

India takes its first step towards opening door to CHIS

News:

• New research model, which involves intentionally exposing healthy volunteers to pathogens in a controlled environment, promises to be efficient and cost-effective, says *ICMR*.

Context:

• India has taken its first step to introduce Controlled Human Infection Studies (CHIS), used in many countries for vaccine and treatment development.

Vision:

• "This paper is aimed at addressing a variety of ethical issues so that research can be conducted in India without compromising on ethical principles while ensuring the protection of human participants," notes ICMR.

Organisational structure:

- Riddled with ethical issues, CHIS has still now been a no-go area for India, but <u>Indian Council</u> <u>of Medical Research's (ICMR)</u> Bioethics Unit is set to change this.
- Outside of India, this relatively new research model which involves intentionally exposing healthy volunteers to pathogens in a controlled Environment, has been used to study malaria, typhoid, dengue, etc.

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- ICMR's Bioethics Unit has introduced a consensus policy statement which is now open for comment and argues the case for bringing in CHIS.
- The document talks of the need, benefits, and challenges associated with CHIS.
- ICMR notes that India has so far stayed away from CHIS, because regardless of the potential scientific benefits, these studies are ethically sensitive and raise concerns about contentious research ethics issues like deliberate harm, possible disproportionate payment and hence inducements, third-party risk, withdrawal from the study and research with vulnerable participants.
- In shorts, "ICMR Bioethics Unit has formulated a consensus policy statement to address the ethical concerns related to the conduct of CHIS and this has been developed through a process of rigorous engagement with experts in the last few months.
- These studies may play a crucial role in advancing the scientific understanding of infectious diseases and thereby accelerating the development of treatment strategies.
- However, being a very specialised type of research involving deliberately infecting healthy volunteers with a specific pathogen under controlled conditions, these may have a lot of ethical challenges and an attempt has been made to address these issues in this document.
- The document is being posted on ICMR website for public consultation till August 16," noted ICMR.

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