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| Adverse Drug Reaction (ADR) | In the pre-approval clinical experience with the new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, that is, the relationship cannot be ruled out. Regarding marketed medicinal products, a response to a drug which is noxious and unintended and which occurs at doses normally used in human prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. Current reporting required by the FDA in http:umis.doh.gov.ph/adverse. *See also adverse event, unexpected adverse event and suspected unexpected serious adverse reaction.* |
| Adverse Event (AE) | Any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. The AE may or may not be related to the investigational product. |
| Affiliated Members | Members of MMMC-REC who are consultant staff of Mary Mediatrix Medical Center practicing as either active, associate-active or visiting staff. |
| Amendment to the protocol | A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. *See protocol amendment.* |
| Anonymized sample or data | Biological sample or data that cannot be linked to an identifiable person through destruction of that link to identifying information about the person who provided the sample or data. |
| Approved Protocols | Protocols that have been reviewed by the MMMC-RERC and *approved without stipulations or after stipulations/ recommendations by the RERC have been complied with.* |
| Archives | Storage for completed studies, inactive files or terminated documents that have not been updated within the last five (5) years. |
| Assent | Authorization for one’s own participation in research is given by a minor or another participant who lacks the capability to give informed consent. The assent is a requirement for research, in addition to consent, given by a parent or legal guardian. It is an agreement by an individual not a competent to give legally valid informed consent like a child or cognitively impaired to participate in research. *See also child’s assent* |
| Bias | The systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value. |
| Child’s Assent | An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of the study. Assent is the child’s way of saying that he/she agrees to take part in the research to the degree that he/she understand it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them. |
| Clinical Trial | A planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of the ascertaining their efficacy and safety. |
| Compensation | Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include remuneration for participating in the study. |
| Competence | Technically, a legal term, used to denote capacity to act on one’s own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. |
| Completed Study | A study that was accomplished according to the protocol and where a final report of the study had been submitted and approved. |
| Confidentiality | The expectation from respondents and research participants that data or information relayed or communicated are kept secret. Also, the non-disclosure of RERC information and documents to other than an authorized individual. |
| Conflict of interest (COI) | A conflict of interest arises when a member(s) of the RERC holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an RERC member has financial, material, institutional or social ties to the research. Potential conflicts of interest must be described and managed as per policy. |
| Deviation/non-compliance/violation | Occurs whenever the submitted and approved protocol is not complied with to the letter, or as approved. |
| Diagnostic | Procedure or technique used in the identification of a disease or determination of the health status of an individual. |
| Direct Benefits | Gain or advantage or good effect derived by a research subject immediately or closely arising from the use of an experimental substances or device. *See also benefits.* |
| Disapproval | A negative action of the RERC on the protocol. The study cannot be implemented if it has been approved by the Board. |
| Disclosure of data | The giving of information in connection with proposed research undertaking or the sharing of the results of the study especially as they pertain to the individuals or the family’s health situation. |
| Document | Hard copies of studies, proceedings, communications, that include the following: \*Study protocols and related documents (such as case report forms, informed consent, diary forms, scientific documents, report, records, expert opinion reviews); \*RERC documents (SOPs, meeting minutes, advice and decisions); \*Correspondence with experts, auditors, study participants, principal investigators, officials of the MMMC or those of other related institutions, agencies and committees; or \*Any other forms of communications such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc. |
| Drug | A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease. |
| DSMB | Data Safety Monitoring Board |
| DSMC | Data Safety and Monitoring Committee |
| Ethical Clearance | A certification that a research proposal has complied with the ethical requirements; action of an ethics or institutional review committee on a research protocol that signifies approval and permission to proceed with the research. *See also approval.* |
| Ethics Review | The evaluation of a research proposal has complied with ethical requirements; action of an ethics or institutional review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research of human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted. |
| Expected SAE | These are risks or events reported in the Investigator’s Brochure and listed in the consent form or other study document. |
| Expedited Approval | An approval granted by the RERC upon the review of the Chair and the Primary Reviewer/s. This is given for protocol that poses low risk, does not involve vulnerable population, does not involve collection of stigmatizing information and for continuing review that do not involve further patient recruitment and does not involve change in the risk/benefit assessment. |
| IDMC | Independent Data Monitoring Committee |
| Lay Member | MMMC REC members who do not have expert knowledge on medical sciences and are independent of the institution. Synonymous with non-medical member |
| Non-clinical Trials | Are studies that do not directly involve Investigational Drugs or device and human participants? |
| Non – Scientific Member | MMMC REC members with no medical or allied sciences background |
| Scientific Member | MMMC REC members with medical or allied sciences background and with expertise on the study protocol being reviewed. Synonymous with medical members |
| Quorum | Presence of fifty percent plus 1 of members, at least six of whom, are described as scientific, (1) nonscientific, and (1) member independent of the institution |
| Termination | Is ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk |
| Unexpected SAE | Refers to an adverse even in a clinical trial subject, which upon the assessment of the sponsor or study investigator is considered as being unexpected, serious or having a reasonable possibility of a causal relationship with the study drug. |
| Vulnerability | The quality or state of being exposed to the possibility of being attacked or [harmed](https://www.google.com/search?sca_esv=573962864&rlz=1C1GCEA_enPH1029PH1029&sxsrf=AM9HkKklJRv2c7hB2psIbcruWEvLcU5ZDg:1697527465783&q=harmed&si=ALGXSlbD4fKmSL7CRU364kGH2u8kO9P3KYq6N8rq3PcqltiOiaXDVFnpSj7JN5KK-HqhQo_cQBRVFVN-dL-LWh7z9f7NJjM2gA%3D%3D&expnd=1), either physically or [emotionally](https://www.google.com/search?sca_esv=573962864&rlz=1C1GCEA_enPH1029PH1029&sxsrf=AM9HkKklJRv2c7hB2psIbcruWEvLcU5ZDg:1697527465783&q=emotionally&si=ALGXSla0Spp1kHC9LAamd4BHsp51qIXbg88bYysrL_OpaLrsIinRYazxIYZE46h7tCjLhlws91jcUMD2BJEmQ1UimzfJ_2ZbSPtbN-dS8axjCPnOD1x_qg4%3D&expnd=1). |