradication of a particular disease. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Race	A group of persons connected by common descent or origin. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Randomisation	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Regulatory authorities	Bodies having the power to regulate. In the ICG GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Research (with human beings)	Any social science, biomedical or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly, or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records.i**. Clinical research** Is often conducted with patients in a medical setting, such as a hospital, and is designed to obtain better information on the natural history or pathogenesis of a condition that may lead to improved strategies for diagnosis, treatment or prevention of a disease.ii. **Epidemiological research**: Usually involves population-based investigations, which may be cross-sectional surveys of selected populations (case-control studies) or all members of a community, or may involve longitudinal study of a population over time (cohort studies). Such research is conducted to obtain an improved understanding of the natural history of a disease or to identify factors that increase or decrease the risk of disease in individuals. Often such investigations involve the study of large populations and they may be observational or interventional in nature.

	The aim is to identify strategies for the better prevention or treatment of disease, through an improved understanding of risk factors for disease or for progression of disease.iii**. Social and behavioural research**: Is often a component of epidemiological research and focuses on the study of behavioural and social factors that may modify risk of disease in individuals or in populations. Such research may involve the collection of sensitive information about a person and their lifestyle (e.g. sexual behaviour). While some forms of research may only involve observation others may involve studying or testing ways of changing behaviour or social circumstances.iv. **Intervention studies:** Are conducted to evaluate the impact of specific interventions on the prevention of disease, often in the context of community-based intervention trials, or in modifying the clinical course of disease, often in the context of clinical trials. Such research may provide the basis for policy decisions and priority setting. Intervention studies usually involve the comparison of different treatment or prevention strategies in which the current intervention method is compared with another method, often new, that may be more efficacious than the existing intervention. If there is no existing effective intervention, a placebo or 'no intervention' may be used as the comparison against which to assess the impact of the new intervention. Ideally, individuals are randomly allocated to receive the different interventions being compared in the trial.v. **Health services and operational research**: Are concerned with the study of methods of delivery of healthcare, access to treatment and quality of care, with the aim of finding improved methods that lead to better care. Such studies often include an evaluation of the cost of providing the intervention and the benefit it provides. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Research design	A formalised and usually systematic plan to collect data that will inform a research hypothesis. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Research Ethics Committee (REC) (can also be known as Ethics Committee, Ethical Review Board, Institutional Review Board (IRB), Human	Group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles. Research ethics committees review proposed studies with human participants (or samples deriving from them) to ensure they conform to international and locally accepted international guidelines, monitor studies once they have begun and, where relevant, take part in follow-up action and surveillance after the end of research. Committees have the authority to approve, reject or stop studies, or require modifications to research protocols.

Research Ethics Committee(HREC)	http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
Research protocol	A document written by the investigator(s) which should typically contain a project summary; general information; background rationale; references and literature review; study goals and objectives; study design; methodology; safety considerations; follow-up; data management considerations and statistical analysis; quality assurance; expected outcomes of the study; dissemination of results and publication policy; duration of the project; problems anticipated; project management structure and process; ethical considerations; informed consent documents; funding organization(s); collaborations; and qualifications of senior researchers. http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf
Respect for persons	Incorporates at least two fundamental ethical considerations, namely: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two seperate moral requirements to acknowledge autonomy and the requirement to protect those with diminished autonomy. (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.)
Risk (in research context)	The probability that an event, favourable or adverse, will occur within a defined time interval. Although often contrasted to benefit (as in a "risk/benefit ratio"), the term "potential harm" is better for that context, leaving "risk" in its formal epidemiological sense to express the probability of a (typically adverse) event or outcome. (CIOMS Epidemiological guidelines)
Sample	A sample is a subset of a population that is used to represent the entire group as a whole. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Sample size	Sample size is the number of observations used for calculating estimates of a given population. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/

Scientific Validity	To ensure scientific validity, the study design should include an answerable valid research question, and clear objectives and be conducted using accepted methods and practices. US Dept of Health & Human Services NIH Clinical Centre - http://clinicalcenter.nih.gov/recruit/ethics.html#2
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of research. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Standard of Care	An accepted standard of care within a given community from diagnosis through to the completion of treatment provides a process that should be followed within that particular context http://www.medicinenet.com/script/main/art.asp?articlekey=33263
Stigma	A process of producing and reproducing inequitable power relations, where inequalities in society are created and sustained through negative attitudes towards a group of people on the basis of particular attributes such as their HIV status, gender, sexuality or behaviour. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Superiority Trial	A study conducted with the prime aim of demonstrating a superior response to the trial drug/ treatment in comparison to either the active control or placebo used http://www.lau.edu.lb/irb/forms/clinical_trials_terminology_glossary.pdf
The Declaration of Helsinki	This declaration by the World Medical Association (WMA) serves as a statement of ethical principles to provide guidance to physicians and others involved in medical research with human beings and identifiable human material or identifiable data. It is one of the most widely known and accepted guideline documents for research ethics. Amendments and clarifications have been made to the original 1964 Declaration and the WMA stresses that the most recent version is the only one in effect. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human use (ICH)	A project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to facilitate a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality,

	safety and efficacy, and regulatory obligations to protect public health. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Therapeutic Misconception	Occurs when a research participant fails to make the distinction between research and treatment, leading to the mistaken belief that the research being conducted is intended to be therapeutic. Lidz CW, Appelbaum PS (2002) The therapeutic misconception: problems and solutions. Med Care 40: V55-V63. http://www.ncbi.nlm.nih.gov/pubmed/12226586
Trial	A generic term that in a clinical context denotes a research activity involving the administration of an intervention to humans to evaluate its safety and efficacy. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/
Undue Inducement	Undue inducement can arise if the level of payment to participants is so high they are persuaded against their better judgement to take part and/or take greater risks in the research being undertaken, effectively compromising the participant's ability to give their 'informed consent' Emanuel EJ et al Lancet 2005;366:p336-40 http://www.unige.ch/medecine/ieh2/ethiqueBiomedicale/enseignement/programmeY2006/me-9-Emanuel-undue-inducement.pdf
Unequal Randomization	The process of allocating trial participants to either treatment or control groups using chance to determine the allocation in order to reduce bias [ICH E6 1.48]- Unequal randomization places participants deliberately unevenly into the groups e.g three participants may be assigned to a treatment group for every one assigned to the control group [ICH E6 1.48] http://www.cdisc.org/system/files/all/article/application/pdf/cdisc_2009_glossary.pdf
Validity	In scientific research design and experimentation, validity refers to whether a study is able to scientifically answer the questions it is intended to answer. https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/research-ethics-glossary/

Vulnerable (research) participants	Individuals whose willingness to volunteer in a clinical trial [or other type of research] may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchal society. http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf
Washout Period	A scheduled period of time during the study when treatment is suspended, usually occurring prior to the introduction of a placebo or active treatment arm. University Hospitals Case Medical Center IRB Policies & Practices www.uhhospitals.org/.../irb-policy-protocol-use-of-placebos-and-washout.