Appropriate Consent General Requirements - Section 6, HBRA

"Appropriate consent" must be obtained:

1. In **writing**;

2. From the subject or tissue donor **personally** (For certain special groups of subjects and donors such as minors and subjects lacking mental capacity, the HBRA spells out the persons who are authorised or additionally required to give their consents for the subject's participation or tissue donation)

3. After subject is **given full explanation** on research & expected involvement

4. **Prior to involvement** of subject (intervention/use of health information or biological material) or tissue donation

5. In the presence of a **witness**

Witness must be older than 21 years, have mental capacity and not be the person taking consent (Can be a research team member)

Exemption from the requirement for witness if the research is :

a) Not invasive;
Procedures that are incisional ie. cutting into tissues of the body. Examples are skin prick tests and venipuncture.

b) Not interventional
Definition of 'interventional': Procedures not primarily for diagnostic or therapeutic purposes which have any physical, mental or physiological effect (temporary or permanent) on the body of the research subject;

and

c) Not restricted human biomedical research

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