**Guidance Resource – For Use as an Example only; Adapted from the MTN**

**[Site/CRS Name]**Standard Operating Procedure (SOP)

**SOP No.:** XXX, version 1.0 Page 1 of 6

**Title:** Obtaining Informed Consent

**Original Effective Date:** XX/MMM/YYYY **Revision Effective Date:** N/A

## Purpose

To define general informed consent procedures.

## Scope

This procedure applies to all staff involved in obtaining informed consent.

## Responsibilities

*[Research Nurses and/or Staff delegated by the Investigator of Record]* to obtain informed consent are responsible for:

* Understanding and following this SOP.
* Being adequately trained and qualified to obtain informed consent, as determined by the Investigator of Record (IoR), by education, training, experience, and knowledge of the trial.
* Conducting the informed consent process with the participant. He/she will inform the potential participant that participating in the study is voluntarily, and that the potential participant has a good understanding about the study procedures/study agents.
* Obtaining from each potential participant informed consent prior to initiation of study procedures.
* Conducting consent process in a private setting free of coercion and undue influence. The possible study benefits will not be overstated nor will the risks be understated. Extra time will be spent as necessary to ensure understanding of these issues.
* Delivering all required information in a manner that is understandable to a potential study participant

*Investigator of Record (IoR)* is responsibile for:

* Retaining overall responsibility for the conduct of a given trial at the site, including delegated tasks such as obtaining consent
* Ensuring staff delegated the task of obtaining informed consent are adequately trained and qualified by education, training, experience, and knowledge of the trial; training and qualifications are completed prior to the staff performing the delegated task.
* Ensuring that staff delegated the task of obtaining informed consent are listed on study-specific Delegation Logs prior to the staff performing the delegated task; Delegation Logs to be kept in the Regulatory binder.
* Having a detailed plan for the supervision and oversight for a given trial
* Ensuring that all applicable staff have received the appropriate training, follow this SOP, and are compliant with all applicable CFR regulations and ICH Guidelines.
* Ensuring applicable SOPs are kept in the Regulatory binder

## Training

* Each staff member receives HSP/GCP training.
* Each staff member receives or has direct access to applicable SOPs.
* Each staff member reviews the applicable SOPs *[Insert frequency of review]*.
* All SOP training is documented and tracked *[Insert where the documentation is kept].*
* New staff are trained on applicable SOPs within *[Insert # of days]* days of employment.
* Staff members whose duties fall within this SOP scope are retrained within *[Insert # of days]* days of the approval of each SOP revision.

DAIDS Version 1.0, September 2017: General Informed Consent Example

## Introduction

Informed consent is an on-going process and starts at the initial contact with the potential participant and continues throughout the entire follow-up period of the study.

Procedures (*revise as applicable)*

1. All materials used for obtaining informed consent and verbal discussions are in a language understandable by the participant.
2. The latest IRB/EC-approved version of the informed consent form (s) [ICF(s)]will be used by the appropriate site staff for obtaining informed consent *[add local languages ICFs, as applicable]*.
3. Participants are offered the opportunity to take the ICF(s) home to read and return on another day to complete the informed consent process, if needed.
4. *[Describe any IRB/EC-approved* *informed consent support materials that will be used during the informed consent process.]*
5. *[Describe here how the participant’s identity and legal age will be ascertained prior to initiating the informed consent process, the site staff responsible for determining this, and how it will be documented, if applicable.]*
6. *[This section should describe the setting/ location in the clinic in which the informed consent process will occur (e.g. Counseling rooms #1-3). This should also include a description of how the setting will be private and free of coercion.]*
7. Potential participants’ literacy will be determined by *[Insert staff responsible, and site-specific procedures for literacy assessment, such as asking participant to read first paragraph aloud, handing the ICF to the participant upside-down, etc. Site-specific forms should be included here, as well as attached as an appendix.]*
8. For literate participants at each visit where consent is obtained, the following will be conducted for the informed consent process ***[The following is an example, edit as needed to reflect site-specific procedures]:***
   1. [*Site staff responsible*] will provide a copy of the ICF and allow the participant to read it.
   2. Review the ICF with the participant, addressing each separate section of the ICF, highlighting the main points, and allowing and encouraging the participant to ask questions or express any concerns he/she may have. Briefly document the participant’s questions and answers provided in the research record. Use the Informed consent support materials as applicable.
   3. After all IC materials have been reviewed, and all participant questions/concerns have been addressed, verify that the participant understands the study and ICF. *[May include a Comprehension Checklist or similar tool]*
      1. As part of the process of assessing the participant’s understanding of the research, clarify any incorrect responses; provide correct information and other explanations.
      2. For participants who are not able to understand all the required information, give the consent form to the participant to take home and read and schedule him/her for another visit date. If, after all efforts, he/she is unable to understand the required information, he/she is ineligible for the study.
   4. If the participant demonstrates that he/she fully understands the material in the ICF, and if he/she chooses to take part, ask the participant to print his/her name and sign and date the ICF(s). [*Ensure this section is updated per local IRB/EC requirements].*
   5. After witnessing the participant’s signature, the staff member facilitating the informed consent process should print his/her own full name, date, and sign the ICF(s). All signature and date blocks included on the ICF(s) must be completed by the applicable signatory. Signatures and dates must be entered in dark ink, and date blocks must be completed by each signatory; site staff may NOT enter the date for participant signatures. Any errors made to the ICF must be corrected per GCP.
9. For illiterate participants at each visit where consent is obtained, the following will be conducted for the informed consent process *[The following is an example, edit as needed to reflect site-specific procedures and indicate roles and responsibilities]*
   1. A second literate person must witness the informed consent process in addition to the staff member conducting the consent process. The witness must be present and observe the entire process, be literate in the primary language of the participant, and will document their witnessing as outlined below. The witness may be someone brought by the participant, or an impartial person (i.e. a person who cannot be unfairly influenced by people involved in the study). *[Edit as per local and institutional requirements]* If the participant does not bring anyone, a study clinic staff member or staff member from another study may serve as the witness. *[Specify which staff roles may serve as witness, for example, laboratory tech, clinic receptionist, nurse supervisor]*
   2. [*Site staff responsible*] will read through each section of the ICF with the participant and the witness, pausing to clarify and ask the participant if he/she has any questions or concerns about each section. Encourage the participant to ask questions or express any concerns he/she may have. The witness may also ask questions.
   3. After the ICF has been read to the participant and all participant questions and concerns have been addressed and documented, verify that the participant understands the study and ICF. *[May include a Comprehension Checklist or similar tool]* and complete the remainder of the informed consent process. The signature blocks on the informed consent forms will be completed as follows *[edit as applicable to meet local and institutional requirements]*:
      1. If the participant can write, ask him/her to print his/her name and the date on the ICF(s) and sign the ICF(s). Document in the the research record that the participant is able to write even though he/she is not able to read.
      2. If the participant cannot write, ask him/her to provide a thumbprint or “mark” on the signature line of the ICF(s). Then print the participant’s name and date below the lines for these items on the ICF(s), and enter a signed and dated note on the form documenting who made these entries. These entries should be made by the study staff member who conducted the informed consent process.
      3. After witnessing the participant’s signature or thumbprint or “mark”, both the study staff member who conducted the informed consent process and the witness must print their own names, the date, and sign the ICF(s). The witness is to understand that by signing the consent form, the witness attests that the information in the ICF(s) and any other written information was accurately explained to, and apparently understood by the participant, and that informed consent was freely given by the participant.
10. Documentation requirements of the informed consent process, as well as providing the participant the completed informed consent form. ***[The following is an example, edit as needed to reflect site-specific procedures:]***
    1. *[This section should outline how the site will document the informed consent process, including any tools used during this process. Include how the informed consent process will be described in the research records.* ] A copy of the signed ICF is offered to the participant and the original is kept on file in a confidential manner in the clinic. [Indicate if the IoR needs to *co-sign the ICF(s) in a timely manner, if needed by local, IRB/EC and/or institutional requirements.]*
    2. No study procedures will be done prior to obtaining informed consent from the participant. The date documented on the ICF(s) must either precede or coincide with the first date of study procedures.
    3. The signed ICF(s) will be considered a permanent part of the participant’s record but should be filed separately from the participant’s study binder in order to protect confidentiality.
11. Ongoing Informed Consent Procedures
    1. *[This section should outline any site-specific ongoing informed consent procedures and timeframes, including tools amd materials used and the site staff responsible for ensuring that this procedure is completed.]*
12. Procedures for Informed Consent Form Revisions
    1. The revised consent form will be assigned a revision number and date. *[This section should also describe how new versions of ICFs will be tracked.]*
    2. IRB/EC approval of the revised consent form must be obtained from the responsible IRBs/ECs ***prior to*** its use with study participants. Consult with IRB/EC to determine if participants must be re-consented.
       1. If the revision is minor and not associated with a protocol amendment (e.g. the contact information for the investigator or IRB/EC member needs to be updated), *[describe here the procedures for updating ICFs for administrative changes, including requirements for notifying the local IRB/EC]*.
       2. If the revisions to the ICF are associated with a protocol amendment, the new ICF may only be used after the IRB/EC approvals of the amendment/ICF.
    3. [*Describe the translation timing and process for informed consent updates here- staff responsible for coordinating and reviewing translations, when this happens in relationship to IRB/EC approval, if IRB/EC approval of translated ICFs is required, or if they are only submitted for acknowledgement.]*
    4. When a new version of a consent is ready to be used (i.e. approved by the IRB/EC and other regulatory entities, as applicable), the *[insert position/title of person]* will inform all applicable staff of the revised version and the implementation date.
13. *[Insert site QA/QC procedures related to the informed consent process. It is recommended that all ICF(s) be reviewed by another staff member prior to the participant leaving the study clinic to check for legible and correct signatures and dates. etc. List other QA/QC procedures as applicable.]*

## List of Abbreviations and Acronyms

CFR Code of [US] Federal Regulations

ICF Informed Consent Form

ICH International Conference on Harmonisation

SOP Standard Operating Procedure

SSP Study-Specific Procedures

*[Insert additional as applicable]*

## Attachments

Attachment *X*: Comprehension Checklist

*Attachment X: Literacy Assessment Tool*

*[Insert additional and update as applicable]*

## References

45 CFR 46; 21 CRF 50

ICH Consolidated Guidance for Good Clinical Practice (ICH-E6)

*[List applicable local laws, regulations, and institutional policies]*

*Network’s* MOP, section on Informed Consent

DAIDS SOP for Source Documentation

DAIDS Protocol Registration Policy and Procedures Manual

*[Insert additional as applicable]***History**

| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| --- | --- | --- | --- | --- |
| 1.0 | *Xx* *Mon Year* | NA | *Xx* *Mon Year* | Initial Release |

## Approval

Author, Author’s Title Date

Reviewer, Reviewer’s Title Date