Ministry of Health and Sports

Ethical Considerations for Human Research Participant Protection:  
*Informed Consent*

Dr. Min Wun  
Member (IRB DMR)  
Secretary (IRB DFDA)
What is informed consent?

- a communication process between the researcher and the participant.
- starts before the research is initiated and continues throughout the duration of the study.
- consent given by a competent individual
- understood the necessary information
- without having undue influence or inducement, or intimidation
- after having decided (given enough time)
What is informed consent?

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate.

*ICH GCP 1.28*
3 Fundamental Aspects of Informed consent

**Voluntariness**
- not be influenced by anyone

**Comprehension**
- Individuals must have the mental or decisional capacity to understand the information

**Disclosure**
- provides necessary information in order to make an informed decision

Dr. Min Wun, DFDA (8 July 2020)
<table>
<thead>
<tr>
<th>CONSENT IS NOT:</th>
<th>CONSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed</td>
<td>Freely Given</td>
</tr>
<tr>
<td>Coerced</td>
<td>Reversible</td>
</tr>
<tr>
<td>Implied</td>
<td>Informed</td>
</tr>
<tr>
<td>Convinced</td>
<td>Enthusiastic</td>
</tr>
<tr>
<td></td>
<td>Specific</td>
</tr>
</tbody>
</table>
Informed Consent Form has two parts:

Part I - Information Sheet
to give information about the research

Part II - Certificate of Consent
for participant to sign if agree to take part
Informed Consent:

- and any other written information to be provided to participants; any revised written informed consent document and written information should receive the IRB’s approval in advance of use;

- should not contain language that causes the participant to waive any legal rights, or release the investigator, institution or sponsor from liability for negligence;

- language used during the informed consent process should be as non-technical as practical.
Prior to participation in a trial, the written informed consent document should be signed and personally dated by the participant, or their legally acceptable representative, and also by whoever conducted the informed consent discussion.
Part - I  Information Sheet

(1) Introduction  (8) Benefits
(2) Purpose  (9) Incentives
(3) Type of Research  (10) Confidentiality
    Intervention  (11) Sharing the Results
(4) Participant Selection  (12) Right to Refuse or
    Voluntary  Withdraw
    Participation  (13) Alternatives to
(5) Procedures  Participating
(6) Risks & Discomforts  (14) Who to Contact
informed consent
CONSENT CAN BE WITHDRAWN AT ANY TIME.

YES YESTERDAY DOESN'T MEAN YES TODAY.
Waiver of Signed Informed Consent

1. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

Even documentation requirement is waived, the investigator must provide participants with a written statement regarding the research

Dr. Min Wun, DFDA (8 July 2020)
Alter or Waive some or all of the elements of consent

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
WHO  When  Where
Questions, Comments and Suggestions would be greatly appreciated!