ETHICS & IMPACT EVALUATIONS

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Research

- For generalizable knowledge
  - Health & non-health projects
  - Health – regulatory & non-regulatory
  - Non-regulatory – basic or clinical involving human participants
- Clinical research - Human research protection same

Evaluation Providers – Evaluation Users

- Team work at the start – inclusion of other stakeholders
- Interim discussion
- Final report discussion

Program Evaluation Standards

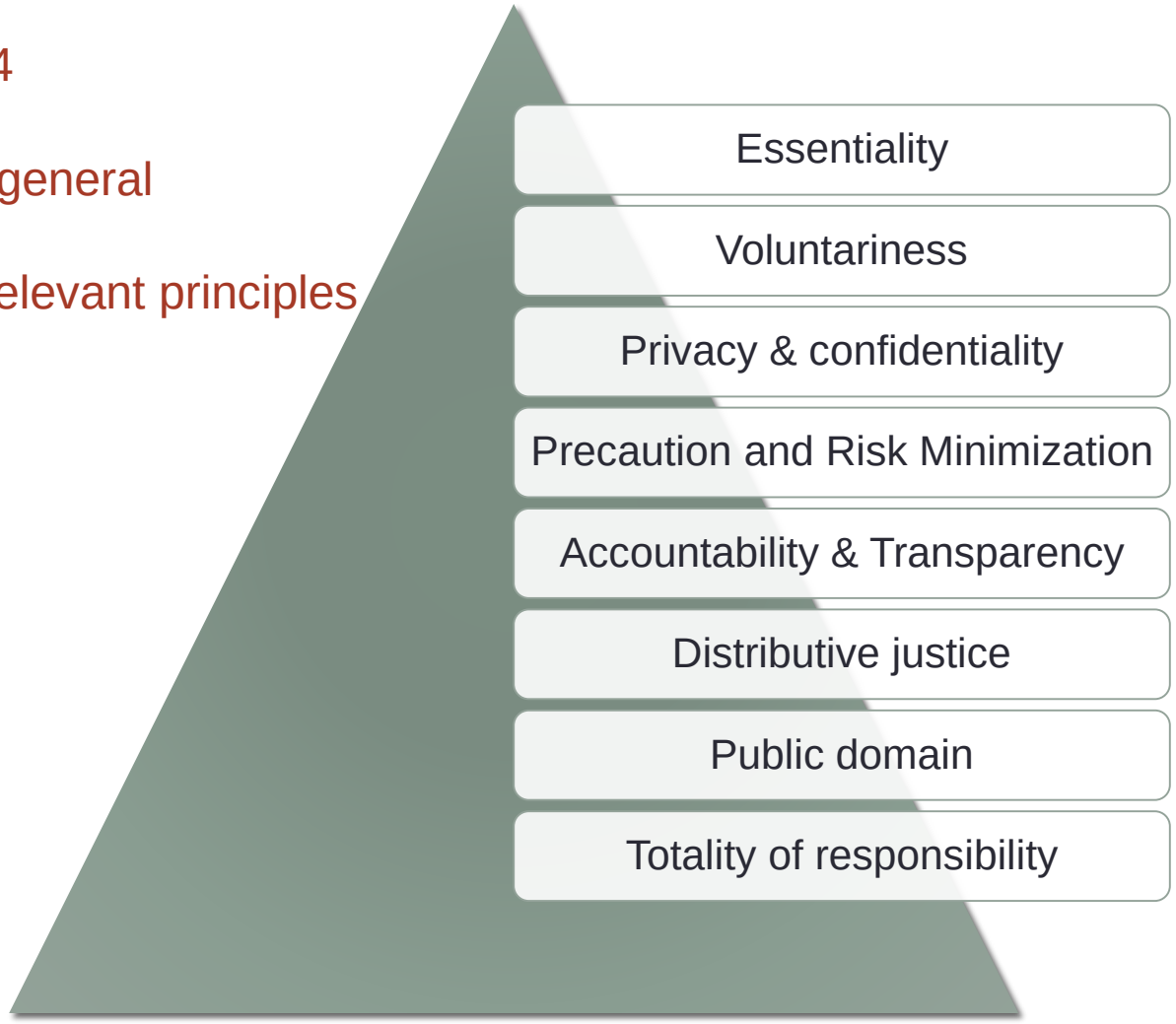
- Utility Standards – information needs of the intended users served
- Feasibility Standards – realistic, frugal and diplomatic
- Propriety Standards – legal, ethical, and welfare of participants aspects
- Accuracy Standards – information revealed and conveyed to determine the value and merit of the program evaluated

Ethical Principles

Weatern – 4

ICMR – 12 general

For IE – 8 relevant principles



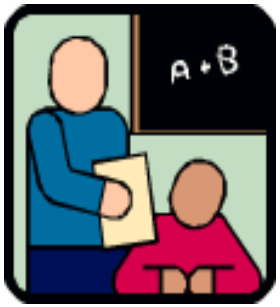
1. Essentiality

- Justification for substantial investment in programs with no known effectiveness (counterfactual) – worthwhile?

- Priortisation in scarce resources

2. Voluntariness – Respect for Persons (Informed Consent)

communicate



Understand

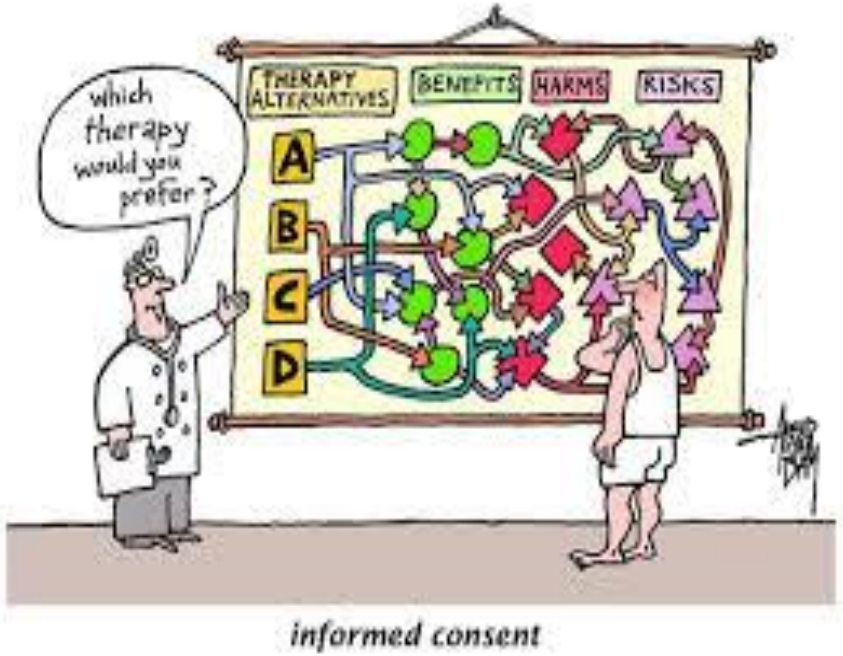
Ability to reason

Documentation

Culture Specific

Illiterate Participant

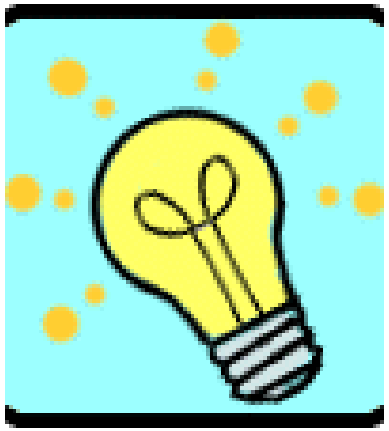
- Impartial Witness must
  - Independent of the trial
  - Present during informed consent process
  - May read information given to the participant

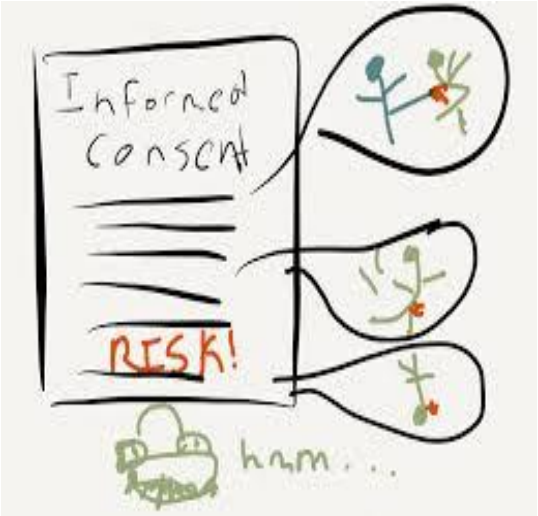


informed consent

Participant not competent/ able to Reason?

- Children
- Mentally challenged
- Mentally ill
- Unconscious





LAR – Legally Authorised/ acceptable Representative

Community Engagement

- Role of gate keepers
- Public health research – survey questionnaires, research on community
- International collaborative study
- Stigmatisation
  - Genetic study
  - HIV/AIDS
  - Abuse

72nd Parliamentary Committee Report on HPV Vaccine Study - Aug 30th, 2013

Andhra Pradesh

Findings

- 69% - no witness signature
- No dates on ICFs
- One person has signed 7 forms
- No signature of PI in some
- Parents/ Guardians – names and signs not matching
- Date of vaccination earlier to date on consent form

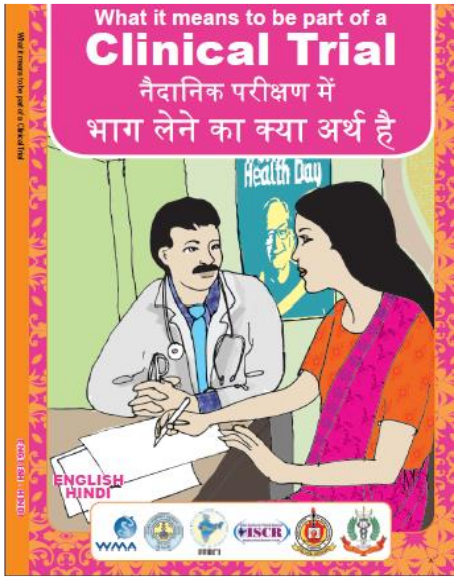
Solutions

- Brief simple worded informed consent document supported by the detailed one

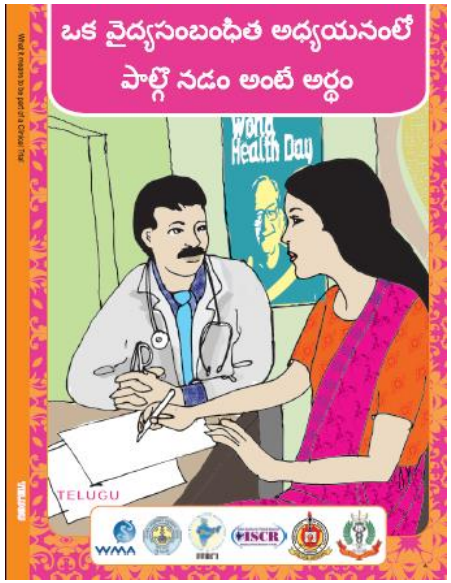
- Multimedia approach
  - Speaking book
  - Informed consent video
  - Digital versions supported by written form

Solution – Multi Media Approach

- Speaking book – English & Hindi



- Speaking book - Telugu



Contents

1. Illiterate Participant
2. Literate participant
3. Non-English speaking participant
4. Paediatric participant
5. Phase I (Non-Therapeutic Clinical trial) Participant
6. Participant in a Psychiatric study
7. Unconscious Participant

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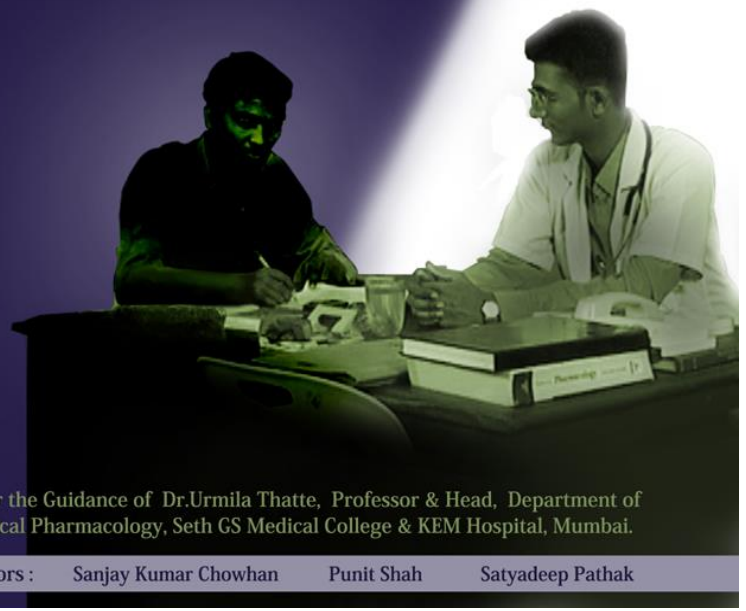
Educational Video for Clinical Research

Developed by Forum for Ethics Review Committees in India (FERCI) in collaboration with Pfizer Limited.

Informed Consent

An Educational Video for Clinical Research

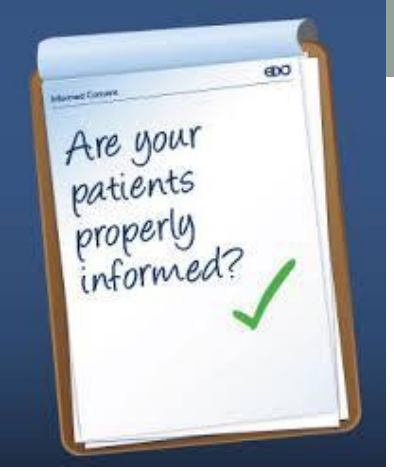


Under the Guidance of Dr.Urmila Thatte, Professor & Head, Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai.

Directors : Sanjay Kumar Chowhan Punit Shah Satyadeep Pathak

Virtual Consent Platform

- To evaluate participant understanding and acceptability
- Multi-lingual ease of presentation
- Cultural sensitivity for specific populations
- Increased access to potential and current patients through a web portal where the information is always available
- Question key understandings of the study to validate patient understanding of the consent leading to amendments
- “self-consenting” prior to the interaction with staff
- Markedly reduce the time required for consenting



F. No. GCT/20/SC/Clin./2013 DCGI
Directorate General of Health Services
Ministry of Health & Family Welfare
Office of Drugs Controller General (India)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002
Dated: 19 NOV 2013

ORDER

The clinical trials on new drugs are regulated under the provisions of Drugs & Cosmetics Rules 1945 as amended from time to time. The detailed requirements and guidelines for undertaking clinical trials are specified under Schedule Y of the said rules. As per the Rule 122 DAC of the said Rules, clinical trials are required to be conducted in compliance with the approved protocols and Good Clinical Practice (GCP) guidelines published by Central Drugs Standard Control Organization, Directorate General of Health Services, Govt. of India as well as applicable regulations.

In view of the above, it has been decided with the approval of the Ministry of Health & Family Welfare, that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation would be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials.

Voluntary Withdrawl

- Power relationship – doctor patient/ health giver/ authority to patient/ participant relationship

- Reduced autonomy or less empowered physically or mentally – difficult to withdraw

3. Privacy & Confidentiality

- Coded or anonymised data collection unless identity is essential
- Support system like counseling mechanism to be in place when program involves sensitive information
- Incidental findings like dangerous/ unhealthy family situations should be expected and solved

4. Precaution and Risk Minimization

- Ethics committee's role
  - Review, approve & monitor
  - Discussion on both science & ethical issues
  - Equitable selection in design – justice principle (race, gender, socioeconomic status)
  - Risk minimisation & benefit enhancement – whenever possible control group to get same benefits as post-trial responsibility (roll out programs)
  - Exemption from adminitering informed consent
  - Training on human research protection and understand sensitivities in specific projects

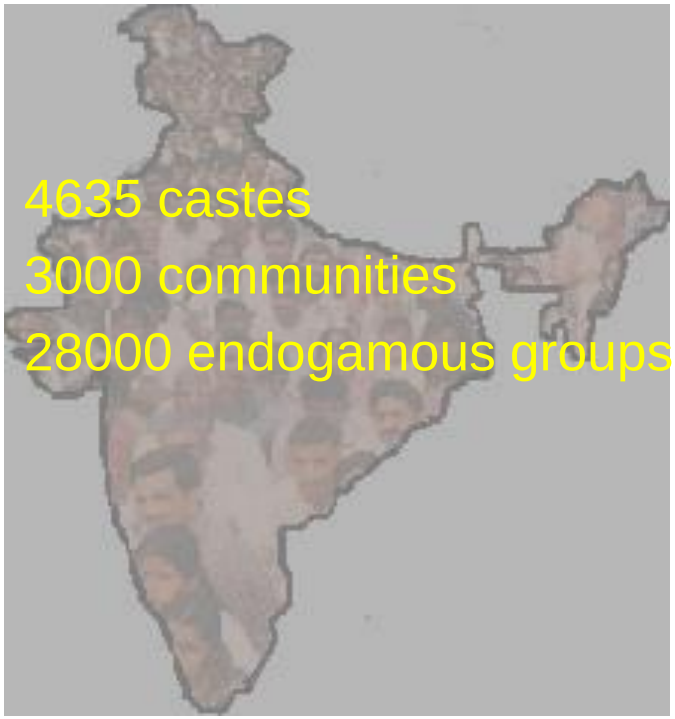
- Community's role

5. Accountability and Transparency

- Proper documentation
  - Shared responsibility
  - Trial documents
- Archiving for audit and inspection – Different periods according to different international and national requirements

6. Distributive Justice

Race, gender & socioeconomic

- 

Policy makers & Politics

7. Public Domain

- Systematic reviews – fraud articles lead to wrong guidance in designing program
- Data integrity - FFP
- Ownership of information – agency, institution, Government : to be decided *a priori*
- Data sharing agreements – *a priori*
- Peer review issues
- Declaration of Helsinki (2008) – registry, negative results, post-trial access

Responsible Conduct of Research,
ICMJE & COPE Guidelines about authorship

8. Totality of Responsibilities

- Research group
- Institution
- Sponsor
- Collaborators

Agreements & MoUs

Other Issues

- Communicating results to participants
- Sensitizing program operators to realities of their projects
- Declaration of Conflict of interest
- Accuracy in reporting
- Conclusions about outcome should be justified and impartial

Thank You

- “Not everything that can be counted counts…and not everything that counts can be counted.”

Einstein