THE ICMR CODE: A CRITIQUE AND SOME RECOMMENDATIONS

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Women’s groups in India have grappled with ethics in medical research since the early 1970s when blatant ethical violations during clinical trials came to light. From
injectable contraceptives being tested on women unaware that they were part of a
trial, inadequate follow-up and downplaying side-effects in trials on Norplant
and anti-fertility vaccines, to illegal trials on quinine by NGOs in place of
research on treating malaria, ethical violations were rampant. The National
Women’s Health and Human Rights Network and the National Health
Commission (NHRC) highlighted these violations and called for a code of
ethics to be followed in health research.

In 1997, draft guidelines were issued by the ICMR seeking input from health
professionals and activists. The “Consultative Document on Ethical Guidelines on
Biomedical Research Involving Human Subjects” was drafted by the Central Ethics
Consultative Committee (CECC) and referred to the NHRC and the National
Health Mission. After multiple consultations, the Code was released in
September 2000.

Regional public debates were held in Calcutta, Mumbai, Hyderabad and New
Delhi, with women’s groups at the forefront of campaigns highlighting violations.

The Code includes many areas not covered by the sketchy 1980 ICMR Policy
Statement on Ethical Considerations Involved in Research on Human Subjects.

However, the Code fails to acknowledge changing social trends, especially in
the context of gender and class inequalities in Indian society. There are
detailed recommendations (pg 3-16) about “Ethical review procedures” and the
setting up of Institutional Ethical Committees. Yet, these details appear to be
bureaucratic procedural matters, and do not embody the spirit of ensuring
ethical bio-medical research. Ethical guidelines should go beyond technicalities and build effective

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safeguards so that the unequal power relationship between researchers and subjects is neutralised and no new avenues of exploitation of research subjects are opened up. It is crucial that the basic principles be stated clearly and unambiguously. The current document falls short of these objectives.

Contentious issues remain relating to newer technologies like genetic research, organ transplantation etc. which need to be publicly debated with groups working in these areas. The document does not clearly articulate the different roles and responsibilities of the stakeholders in the research process, the rights and responsibilities of the research participants, and the role of the ethics committee in ensuring the ethical conduct of research.

1. INFORMED CONSENT:

Informed Consent is central to ethical biomedical research, but has not received adequate attention. The draft acknowledges the ethical principle of informed consent but mentions that the IPC is not clear on this aspect. This is problematic as it is important for investigators to seek informed consent. The IPC highlights important issues such as the need for obtaining informed consent during an ongoing trial etc. However, some issues which still need consideration are:

i. Information about potential risks and benefits should be provided verbally and in writing.

ii. A social worker that the doctor should be involved in counselling. During counselling, the signature should be witnessed by a person not involved in the trial.

iii. For research involving the whole community, a group of community leaders should not be consulted adequate. They are better to have a participatory approach to set adequate.

iv. Where a new study builds on previous work, special care should be taken to ensure that the new study.

v. Even when the research design involves minimal risk, e.g. only collecting data from outside the trial site, adequate communication should make a different case of the risk.

vi. Health insurance should be mandatory for trial participants, and should be communicated while obtaining informed consent.
II. ASSISTED REPRODUCTIVE TECHNOLOGIES (ARTS):

Instead of guidelines for research, the section on the Draft read like promotional literature for such technologies. There was a heavy emphasis on medical benefit, and little on ethical concerns. The authors made a clear statement that ARTs should not be seen as a last resort, but rather as a choice for those who want to have children. This view is widely accepted, but the Draft seems to have focused more on the medical aspects than on the ethical implications. The Draft also suggested that ARTs should be available to all who want them, regardless of their financial situation.

The Code recognizes the importance of ensuring that ARTs are accessible to all who wish to use them, and that they are not used as a means of population control. This is in line with the principles of human rights and the right to reproductive health. The Code also recognizes the importance of ensuring that ARTs are used ethically, and that they are not used to harm children or to discriminate against certain groups.

Ethical guidelines should not accept social stigma attached to infertility as a norm. Societies have to rethink ways for childless couples to deal with infertility, for instance, adoption, foster parenthood, etc.

The Code reinforces conservative attitudes by recommending matching of donors and recipients, and by emphasizing the need for informed consent. It also highlights the importance of respecting the autonomy of all individuals involved in ARTs.

The Code focuses only on risks to the subject and does not touch upon other ethical issues involved with ARTs which have a direct impact on family structures and the overall society. It is also important to consider the long-term effects of such technologies on human rights and the right to privacy. The Code should also address the issue of how to ensure that ARTs are used in a way that does not discriminate against certain groups, such as those who do not have access to ARTs due to financial constraints.

III. CONTRACEPTIVE RESEARCH

Lack of adequate attention to this area of research in the Draft was a serious lapse pointed out by us. The Code now carries the emphasis on contraceptive research as the general heading of "Special Concerns" in the section of ARTs. However, it may be useful to highlight three crucial issues – informed consent and information about the
alternatives available, proper follow-up — even when a subject has withdrawn from the trial — as in abortion, and follow-up of children born due to contraceptive failure.

Yet, we feel that the issue of contraceptive research deserves more attention. The bulk of contraceptive research is targeted towards women, a sector of society that, since contraception is aimed at controlling fertility levels and improving access to health facilities, needs to have a long-term focus on the health of women and their children. This focus is complicated by the fact that contraceptives are used by healthy women and men in the midst of their childbearing years, and the health implications of contraceptive use have to be different from that used in the midst of reproductive years. Thus, the guidelines offered by the Canadian Women's Committee on Population and Development, which in 1989 called for contraceptive research, development and use, need to be re-examined and updated.

A) Contraceptive Research and Development

1. Hazardous contraceptives
   - Methods currently in use should be promoted which:
     a. Enhance women's health and well-being;
     b. Are reversible in the case of spacing methods;
     c. Are reversible in the case of permanent methods;
     d. Exhibit demonstrable advantages over existing contraceptives.

2. Research must assess the degree of risk to children conceived as a result of contraceptive failure, and be allocated to the development of safer methods of contraception, such as long-term implants, that offer protection from sexually transmitted disease, as well as to the development of male contraceptives.

3. Research should be conducted to improve the delivery and provision of contraceptives to women in low-resource settings, particularly in women who are not married, and who often need more support to use contraceptives effectively.

4. Research should focus on evaluating the acceptability of contraceptive methods among different populations, including women in low-resource settings.

5. Research should also focus on increasing the availability of contraceptive methods, particularly in low-resource settings, and assessing the acceptability of a method to proceed from one research stage to another.
2. Contraceptive research must be subject to review by interdisciplinary ethics committees.

3. There should be transparency in contraceptive research, including criteria for funding and mechanisms for determining safety, funding and partial information.

B) Contraceptive Testing, Evaluation, Approval and Monitoring

1. Written informed consent must be obtained from all the participants of the research trials, in accordance with the guidelines laid out in Point (1) above on informed consent.

2. Researchers, government and funding institutions are responsible for ensuring the safety of trial participants, and taking all steps to prevent any adverse effects. Participants must be debriefed if they feel uncomfortable during the trial.

3. Country trials must be conducted in a manner that all participants are informed of the risks and benefits. Clinical trials must be conducted in accordance with the Declaration of Helsinki.

4. Long-term monitoring and follow-up are necessary to determine the effects of the contraceptive on the health of the participants.

5. Contraceptive trials should immediately cease if the potential arises for serious risk to trial participants.

Users' responses to and assessment of the contraceptive method under review must be recognized as valid research findings and incorporated into the evaluation.

6. Independent mechanisms must be established to monitor research trials to ensure compliance with international ethical standards.

C) Post-Marketing Surveillance

In this age of decentralization, it is surprising that the Draft makes only a passing reference to the importance of post-marketing surveillance. The Code does not address this issue in any detail, despite the significant role that post-marketing surveillance plays in ensuring the safety of contraceptive methods.

The Code does, however, highlight one area of frequent violation of ethical standards: the commercialization of contraceptive devices without adequate clinical trials. The Code calls for the establishment of an independent body to monitor the development and marketing of contraceptive devices, ensuring that they are safe and effective before being made available to the public.

The Draft takes a more specific approach, recommending that post-marketing surveillance should be conducted for all new contraceptives, regardless of their stage of development.
Our experience with PMS of contraceptives demonstrates the problems inherent in the concept. PMS being conducted by the pharmaceutical company which stands to gain directly, denies scientific objectivity.

Some recommendations to monitor PMS:

- Monitoring mechanisms should be an integral part of the licensing
- PMS should be time bound
- Licensing bodies should be independent of the pharmaceutical companies
- Adequate information must include all potential side-effects, however rare
- Commercial and non-commercial monitoring must be part of the annual
- Adequate information on rare but serious side-effects, long term problems, etc. must be set into motion
- Results of PMS should be subject to independent expert analysis

MEDICAL RESEARCH IN THE AGE OF PRIVATISATION

In a liberalised economy, medical research is increasingly being carried out by private institutions, NGOs, pharmaceutical companies and private colleges etc. Private medical research is de-natured. The professional and ethical considerations of the research have not been given adequate attention by the ICAM Code. The gains of research might remain un-harvested and have little impact on the health of communities if the ethical considerations are neglected in the process. The ethical considerations are crucial. While not arguing for increased civilian and bureaucratic control, creative and effective ways of checking the free-for-all are vital.

Industry-sponsored research has given rise to a gamut of issues which need to be addressed. Incentives are given for research activities which valued in the latest ICAM Code as compared with the 1980 guidelines. When "efficiency-based" economic and supremacy of "local standards," which are obviously lower standards prevail, there is cause for serious alarm (as in HIV drug trials in Africa).

The Code has moved ahead of the Draft which devoted only a small paragraph to "Externally sponsored Research."

The Code, in its section on "International Collaboration/Assistance in Research," has moved ahead of the Draft. It recognises the importance of the issue, but does not provide adequate safeguards against exploitation of research subjects from a developing country. For instance, by talking about "best possible nationally available care", the Code allows for by-passing international standards, which will work against research subjects.
Some new developments have disturbing implications. For instance, according to The Economist, India promises to become a world center for testing new medicines. In November, 2005, the National Research Council of India reported that the country has the potential to become a large-scale supplier of clinical trials for pharmaceutical companies. This is due to the development of new drug delivery systems, the availability of a large pool of volunteer subjects, and the relatively low cost of medical care. It is claimed that a large part of the total expenditure of around $500 million that is required to discover and develop a drug is spent on animal trials. India is likely to benefit from this trend as it has a large pool of volunteers and low costs for medical care. This could lead to an increase in the use of animal testing in order to reduce costs. However, this trend is likely to lead to increased animal suffering and could have negative consequences for the development of new drugs.

The use of animal testing by biotechnology companies in the Third World must be questioned. This is because the use of animal testing is not ethically justified, especially when it comes to developing new drugs. The use of animal testing is not only costly, but it also has a negative impact on the environment. In addition, the use of animal testing is not always effective, as it is not always possible to extrapolate the results obtained from animal testing to humans. Therefore, the use of animal testing is not justified, and alternative methods should be developed in order to reduce the reliance on animal testing.

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New ethical guidelines in addition to keeping pace with scientific developments, must prioritize safeguarding the rights, health and well-being of research subjects. Given the potential impact of medical research, it is imperative to develop a pre-people, pro-woman definition of "overall purpose" of research.
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