



Controlled Human Infection Studies and Ethical Concerns

For Prelims: [Controlled Human Infection Studies](#) , [Malaria](#), [Dengue](#), [Vaccines](#)

For Mains: [Indian Council of Medical Research Guidelines](#), Ethical Concerns Related to Controlled Human Infection Studies

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Why in News?

The [Indian Council of Medical Research's \(ICMR\)](#) Bioethics Unit has drafted a consensus policy statement addressing the ethical aspects of [Controlled Human Infection Studies \(CHIS\)](#), opening the door for its potential implementation in India.

What is Controlled Human Infection Studies and Related Ethical Concerns?

▪ About:

- CHIS is a research model that **intentionally exposes healthy volunteers to pathogens** under controlled conditions.
- It has been utilized in various countries to study **diseases such as malaria, typhoid, and dengue**.

▪ Benefits of CHIS Implementation: ICMR recognizes that CHIS has the potential to provide numerous benefits for medical research and public health:

- **Insights into Disease Pathogenesis:** CHIS can offer unique insights into **how diseases develop and progress**, leading to a deeper understanding of infectious diseases.
- **Accelerated Medical Interventions:** By allowing researchers to study disease progression more rapidly, **CHIS can expedite the development of new treatments and vaccines**.
- **Cost-effective and Efficient Outcomes:** CHIS requires **smaller sample sizes compared to large clinical trials**, making it a more cost-effective research model.
- **Contributions to Public Health Response:** Findings from CHIS can inform public health responses, healthcare decision-making, and policy development.
 - Understanding disease dynamics through CHIS can enhance preparedness for future pandemics.
- **Community Empowerment:** Involving communities in CHIS research can empower them to **take ownership of their health** and participate actively in healthcare initiatives.

▪ Ethical Challenges:

- **Deliberate Harm and Participant Protection:** Exposing healthy volunteers to pathogens raises concerns about potential harm to participants.
- **Inducement and Compensation:** Determining appropriate compensation for participants in CHIS can be challenging.
 - Offering too much compensation might **unduly induce people to participate**, potentially compromising informed consent.
 - Conversely, offering inadequate compensation **might exploit vulnerable**

individuals.

- **Third-party Risk:** The risk of disease transmission to third parties beyond the research participants is a concern.
- **Justice and Fairness:** There is a concern that CHIS may disproportionately involve participants from **low-income or [marginalized communities](#)**.

Way Forward

- **Ethical Considerations:** The first step is to establish an **independent ethics committee to evaluate the CHIS protocols thoroughly**.
 - The committee should consist of experts in relevant fields, including medical ethics, infectious diseases, and legal representatives, to ensure that participant safety and rights are protected throughout the process.
- **Informed Consent and Withdrawal:** Volunteers should be fully informed about the risks involved in participating in CHIS.
 - Informed consent should be obtained, and **participants should have the right to withdraw at any time without penalty**.
- **Risk Minimization and Medical support:** Measures should be in place to minimize the risk to participants.
 - This includes **close medical monitoring during the trial** and access to appropriate medical care and treatment if any participant becomes ill.

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