Ten commandments for a prompt ethics review committee approval

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In scientific world need for framing and implementing guidelines to protect research subjects was under consideration for long. In modern history, it began with a judicial verdict in response to unethical and inhumane experiments by Nazi physicians and Nuremberg code was made. It was later made imperative to have a written protocol of the research procedures for approval by independent review board in declaration of Helsinki in 1964. This declaration later served as a base to form Ethics Review Committee (ERC) at institutional level. In today's scientific galaxy, researchers often complain against ERC as impediment and reason of delay in their research. In quest of approval, they often forget that ERC's primary objective is to guide the researcher for protection of participants, societal values and interests and Committee at times can be highly critical. The following points will help researchers to get at an easy and early approval from ERC.

1. **Confidentiality:** Confidentiality is the corner stone of ethical research. One should make sure beforehand that it's being addressed in protocol. For example, keep a master copy with names and/or medical record with only the principal investigator and the rest team with a list having case-matched anonymous serial numbers. In case of publication, caution should be assured that no identified element be published that may breech confidentiality of patient.
2. **Safety:** It's the prime obligation of ERC to ascertain that the proposed research has no risk to its participants. This becomes problematic to address when research is about drug trials since it may have risks. In such cases, ERC looks for an informed consent with clear statement about risk and mechanism placed in proposal that will identify any harm and will ensure compensation. It is also the responsibility of researcher to ensure the safety of the whole research team.
3. **Informed consent:** The issue of informed consent becomes more pronounce in cases of vulnerable/incompetent persons like patients with psychiatric illnesses or children below consenting age. Essential components of an informed consent include a language and comprehension that target population can understand, it should contain purpose, methods, and risk benefits involved in the research, it ensures that refusal to enrolment, or withdrawal at any point will not cause harm or disadvantage and it should contain information of a contact person who can answer any question that arises in future relating to research and it participant's rights. ERC has a prerequisite that researcher submits translated copies of informed consent in their own languages.
4. **Compensation, undue inducement and coercion:** ERC will also look into the policy of researcher for providing compensation to participants for their time and travel. However, researcher should be confident that the compensation he is offering is NOT an undue inducement for that group. For example providing one gallon of clean water to people who are in severe dearth of water and asking to give 10 ml of blood for research in genetics! For few this may be a simple compensation but ERC will see this as 'undue inducement' since getting this offer will blur their consenting capacity. Similarly, a welfare hospital situated in a slum area deprived with health facilities may make policy that it will only entertain patients who will give consent that their investigations be used as research purpose

also. This threatens the local population with no treatment if they don't give consent thus it's a coercion. ERC will very specifically see such issues so the researcher should be clear in his drafting to avoid any delay.

5. **Funding and conflict of interest:** ERC will enquire about cost of any test or treatment that study involves and who will bear it. Any additional burden on participant will straight away disapproves the proposal. All the sources of funding should be declared and provide all relevant details, in case there is a donor agency. Researcher should be specifically cautious about conflict of interest. ERC will need researcher agreement with donor agency specifically about ownership of data. Remember anything that you like to hide from ERC will probably have some unethical element.
6. **Content expert:** Although science gives equal opportunity to every researcher but to ensure that research meets its outcome without any harm to participants, ERC presses to have an area expert in research team. It is not mandatory to have content expert as author but shall necessarily be declared as supervisor/advisor.
7. **Identifying ethical issues:** It is always better that researcher himself mentions ethical issues in proposal along with possible ways of addressing those. This reflects to ERC that researcher is not only aware of ethical aspects but also willing to solve them.
8. **Data management:** ERC would like to know the plans regarding data management. This is essential, as it will ensure confidentiality, credibility and smooth conclusion of study. There is no requirement that one of the authors should be expert in data management but proposal should define that how this will be done and whose services they will request for.
9. **Clarity of proposal:** Be clear enough to describe proposal in detail. Any confusion, difficult terms and complex phenomena without explanation will end up in delay. ERC will ask for clarity and researcher may lose deadlines to complete research. It is always good that draft should be clear and comprehensive with brief explanations to difficult terms.
10. **Exceptions from ERC:** There is no exception for ERC, to begin with. Every proposal or even case report should be submitted to ERC. However, retrospective studies without any identifiable data, case reports, review of studies involving public data, studies not involving human subjects and evaluation of practice guidelines should be submitted to ERC for exemption of approval. Now it has become prerequisite of every medical journal to have letter of approval or exemption for publication.

ERCs generally meet once a month and they have a deadline for inclusion of proposals for discussion in next meeting. It is often helpful to check in advance with ERC office of the deadlines to avoid any delay in approval. Researcher should remember that ERC is NOT a barrier to research rather an agency to provide help. It gives suggestions to improve ethical aspects of research. Researchers should also remember that shortest distance between two points is *straight line*, which means avoiding shortcuts will ensure earliest approval from ERC!

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Conflict of Interest: None declared
Rec. Date: Feb 03, 2014 Accept Date: Mar 16, 2014

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