Indian Society for Clinical Research

Ethics Council presents :

# ΣthiX

*Let us own our Ethos*

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## From the Editor's Desk:
# Navigating the Frontier of Research Ethics

Welcome to the latest edition of ISCR Ethics Council newsletter. As we navigate the midpoint of 2026, the landscape of clinical research and ethical oversight is evolving at a breath-taking pace. The role of the Ethics Committee has expanded. We are no longer just "reviewers of documents"; we are the guardians of a digital-biological intersection. The traditional boundaries of the "investigational site" are dissolving, replaced by a digital-first ecosystem that demands both technical agility and a steadfast commitment to participant welfare.

In this issue, we dive deep into the dualities of modern research: the high-tech promise of automation and the high-touch necessity of human rights. We bring forth **"Digital Integration"** -our country, India is undergoing a massive digital transformation. We examine how the "Digital India", initiative is making research more accessible—while presenting newer hurdles. Up scaling we have included the topic of, **"The Intelligence Revolution"** wherein we discuss application and implications of Artificial Intelligence and Machine Learning impacting EC's evaluation through AI-driven methodologies without stifling innovations. **"Protecting the Silent"** - through Informed consent which is an integral part of review by ethics committee for vulnerable populations has been specifically included , emphasizing that "informed" is a standard of understanding, not just a signature on a page.

To keep the readers updated, we have placed, Global **Regulatory updates from Dec 2025 to 31st April 2026** and as a fun activity have included a **Cross word puzzle** related to Ethics Committee besides glimpses of our ICTD celebrations.

As we embrace AI and digital tools, our focus must remain sharp on the human element that sits at the heart of every data point. I hope the insights shared in this edition spark meaningful dialogue within your respective committees. As always, we welcome your feedback and contributions to this evolving discourse.

**Best wishes,**
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*"Ethics is knowing the difference between what you have a right to do and what is right to do."*
*- Potter Stewart*

## Digital Integration in India: The Role of Ayushman Bharat Digital Mission in Data Verification and its Impact on Ethics Committee Review and Real-World Evidence

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### Background

The Ayushman Bharat Digital Mission (ABDM) is essentially the "digital backbone" of progressive India's healthcare system. ABDM will shift "Data at Rest" (trapped in hospital basements) to "Data in Motion" (securely flowing to researchers with patient consent), creating a global hub for "Indian Health Data Space" which is cost-effective and with high-integrity building clinical evidence. Evolving from siloed paper records to a standardized, interoperable digital framework, fundamentally and critically impacts data verification, Ethics Committees (ECs) evaluation of research, and generation of Real-World Evidence (RWE).

### Conceptual Framework of ABDM Integration

| Component | Traditional Method | ABDM Integration | Research Impact |
|---|---|---|---|
| Participant Identity | Paper IDs / Manual logs | Ayushman Bharat Health Account(ABHA) ID | Zero "Duplicate /Phantom" participants |
| Consent | Static Paper Forms | Electronic Consent Manager | Higher ethical compliance |
| Data Source | Physical Patient Files | Standardized Digital Records | Interoperable & Clean Data |
| Evidence Type | Controlled Trials (RCTs) | Real-World Data (RWD) | Population-scale insights |

**The Road Ahead: The DPDP Act Connection**

The effectiveness of this digital integration is intrinsically linked to the **Digital Personal Data Protection (DPDP)** Act leading to -

i. **Anonymization Standards:** Developing clear protocols for when data is truly "anonymized" versus "pseudonymized."

ii. **Data Fiduciary Responsibility:** Hospitals acting as "Data Fiduciaries" must ensure that the digital integration doesn't lead to unauthorized leaks, a process that ABHA's secure gateway is designed to mitigate.

- **Impact on Data Verification: ABDM- The "Single Source of Truth": Journey from Manual Audits to Digital Trust**

  In traditional research, verifying data (including source data) is labour-intensive and prone to error with fragmented records. ABDM addresses through:

- **Verified Digital Identities:** By linking health records to a unique ABHA-ID, researchers can conduct Identity Proofing with a verifiable, validated medical history, reducing the risk of "duplicate" or "phantom" subjects in large-scale epidemiological studies and clinical trials.
- **Unified Health Interface (UHI):** Provides a standardized way to pull verified data from different hospitals (government and private) without needing to manually transcribe records into Case Report Forms (CRFs) providing a ***Point-of-Care Validation,*** a Real-time data entry by practitioners within the ABDM ecosystem , reducing the "recall bias" that often plagues retrospective data verification.
- **Immutable Digital Audit Trails:** Since records move through an interoperable gateway, the ***"provenance"*** of the data (who created it and when) is digitally signed, making it harder to falsify medical history.

F **Impact on Ethics Committee (EC) Review:** Shifting to Proactive Oversight

ECs are tasked with protecting participant rights and ensuring data integrity and are often overburdened with administrative reviews. ABDM provides a framework for more rigorous, tech-enabled oversight:

- **Dynamic Informed Consent:** Instead of a one-time paper signature, ABDM supports a ***Consent Manager*** framework. ECs can oversee models where patients grant or revoke access to their health data for specific research modules in real-time (e.g., sharing lab results but not genomic data).
- **Automated Compliance Monitoring:** ECs can request audit trails of who accessed what data and when. This digital transparency ensures that researchers adhere strictly to the approved protocol, making the ***"Annual Progress Report"*** more than just a self-declaration.
- **Privacy-Preserving Reviews:** Researchers can present ***"de-identified"*** or ***"anonymized"*** datasets to ECs more reliably using ABDM's data standards, ensuring that patient confidentiality is baked into the study design from the start.
- **Risk-Based Monitoring:** ECs can use digital flags to identify high-risk data patterns or deviations in real-time, allowing for interventions before a protocol violation becomes systemic.

F **Impact on Building Real-World Evidence (RWE)**

RWE relies on data from outside the controlled environment of clinical trials (e.g., electronic health records, insurance claims). India has historically lacked large-scale, longitudinal data to support local clinical decision-making. ABDM accelerates this by:

- **Longitudinal Data Tracking:** Following patient's journey across multiple providers—from a primary health center to a tertiary specialist—creating a complete

*"cradle-to-grave"* dataset for long-term outcome studies.

- **Post-Market Surveillance:** ABDM enables ***"Passive Surveillance."*** It makes it easier to track the long-term safety and efficacy of drugs or medical devices after they are released to the general public (Phase IV studies).
- **Population-Scale Insights:** By aggregating data, India can generate stratified RWE based on regional, dietary, or environmental factors, ensuring that medical evidence is truly representative of the Indian population rather than just urban clinical trial participants.

**Key Synergies and Summary Table**

| Feature | Impact on data Verification | Benefit to Ethics Committees | Impact on RWE |
|---|---|---|---|
| **Interoperability** | Cross-references data across hospitals. | Ensures data transparency. | Provides a holistic patient view. |
| **Consent Manager** | Validates that data use is authorized. | Enables granular, ethical control. | Increases patient trust and participation. |
| **Standardized APIs** | Reduces manual entry errors. | Simplifies the data audit process. | Allows for "big data" analytics. |

F **Case Study :** National Diabetes Registry:

Integrating a Chronic Disease Registry for Diabetes into the ABDM framework will shift India from a "snapshot" healthcare model to a "continuous" care model. By leveraging on the ABHA-ID, a longitudinal map of diabetes progression can be created that was previously difficult, fragmented and resource consuming. Following ABDM integration:

**The "Live" Patient Profile**

a) **Automatic Syncing:** Instead of manual entry, the registry pulls HbA1c levels, fasting glucose, and lipid profiles directly from ABDM-linked laboratories.

b) **Comorbidity Mapping:** The system automatically flags if a diabetic patient develops hypertension or retinopathy by pulling diagnosis codes from different specialists (Cardiologists/Ophthalmologists) into the single registry profile.

c) **Verified Medication Adherence:** By linking with digital pharmacy records, the registry can verify if a patient is actually refilling their Metformin or Insulin or oral hypoglycaemic agent's prescriptions, providing an evidence to patient-reported data.

d) **Cohort-Specific Consent:** An EC can mandate that patients provide a specific "Research Consent" via their ABDM app before their data is used for secondary analysis.

e) **Automated De-identification:** The EC can oversee a "trusted research environment" where researchers access data patterns (e.g., "How many patients in Gujarat aged 40-50 have uncontrolled HbA1c?") without ever seeing the names or addresses of the individuals.

f) **Benefit Sharing Monitoring:** ECs can track if the registry is actually leading to better outcomes for the participants, ensuring the research remains "beneficence-oriented."

g) **Drug Effectiveness in "The Wild":** RWE can compare how a new SGLT2 inhibitor performs in a rural population in Bihar versus an urban population in Delhi, accounting for diet and lifestyle differences captured in the registry.

h) **Predictive Complication Modelling:** By analyzing thousands of longitudinal records, AI models can predict which patients are at the highest risk of Diabetic Foot Ulcers or Chronic Kidney Disease (CKD) 24 months before they happen.

i) **The "Red Flag" System:** create an automated "Ethics-Approved Alert System." If a patient's data shows a sudden, life-threatening spike in glucose levels across any linked lab in India, the registry can trigger an automated alert to their primary physician, turning a research tool into a life-saving clinical intervention.

j) **Policy and Resource Allocation:** The government can use the RWE to identify "diabetes hotspots," allowing for the targeted distribution of subsidized insulin or the setup of dialysis centers where the data shows the highest rising trend of complications.

k) This registry becomes a goldmine for generating evidence specific to the Indian phenotype (e.g., Lean Diabetes).

**Comparison: Traditional vs. ABDM-Enabled Registry**

| Feature | Traditional Registry | ABDM-Enabled Registry |
|---|---|---|
| **Data Entry** | Manual/Paper-based | **Automated via API** |
| **Patient Tracking** | Lost to follow-up if they move | **Follows ABHA ID across India** |
| **Verification** | Periodic Audits | **Real-time Digital Signatures** |
| **Scope** | Usually single-hospital | **Pan-India Interoperable** |

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## Leveraging AI and Machine Learning for Patient Recruitment and Retention, Protocol Automation, and Outcome Prediction: Challenges and Opportunities


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Artificial intelligence (AI) refers to machine-based systems that analyze input data to generate predictions, recommendations, or decisions, AI-based and machine learning (ML)-based technologies have advanced significantly with improvements in computational power and data availability leading to increasingly sophisticated applications in medicine and clinical trials Artificial intelligence (AI) has been around for almost 100 years, and the use of AI is not what makes it new. In a very broad sense Artificial Intelligence is used to analyse vast amounts of Data.

***What Kind of Data is Required?***

1. Electronic Health Records (EHRs) and Electronic Medical Records (EMRs): Rich patient-level clinical data including diagnoses, medications, lab results, imaging studies, and physician notes.
2. Genomic and Biomarker Data: Genetic sequences, proteomics, metabolomics, and other biomarkers that might predict treatment response or risk of side effects.
3. Clinical Trial History Data: Historical trial data, outcomes, adverse events, and patient retention rates can guide the design of future trials.
4. Real-World Evidence (RWE): Claims data, patient-reported outcomes (PROs), data from wearable devices, and registry data can provide a broader and more realistic understanding of the patient experience.
5. Imaging Data: Medical images (CT, MRI, X-ray) relevant to certain therapeutic areas (e.g., oncology trials) can be analyzed with computer vision and deep learning models.

***Sources for Data***

1. **Hospital and Clinical Databases:** Internal hospital databases and clinical repositories (often requiring data use agreements and Institutional Review Board (IRB) approvals.
2. **Claims Databases and Insurance Providers:** Large insurers and claims clearinghouses can provide population-level data.
3. **Public Repositories: Genomic data:** NCBI's GEO, EMBL-EBI repositories Imaging data: The Cancer Imaging Archive (TCIA) Clinical Trials data: ClinicalTrials.gov database, FDA's Sentinel Initiative data
4. **Wearable and IoT Device Manufacturers:** Partnering with device vendors (e.g. Fitbit, Apple, Garmin) to access anonymized health metrics.
5. Patient Registries and Cohorts: Disease-specific registries maintained by research foundations or patient advocacy groups.

## PATIENT RECRUITMENT AND RETENTION

Patient recruitment represents the most critical bottleneck in clinical trial conduct, with AI offering transformative solutions through automated participant identification and matching systems. Advanced natural language processing (NLP) algorithms scan electronic health records (EHRs), clinical notes, and laboratory results to identify potentially eligible participants with unprecedented efficiency and accuracy.Machine learning models can also predict a patient's likelihood of enrollment success by analysing historical patterns, demographic factors, and clinical characteristics. This predictive capability enables targeted recruitment strategies, focusing resources on participants most likely to enroll and complete study participation, ultimately reducing delays and costs associated with trial execution

## OPPORTUNITIES

**Recruitment gains:** Predictive models identify likely-eligible patients and even estimate willingness to enroll based on historical behavior.

**Diversity improvement:** Algorithms can flag underrepresented populations and adjust outreach strategies.

**Retention optimization:** Models trained on dropout patterns can trigger interventions (reminders, telehealth check-ins, transport support).

## CHALLENGES

Bias in training data can skew recruitment, especially if certain populations are historically underrepresented.

## PROTOCOL DESIGN & AUTOMATION

Protocols often fail because they're too complex or unrealistic. AI can help simulate and optimize them before a trial even begins.

## OPPORTUNITIES

Protocol feasibility analysis: ML models simulate enrollment timelines and site performance.

Eligibility criteria optimization: AI suggests relaxing or tightening criteria to balance safety and recruitment speed.

Workflow automation: Tools can auto-generate schedules, monitoring plans, and even draft protocol documents.

## CHALLENGES

Over-automation can produce protocols that look optimal on paper but fail in real-world clinical settings due to human and operational variability. Advantages and limitations of using artificial intelligence (AI) in clinical trials.

## ADVANTAGES

AI can transform key steps of clinical trial design, from study preparation to execution, leading to improved trial success rates

Improve patient recruitment and protocol design, leading to higher chances of trial success

Monitor patients and analyse data, leading to more accurate measurement and interpretation of results

Predict clinical outcomes, which is essential for precision medicine and can help eliminate statistical variability of general populations

Allows healthcare professionals to better understand the patterns and needs of their patients through in-depth data analysis

## LIMITATIONS

Requires significant investment in technology and infrastructure,

Requires specialized expertise in both clinical research and machine learning,

Raises ethical concerns around data privacy and informed consent,

Lack of empirical data validating the effectiveness of AI-based medications in planned clinical trials is the main obstacle to successful deployment.

In clinical trials, it must be verified how accurately the established AI algorithms solution works as compared to the clinical standards like sensitivity and specificity of diagnostic tests

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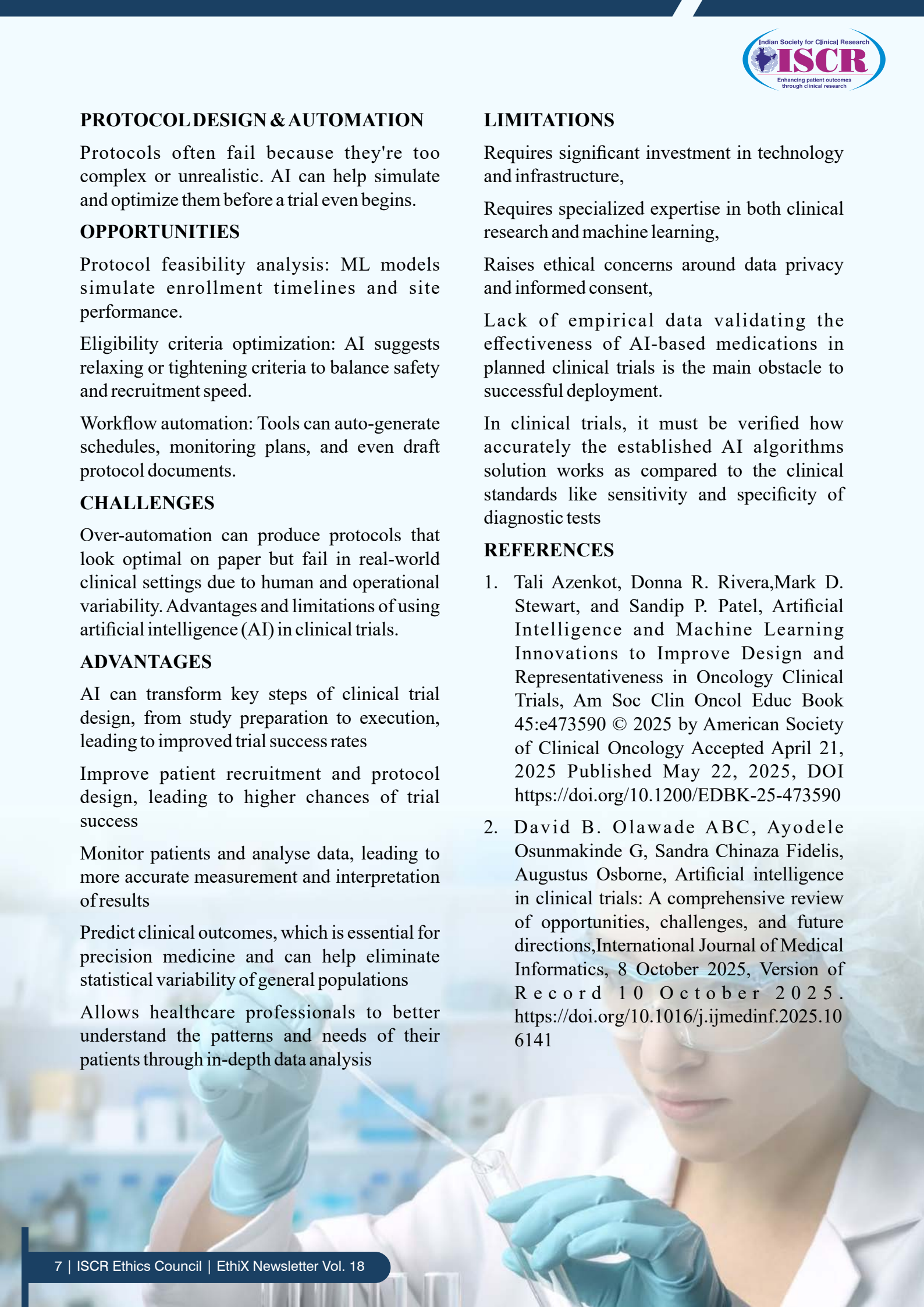

## Title: Ethical and Practical Considerations in Informed Consent for Vulnerable Populations and Biobanking: Frameworks and Assessment Tools

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Vulnerable originates from Latin verb 'vulnerare' meaning 'to wound'. It refers to a person's state of being susceptible to manipulation, coercion, persuasion or temptation.

### I. Vulnerable population

They are as outlined in 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants'

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent
- children (up to 18 years);
  - women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones,riot areas or disaster situations;
- afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies;
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners)

### I.a Ethics committee responsibilities during review in vulnerable population:

i) Determine whether the prospective participants for a particular research are vulnerable.

ii) Justification of inclusion of vulnerable groups in study

iii) Look into 'conflict of interest' issues

iv) Risk benefit analysis assessment

v) Frequent review & monitoring, including site visits

vi) Only full committee reviews

vii) ECs should have standard operating procedures /SOPs for studies dealing with vulnerable population

viii) ECs to have checklists for research in children, pregnant women( with or without viable foetus),students,

cognitively impaired individuals, samples for genetic research and counseling etc.

ix) ECs to encourage 'Informed consent process' to include answers to open ended, non-directive questions like "what", "where", "how often", "when", and "please describe".

**I.b Strategies to improve communication with vulnerable population**

I) Use videotapes, group discussions, simulations or animated cartoon illustrations in the informed consent process. The 'Speaking Book' was launched in South Africa to explain to illiterate population. It had cartoon depiction apart from voice messages with press of buttons

ii) Video clips about participants' rights could be arranged in different waiting areas of the institutions.

iii) Supported decision making

iv) Training programs on 'Informed consent'. It can consist of:

- Background and history of informed consent
- Aspects of clinical research with vulnerable patients, minors, illiterates
- Local laws and ICH-GCP Guidelines

v) In academic settings, students involved in clinical research could be encouraged to place themselves in the position of a patient e.g. a child or an unconscious patient. Role plays with feedback could be enacted on the same

vi) Communication techniques and hands-on training with model informed consent Form, psychological conversation techniques, e.g. on how to explain exactly which elements of treatment and care

vii) Alternatives to leaflet such as the 'Speaking Book'

**I.c Assessment tools**

Quality evaluation tool

I) **MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), UBACC** (University of California, San Diego Brief Assessment of Capacity to Consent). It is a reliable and valid means of assessing their participant's capacity to consent to participation. It has four components for understanding, appreciation, reasoning, and the ability to give one's preference.

ii) Quality of Informed Consent Questionnaire (QuIC)-It evaluates whether Informed Consent is truly understood and not merely documented.

Comprehension assessment tool

'

iii) Teach Back Method'- It is a strategy to assist researcher's ability to explain the informed consent process in a clear way and facilitate the understanding of the participant to repeat back in his/her understandable language

**II. Biological samples & biobanking**

Biospecimens or biological samples include blood, dried blood spots, body fluids, urine, tissues, organs, cord blood, oocytes, sperm, semen or embryos and biobank is an organized repository to retrieve biological data for research purposes.

Repository activities can include

- collection of biospecimens and/or data;
- storage of biospecimens and data including its management
- retrieval and disbursement to researchers

As the biobank involves storage and research at a later date, the ethical concerns regarding ownership, access and knowledge sharing should be maintained with great responsibility. As an important principle of research, it should be underataken on least identifiable data.

**IIa. Types of samples:**

| | | |
|---|---|---|
| Anonymous or unidentified | No identifiers are present from the start or if collected, are not maintained. Such samples are received by biobanks without any identifiers and supplied to researchers | |
| Anonymized | This involves systematic de-identification, reversible or irreversible: link of samples/data to personal identity is reversibly or irreversibly cut. | |
| | Coded or reversibly anonymized: There is an indirect link of sample/ data to the participant's identity with restricted access. This link could be re-linked if required; therefore, it may also be termed reversible anonymization. | Irreversibly anonymized: Link to the participant's identity is removed and cannot be re-linked. |
| Identifiable | A direct link of sample/data to the participant's identity exists. | |

**IIb. Ethical issues of informed consent in bio banking samples:**

- Specific endpoints and study structure are not known at the time of collection of bio specimens
- Need of multiple informed consents depending on storage, analysis, incidental findings, sharing of sample/data, national or international sharing, return of results to participants etc
- Ownership of data/samples
- Extended or secondary use of samples/data
- Transfer of bio specimens ( need of material transfer agreement and memorandum of understanding)

**IIc. Types of Informed consent in biobanking:**

I) Blanket or broad consent: This is an open consent given only once to collect the sample, store it and use it for any research at any time in future without the need to revert to the individual for a re-consent. Present and future access is allowed.

ii) Tiered consent: Participants can choose from several options. It includes an opt-in option for future use specifying general permission, or use only related to some aspects of research, sharing of biospecimens/data benefit sharing, etc. It also takes into consideration return of results for which options are also provided for consent.

iii) Specific consent: Consent is obtained for a specific research purpose. Participants have to be re-contacted for every new use of their stored samples/data if the scope of research is outside that for which they had originally given consent.

iv) Delayed consent: It may be administered in the post-medical procedure period when biospecimen or data may be collected for appropriate research from critically ill patients who may not have given prior consent for research. The legally acceptable representative can also give consent in this case.

v) Withdrawal of consent or destruction of sample: The donor has the right to ask for destruction of her/his collected sample(s) and discontinuation/withdrawal from participation in the research. In longitudinal studies, a participant may withdraw from one component of the study, like continued follow-up/data

collection when withdrawal may be referred to as partial

vi) Waiver of consent : only for anonymized samples/data. Approval of the ethics committee of institution or repository has to be obtained.

vii) Re consent : Secondary or extended use of samples

viii) Paediatric donors: Reconsent has to be taken after attainment of legal age of consent. Re consent gives the power to agree or withdraw from the study. A biobank can decide it's policy regarding re contact.

**Transfer of Human Biological Material (THBM) ICMR Portal**

(https://tbm.icmr.gov.in/) streamlines the application process required for importing or exporting human biological samples, especially for commercial, contract research, or international collaboration. It serves as the primary digital hub, ensuring compliance with 2024 regulatory requirements for transferring samples, biological materials, and reagents

Informed consent in vulnerable populations and biobanking is a dynamic, evolving process requiring ethical vigilance, robust governance, and innovative communication strategies. Balancing scientific advancement with participant autonomy, dignity, and trust remains central to responsible research.

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# Key Regulatory Updates Across Major Health Authorities: December 15 to April 30, 2026

## 1. India

### a) CDSCO & DCGI

Focus on "Ease of Doing Business" and stricter quality standards.

1. **Jan 1, 2026: Enforcement of Revised Schedule M :** DCGI mandates full compliance with updated Good Manufacturing Practices (GMP) for all pharmaceutical units. A shift from document-driven to a system-driven quality risk management (QRM) approach, aligning with global WHO-GMP and PIC/S regulations.
2. **Jan 2, 2026 : Indian Pharmacopoeia (IP) 2026 :** The 10th edition of IP 2026 released which introduces 121 new monographs, bringing the total to 3,340. It enhances standards for anti-TB, anti-diabetic, and anti-cancer drugs, along with adding monographs for new vaccines and, for the first time, 20 blood components .
3. **Jan 20, 2026 : Prior Intimation System :** Amended the New Drugs and Clinical

Trials Rules, 2019 (via G.S.R. 46(E)). Manufacturers now only need to provide "prior intimation" rather than seeking a license for small quantities of drugs used for analytical , non-clinical testing, and specific BA/BE studies but excludes sensitive categories like hormones, cytotoxics, and specific biologics. Manufacturers must still follow strict Good Manufacturing Practices.

4. **Feb 23, 2026 : Immediate NOC Issuance:** The circular, effective from **June 1, 2026,** dictates that No-Objection Certificates (NOCs) for testing drug samples at designated government laboratories will be issued immediately upon receipt of the application, bypassing the prior technical scrutiny phase.

5. **Feb 25, 2026 : Dossier-Based Licensing :** CDSCO issued a Guidance Document to standardize drug manufacturing licenses across India through a dossier-based submission, to streamline the approval process, reduce redundant evaluations, and bring uniformity to licensing standards across different States/UTs .

**b) ICMR**

6. **April 29, 2026 : Institutional Realignment :** Functional realignment and renaming of ICMR institutes/centers as the National Institute of Health Research (NIHR) to foster a more integrated research ecosystem.

**2. United States: FDA**

The USFDA focused on accelerating access to breakthrough therapies and modernizing clinical trial designs.

1. **April 23, 2026 : RAPID Coverage Pathway:** A joint initiative with CMS to accelerate patient access to life-changing medical devices(Class II and III) by aligning FDA approval and Medicare coverage within roughly 60 days post-authorization by proposing National Coverage Determinations (NCDs) the same day as FDA approval, reducing the, in some cases, year-long wait.

2. **April 23, 2026 : Gene Therapy for Hearing Loss :** Otarmeni (lunsotogene parvec-cwha), the first-ever gene therapy was approved under the National Priority Voucher Program to treat genetic hearing loss. Developed by Regeneron for children and adults with OTOF gene mutations, this one-time, dual-AAV1 vector treatment aims to restore hearing by restoring otoferlin protein production.

3. **April 28, 2026 : FDA unveils real-time trial proofs-of-concept and upcoming pilot program for RTCT :** Successful initiation of two proof-of-concept for Real Time Clinical Trials (RTCT) that will report endpoints and data signals to the agency in real time. It released a Request for Information (RFI) regarding a proposed pilot program for RTCT that will launch this summer .

4. **April 30, 2026 : Compounding Restrictions :** Proposed to exclude Semaglutide, Tirzepatide, and Liraglutide from the 503B Bulks List, significantly impacting the compounding pharmacy market for weight-loss drugs.

**3. European Union: EMA & EC**

The EU is refining its Medical Device Regulations (MDR/IVDR) and advancing digital submission standards.

1. **December 16, 2025: Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Regulation (IVDR) 2017/746 :** EU released a 170-page proposal (COM[2025] 1023 final) to amend the MDR and IVDR. The proposal aims to streamline procedures, reduce administrative burdens, and prevent device shortages, with key changes expected to be discussed through early 2026 before adoption.

2. **March 27, 2026 : Real-World Data (RWD) Framework :** The HMA-EMA

Data Quality Framework for EU medicines regulation released to enhance regulatory decision-making, provides comprehensive guidelines for using RWD. It defines standards for data quality—specifically relevance and reliability—to ensure RWD can be used for regulatory decisions in safety monitoring and effectiveness.

3. **April 10, 2026 : Mandatory Digital Submissions :** The EMA announced that the use of the PLM web-based electronic Application Form (eAF) will become mandatory for all centrally authorized products (CAPs) starting September 1, 2026.

4. **April 29, 2026 : Vaccine Confidence Advisory Group :** EMA launched a high-level expert panel to strengthen public trust in vaccines and counter misinformation.

4. **World Health Organization (WHO)**

1. **Jan 16, 2026 : Vector Control :** WHO Prequalification of Vector Control Products (PQT/VCP) unit announced key updates, including revised specifications for technical materials and updated guidelines for semi-field studies. Updated statistical analysis guidelines for semi-field studies (ITN implementation guidance 5.3) and revised specifications for various technical materials (e.g., Transfluthrin).

2. **Feb 3 , 2026 : New Prequalification :** Prequalified a new stand-alone Measles vaccine(3rd Feb) and a new TB NAT (Nucleic Acid Test) assay(21st April) .

3. **Feb 10, 2026 : ePQS Portal Mandate :** Announced that the use of the electronic Prequalification System (ePQS) will be mandatory starting May 11, 2026, for all medical product applications.

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- *EMA News & Press Releases:* ema.europa.eu
- *WHO Prequalification Updates:* extranet.who.int/prequal



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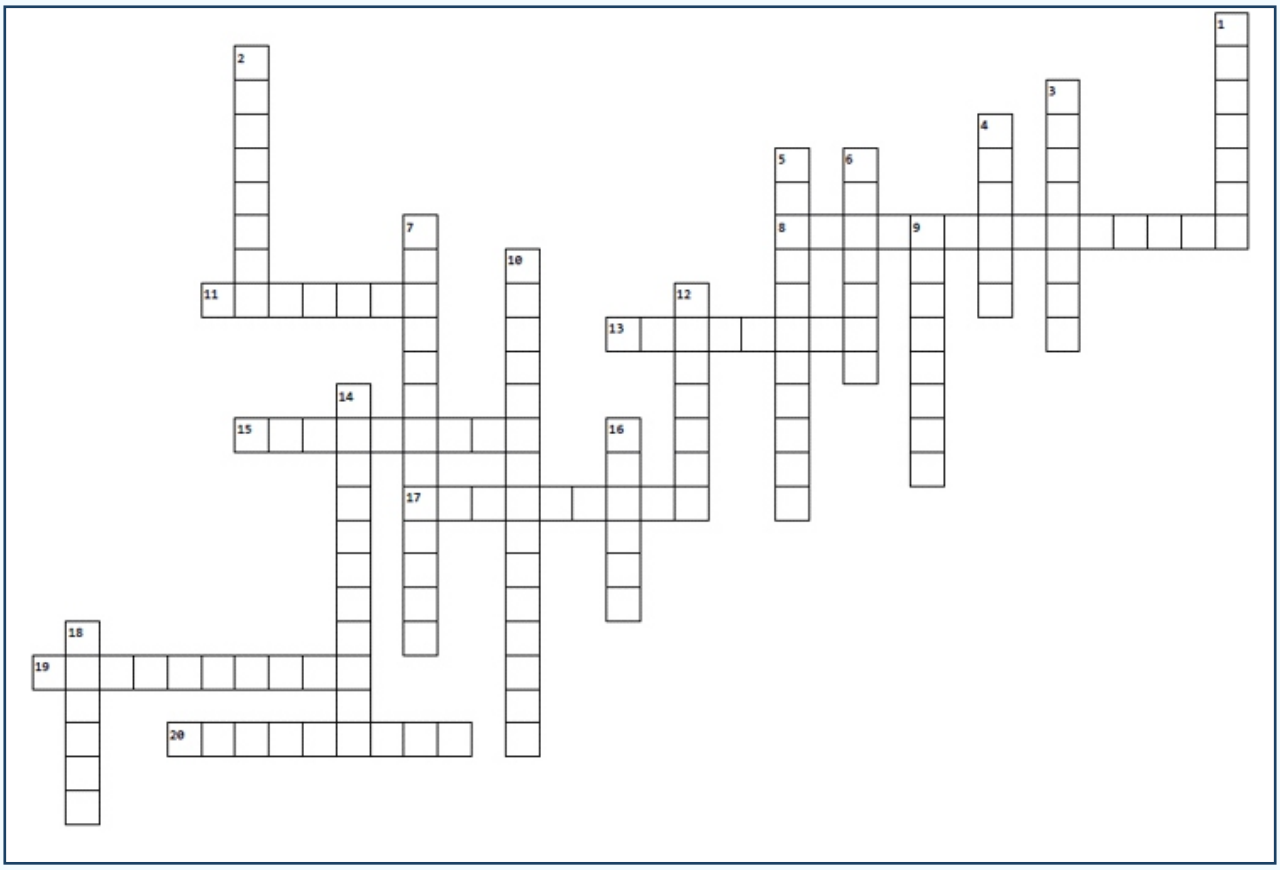
# Ethics Committee



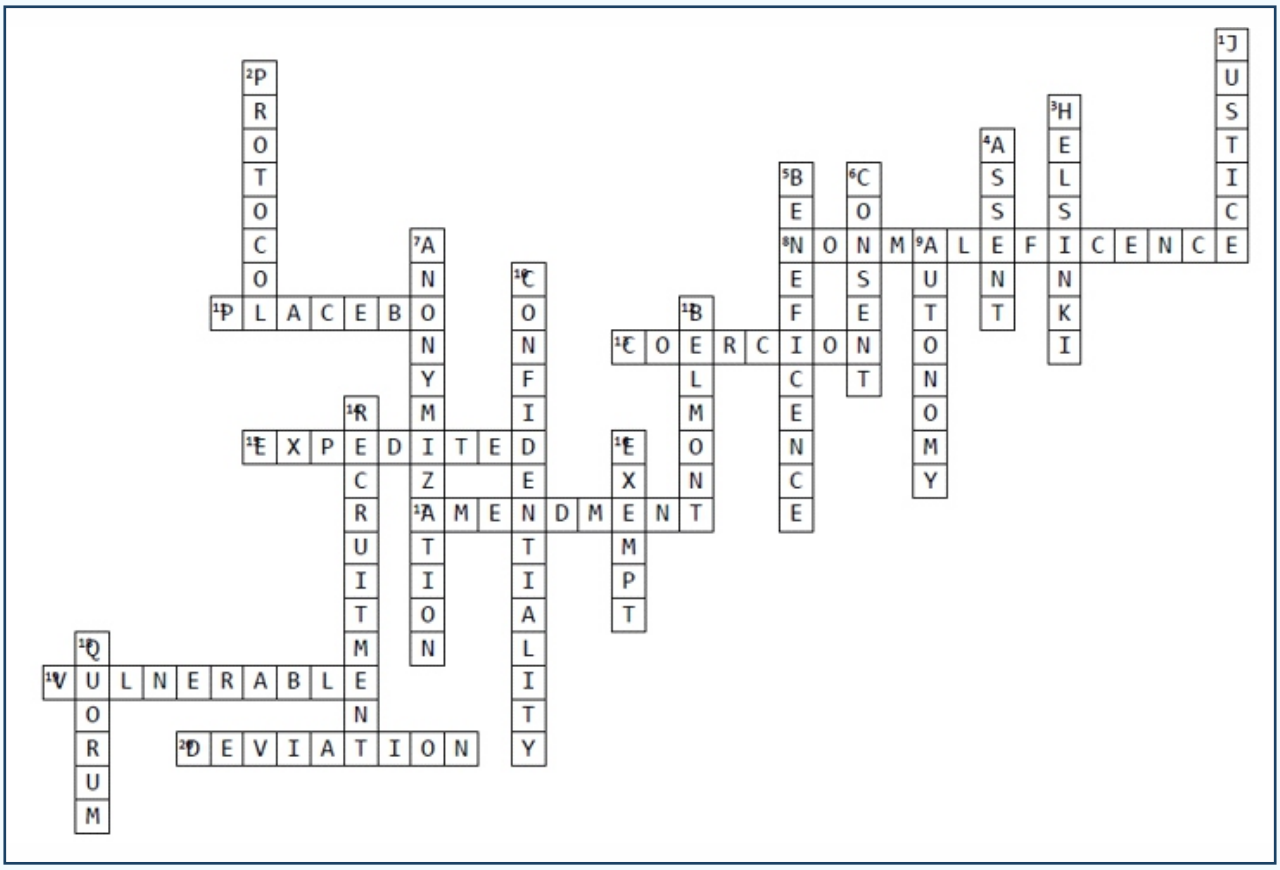
**Across**

8. Obligation to do no harm.
11. Inactive control substance.
13. Threat of harm to obtain compliance.
15. Review for minimal risk studies.
17. A formal change to a protocol.
19. Subjects requiring extra protection.
20. Failure to follow the approved protocol.

**Down**

1. Fair distribution of research burdens.
2. The study's master design document.
3. The WMA's ethical declaration.
4. Agreement from a minor.
5. Principle of maximizing benefits.
6. Voluntary agreement to participate.
7. Removing identifying particulars from data.
9. Respect for persons as independent agents.
10. Protecting identity from unauthorized disclosure.
12. Landmark 1979 US ethical report.
14. Process of enrolling participants.
16. Research not requiring full committee review.
18. Minimum members for a valid meeting.

# Ethics Committee-Answers




## Ethix Newsletter – Edition May 2026
## Celebrating International Clinical Trials Day (ICTD): Theme "Patient's First"

**ICTD activities conducted in May 2026:**

The Ethics Council successfully conducted eight impactful activities during May 2026, aimed at enhancing awareness, capability building, and engagement across various stakeholder groups.

1) **Awareness Program, GMC, Bhandara: 04-May-2026**
   - 100 undergraduate medical students participated

2) **Poster Competition, GMC, Bhandara: 11-May-2026**
   - 22 participants participated; 3 winners were announced on 20-May-2026

Above events were conducted at the Department of Pharmacology, Government Medical College (GMC), Bhandara, led by Dr. Mrunalini Kalikar.


### 3) Patient Awareness Program, AIIMS Nagpur: 20-May-2026

- Led by Dr. Ganesh Dakhle
- Organised by Department of Pharmacology and Institutional Ethics Committee (IEC), AIIMS Nagpur, in collaboration with ISCR and QRed Clinical Research Services
- Dr. Chaitali Chindhalore welcomed participants, highlighted the importance of ICTD.
- Dr. P. P. Joshi, Executive Director emphasised: Ethical clinical research, Clinical trials as a foundation for medical advancement and the importance of transparency and patient trust as well as

AIIMS Nagpur's commitment to quality healthcare research.

- Four patients shared their experiences, highlighting: Understanding informed consent, Safety monitoring and their contribution to medical innovation.
- This patient awareness programme was also attended by investigators and departmental colleagues in AIIMS, Nagpur.



4) **Online Poster Competition: 15-May-2026**

- Theme-Enhancing Patient Experience in Ethical Clinical Trials catered to post-graduate medical students, Principal Investigators, Sub-Investigators, Ethics Committee members, Clinical trial site staff members and research professional.
- 31 participants
- 3 winners and 2 consolation prizes announced on 28-May-2026
- A heartfelt thank you to our esteemed judges for their invaluable time, expertise, and insightful evaluations, which greatly enriched the event. We extend our sincere appreciation to all participants for their enthusiastic participation, impressive presentations, and for making the session vibrant and engaging.
- Led by Ms. Vrunda Pandya

**Our Judges:** Dr. Durga Gadgil and Dr. Srikanth Krishnamurthy reviewing posters along with ISCR representatives (Vrunda Pandya and Durga Mane) for selection of winners.

5) **Good Clinical Practice training, Assured Care Plus Hospital, Nashik: 19-May-2026**

- Attended by 33 participants
- Covered ISCR and ICTD, ICH E6(R3) updates, and stakeholder responsibilities including Investigators, Ethics Committee, and Sponsors
- Participants included Investigators, Ethics Committee members, CRCs, and hospital research staff
- The session was well received and highly interactive, with active participation from attendees. The discussions enabled better understanding of key aspects of GCP, practical challenges in trial conduct, and evolving regulatory expectations.
- Our sincere thanks to Dr. Suneel Vartak, Principal Investigator (PI), and Dr. Atulram Agrawal, Medical Director and Head of Institution, for their support in facilitating this event.
- Led by Vrunda Pandya, organised with support from Vinayak Desai and Dr. Deepak Ghumare

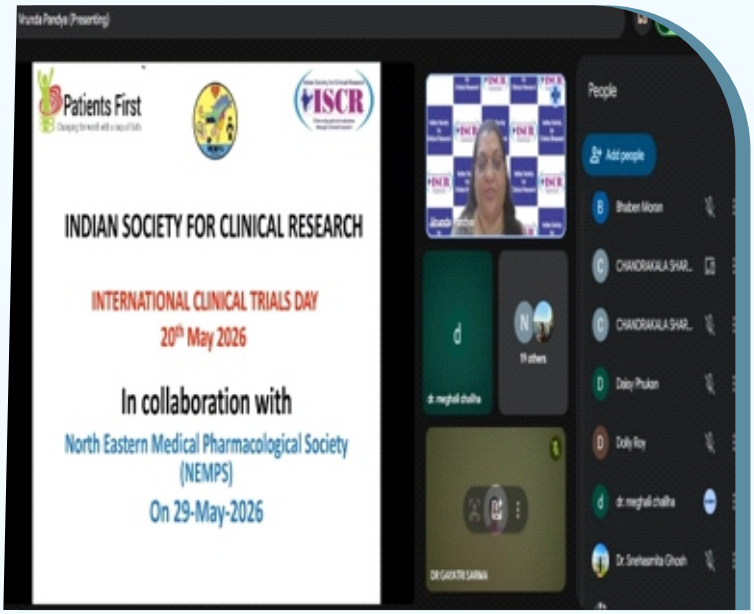
6) **Good Clinical Practice (GCP) training, Vitthal Hospital, Pune: 22-May-2026**

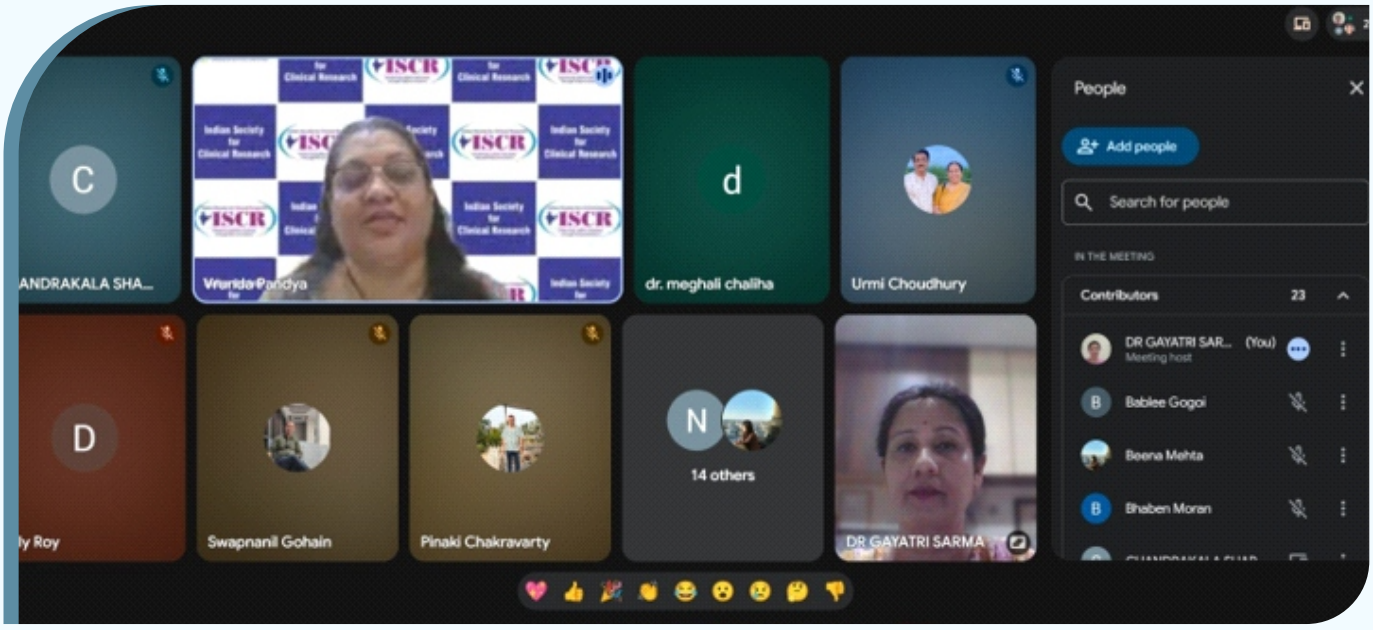
- Attended by 44 participants
- Covered ISCR and ICTD, ICH E6(R3) updates, and stakeholder responsibilities
- Participants included Investigators, hospital staff, and clinical research personnel
- Session had a strong focus on clinical trial conduct awareness and was highly interactive, with engaging discussions around practical aspects of trial execution
- Led by Vrunda Pandya, with support from Mr. Vijay Kumbhar and Dr. Rashmi Tandle

7) **The Ethix Newsletter -** May 2026 has been curated as a celebration edition, showcasing ICTD activities and strong stakeholder engagement across the initiatives.

8) **A virtual Clinical Research and ICTD Awareness Program: 29-May-2026**

- Conducted in collaboration with the North Eastern Medical Pharmacological Society (NEMPS) to further expand outreach and awareness
- Attended by 30 participants
- The session was well-received and marked by engaging discussions, particularly around clinical trial conduct and the Indian regulatory landscape. The interactive nature of the program helped participants gains practical insights.
- Led by Vrunda Pandya, with valuable support from Dr. Meghali Chaliha, Professor of Pharmacology, Assam Medical College and Hospital (AMCH), Dibrugarh and President, NEMPS, and Dr. Gayatri Sarma, Associate Professor, AMCH and Scientific Secretary, NEMPS

**Acknowledgement:**

We sincerely acknowledge the guidance and support of the ISCR leadership team, including Dr. Ganesh Dakhle, Dr. Mrunalini Kalikar, and Mr. Sachin Sadekar, which played a key role in the successful execution of these initiatives.

**Summary:**

Across these eight initiatives, the Ethics Council engaged a wide spectrum of stakeholders-medical students, investigators, ethics committees, participants, and research professionals through awareness sessions, competitions, and training programs, reinforcing commitment to ethical clinical research practices.

**Prepared by:**

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