Informed Consent

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Adaptation from Prof Joseph Ntaganira

Why informed consent

The principle Respect for Persons

- Informed consent:
  - Information: risks, benefits, alternatives
  - Voluntariness: no coercion
  - Freedom to withdraw

- Special protection for those lacking capacity for self-determination

Informed consent lay out;

The consent form/document should have two parts:

- (a) **a statement** describing the study and the nature of the subject's involvement in it; and
- (b) **a certificate of consent** attesting to the subject's consent. Both parts should be written in sufficiently large letters and in simple language so that the subject can easily read and understand the contents. As far as possible, medical terminology should be avoided in writing up the consent form.

Informed consent lay out (cont'd);

- The statement is given or read to each prospective subject. Any questions the subject may have are then answered and, if consent is given, the certificate is signed by the subject or, if consent was verbal, by the staff member who provided the information and ensured that it was understood.

- By signing, the staff member confirms that consent was given freely. A signed certificate must be obtained in this way for each subject admitted to the study, and a copy must be offered to the subject.

- The statement can also be called **Participant information sheet**.

- The certificate of consent can also be called **Signature sheet**.

The certificate of consent should end with a paragraph such as the following:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my further medical care."

What are the elements to include in IFC?

- Please separate into groups of 4

- List of the sections of the informed consent

[YOUR INSTITUTIONAL LETTERHEAD]

Please do not submit consent forms on the WHO letter head

[Informed Consent Fonn for _____ ,
Name the group of individuals for whom this consent is written.

Explanati
Example Ill

(1\ame of Principal lnYestigator]
(1\ame of Organization]
(1\'llme of Sponsor]
(1\ame of Proposal and Yersiou]

This Informed Consent Fonn bas two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You " i ll be giYen a copy of the full Infonned Consent Fonn

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing.

Explanation ®

Example -

Purpose

Explain in lay tenns why you are doing the research. . (?f)\

Explanation W

Example -

Type of Research Inten •ention

Briefly state the type of intervention that will be undertaken.

Explanation CT)

Example -

Participant selection

State why this participant has been chosen for this researcdL

Explanation ®

Example -

, .oluntary ParriCipation

Indicate d early that they can c to p'Jrticip a or not. Smte, onlv if it is applicable, that they wilhtill recef re all the sen>ces they usually do whether they choose to participate or not.

Explanation ®

Example .

Iu!ormation 0 11 the Trial Drug (Name of Drug]

Include this section only if the protocol is for a clinical trial

I) give tbe phase of the trial) Wlain what that 01eans. Explain to the participant why you are comp31'ing or testing the dmgs.

2)prov>de as nn1Ch infomiatio as is app1opiiate and understandable about the drug such as its 01anufacturer or location of manulacnu-e and the re3Si0ll for its development

3) explain the !mown experience wiib this drug

4)explain COIDpfehensively all the blown side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that *are* being used in the trinl

Example •

Procedw·es and Protocol

scribe a ·explain the e:uet procedures that will be followed on a step-by-step basis, tbe tests that vjll be done, and any drugs that will be gi\-en. Explain from the outset what some of the more unfamiliar procedures invo M (placebo, randomization, biopsy, etc.) Indica te which proce is routine and wllich is experimental or research.

Explanation ?

In this te m p l a , this section h-u been divided into two: firstly, an t'Cplanation of 11Qfamiliar procedures and, secondly, a description of process.

A. Vu!runilinr Procedur. .

This section should be included if there niay be procedures which are not familiar to the participant.

If the **protocol is for a clinical trial:**

1) invol vin2 11111doctiz. tion or blinding, ibeparticipants should be told what that means and what chance they ha\-e of getting which drug (i.e. one in four chances of getting the test dmg).

Example .

2) involving an in1ctive dtu2 or placebo. it is important to eosw-ethat the pruticipants understand what is meant by a placebo or ioacti\-e drug.

Example .

If the orotocol is for clinical research:

Firstly, •"Plain that !here are standards/guidelines that will be followed for the treallllent of their cocdition. Secondly, if aspart of the research a biopsy will be tmn, or surgery cauied oui, then expfain wbethtt it" i l l be U1der local autsthesia, sedation or g eral anestbe>ia, and wh.11SO1 of symptoms and side effects lhe pirticipnnl should eicpttt under ch category.

Exaiq>le •

For any clinical study (if relevMQ

If blood samples are to be ta e u •"Plain how many times and bow much. in a Language that the person Ulderst'Jllds. It may, fore:<llllple, be inappropriate to tell a tribal villager that blood equal to a wine-glass ftlll will be taken but it may be veiy app.-opi ate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this re.search, then explicitly mention here ihat the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after _____ years, when the research is completed.

E'"Planation ®

Example .

B. Dtsciiption of the Process

Dtscnbe to lhe particip'Ull what " i l l happen on a step-by-step basis.

Explanati! ! . @)

Examplr -

Duration

lnchlde a statemem about the time commitments of the research for the participant includiag both the duration of the research and follow-up, if relevant.

E:<mlple •

Side Effects

Potential p:uticipams should be told if there are any known or amicipated side effects and what will happen in the e\em of a side eflec.t or au une-..pected event.

E-.ample .

Ri<ks

E"Plain and descnbe any possible or anticipated risks. Dtscribe tile l e \l of care th3I vi l l be available in the e\=I th3I harm does occur, who \\ill *provide* it, Md who will pay for il

ExpJanation..11.)

Examplr . - -

B•n•fits

Mention only those activities that l>ill be actual benefits and not those to which they are entitled **regardless of participation.**

Explan.ab

Example . -

lnctnrfrts

State clearly what you \\ill pro, de the panicipants with as a result of their participation. WHO does not encourage ineenti\ es. However, it recommends that reimbunements for expenses iocurred as a result of participation in the research be provided.

Explanation ®

Example .

Confidtntialit\'

Explain how th. research tam will m.Untain the confidentiality of data, especially with rtsptct io tbe information about the participant which would otherwise be known only to the physician but would now be available to the entire research team.

Explanation CT)

Example •

Sha1in: the ResuJts

Where it is relevant, your plan for sharing the information with the participants should be provided.

Explan.abo

Example . - -

Righi to Rtfust or Wilhdraw

This is a reconfirmation that participation is vohmtal)• and includes the rigl11to withdraw.

Explan.ati

Example r

4\lternar:iYts to Participating

Include this section only if the study in\ olves administration of investigational drugs or use of new therapeutic procedures. It is important to explam and describe the established standard treatmenL

Example .

Who 10 Conr>ci

Pro\>ide the name and contact information of someone who is in\ oh-ed. informed and accessible (a local person who can actually be ccntacted. State also that the proposal has been appro\-ed and how.

Example •

PART II: Ctnifi<nrt of Constnt

This section can be written in the first persoo. It should include a lew brief statements abo\11 the research and be followed by a statement similar ro the one in bold below. If the participant is illiterate but gives oral consent, a witness arust sign. A researcher or the person going over the informed consent nmst sign each ccnsent.

Explanati
Example . -

I lun·t rl'nd "' 'for 'lo i11g Uifor11ulio11, or it hn.l bl'l'n rtad to 11Ji'. I lta,., had thl' opporr.ru1Uy ro mk q11!stions about it mid DlIJ' qutsn'onr tliai I lta·r a,sk d ha11 bi't'll a11snf'rtd to '")' .sarU/acriou.. I (011se11t 1ob111tari{r to pa11itipatt' n,s aparn'ripa.111iu ;/tis JTsta.r<lr n11d 1111d1nta11d that I Ju"" tltt right ro ttirlfdranf f0111 tlrr t'tstarrl1 n1 n11y n,,,, 11tl1011i i11 mr'o r affetri11g II{)' nttdiral tall.

Print :"•- of Pu ·ticipom________________

Siguatur< of Pnnidpont- - - - - - -

Date ______________________________
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no conntttiou ro the researcli team).

I l1nt't' 1tit11ts.sed tht ntru1·tue rtru:ling of 11t' ro1utttt /or1u to tltt pottun'al pDJ'f1°c(pa111 aJJd tlit iuditiduaJ. ltns Jiad rltt opporn111ity to a.sk qu,srious. I co11finu tl1aJ r11t i11tti1'dunl l1as gitn1 co11.Uut fru (r.

Pritu name of nitues;____________________ AND Thumb print of participant

Siptatnre of nitne-;s- - - - - - - - -

Dae•- - - - - - - - - - -
Day/month/year

D

I ltm(' arnrrat,lr read t>r .,;11 1,su d'" nrr11rn1' rendi11g t>f rl"' romnrr fornr rt>t/l(' p«mrial parlitipa11t, n11d rite i11tfi,id11al ltas liad ti" oppt>rlwtil)' fo ask q11tsriom. I ro1tjir111titat rite i11tli•id1lal lin.sgi;.,,, co11st11tfrttl '"

Print :"• o Rts•a r btr___________
Signature of Rtsearcb• r ______________________

D•t•- - - - - - - - - - - -
Day/m onrh/y<ar

In writing up the statement take note of the following points:

Describe the measures that will be taken to ensure that the proposed research is carried **out in accordance with existing ethical guidelines**:

- "Recommendations guiding physicians in biomedical research involving human subjects" (Declaration of Helsinki, see Part 2, number 1),
- "International ethical guidelines for biomedical research involving human subjects" (Council for International Organizations of Medical Sciences, see Part 2, number 2) and
- "International guiding principles for biomedical research involving animals" (Council for International Organizations of Medical Sciences, see Part 2, number 3).

For studies in humans (or involving human biological materials) evidence must be provided that the proposed research has been approved by the local, institutional or equivalent ethics committee and/or the national ethics committee and that research

In writing up the statement take note of the following points (cont'd):

- Whether **commercial products** may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products.
- Whether the investigator is serving only as an investigator or as both investigator and **the subject`s physician**.
- The extent of the investigator's responsibility to provide **medical services** to the participant.

In writing up the statement take note of the following points (cont'd):

- that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be **informed** of any finding that relates to their particular health status.

- that subjects have the **right of access** to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure).

In writing up the statement take note of the following points (cont'd):

- That **treatment** will be provided **free of charge** for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment.

- In what way, and by what organization, the subject or the subject`s family or dependants will be compensated for **disability or death** resulting from such injury (or, when indicated, that there are no plans to provide such compensation);

Additional Elements:

- When appropriate one or more of the following elements of information will also be provided to each research subject:
  - If the subject is or may become **pregnant**, a statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus.
  - For prospective clinical studies on methods of fertility regulation, the consent form should indicate what advice and choice of management will be offered to the subjects in case of **unplanned pregnancy.**
  - A description of circumstances in which the subject's participation may be **terminated** by the investigator without the subject's consent.
  - What will happen if the subject decides to **withdraw** from the research and how withdrawal will be handled.

Biological specimens:

- If biological specimens are to be taken during the course of the study, the subject must be told how any **left over specimens** will be disposed of when the study has been completed. If the investigators would like to store such left over specimens for use in future research, supplementary voluntary and informed consent must be sought and obtained for such storage and use and any time, use and anonymity restrictions the subjects may wish to impose must be respected and adhered to.

- The possible **research uses**, direct or secondary, of the subject`s medical records and of biological specimens taken in the course of clinical care.

- Whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible **future use**, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed.

Assessment of Understanding

- Why the need for an assessment of understanding?
  - Documentation.
  - Objective evaluation.
  - ‘’Decades of research show that poor understanding of consent documents is widespread, and that many individuals are not able to discern important differences between research and routine care… Many participants, moreover, believe that the consent forms are primarily designed to protect investigators rather then research participants. In addition, most participants have already decided to participate prior to the informed consent process.’’

Dunn and Gordon, ‘’Improving Informed Consent and Enhancing Recruitment for Research by Understanding Economic Behavior,’’ JAMA, February 2, 2005, Vol. 293, No.5

IPM009A
F i Venion 2.0 d-.cl 22 Odober 2010

Screening ı) Number		**Participant Initials**	**Date**

PM 009Ahfonned Consent Comnrehensioo Evaluation Checklist

		II	Comments•
1.Please describe your understanding of the purpose o(this sludy.	**testino to learn if daMnri:ne rinos are safe**		
	tesling lo learn 11dapivirine mgs prevent HV		
2.What do you LRlerstand that you are being asked lo do in this study?	wear a vaginal ring for more than 1'fe8' and up to 3 '.jeers		
	have lllc exams and HIV tests		
	come lor monthly visits for more than 1)'ear and 14> lo 3		
	rot get pregnant in the nex1)ea: and up lo 3 years		
3.What do you Lndersland about possble risks that !right happen as a result of being in the study?	**oM"I or discomfort i1the ina**		
	enmenassment dumo exams or estions		
	possibility of lOcial harms		
	bruisinn or sorenessadditional HIV tesls are renured		
4.What will happen to you if you decide not lojoin the study?	free to make her own decision about ioininQ		
	there •U be no eft'ed on access k> care		
5.Please tell me about the dllerent 9'0l4>S of women in the study.	there are two mgs -one with daplvine and one IMthout **dAniuiine**		
	no one knows who receives which ril'V1		
6.How wil the infoonation about you be protected?	information about i is kept LnCler lock and key		
	ontv , _.,..'MJC'kkio on the conM'IU have access		
7.What are the benefits to you or participating in this study?	med cal exams,lab tests ror HV and genital nfections, COI.llseting, making a oontn1>ution to IOlving the HIV/AIDS oroblem *fmust mention at least one* of thesel		
8.What should you do Hyou have any questions about what Is h8Pl><!Rnjg this shodll?	knows contact inlormation for research centre		
9. s there anything else you'd tike to ask or tak about?			

Screening ID Number | Participant Initials | Date

Enrollment Outcome:

Proceed to enrollment
Declined to consent LJ
Rescheduled for another consent visit
Unable to consent

Ongoing Outcome:

Demonstrated adequate comprehension
Referred for additional counseling n

'Use letter code below and write additional comments if necessary

a. Answered correctly the first time
b. Answered correctly, but seems unsure or answer
c. Only able to answer after being helped
d. Not able to answer correctly, even after additional counseling e.
Other (describe)

Literacy tests

- Why the need for a literacy assessment?
  - Documentation.
  - Objective evaluation… can’t you just ask? What if people can write their name but not read/write?

Participant Initials:

SCIU::t:N1NG I VISIT

Pbllt'#III h t tol'Cldítw ..... Ttl l• t o ••h n ..,.,.Md

<.--allwo.ds bu

3. Is the participant literate?

___ Yes

___ No

Research staff initials: _ _ _

Date: _ _/_ _ _/_ _ _ _

Translations are correct

- Usually an English original version from sponsor.
- Translation into Kinyarwanda.
- Back-translation into English.

- Done by different translators; identical back-translations should raise concern.
- Use of a lexicon is approved.
- Cultural sensitive and understandable translations ex vaginal ring or placebo.

Vulnerable subjects

- The use of vulnerable subjects as research participants should be avoided and must be justified if it is proposed. Vulnerable subjects include those in prisons, minors, mentally handicapped or emotionally disturbed persons. However, if a study promises considerable benefit that would not otherwise be available to a minor or other subject incapable of providing informed consent, those subjects may be recruited and consent may be granted by a parent or guardian, in accordance with applicable law. Whenever a minor child is in fact able to give consent, his or her consent must be obtained in addition to the consent of the minor's legal guardian. The use of prisoners or other institutionalized persons as research subjects, or of those likely to be incarcerated, should be avoided because such individuals are in a socially vulnerable position.

Illiterate participants

- The document should be signed by the subject or, when the subject is illiterate, by the staff member who provides the information, and who ascertains that it was understood and confirms that consent was given freely.

- Whenever feasible, the recruitment of illiterate subjects should take place in the presence of a literate witness. Whenever possible, the witness should be selected by the subject and he/she should not be connected with the research team. The witness should also sign the certificate of consent, confirming that the subject has been properly informed and voluntarily consents to participating in the study.

Material Transfer Agreements

- When lab samples are sent overseas for testing; this should be mentioned in the ICF in a separate box and initialled by the participant.

Common problems with Informed Consent Form content and readability

Problem	Comments
Title is not exact title on protocol	Perhaps an attempt by study staff to make the consent title more understandable
No mention of sponsor by name	Investigator might not want the subject to know that the study is sponsored by a pharmaceutical company
Inadequate discussion of compensation for injury and who will cover these costs (errors and omissions insurance purchased by the sponsor)	Happens frequently. The wording is confusing and often discusses the subject's health insurance
No mention of follow up of pregnancy to term; use of adequate birth control	Many investigational drugs are too risky to test in pregnant women but the consent does not strongly state that a woman must use birth control while on study, and does not indicate what happens should she become pregnant

Common problems with Informed Consent Form content and readability; severe (cont'd)

Problem	Comments
Risks do not match those in the IB; risks downplayed	Investigator does not want to frighten potential subjects
No statement of subject payment in benefits or cost reimbursement section	Payment for travel, day care, time spent at research site, … are not listed
Not updated with new safety information	This is a GCP requirement, although difficult to determine when it is 'triggered'
Content does not have changes recommended by the IRB	IRB's usually have good reasons for requesting changes and these requests must be honored

- Extra information

- Documenting time;- on ICF form is best way, CRF could have checkbox asking ‘’Was consent obtained prior to any study tests/procedures’’,on note written by study staff.
- Assent (American Academy of Pediatrics endorses 7 as an appropriate age for assenting but FDA/GCP regulations state that an appropriate age of consent should be considered based on a number of factors, including age, maturity, and psychological state of the children involved.
- Payment to research subjects for participation in studies is not considered a benefit but a recruitment incentive. Financial incentives are most often used when health benefits to subjects are remote or nonexistent.