

INFORMED CONSENT



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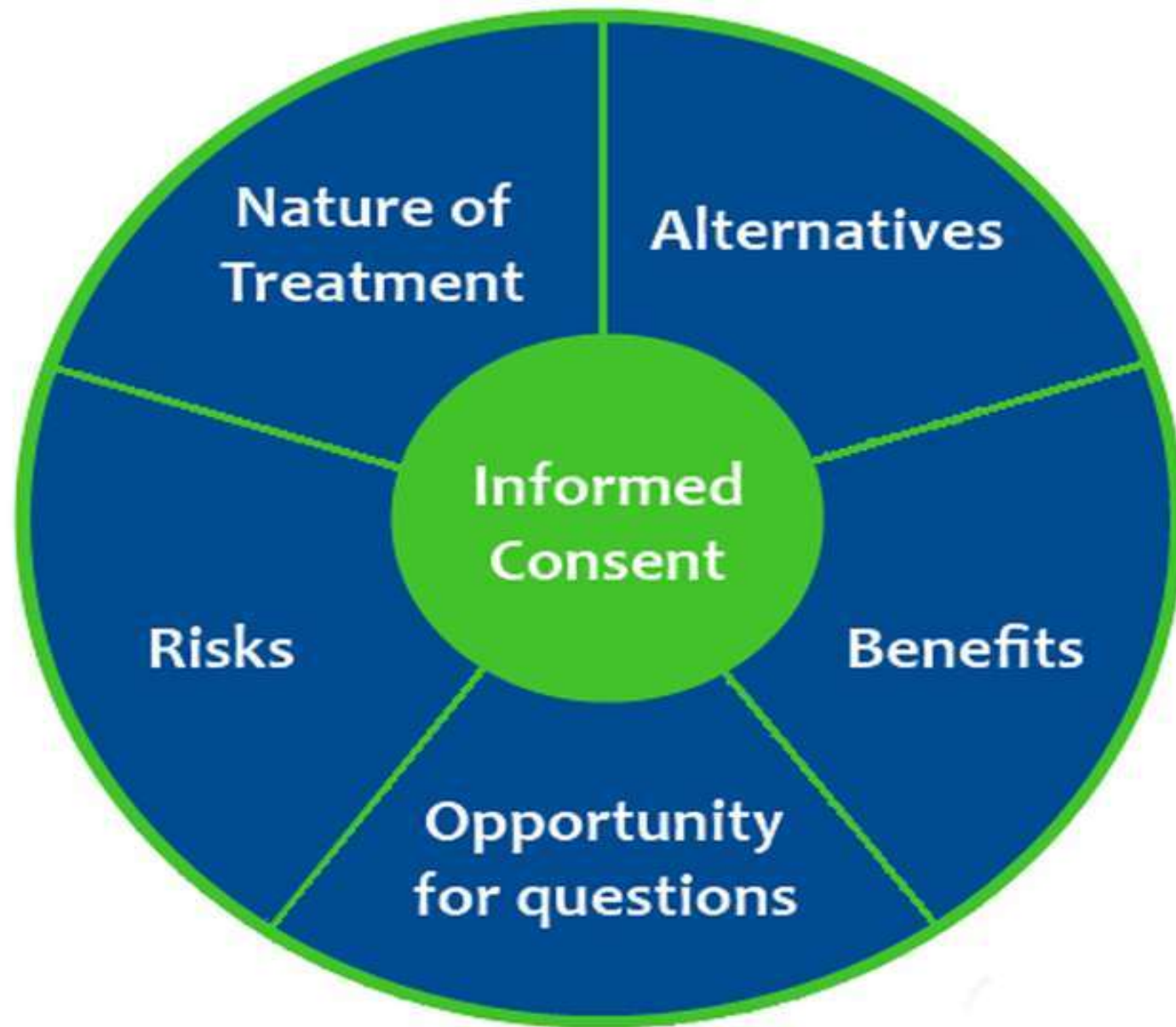
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Patients' informed consent is a legal regulation and a moral principle which represents patients' rights to take part in the clinical decisions concerning their treatment.

- <https://youtu.be/xTIdmv2VzNs>

**THREE
IMPORTANT
POINTS:**

- IT MUST BE VOLUNTARY
- IT MUST BE INFORMED
- THE INDIVIDUAL MUST BE CAPABLE OF GIVING CONSENT.



What are the Main Barriers to Effective Informed Consent?



Patient language and cultural issues



Poor quality of consent form



Patient inability to comprehend



Clinician inability to detect patient's lack of comprehension

DR KHARE *VERSUS* DR KHOTE



DOCUMENTATION ERRORS



INFORMED CONSENT FORM TO PARTICIPATE IN A CLINICAL TRIAL

Study Title: A Phase IV, Randomized, Controlled Study of the Safety and Immunogenicity of [REDACTED] Post-exposure Prophylaxis regimen in Patients with Potential [REDACTED] Exposure.

Protocol Number: [REDACTED]

Screening Number: 04-0400	Participant's Name: Dr. Vijaya Sandeep Gunjal	
Date of Birth/Age: 16-01-2000	Sex: Male/Female	
Participant Address	1983 BB, Customs Quarters, Katrak Road, near Wadala Church, Mumbai - 31.	
Qualification (of the participant)	MBBS MD	
Occupation (of the participant)	Student <input checked="" type="checkbox"/>	Self Employed
	Service	Housewife
	Others	
Annual Income (of the participant)	Not applicable	
Nominees for purpose of compensation in case of trial related death	Sandeep B. Gunjal	
Relationship of nominee with the participant	Husband	
Address of Nominee	same as above	
Contact details of Nominee	9123456789	

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Basic elements of Informed Consent

- Purpose of the research
- Duration of the study
- Frequency of visits
- Procedure
- Findings
- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensation for Injury
- Who to Contact
- Right to refuse or withdraw
- Voluntary participation

IMPARTIAL WITNESS

- A **literate** person
- Who understands the **same language** as the participant/his LAR
- Who is **independent** of the research (**not connected/related** to the research/ research team)
- Would **not be unfairly influenced** by people involved with the study
- **Who is not a relative of the participant/his LAR**
- Who attends the informed consent process if the participant and/or their LAR cannot read, and understand the informed consent form and any other written information supplied to the participant
- Who should be **present throughout the consent process** as witness
- Who **fills the informed consent form** on behalf of the illiterate participant

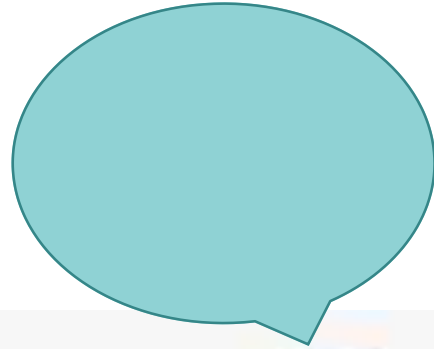


SUPPOSE

Trial

- Potential volunteer- Preferred **Hindi** language for reading, listening & writing

NEVER filled by PI or Co-I apart from his sign, date & time





SUPPOSE

Trial

- Potential volunteer-Preferred **BENGALI** language for reading, listening & writing

Do NOT consider such participants for the trial

SUPPOSE



Trial

- **Four** potential volunteers are available today for consenting at 10am
- All four potential volunteers- Prefer **Marathi** language for reading, listening & writing

Never do group consenting- Issues of privacy & confidentiality

SUPPOSE

Trial

- Recruited till today= 5
- One potential volunteer is waiting for the consent
- The potential volunteer- Prefer **Hindi** language
- EC approved travel reimbursement per visit= **Rs1000/-**





SUPPOSE

- Always by the PI or Co-I (competent person)
- Always inform both risks as well as benefits of the trial participation
- Never influence the participant
- Respect confidentiality of the participants
- Never give wrong information



SUPPOSE

Trial

- In a **pediatric** population
- Age group **>2 to <15** years
- The potential volunteer with age of **8 years** and preferring **Hindi** language

Scenario I



Consent

In a **non adult**
population (age <18yrs)

Age <7yrs- **Parents/LAR**

Age >7 but <12yrs-
Parents/LAR + Verbal assent

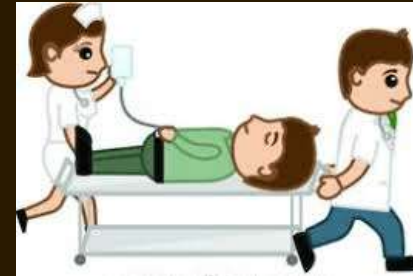
Age >12 but <18yrs-
Parents/LAR + Written assent

Re-consent or fresh consent

Re-consent is required in the following situations when:

- **new information** pertaining to the study becomes available which has implications for participant or which changes the benefit and risk ratio;
- a research participant who is **unconscious regains consciousness** or who had suffered loss of insight regains mental competence and is able to understand the implications of the research;
- **a child becomes an adult** during the course of the study;
- research requires **a long-term follow-up or requires extension**;
- there is **a change in treatment** modality, procedures, site visits, data collection methods or tenure of participation **which may impact the participant's decision** to continue in the research; and
- there is possibility of **disclosure of identity** through data presentation or photographs (this should be camouflaged adequately) in an upcoming publication.
- the **partner/spouse** may also be required to give additional re-consent in some of the above cases.

Reconsent





**You as
Investigator**



- You are conducting a clinical trial on the patients of newly diagnosed hypertension at your institution.
- While recruiting the participant, you want to take a written informed consent from an adult male **illiterate** participant.
- If you are the Principal Investigator, how will you obtain and record the consent from this participant?

Discussion time



- After obtaining the IEC approval for your clinical trial, you want to recruit the participants in your clinical trial which involves the study group as **paediatric** patients.
- If you are the Principal Investigator, how will you obtain and record the consent from the participants?
 - Age <7yrs
 - Age 7-12yrs
 - Eventually becomes 18 yrs

Discussion time



THANK YOU...