Ensuring Autonomy: Consent, assent & dissent in Paediatric Research

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Overview

- What is autonomy
- Informed consent
  - Who, when, where, how
- Informed assent
  - Who
  - Age appropriate
- Waiving off parental consent
  - When
  - Why
  - How

Respect for persons (Autonomy)

- Involves -
  - Autonomy - freedom of action
  - Protection of those with diminished autonomy
- Takes into account and gives consideration to the individual's views on taking part in research
- Guarantees right to self determination
- Related to the process of informed consent

Informed consent

Informed consent

- For all research (clinical trials, epidemiological research) involving humans the principal investigator must obtain the voluntary informed consent from the prospective subject
- Responsibility of obtaining such consent lies with PI

Informed consent

- In the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law

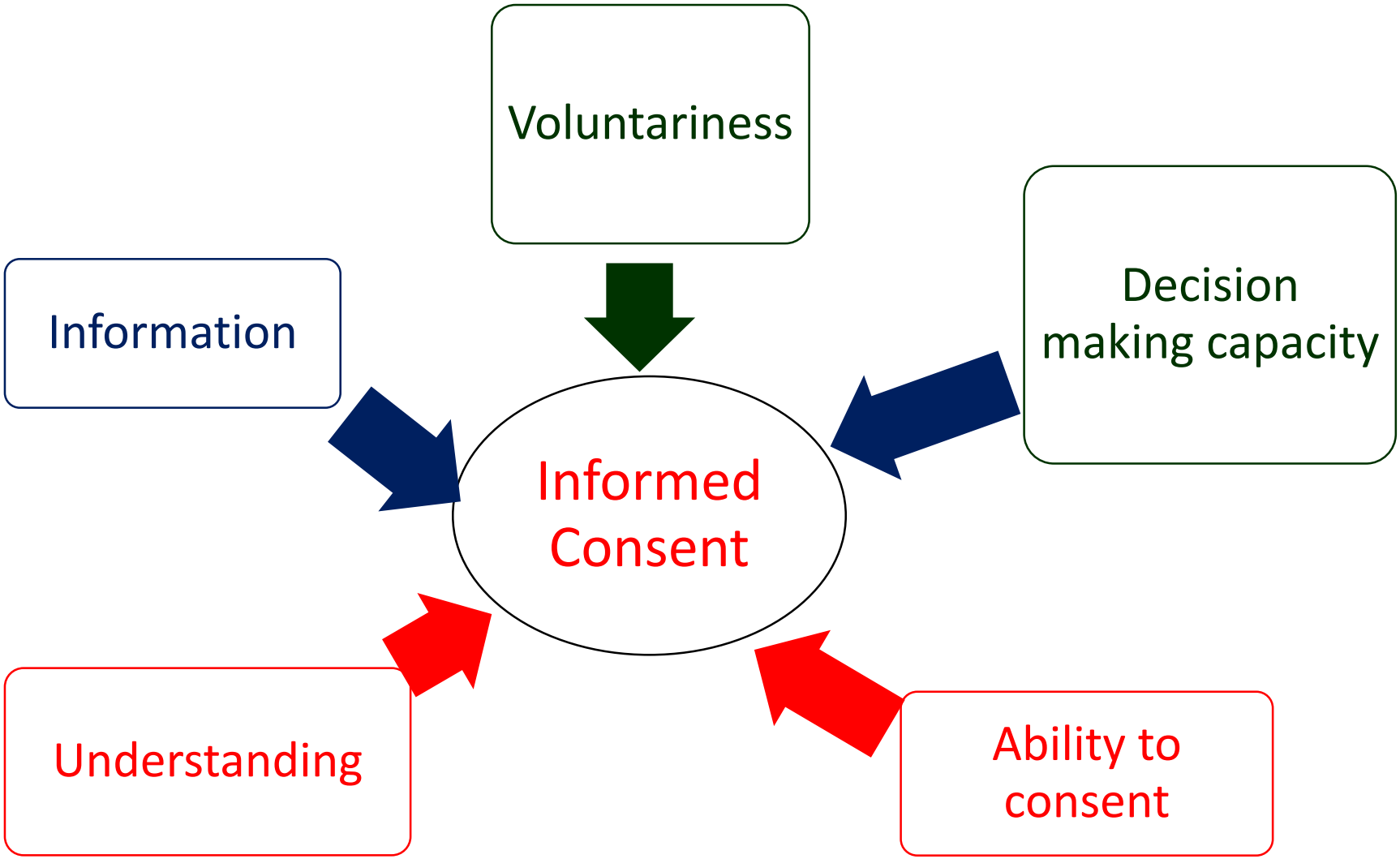
Informed consent

- Waiver of individual informed consent is to be regarded as exceptional, and must in all cases be approved by an ERC unless otherwise permitted under national legislation
- If a waiver is requested, PI should justify it

To obtain informed consent.....

- Information provided should be relevant
  - Need to change if new information is received
  - May need re-consenting
- In a manner that it is understood
- Avoid unjustified deception or withholding of relevant information
- Avoid undue influence or coercion
- Time to ask questions/ clarify doubts

Informed consent is a process.



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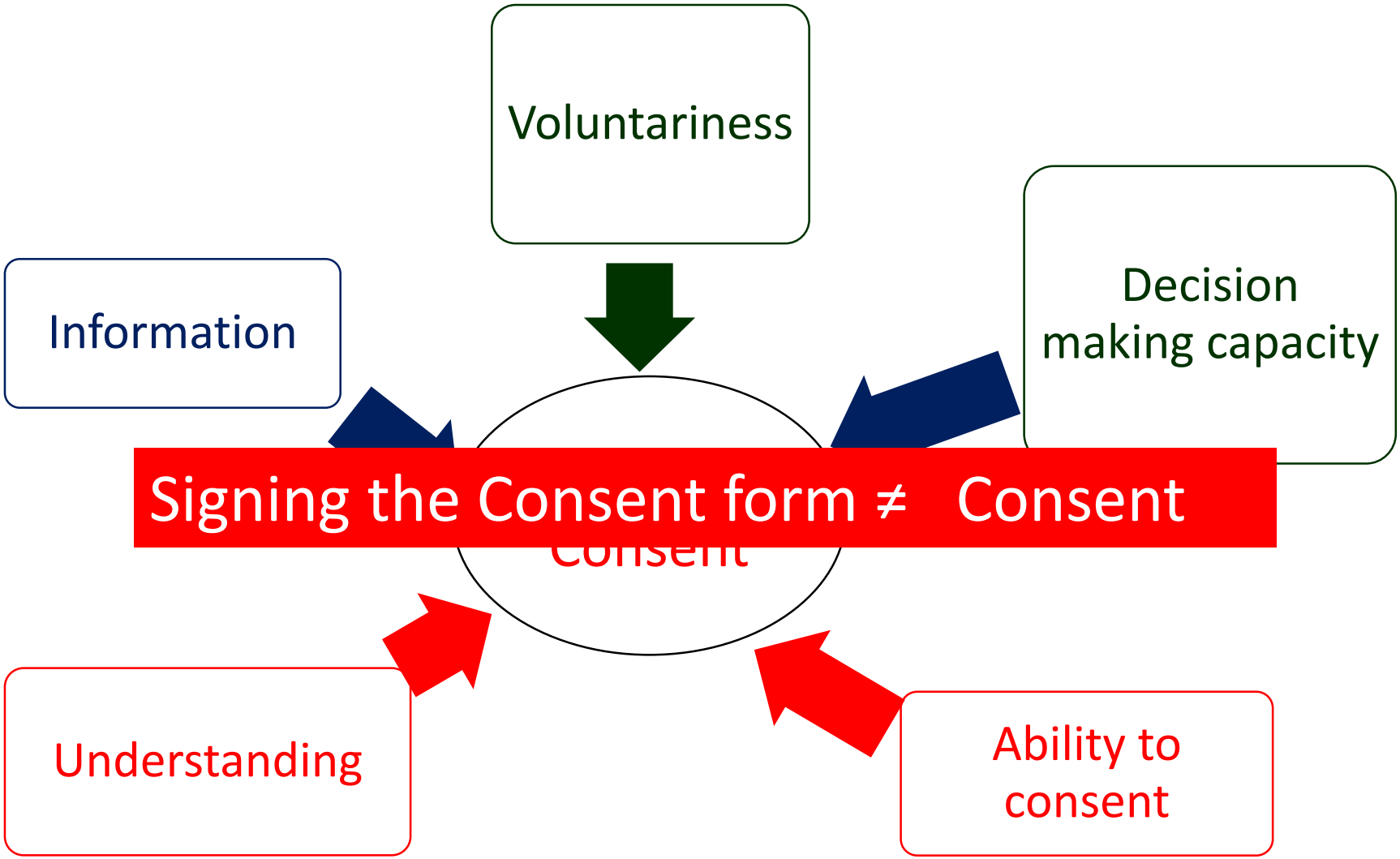
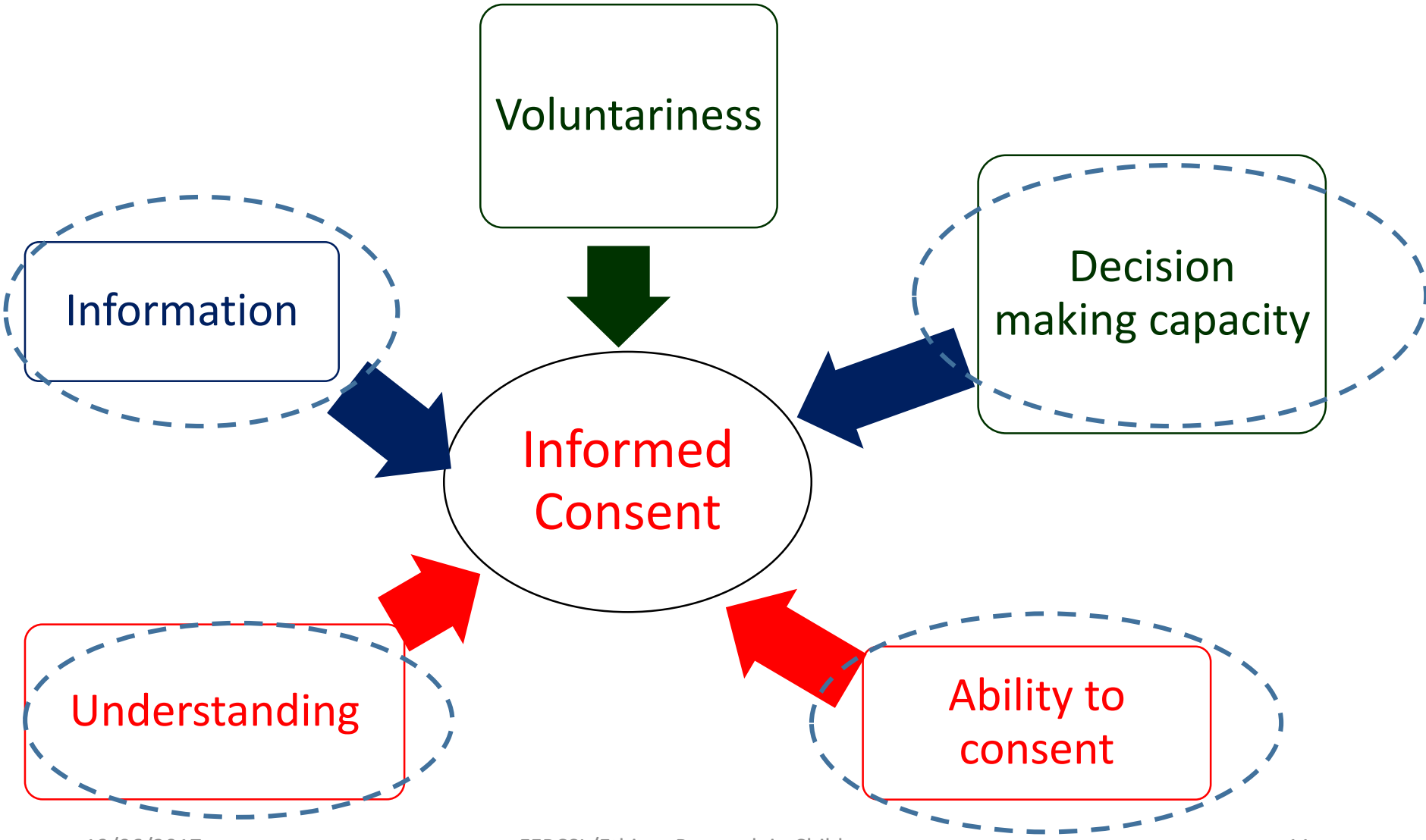


Informed consent in children



Capacity to consent

- For adults we assume capacity unless we have evidence to the contrary; for children we assume the opposite.

Children/Minors

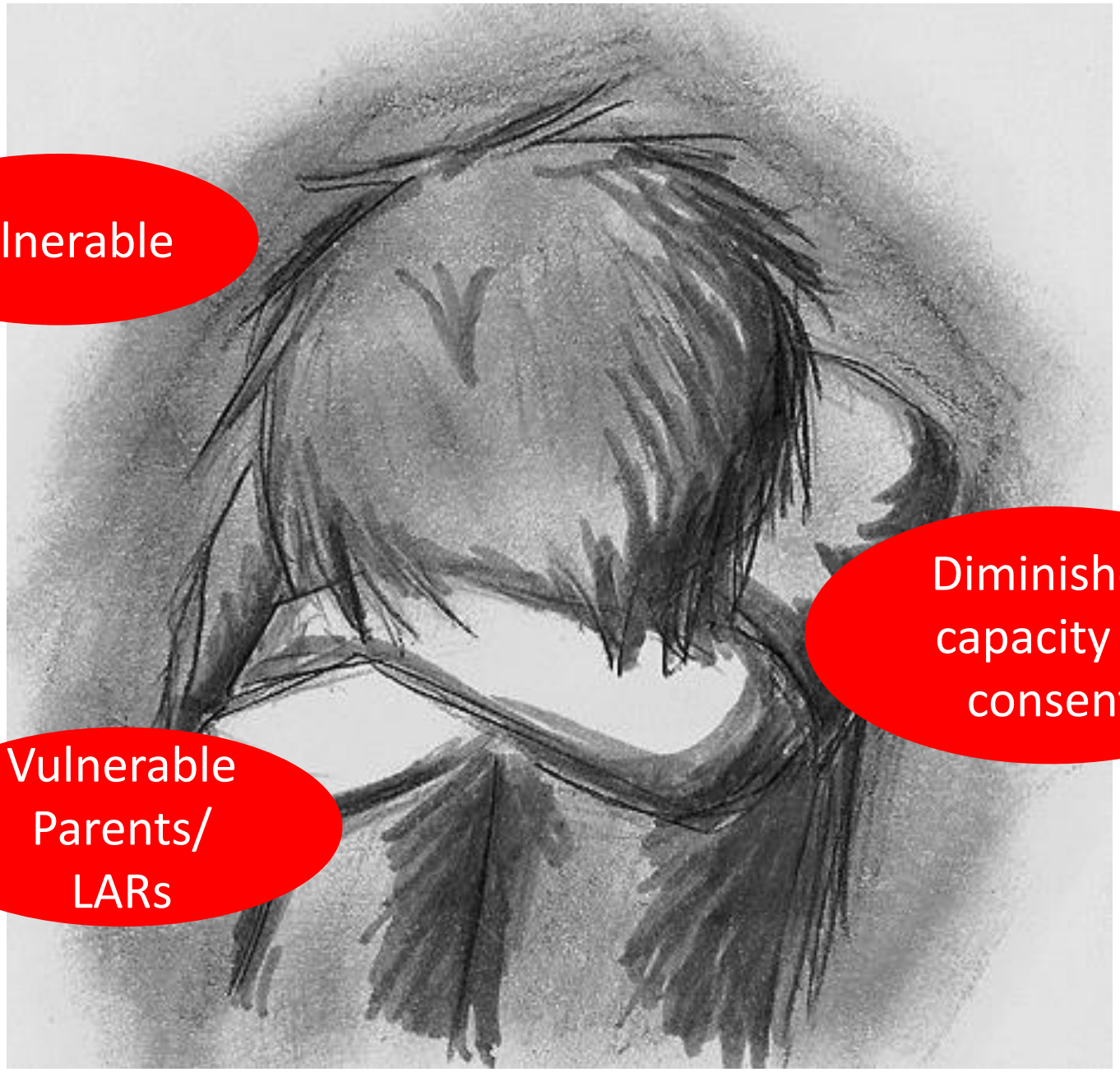
- Persons who have not attained the legal age to consent for research
  - in Sri Lanka anyone under the age of 18 is a child

- When children are involved in a research activity it is necessary to obtain their assent and consent of their parents.

Children

- Consent from parent/ legal guardian – a MUST
- Assent from those who are capable of understanding what will be done
  - Absent of dissent ≠ assent
- Dissent/deliberate objection of a child MUST always be respected despite parental consent

Consenting for children


Vulnerable
Diminished capacity to consent
Vulnerable Parents/ LARs

Need for parental/ LAR's permission

- To ensure that vulnerable children are protected from research risk


You must sign for your child.

Consenting for the child

- Who can consent/ give permission
  - Parents - one or both?
  - Legally authorised representative
- What does this consent entail?
  - Long term activities/ follow up
- Where and how is the consent obtained

Parental permission/consent form

- Should be appropriately designed
- Should clearly state what is expected of the child and parent
- Should clearly state what the parent is consenting for on behalf of the child
  - "I give permission for my child to take part in the study"- Unacceptable

Informed assent

Assent

- Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Assent by minors

- Children - 8-12 years
  - < 8 yrs - would lack the capacity to understand what it entails, parental consent alone is sufficient
  - 9 yr-olds - can understand risk and benefits but are less able to consider multiple conflicting points

Assent by minors

- Adolescents/ youth - 12-18 years
  - Mid- and late adolescents (≥ 14 yrs) - understanding of research and the cognitive ability to make decisions about research participation are similar to these abilities in adults
  - 14-year-olds - as skilled as adults in understanding multiple viewpoints and in considering conflicting information

    - *Weithorn LA. Children's capacities to decide about participation in research. IRB 1983;5:1–5.*

Assent by minors

- To give assent the child or adolescent should
  - engage meaningfully engaged in the research discussion
  - be involved in the actual decision making process
  - in accordance with his/her capacities

Assent

- The process of obtaining assent must take into account
  - the age of children
  - their individual circumstances, life experiences, emotional and psychological maturity
  - intellectual capabilities of child
  - the child's or adolescent's family situation

Assent

- If children reach the legal age of maturity during the research, their consent to continued participation should be obtained
    - If they now refuse consent.....?

Assent forms

- Age appropriate

- Use of templates - adapted appropriately
- http://www.who.int/rpc/research_ethics/informed_consent/en/

- When you “copy-paste”.....

Deliberate objection

- Is an expression of disapproval or refusal of a proposed procedure
  - Verbal or non verbal

- A deliberate objection by a child or adolescent to taking part in research must be respected even if the parents have given permission

Overriding deliberate objections in reserach

- The minor needs treatment that is not available outside the context of research
- The research intervention
  - has a clear prospect of clinical benefit

  and
  - the treating physician and the LAR consider the research intervention to be the best available medical option for the minor
- Parent or guardian may override the child`s objections
  - Parents' interests < child's interests

Waiver of parental permission

Waiver of parental permission

- ERC should decide
- Waiver should be consistent with existing laws

- E.g.
  - In instances where waiver would not adversely affect the rights and welfare of the subjects, and the research involves no more than minimal risk.
    - Use of existing medical records

Waiver of parental permission

- ERC should decide
- E.g.
  - When parents' permission is not feasible
    - Parent not fit to consent
  - When parents' permission is undesirable to protect subject
    - Studies on abuse, domestic violence, sexual behaviours of children

Waiver of parental permission

- When parents' permission is undesirable to protect subject
  - Studies on child abuse, domestic violence, sexual behaviours of children, drug use

- Special protections must be devised to ensure that the best interests of these children or adolescents are being served

"Emancipated" or "mature" minors

- Are authorized to consent without the agreement or even the awareness of their parents or guardians
  - Married/ are parents themselves/ pregnant
- Not legally valid in Sri Lanka

For studies in children

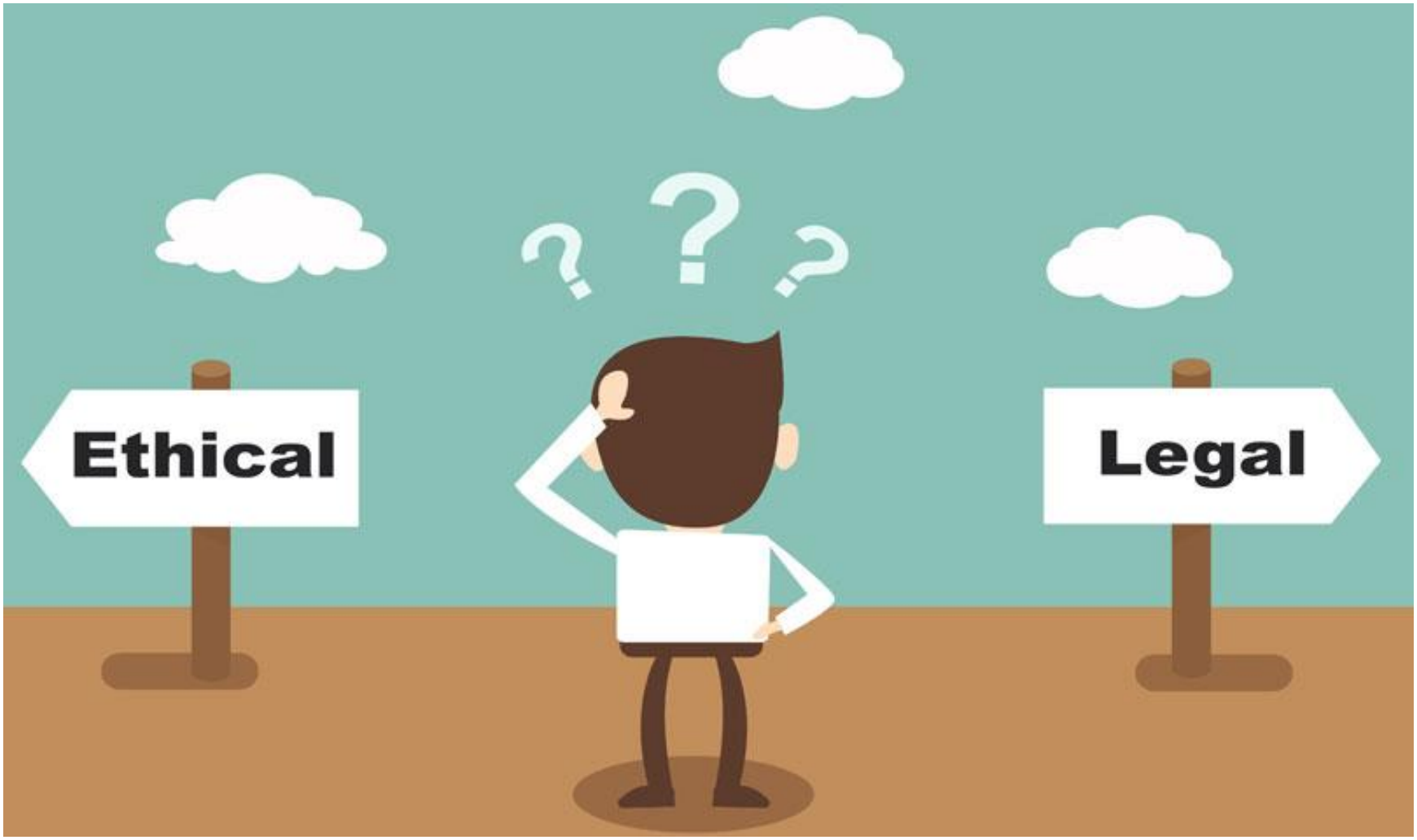
- Parental (LAR) Information sheets
- Parental (LAR) permission/consent forms
- Information sheets for children (7 -12 years) and adolescents (12 - 18 yrs)
- Assent forms for minors

- In English and appropriate local languages

Summary

- What is autonomy
- Informed consent
- Informed assent
- Waiving off parental consent

- How autonomy of minors should be maintained


Ethical
Legal