ITEMS TO BE INCLUDED IN

**A Protocol (or associated documents) for health-Related Research Involving Human**

Sumber: International Ethical Guidelines for Health Related Research Involving Human (CIOMS-WHO: 2016

Appendix-1: page 99

(Include the items relevant to the study/project in question)

1. Title of the study;
2. A summary of the proposed research in lay/non-technical language;
3. A clear statement of the justification for the study, its significance in development and in meeting the needs of the country /population in which the research is carried out;
4. The investigators` views of the ethical issues and considerations raised by the study and, if appropriate, how it is proposed to deal with them;
5. Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent and relevance of animal studies and other preclinical and clinical studies (Guideline 4);
6. A statement that the principles set out in these Guidelines will be implemented;
7. An account of previous submissions of the protocol for ethical review and their outcome;
8. A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and *relevant* demographic and epidemiological information about the country or region concerned;
9. Name and address of the sponsor;
10. Names, addresses, institutional affiliations, qualifications and experience of the principal investigator and other investigators (Guideline 1);
11. The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables (Guideline 1);
12. A detailed description of the design of the trial or study. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open (Guideline 5);
13. The number of research participants needed to achieve the study objective, and how this was statistically determined;
14. The criteria for inclusion or exclusion of potential participants, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons (Guideline 3);
15. The justification for involving as research participants children or adolescents, persons who are unable to give informed consent or vulnerable persons or groups, and a description of special measures to minimize risks to such persons (Guidelines 15, 16 and 17);
16. The process of recruitment, e.g. advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment (Guideline 3);
17. Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval and treatment period for investigational and comparator products used);
18. Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to persons (Guidelines 4 and 5);
19. Any other treatment that may be given or permitted, or contraindicated, during the study (Guideline 6);
20. Clinical and laboratory tests and other tests that are to be carried out;
21. Samplesofthestandardizedcase-reportformstobeused,themethodsofrecordingtherapeutic response (description and evaluation of methods and frequency of measurement), the follow-up procedures, and, if applicable, the measures proposed to determine the extent of compliance of persons with the treatment;
22. Rulesorcriteriaaccordingtowhichparticipantsmayberemovedfromthestudyorclinicaltrial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated;
23. Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications (Guidelines 4 and 23);
24. Theknownorforeseenrisksofadversereactions,includingtherisksattachedtoeachproposed intervention and to any drug, vaccine or procedure to be tested (Guideline 4);
25. The potential individual benefits of the research to participants and to others (Guideline 4);
26. The expected benefits of the research to the population, including new knowledge that the study might generate (Guidelines 1 and 4);
27. For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death (Guideline 14);  to be included (or
28. Provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care and the organization responsible for paying for it, and for how long it will continue (Guideline 6);
29. For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child (Guideline 19);
30. The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective participants, including the name and position of the person responsible for obtaining consent (Guideline 9);
31. When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative (Guidelines 16 and 17);
32. An account of any economic or other inducements or incentives to prospective participants to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the participants, such as payment for medical services;
33. Plans and procedures, and the persons responsible, for communicating to participants information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect participants’ willingness to continue in the study (Guideline 9);
34. Plans to inform participants about the results of the study;
35. The provisions for protecting the confidentiality of personal data, and respecting the privacy of persons, including the precautions that are in place to prevent disclosure of the results of a subject’s genetic tests to immediate family relatives without the consent of the subject (Guidelines 4, 11, 12 and 24);
36. Information about how the code, if any, for the persons’ identity is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency (Guidelines 11 and 12);
37. Any foreseen further uses of personal data or biological materials (Guidelines 11 and 12);
38. A description of the plans for statistical analysis of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary (Guideline 4);
39. Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee (Guideline 4);
40. A list of the references cited in the protocol;
41. The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor’s financial commitments to the research institution, the investigators, the research participants, and, when relevant, the community (Guideline 25);
42. The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research participants of the parts of the information that it decides should be passed on to them (Guideline 25);
43. For research that is to be carried out in alow-resource setting, the contribution that the sponsor will make to capacity-building for scientific and ethical review and for health-related research in the host country, and an assurance that the capacity-building objectives are in keeping with the values and expectations of the participants and their communities (Guideline 8);
44. The research protocol or documents send to the research ethics committee should include a description of the plan for (continued) community engagement, and present resources allocated for the community engagement activities. This documentation must clarify what has been and will be done, when and by whom to ensure that the community is clearly mapped and denied and can be proactively engaged throughout the research to ensure that the research is relevant to the community and is accepted. The community should participate, when feasible, in the actual discussion and preparation of the research protocol and documents (Guideline 7);
45. Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results (Guideline 24);
46. In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority (Guideline 24);
47. Plans for publication of research results in certain fields (for example, epidemiology, genetics, sociology) that may present risks to the interests of communities, societies, families, or racially or ethnically denied groups and for minimizing risks to these groups, notably by maintaining con confidentiality during and after the study and publishing the resulting data in a manner that is respectful of the interests of all concerned (Guideline 4); and
48. A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures.