INSTITUTE OF PUBLIC HEALTH

14 September 2016

To,

Dr. Roli Mathur,
Scientist E and Program Officer for Bioethics,
Indian Council of Medical Research

Sub: Suggestions on Draft "**National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2016**"

Greetings from Bangalore!

We thank the ICMR for providing an opportunity to give comments on the draft **National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2016.** We also comment ICMR's pro-active step in revising and updating the existing guidance in line with various global and national health research priorities and guidelines.

We conducted a consultation among several public health researchers at IPH, Bangalore and organized the suggestions in the document attached. We have provided both overall comments on the draft guidance as well as specific comments line-by-line indicating them in the format presecribed by ICMR on your website.

We hope these comments will be useful in finalizing this important guideline and are willing to provide any further clarification or assistance in the same.

Yours truly,

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Copy to:

1) Dr. Soumya Swaminathan, Director-General, Indian Council of Medical Research

Comments on the draft National Ethical Guidelines for Biomedical and Health Research involving human participants in India

Institute of Public Health, Bengaluru

Background

In response to the call by ICMR for comments and suggestions regarding the draft document on guidelines for health research involving human subjects in India, we at Institute of Public Health, Bangalore (IPH) had a discussion of these draft guidelines in great detail. The discussion was facilitated by the members of the IPH ethics committee.

In this document we have compiled our comments, concerns and suggestions with an aim to improve the guidelines so that it may comprehensively respond to the ethical issues and dilemmas in research involving human subjects.

All members that were part of the discussion at the institute are actively involved in public health research and/or advocacy, and are also part of the ethics committee of the institute.

IPH is a community of public health researchers that have experience in health systems and policy research and with social science methods in public health research.

We have arranged our comments as follows:

1. Broad concerns with the draft guidelines

2. Gaps that have not been addressed in the guidelines

3. Chapter and line-wise comments and suggestions

We would like to begin with **commending the ICMR** for this revision that is much needed and has been long overdue. These draft guidelines include new chapters giving guidance for health research in public health and research in social and behavioural sciences. International collaborations and research during humanitarian emergencies and disasters have also been addressed in great detail in this revision. The guidelines are a step in moving health research standards in India in line with various global standards prescribed and ICMR's leadership in this is laudable.

1. Broad concerns

1.1. ***Composition of the ethics committees***

The composition of the ethics committee as per the guidelines requires 1-2 clinicians, 1-2 basic medical scientists, a social scientist, a philosopher and a lay person. While the training and background of the members as proposed may enable them to respond to ethical issues in clinical research we find it inadequate to respond to ethical issues in public health research especially when social and behavioural science methods are employed. Further, the proposed composition privileges doctors over various other professionals including nursing, pharmacist or other allied health science backgrounds. An ethics committee would

benefit from having members from diverse backgrounds and would enable it be more aware and responsive to the diverse ethical issues that emerge especially in public health research.

Further, the qualifications or criteria for selection of members to an ethics committee are not very well defined/ stated. For example there is no mention of the involvement in research of the clinician invited to be a member. Similarly, there is not enough guidance on selection of the philosopher/ ethicist/ theologian and lay person from community. In our experience this selection needs to be careful and purposeful to avoid selection just for the sake of fulfilling the norm. In addition, we are concerned that the lay person selected is usually someone the research institute/ researchers have a relationship with because of working in their community. Conflicts of this nature in selection of members have not been addressed in the guidelines.

Suggestion: We suggest an ethics committee with persons from more diverse backgrounds in addition to the clinician and basic medical scientist who may have limited experience and knowledge with regard to public health and social science methods. Guidelines could offer some flexibility in the composition based on the predominant research domain. Also, there should be some guidance/ criteria for selection of members in more detail than there is currently. Perhaps a basic minimum for members selected to be on an ethics committee should be some involvement in research. And finally, invitation of members into the committee should take into account possible relationships with the Institute beyond the role of the ethics committee (conflict of interest due to previous or ongoing work with the research Institute).

1.2. Categorization of type of review as exempt, expedited or full review are not clear

The categorization of type of review is described by examples in the guidelines, which is not meant as an exhaustive list of the various types of research that could qualify for these categories. In our experience, the application of the guidelines are difficult and very often the tendency is to subject all studies to a full review. Especially difficult is the differentiation between not more than minimal and more than minimal.

Suggestion: To have clear cut guidelines or an algorithm to help in the categorization of research protocols. For example, the presence of identifiable or anonymised data is the deciding criteria for exemption of review, similar criteria or guiding principles can be better presented to make decision making easier and verifiable.

1.3. The chapters 7 and 8 on epidemiology, public health research and social, behavioural science research

We find the distinction between public health research and social behavioural science research odd and artificial. Social science methods are being increasingly used in public health research. The problem with this artificial distinction is that emerging fields such as health policy and systems research which are at the interface of public health research and use social science methods are missed and are inadequately addressed in the document.

The public health research designs mentioned in chapter 7 are primarily epidemiological research designs and this is a limited traditional description.

Suggestion: A more appropriate description of the chapter would be Public health research following which there could be sub chapters on epidemiological methods/designs, social science methods/ designs including Participatory action research, theory-driven social/political science research, health policy or programme evaluations including implementation research.

1.4. International collaboration and the HMSC (Health Ministry Screening Committee) for biomedical research involving foreign assistance

It is not clear whether only biomedical research needs to be sent for approval to the HMSC or public health research also. In addition, the need for this extra layer of approval in addition to the ethics committees abroad and locally has not been adequately explained. There is no guidance on the procedure and processes or on the outputs of such a screening committee.

HMSC based on information provided appears to be a bureaucratic formality rather than of being of use either to the wider research community or society. If such a committee approval is indeed stipulated/required by the Government as as a governance measure/oversight over international research, then it should somehow be adapted to be relevant to the wider research community or society.

Suggestion: To provide some guidelines for seeking this approval including what types of research require approval and the necessity/ scope for such a screening committee. Further, the process and outputs of this screening should also be part of this guideline document. A registry of internationally funded research in the public domain would be a useful output of HMSC. If the HMSC does not put out in a transparent way, its own functioning, and create/manage a repository of such studies that it oversees, it may become a problem than a solution. Also, please consider post-hoc HMSC approval so that this step does not become a deterrant to ongoing research that already have several checks and balances. While the HMSC may be much more accessible to Government's own research institutes, the step may become problematic for smaller, non-governmental research institutes. It may be useful to require mandatory submission to HMSC before starting such research projects (assuming other requirements including international and local ethics committee clearances are available), and the HMSC may take 6 months to approve the study with an undertaking from the team that they will pause/stop the study if the HMSC finds something is not in order.

Also, the consequences of non-submission or non-compliance with HMSC submission have not been indicated. Apellate agencies to HMSC decisions are also not indicated.

1.5. Scope of the guidelines and definition of research

The scope of the document has been defined as applicable to all biomedical, socio-behavioural and health research conducted in India involving human participants, their biological material and data. This scope then goes on to describe the purpose of this research but fails to define here what is meant by research. Research is defined in the first

chapter (line 64) as pertaining to a broad range of scientific enquiry on human participants for developing generalizable knowledge that improves health, increases understanding of disease and is justified ethically by its social value.

In this definition we contest the term generalizable – as all biomedical or public health research may not be generalizable. Case studies and individual narratives may not produce generalizable results and yet are research. Various context-specific research approaches in health policy and systems research and implementation research do not in fact strive for generalizable knowledge, but rather for context-specific insights.

Suggestion: To reword the scope of the document to clearly articulate what research is and then what is addressed by this this document. Widely accepted definitions including terms such as systematic investigation could be used to articulate the concept.

1.6. ***Order of chapters and placing chapter 14 on responsible conduct of research at the end of the document.***

This is an extremely important chapter and we feel it should be placed much before in the document. An understanding of these practices in conduct of research will enable a much better understanding of the ethical issues arising in different research areas.

Suggestion: To place this chapter after discussion on general ethical issues.

1.7. ***Inclusion of list of references and links to key documents mentioned in text such as Helsinki declaration, Belmont report, GCP guidelines and the Nuffield Council on Bioethics.***

There should be a list of references from which information has been curated, such as line 2061- 2070 been sourced from Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioural and Social Sciences by the National Research Council.

2. Gaps that have not been addressed in the guidelines

2.1. ***Registration of ethics committees and mechanisms to monitor functioning***

There is a mention of registering ethics committees as a good practice but there is not enough guidance on the process of registration and where to get this registration except for the case of those involved with clinical trials and CDSCO.

Further, the monitoring ethics committees are not addressed and there should be some guidance on how this can be achieved and what mechanisms exist.

2.2. ***Responsibilities of ethics committees towards gender and equity research***

There is growing concern that especially in health research; questions regarding gender and equity are seldom addressed. It may be a responsibility of the ethics committee to encourage these issues and these should be incorporated in the review process wherever appropriate. Ethics committees ought to strive not only for ethical research practice but also

for ethical research processes, which include fair team composition and striving for gender balance in research.

2.3. ***Responsibility of ethics committees to research participants and researchers***

In case a research participant wants to complain or report a deviation in research procedures there is currently no way the participant can approach the ethics committee, the only contact being the researcher. Ethics committees should be accessible for any such complaints. Similarly, members of a research teams may have ethical issues during the study or at time of publications that should be addressed by the ethics committees. Hence, it is important for ethics committees to make themselves accessible through the internet or through other means for lay citizens or others to approach them if necessary, without the involvement of the researcher.

2.4. ***Ethics committees ensuring publications/ reports and data sharing.***

Ethics committees should also play a role in ensuring that research is published or at least reported in public domain. Further, these committees should also encourage data sharing in public domain. This could be encouraged by having a publication plan and data sharing plan with timelines as required documents along with protocol submission.

2.5. ***Monitoring of research by ethics committees***

This has been mentioned as a responsibility of the ethics committee but there is not enough guidance on how this should be done, how often and under what circumstances.

3. Chapter and line wise comments and suggestions

S No	Chapter	Line/ Table	Point	Comment	Suggestion
1	3	380	3.3.7	It is not clear who would be appellate authority in case the head of the institution in capacity as researcher is part of a dispute with the EC.	To suggest an alternate mechanism in case head of institute has a conflict with the EC
2	3	382	3.3.8	The provision for alternate members to enable quorum is welcome however the potential for misusing this provision also exists	To include in guidelines that these alternate members should be aware of all proceedings of the EC regularly
3	3	Table 3.6	2	Why should a proposal approved need to be revised and if it is being revised would this not be a re submission requiring review	Once approved only minor changes/ amendments are possible any other revisions of approved proposals should be reviewed as per categorization
4	5	845	5.1.3	Is empowerment really meant	Guidelines should state

				in this statement and is it a fair expectation that information will empower decision making	instead that participants must be informed to the extent possible to make decision
5	7	1745	7.0	Intent of researcher may be critical to decide whether the activity is part of the public health program or research but who decides?	To include that the decision of whether an activity is research or not is made by the EC
6	7	Table 7.1		There is a repetition of risk benefit assessment from Q 5-10. Also point 10 asks the question- is social justice implied – this may be impossible to answer in a review of proposal	To make review structure relevant. Also, to include dissemination and sharing of results, policy implications etc.
7	7	1980-1982	7.3	The term mild deception qualifying for an expedited review raises the question of what is meant by mild deception and why can this be reviewed expedited	Any study involving deception (mild or major) should be subjected to a full review as stated earlier in table 3.6 point 3, second bullet.
8	8	2100-2102	8.2.8	Description of an etic view is factually incorrect and the example cited is inappropriate	To include a correct definition of etic view with appropriate example