Informed consent process

Dr. Abel Arul Nathan

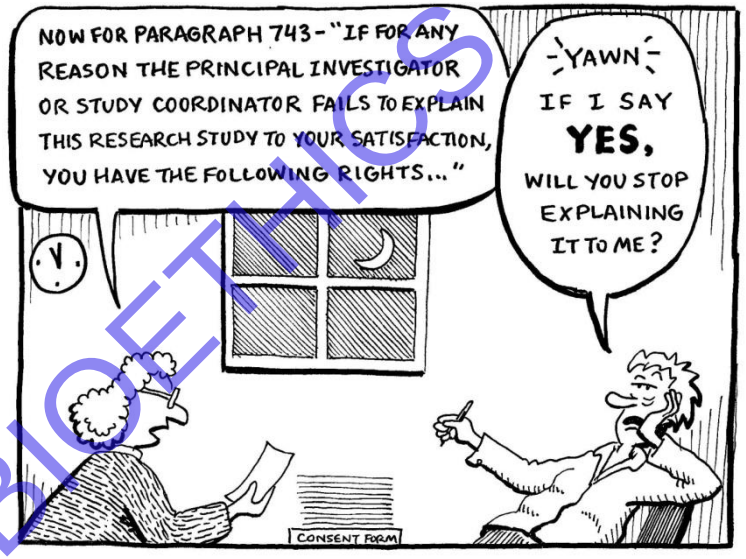
What is an informed consent process?

- A process wherein the researcher obtains a **voluntary** written informed consent from the participant
- Has to be an IEC validated document
- Oral consent – only on special IEC approval

Why do we need informed consent?

A competent individual is entitled to choose freely whether or not to participate or continue to participate in the proposed research study

How it should not be!



- Should not be voluminous
- Should not be boring
- Should not be full of technical terminologies

Three main components of an ICP

- Providing **relevant information** to the potential participants

- Ensuring **competence** of the individual

- Ensuring that the information is **easily comprehensible** for the participants and assuring **voluntariness** of the participation

Elements of an ICP

Elements of an ICD	Additional elements (optional)
1. Statement mentioning that it is research	1. Alternative procedures or treatment
2. Purpose of research and methods	2. Insurance coverage
3. Duration, frequency, methods	3. Possible stigmatizing condition
4. Benefits to participant, community or others	4. Biological material and data, including
5. Foreseeable risks, discomfort or inconvenience	i. Current and future uses
6. Confidentiality of records	ii. Period of storage, secondary use, sharing
7. Payment/reimbursement for participation	iii. Right to prevent use of biological sample
8. Treatment and/or compensation for injury	iv. Provisions to safeguard confidentiality
9. Freedom to participate/withdraw	v. Post-research plan/benefit sharing
10. Identity of research team and contact persons	vi. Publication plan/photographs/pedigrees

Ref: ICMR Guidelines, Section 5, Informed Consent Process

Competence of the participant to be considered

- For adults above 18 years of age – informed consent
- For participants below 18 years of age – assent and parental consent

Other requisites of an ICP

- When individual not capable of giving voluntary written informed consent, an IEC approved LAR (legally authorized representative) can do so

- Mandatory to administer the consent before the initiation of the study procedures

- Privacy and confidentiality to be maintained at all stages

ICD must include…

- Written
- Oral
- Audio- visual

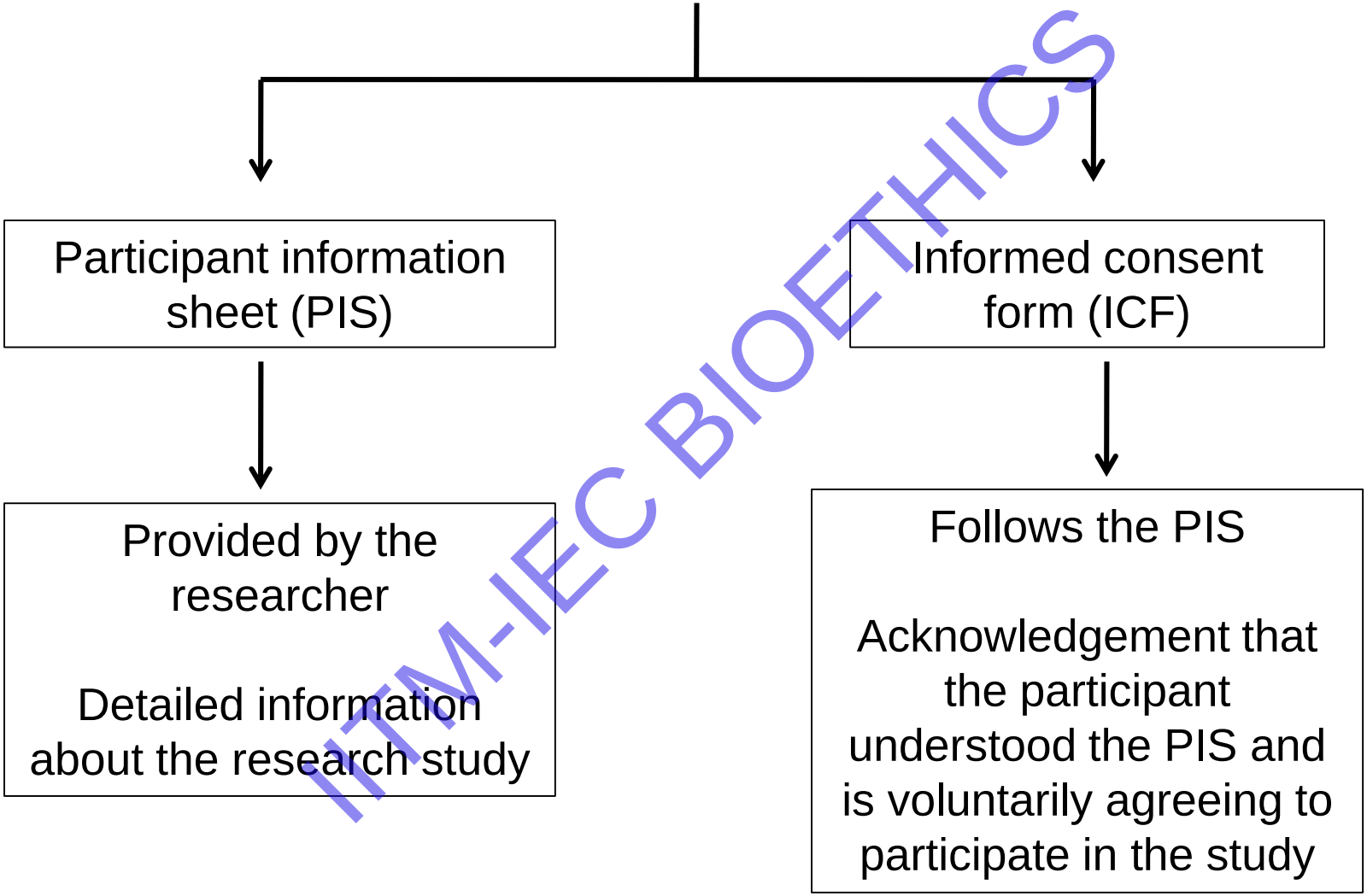
- Understandable language
- Alternatives to participation
- Statement that study involves research
- Expected duration of the project
- Confidentiality of records
- Sponsor of study
- Contact information
- Purpose and procedures including all invasive procedures

- Statement that consent is voluntary
- Risks & Discomforts
- Right to withdraw
- Benefits
- Consent for future use of biological material
- Compensation for participation

- Benefits if any on future commercialization
- Genetic basis for drug development
- Compensation for study related injury
- Nominee details

- If written consent is not obtained, give reasons:

Informed consent document



PARTS OF A PIS		
	INTRODUCTION TO STUDY	
	PURPOSE OF THE STUDY	
	DESIGN OF THE STUDY	
	STUDY POPULATION	CONTROL GROUP:
		STUDY GROUP:
	DURATION OF THE STUDY	
	STUDY PROCEDURE	
	RESULTS OF THE TEST	
	TREATMENT	
	FOLLOW UP	
	ADVICE DURING TREATMENT	
	POSSIBLE BENIFITS OF THE STUDY	
	WITHDRAWAL FROM STUDY AND REFUSAL TO PARTICIPATE	
	COST OF THE STUDY	
	PAYMENT FOR PARTICIPATION	
	CONFIDENTIALITY	
	CONTACTS	

INFORMED CONSENT FORM

I, _____have received the information sheet on the above study and have read and or/ understood the written information.

I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trail. I have been given the chance to discuss the study and ask questions.

I am aware that my participation is voluntary. I understand that I may withdraw any time without this affecting my future care.

I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

I understand that the information collected about me from my participation in this research and section of any of my medical note may be looked at by responsible persons (ethical committee / regulatory authorities).

INFORMED CONSENT FORM

I give access to the research personnel of this project to have access to my records.

I understand I will receive a copy of the patient information sheet and written inform consent form.

I understand that my identity will not be revealed in any report or publication.

I agree to take part in the above study voluntarily.

I agree for my left over samples to be used for future research purposes.

I decline for my left over samples to be used for future research purposes.

NAME OF RESEARCH PARTICIPANT	SIGNATURE/THUMB IMPRESSION	DATE
NAME OF THE IMPARTIAL WITNESS	SIGNATURE OF THE IMPARTIAL WITNESS	DATE
NAME OF THE PERSON ADMINISTERING CONSENT	SIGNATURE OF THE PERSON ADMINISTERING CONSENT	DATE

Responsibility of researchers

- Only IEC approved version of the PIS/ICF to be used (including all languages)
- Adequate information should be conveyed in a comprehensible manner
- Differently abled participants – appropriate methods to be used – eg: Braille
- No restriction of participant's right to ask questions
- No unjustifiable assurances, influence or intimidation

Responsibility of researchers

- Must ensure competency – medically / legally incompetent – LAR to sign – illiterate participant or LAR – impartial witness (not related to the participant) to sign
- The above should be documented – AV recording
- Ensure that patient-clinician relationship or any other treatment / benefits are not affected – participation / withdrawal / refusal
- Reimbursement / compensation – participation / related injury / death – as approved by IEC

Documentation of the ICP

- Signing of ICF is mandatory – participant / LAR / impartial witness
- Researcher administering the consent must also sign
- Institutionalized subjects – Head of the institution must also sign
- Additional consents – partner/spouse

  secondary family members

Waiver of consent

- Researcher has to apply to the IEC for waiver of consent
- Research should involve less than minimal risk
- Waiver is a must and is scientifically justified
- Retrospective studies – anonymised delinked
- Public health / programme evaluation studies
- Analyses of data from public domain
- Humanitarian emergencies / disasters – cannot give consent

Re-consent or fresh consent

- New information becomes available – impacts benefits / risk ratio
- Change in competence of the participant
- Child becomes adult
- Long-term follow up / amendment / extension / occurrence of new events

Post consent process

- A copy of PIS and signed ICF to be given to the participant
- Researcher is obliged to give details on confidentiality maintenance
- Original PIS / ICF should be archived

Assent for involving children

- Consent from LAR (If so, specify from whom)
- For children<7 yrs parental / LAR consent
- Verbal assent from minor (7-12 yrs) along with parental consent
- Written assent from minor (13-18 yrs) along with parental consent

Thank you