**STUDY CASE RECORD FORM (INDEX)**

**Instructions**

**Cover**

* The cover (front and back ) should be thick and White in colour

**Nigerian PrEP Demonstration Project**

**STUDY CASE RECORD FORM**

**(INDEX)**

**SITE: JUTH NAUTH UCTH**

**Insert sponsors here**

**STUDY IDENTIFICATION NUMBER**

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*Site Study Couple I/P Chk*

* Also the study ID number should be on the edge of CRF Cover for easy of identification when filed.
* Each page of this CRF should be in triplicate and coloured differently (White, light blue and light pink) for index CRF
* This CRF should be in three section with each section separated by a slightly lesser thick paper with the name of the next section boldly written across. The sections in study CRF(index) are
	+ Enrolment
	+ Follow up
	+ Non routine Form

**Content study CRF (index)**

The content of the CRF should be arranged as listed below

* **Cover Page**
* **Enrolment divider**
1. Demographics form
2. Index Medical History form
3. WHO Adult HIV Staging System form
4. Sexual behaviour form
5. Safer conception form
6. Alcohol and depression scales form
7. Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Index enrolment checklist
* **Month 3 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 6 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 9 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 12 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 15 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 18 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 21 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Month 24 Follow up divider**
1. Sociodemographic update
2. HIV knowledge index
3. Index Medical History
4. WHO Adult HIV Staging System
5. Sexual behaviour
6. Safer conception
7. Alcohol and depression scales Social support and stigma
8. Social harm report
9. Index prevention preference questionnaire
10. Index enrolment risk taking behaviour 1
11. Index enrolment risk taking behaviour 2
12. Index physical examination
13. Index drug dispensing record
14. Study drug adherence
15. CD4 and Viral load
16. Index visit summary
* **Non Routine CRF(Logs)**
1. Index concomitant Medical log
2. Index concomitant Medical log
3. Index concomitant Medical log
4. Index concomitant Medical log
5. Index reportable adverse event log
6. Index reportable adverse event log
7. Index reportable adverse event log
8. Index reportable adverse event log
9. Index protocol violation log
10. Index protocol violation log
11. Index protocol violation log
* **Cover page (white)**