|  |
| --- |
| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** |
| **Study Site:**  | **SOPs Number** : DA-402 |
| **Title** **INVESTIGATIONAL DRUG ADHERENCE COUNSELLING**  |
| **Version Number**:  | **Version Date:**  | **Effective date**:  |
| **Approval name Signature Date**  |

**Annual Review**

|  |  |  |
| --- | --- | --- |
| **Review date**  | **Revision Date**  | **Signature** |
|  |  |  |
|  |  |  |

**Document History**

|  |  |  |
| --- | --- | --- |
| **Version number**  | **Reason for change**  | **Date**  |
| 1.0 | Initial release  | 28th March 2015 |
|  |  |  |
|  |  |  |

**Distribution List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Location**  | **No of copies** | **Name/Location**  | **No of copies** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Introduction**

Investigational Drug adherence is a key part in the Nigeria PreP Study. It refers to the whole process from choosing, starting, managing to maintaining investigational drug regimen towards achieving the overall study objective – reduction of HIV transmission among serodiscordant couple. Non-adherence is the discontinuity or cessation of part or the entire study investigational drug regimen, such as dose missing, under dosing, or overdosing, and drug holidays. The significance of adherence to achieving treatment objective has become recognised, which is important in optimising the participant's response to therapy. In contrast, non-adherence can lead to failure to achieve the treatment and study goal, a rise in plasma microorganism load, and the development of drug-resistant strains.

1. **Objectives**

This SOP describes practical step to support participants in making informed choice on study drug, assist participant in adopting drug adherence behaviour and the enhancement of participant’s ability in managing and maintaining the study therapeutic goals.

1. **Responsibility**

The Principal Investigator, study Pharmacist, Adherence counsellor and Adherence team.

1. **Procedure**

The Adherence Counselor/Pharmacist will:

1. Cross-check participant’s ID numbers on the prescriptions.
2. Introduce and orient the client
	1. Name, designation and role

i.e. “*My name is …………. I am a counselor/Pharmacist at this centre. My role is to discuss issues pertaining to the study drug and any other concerns that you may have.*”

* 1. Confidentiality (including discussion of sensitive issues) and anonymity.

i.e. “*Whatever we discuss will remain within this centre and is confidential. Any information that we get from you in relationship to study drug, HIV status or partner is kept in your file, with only your ID numbers on the outside. These files will be kept secured in the study office.*”

* 1. Adherence process outline.

i.e. *“Our services are for people who join to the study voluntarily. We will talk for 20 to 30 minutes about the study drugs and how to assist you with taking the drug religiously”*

* 1. Record taking by counselor

i.e. *“At the end of the session I will take down a few notes on our discussion for record keeping purposes.”* Discuss measures you will take to keep confidentiality.

#### General preparation

Determine treatment readiness, characterise potential and actual barriers to adherence, and provide relevant treatment knowledge and educational interventions.

Key issues you must cover:

* Thorough assessment is important to explore the potential and actual factors in a participant's life that could influence drug adherence. These include: health status, social background, and one's perception of illness and treatment.
* Study medication information is provided in the same setting, covering the nature of the study drug, their effects, and the importance of adherence.
* Ongoing assessment shall follow, to track the participant's knowledge on the subject, his/her understanding of the treatment process, and to evaluate one's readiness to initiating and adhering to a study drug.

#### Study drug initiation

The most important time to address the importance of adherence to treatment and medication regimens is before starting therapy.

* Discuss and assess the participant’s commitment to medication adherence.
* Discuss the risks and benefits of study medication.
* Address the potential and actual factors that could influence adherence prior to initiation of study medication.
	+ Perception of illness and desire for treatment;
	+ Social stability, including such factors as housing status, regularity of life-pattern, job nature, need to travel,
	+ Behavioural risk factors like substance abuse; mental status; baseline knowledge.
* Conduct counselling to remove such barriers, while special support system is identified that may be utilised, such as family network or NGOs.
* Develop medication care plan.
* Discuss the study medication regimen.
* Obtaining participant's agreement to have study medication initiated.

On the day of medication focus more on addressing the specificities of the prescribed drug regimen. The participant shall agree on the drug dosing schedule. The contents of the counselling are therefore:

* Assessment to check the participant's understanding of the provided information and the importance of adherence.
* Discussion on the regimen.
* Development an individualised medication schedule - assessment of one's life pattern is made, followed by the establishment of a schedule for medications. The mutually agreed medication schedule is written down on the information and scheduling sheets and would be given to the participant.
* Introduce a two-week drug taking diary exercise. Ask the participant to record the drug taking behaviour and side effects identified on the drug taking diary in the following two weeks. Encourage participant to bring back the remaining drugs for pill count at every visit.
* Offer psychological support when necessary.
* Reach agreement with participant on the treatment plan. Had over the Drug information sheet and schedule to participant to reinforce memory.

#### Consolidation

#### The initial phase of starting medication is a critical period for the participants in establishing the confidence and adopting a drug taking behaviour. They may be unfamiliar with the medication schedule and encounter adverse effects. The support of the adherence counsellor is important for enhancing participant medication adherence and their management of adverse effects. Consolidation counselling is started once the study medication is initiated and within the period of one to three months, the objectives of which are:

* to monitor the drug adherence level of Participant
* to reinforce Participant's drug adherence behaviour
* to assess and manage the adverse effects of study medication

Counsellor should address the following:

* Participant's knowledge of study medication.
* Participant's study medication taking behaviour
* Monitor adherence (Recall, pill count etc.)
* Factors affecting adherence.
* and provide of adherence support.

#### Maintenance

When the study medication is stabilised, frequent and regular monitoring of drug adherence is important to maintain optimal behaviour. The counsellor measures and assesses adherence on an ongoing basis to allow comparison of a given participant's adherence across time. This also serves as opportunity to evaluate side effects, identify barriers and provide support and reinforcement to participant.

Counsellor should address the followings:

* Assessment of drug adherence (Recall, pill count).
* Assessment of knowledge of study medication, drug taking behaviour, barriers and facilitators to drug adherence on every visit.
* Watch out for any new side effects, identifies barriers to drug adherence such as change in life pattern and such undesirable practices as drug holiday, partial dose omissions.
* Encourage and reinforce adherence.

Finally;

* Review with participant his perception of health goals.
* Review the regimen and the medication schedule and simplify the regimen to facilitate a better match of schedule to life pattern.
* Assess and management of side effects.

**This SOP has been read and understood by**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Date**  | **Name** | **Date**  |
|  |  | 8. |  |
|  |  | 9. |  |
|  |  | 10. |  |
|  |  | 11. |  |
|  |  | 12. |  |
|  |  | 13. |  |
|  |  | 14. |  |