

Informed Consent & Re-Consent

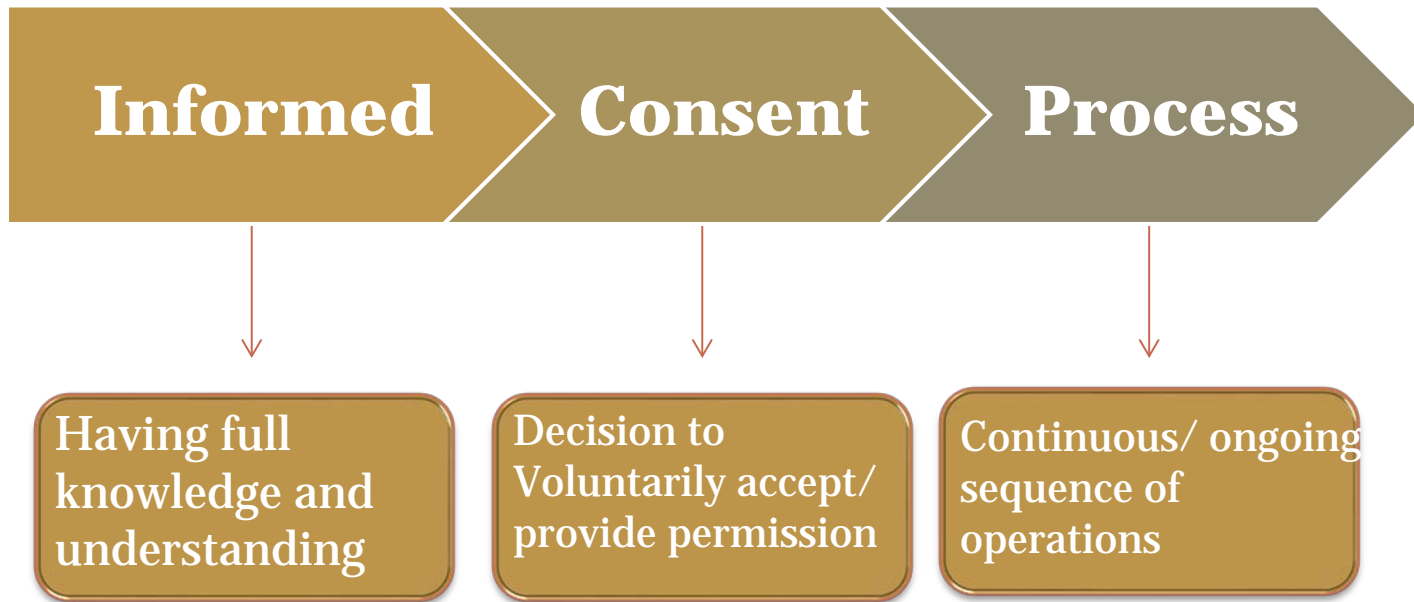


VCU

VIRGINIA COMMONWEALTH UNIVERSITY

Office of Research & Innovation – Human Subject Protection

Informed Consent



- **Ongoing process**
- **Make sure subjects fully understand**
- **Voluntary**
- **No coercion**

Regulations

- **21 CFR 50.20 (FDA)-- 45 CFR 46.116 (HHS)**
 - An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider **whether or not to participate** and that **minimize the possibility of coercion or undue influence**.
 - No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or **appear to waive any of the subject's legal rights**, or **releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence**.

Informed Consent Document

- Use “lay language” – understandable age/ability level vocabulary
- Include all elements of consent (unless some or all waived) – every effort should be made to include any and all elements
- Use templates provided by VCU
- Do not overstate benefits
- Not coercive

Basic 8 Elements of Consent

- Statement that the study **involves research**, an explanation of the **purposes of the research** and the **expected duration** of the subject's participation, a **description of the procedures** to be followed, and identification of any procedures which are experimental;
- Description of any reasonably **foreseeable risks or discomforts** to the subject;
- Description of any **benefits to the subject or to others** which may reasonably be expected from the research;
- Disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the subject;
- Statement describing the extent, if any, to which **confidentiality of records** identifying the subject will be maintained (and that notes the possibility that the Food and Drug Administration may inspect the records - if the research is FDA-regulated);
- For research involving more than minimal risk, an explanation as to whether **any compensation** and an explanation as to whether **any medical treatments are available if injury occurs** and, if so, what they consist of, or where further information may be obtained;
- An explanation of **whom to contact** for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- Statement that participation is **voluntary**, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Problems

- To Avoid:
 - Reliance on the form, lack of interaction
 - Fixed point, not ongoing
- Information outside the scope of the research
 1. Therapeutic misconception
 - Misrepresentation of research as therapy
 - Overstatement of benefit
 2. Undue influence [45 CFR 46.116](#)
 - Potential to alter decision-making process such that subject may not appropriately consider risks
 3. Exculpatory language [45 CFR 46.116](#)
 - Subject waives or appears to waive legal rights

The Initial Process

- Obtain subject's voluntary informed **consent** to participate, **prior to any** study activity
- Always use the most **current** IRB-approved documents
- Give the subject **information** about the research
- Make sure all information is **understood** by subject
- Make sure the subject has **time** to consider all options
- Answer all of the subject's **questions** before deciding

The Ongoing Process

- **Subject (and you) sign and date consent form**
- **Give subject copy of signed consent form**
- **Document the informed consent process**
- **Continue to inform the subject throughout the study**
- **Continue to re-affirm subject consent**

Documentation of informed consent (46.117)

- Informed consent shall be documented by the use of a written consent form approved by the IRB and signed **by the subject** or the subject's **legally authorized representative**. A copy shall be given to the person signing the form
 - (1) full written consent document OR
 - (2) “short form” document to be used in conjunction with full consent document, and summary of an oral presentation of the informed consent process.
- Needs to be justified & witness must be present for oral presentation-will sign short form consent AND a copy of the summary

Special Populations

- **Minors**
- **Limited Decision-Making Capacity**
- **Blind or Illiterate**
- **Non-English Speaking**

Waiver of Consent [45 CFR 46.116]

- **ALL of these requirements must be met to waive ALL or SOME elements of consent:**
 - The research involves no more than minimal risk to the subjects:
 - The research could not practicably be carried out without the waiver or alteration
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects:
 - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Informed Consent

	Includes All Elements of Consent	Includes Some Elements of Consent	Includes No Elements of Consent
The participant WILL sign	No Waiver	Waiver of Some Elements of Consent	Full Waiver
The participant WILL NOT sign	Waiver of Documentation of Consent	Waiver of Documentation of Consent Waiver of Some Elements of Consent	Full Waiver

Consent and the Recruitment Process

- When accessing information about prospective subjects for recruitment purposes, a waiver of informed consent for recruitment should be requested
 - IRBs routinely approve this type of waiver, given the typically very low risk to subjects of investigators accessing personally identifiable information

Consent and the Screening Process

- For some studies, screening tests to assess eligibility are required
 - e.g. questionnaires, blood draws to determine eligibility, withdrawal from medication (wash-out), etc.
- Screening procedures “are considered part of the subject selection and recruitment process and, therefore, require IRB oversight”
- A separate screening consent or the inclusion of screening procedures in the study consent form is appropriate
 - If you are screening subjects via telephone or online questionnaire, you may be able to request a waiver of documentation of consent

When might Re-Consent be Applicable?

- 45 CFR 46.116 (b)(5) and 21 CFR 50.25 (b)(5) state that, when appropriate, the informed consent document include a statement that “**significant new findings** developed during the course of the research which **may relate to the participant’s willingness to continue participation** will be provided to the participant.”

Possible Situation for Re-Consent

- New risk/benefit profile (new risks, an increase in the magnitude of risks, or a decrease in the expected benefit)
- Study procedures have been added, modified, or removed
- New alternative treatments become available
- Participant regains decision making capacity
- Original Informed Consent was obtained improperly (wrong document, not by an authorized person).
- Unanticipated Problem
- Must Re-Consent
 - Minor participant reach the age of 18 and still participating in the research
 - Someone who was consented by a LAR becomes able to consent on their own

How to Re-Consent

- **If the panel requires re-consent, the original informed consent process should be followed, including waivers.**
- **Amendment to original consent form**
- **New Informed Consent Form**
- **Verbal (Waiver of Documentation required)**

Should Re-Consent be Considered?

- Go to the [Kahoot Website](#) and enter the game pin displayed on the screen.



**Minor increase in
number of subjects
enrolled.**

**Collection of
new/different
information from
subjects.**

Identification of long term affects for subjects who have already completed the study.

**A change in the
Principal Investigator
and contact
information.**

Changes such as additional tests, visits, or procedures are made to the protocol that may affect the willingness to participate.

**New risks are
identified that are
definitely related to the
research.**

**Changes that do not
increase risks or
impose additional
burdens to subjects.**

Minor administrative changes (study facility, IRB Address change).

Sources and Resources

- **45 CFR 46.116 (d):**
[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116\(d\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116(d))
- **45 CFR 46.117:**
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>