- Workshop: Ethics Workshop for Researchers
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- Presentation: What ERCs consider in Biomedical Research
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What ERCs consider in Biomedical Research

Chandanie Wanigatunge

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The conduct of research is ethical if it will contribute valuable and relevant knowledge that promotes health and well-being.

- Declaration of Helsinki

Let's put on the ERC hat……..

Eight ethical requirements

Requirement	Justifying ethical values
1. Social value	Scarce resources and non-exploitation
2. Scientific validity	Scarce resources and non-exploitation
3. Fair subject selection	Justice
4. Favourable risk-benefit ratio	Nonmaleficence, beneficence and nonexploitation

Eight ethical requirements

Requirement	Justifying ethical values
5. Informed consent	Autonomy
6. Respect for human subjects	Autonomy
7. Independent review	Public accountability, minimizing influence of potential conflicts of interests
8. Collaborative partnership	Justice, Scarce resources and non-exploitation

1. Social or scientific value

- Will research contribute valuable and relevant knowledge that promotes health and well being?

"Who, What, How?"

Check……

- Beneficiaries of the research (Who?)

- Assess the importance of the health problems being investigated and the prospective value of the research for the beneficiaries (What?)

Check....

- How the value of the research has been enhanced for the beneficiaries
  - through dissemination of knowledge
  - product development
  - long-term research collaboration
  - health system improvements

(How?)

- Background/Justification section of the research proposal should address these issues in a manner comprehensible to those without specialized scientific knowledge of the (clinical) issues under consideration

2. Scientific Validity

- Research should be designed to produce beneficial and generalizable knowledge

- Design should be such that it can be feasibly implemented in the settings where it will be conducted

Scientific validity

"Research involving human participants, (or human tissue and data) is justified and valid only when the design of the research is scientifically sound

and

the principal investigators and the other research personnel are competent."

- Declaration of Helsinki

Scientific validity

"Scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit"

- CIOMS 2010

Scientific validity

- The methods to be used should be appropriate to the objectives
- Should display a thorough knowledge of the scientific literature
- These should be adequately reflected in the research proposal submitted for review and approval to the ERC

Check……..

- Objectives
  - General
  - Specific

Check ……

- Methodology
  - Study design – can the given objectives be achieved?

Check ……

- Study population
  - Inclusion / exclusion

- Must be based on science and not on convenience

Check ……

- Methodology
  - Sample size

Check ……

- Methodology
  - Sampling
    - Purposive /non-probability sampling - unscientific
  - Details of allocation/ randomization

Check …….

- Data collection method
  - Tools – do they meet the needs/objectives?
    - Are these validated?
    - Questionnaire

Check……

- Method of data analysis
  - A researcher collects data using a questionnaire with 80 questions/variables and plans to analyse only 15 of these variables

3. Fair Subject Selection

- Should not be chosen merely because they are convenient

- Excluding specific groups for convenience

Check…….

- Study population
  - Is this the best population to address the research question?
  - Are there vulnerable groups involved?
    - Can the study be done in another population

4. Favourable Risk benefit ratio

- Minimize risks
- Enhance benefits
- Potential benefits to individual or society outweigh the risks

No research is risk free.

Types of risks/harms

- Physical – with experimental research
- Psychological – with behavioural research
- Invasion of privacy
  - involves either covert observation or "participant" observation of behavior that the subjects consider private

Types of risks/harms

- Breach of confidentiality
  - When records are assessed
- Social
- Economic

Check ……

- Methodology
  - Safety - of the product, evidence

Check……

- How risks have been assessed and addressed in the protocol

- *"Taking part in this study involves no risks."*

- Any coercion/ undue benefits
- *"By taking part in this study your wound will be assessed more often." (from an ICF) - needed? true? usual practice?*

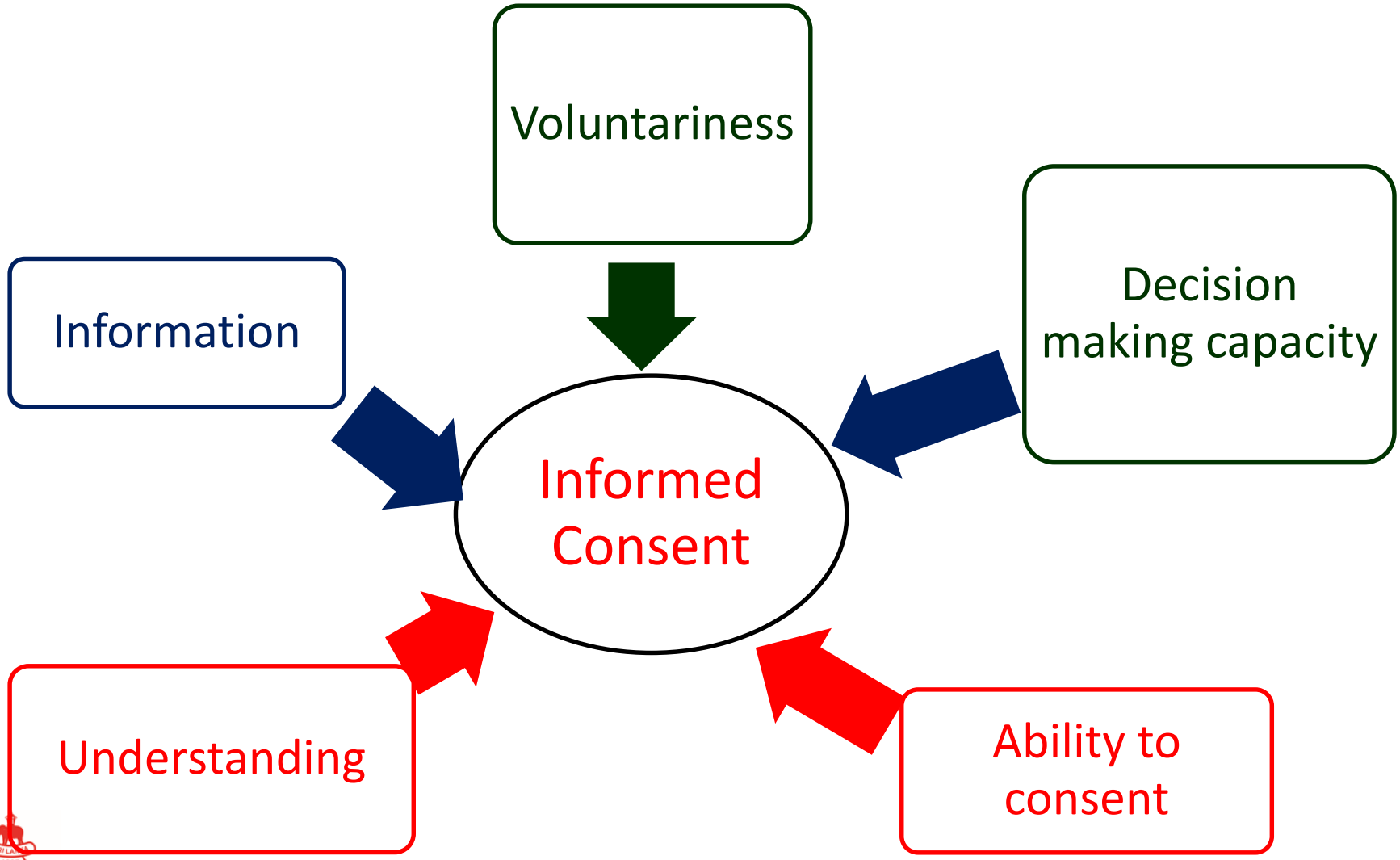
5. Respect for potential or enrolled subjects

- Privacy, autonomy, respect for cultural norms
- Confidentiality
- Ability to withdraw without penalty
- Alternatives available

6. Informed consent

- Providing information
- Obtaining consent

Informed consent is a process.



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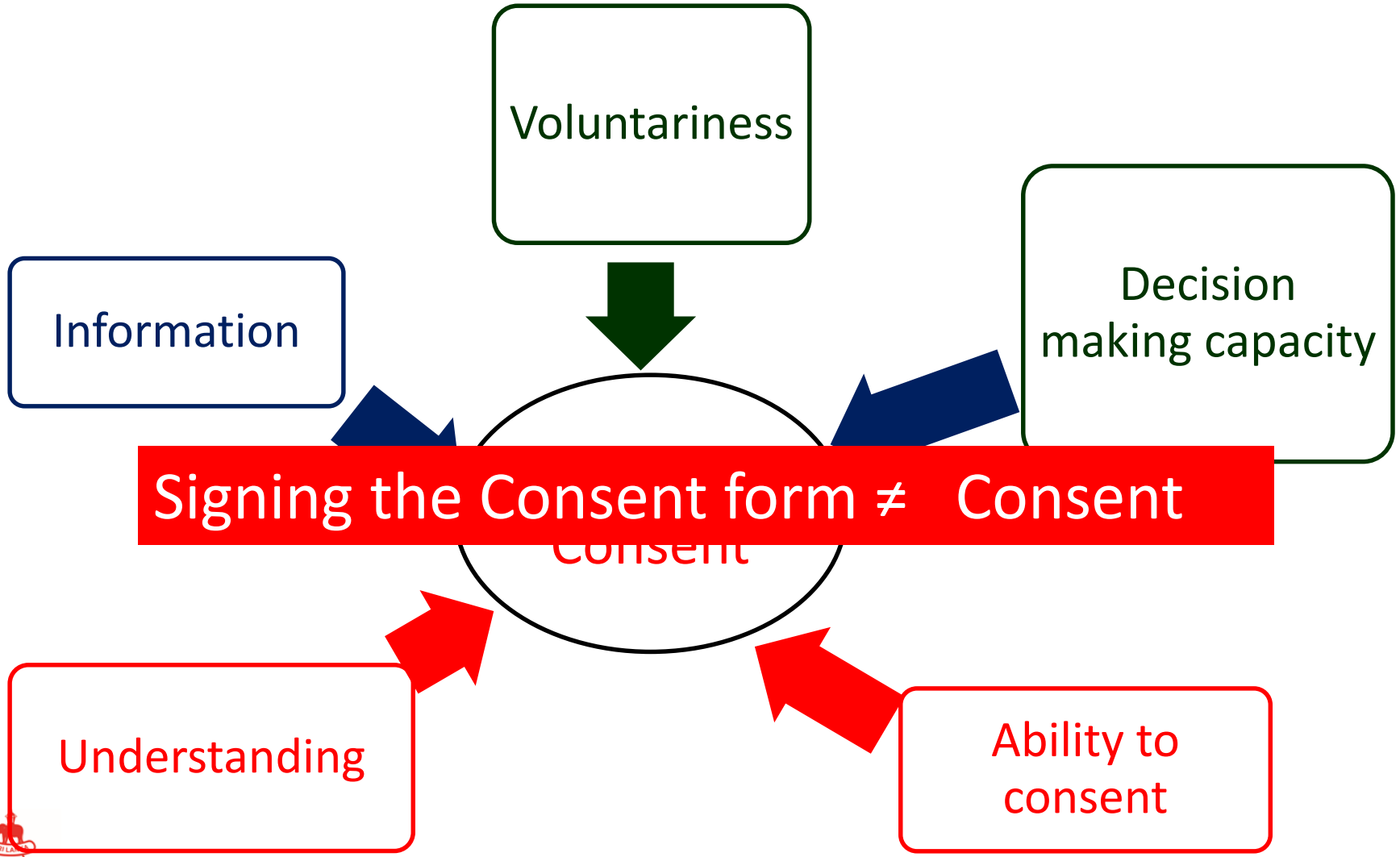

Check ……

- Information sheets
  - Information given
  - Language used
  - Information sheet should contain all what a "reasonable person" would want to know to take part in the study
- Consent forms
- Assent forms

7. Independent Review

- Occurs through multiple groups
  - Funding agencies, ERCs/IRBs, Data and safety monitoring boards
- Is needed
  - Because the legitimate interests of the researchers may create a potential conflicts of interests
  - These conflicts may unwittingly distort the judgement of the researcher

Check ……

- Conflict of interest statement in the application

- ERCs should have a clear protocol on how ERC would handle a COI of its members

8. Collaborative partnership

- Who are the collaborators
- What are the agreements with them

Check …….

- Details of collaborators
  - CVs if necessary

- Agreements with them
  - Material transfer
  - Data ownership
  - Patent rights
  - Publication rights

Check……

- Conflict of interest statement in the application
- Any COI among ERC members

Finally……

- Do NOT assume anything
- If it is not written – It IS NOT KNOWN and will NOT BE DONE

Title

"Low cost radio-metacarpal external fixator for comminuted displaced distal radius fractures"

Objectives

2.1 To assess the stability of the low cost wrist spanning radio-metacarpal external fixator among the patients who are managed at XXY.

2.2 To assess the outcome of the low cost radio-metacarpal external fixator among the patients who are managed at XXY.

2.3 To describe the limitations of the low cost radio-metacarpal external fixator with the view of further modifications

4.1 Study design:

- The study consists of three components.
- Component 1: Cross sectional study to get the preliminary data on stability and the outcome of the newly invented low cost wrist spanning radio-metacarpal external fixator for comminuted displaced distal radius fractures among the 10 patients in whom it has been used. This is done to get the necessary event rates to calculate the sample size for component 2.
- Component 2: Quasi experimental study (Non-randomized clinical trial) to properly evaluate the objectives No.1 and 2.
- Component 3: A qualitative study to achieve objective 3.

7. Conflicts of interest:

- This device was invented by the principal investigator and has applied for patent under his name. Yet there is no financial interest and the innovation was done with altruism for the benefit of the patient