

Section 6 Visit Checklists

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Section 6 Visit Checklists

This section contains sample visit-specific checklists that detail the data collection forms and protocol-specified procedures that must be completed at each study visit. There are separate checklists for screening visits, enrollment, randomization, and induction visits, dosing visits, counseling visits, and follow-up visits. Detailed procedural guidance for performing clinical and laboratory procedures are contained in Sections 10 and 11 of this manual, respectively. Detailed forms completion instructions are contained in Section 7. Sites may adapt the sample checklists included in this SSP Manual to reflect their local procedures.

6.1 Use of Checklists

Section 3 and Appendix C of this manual provide detailed information on source documentation requirements. For example, chart notes may be required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those specified on a checklist may have been performed and/or why procedures specified on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements). Specific tips for completing the visit checklists include:

- Enter the Participant ID (PTID) number and visit date in the top section of each checklist.
- Enter the date the procedures are actually completed along with your initials.
- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason on the checklist; initial and date this entry.

6.2 Sequence of Procedures

Sites are encouraged to adhere to the sequence listed on the checklists if possible. However, sites may alter the sequence of procedures, to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for study screening must be obtained before any screening procedures are performed.
- Risk Assessment must *always* be administered before HIV pre-test and risk reduction counseling and must be administered by a staff member who has not previously provided HIV counseling to the participant.
- Pre-test counseling must be provided before HIV specimen collection for testing.

Screening, Enrollment and Randomization

Screening

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm identity
		Review and sign Screening Consent Form. Provide copy to participant
		Complete Informed Consent Screening Comprehension Quiz
		Assign PTID
		Complete screening portion of the Screening and Enrollment Log
		DSM-IV Worksheet
		Screening Assessment Form (SA-1)
		Complete Locator Form
		Complete Demographics Form (DEM-1)
		Complete Risk Assessment Form (RA-1)
		Complete Pre-test HIV counseling
		Collect blood for hepatitis B & C, platelet count, CBC, bilirubin, creatinine, ALT, HIV rapid test (HTR-1)
		Collect screening urine for opiates and other drugs and pregnancy determination (UTR-1)
		Complete Post-Test HIV counseling (should be same day as HIV results)
		Complete Physical Exam
		Complete Medical History Form
		Complete Pre-existing Conditions form (PRE-1)
		Provide Study ID Card, if applicable at the site
		Concomitant Medications Log (CM-1)
		Discuss local health care and drug treatment services – refer to services upon request

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Screening procedures may be completed over multiple visits.

If a volunteer is found ineligible, withdraws consent or refuses further screening at any time prior to randomization, discontinue further assessments. The reasons for discontinuing screening must be documented in site screening log and in a chart note.

Remember: brief notes on provision of HIV counseling, volunteer's reactions, issues and concerns discussed, etc., should be documented in the source records.

Enrollment (after initial screening visit and before the completion of the randomization)

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Pre-enrollment urine pregnancy screening (UTR-1)
		Enrollment Consent Form
		Informed Consent Enrollment Comprehension Quiz (ICQ-1)
		Informed Consent for Enrollment Evaluation Survey (optional) (ICS-1)
		Consent for Storage and Future Use of Blood Samples (optional- may be signed at any time post enrollment)
		Update Locator information, if necessary
		Review laboratory results with participant (LLS-1)
		Complete enrollment portion of the Screening and Enrollment Log
		Eligibility Checklist

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Participants who do not enroll within 28 days or who are otherwise found to be ineligible may re-screen for the study once. Re-screening may be conducted after 30 days from the initial blood draw for HIV screening.

Remember: The specimen storage consent is optional and the volunteer may participate in the study without providing consent for specimen storage.

Randomization

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity and willingness to participate (if randomization day is different from day of signing of the enrollment informed consent form)
		Review Eligibility Checklist (if randomization day is different from day of signing of the enrollment informed consent form)
		Update Locator Form
		Update Concomitant Medication Log (CM-1), if needed
		Urine pregnancy test (if randomization day is different from day of signing of the enrollment informed consent form- if negative, a new UTR-1 does not need to be completed)
		Assess use of drugs in the past 24 hours
		Complete COWS Worksheet
		If COWS is ≥ 8 , perform randomization procedure (ENR-1)
		Inform participant of assignment and develop visit schedule
		Complete Randomization Log
		Offer first dose of hepatitis vaccine, if appropriate
		Schedule counseling visits

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Remember: Use Induction – Day 1 Checklist in addition to this one.

First 3 Days of Induction (Same Procedures Regardless of Study Arm Assignment)

Induction – Day 1

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Explain process of detoxification to participant. Document in the participant’s source file.
		Update Concomitant Medication Log (CM-1), if needed
		Assess participant’s use of drugs and alcohol over the previous 24 hours, especially the time when an opiate was last used. Record on COWS.
		Administer COWS. Regardless of last use of drugs, observe for visible and objective signs of withdrawal. If COWS score is less than 8, repeat COWS in one hour. Continue repeating at one-hour intervals until the score is 8 or greater. If the participant fails to develop objective signs of withdrawal while under observation, she/he will be given an appointment for the next day when induction will be performed.
		Offer participant sip of water before giving the BUP/NX tablets. No liquids should be taken while the tablets are dissolving
		Using the Induction Guidelines in Table 2 of the BUP/NX Treatment Manual, administer dose of BUP/NX ensuring that tablets are placed under tongue correctly. Observe participant until tablets are dissolved completely. Record on the Induction Record (IR-1)
		Repeat the COWS in one hour. Following the <i>Induction Guidelines</i> and based on current COWS, administer another dose of BUP/NX if needed. Maximum total dose for Day 1 is 8 mg. Record on the Induction Record (IR-1)
		Observe the participant for another 30-60 minutes to ensure that withdrawal symptoms have resolved and that participant does not appear sedated
		Assess adverse events if any. Record on the Adverse Experience Log (AE-1)
		Complete EAE form, if necessary
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills or other drugs while on BUP/NX
		Schedule appointment for the next morning (or at the same time that the first dose was administered today).
		Provide participant with phone number for emergency contact
		Document all procedures in signed and dated chart notes

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Remember: First day of induction must occur on the day of randomization.

Induction – Days 2 and 3

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Update Concomitant Medication Log (CM-1), if needed
		Assess participant’s use of drugs and alcohol over the previous 24 hours, especially the time when an opiate was last used. Record on COWS Worksheet
		Administer COWS
		Offer participant sip of water before giving the BUP/NX tablets. No liquids should be taken while the tablets are dissolving
		Using the Induction Guidelines in Table 2 of the BUP/NX Treatment Manual, administer dose of BUP/NX ensuring that tablets are placed under tongue correctly. Observe participant until tablets are dissolved completely. Record on the Induction Record (IR-1)
		Assess adverse events if any. Record on the Adverse Experience Log (AE-1)
		Complete EAE form, if necessary
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills or other drugs while on BUP/NX
		Schedule appointment for the next morning (or at the same time that the first dose was administered today).
		Provide participant with phone number for emergency contact
		Document all procedures in signed and dated chart notes

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Counseling Visits

Weekly and Monthly Counseling Visit

Weekly from Week 1 – Week 12

Monthly from Week 16 – Week 52

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Conduct counseling session according to the Counseling Manual
		Make referrals as needed
		Document visit and referrals in signed and dated chart note
		Complete appropriate CRF (CAW-1 or CAM-1) and BDRC contract

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Remember: On days that the participant is scheduled to receive both counseling and BUP/NX, counseling should precede the administration of the BUP/NX.

DETOXIFICATION ARM

Safety Phase

Week 1 (starting at Day 4) – Week 4

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
<i>(Week 4 only)</i>		Update Locator Form <i>(Week 4 only)</i>
		Assess use of drugs in the last 24 hours
		Concomitant Medications Log, if needed (CM-1)
		Administer Suboxone, Weekly Dosing Record (DR-1) , continue to reduce dose by 2 mg per day until 0 mg is reached. Detoxification is to be completed by Day 18. <i>(Daily through Day 18)</i>
<i>(Weekly)</i>		Complete Medical History Form (non-DataFax) <i>(Weekly)</i>
<i>(Weekly)</i>		Complete Physical Exam (non-DataFax) <i>(Weekly)</i>
<i>(Weekly)</i>		Collect Blood for platelet count, CBC, bilirubin, creatinine, and ALT (LLF-1) <i>(Weekly)</i>
<i>(Weekly)</i>		Collect Urine for testing for Opiates and Other Drugs (UTR-1) <i>(Weekly)</i>
<i>(Week 4 only)</i>		Collect Urine for testing for Pregnancy (UTR-1) <i>(Week 4 only)</i>
		Specimen Tracking Sheet (non-DataFax), (optional)
<i>(Weekly)</i>		Complete Social Impact Assessment (SIA-1) <i>(Weekly)</i>
<i>(Weekly)</i>		Complete Social Impact Log (SIL-1) , if necessary <i>(Weekly)</i>
<i>(Week 4 only)</i>		Acceptability Assessment (AA-1) <i>(Week 4 only)</i>
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX
		Confirm next visit
		QA/QC checks on all documents

Submit DataFax forms to SCHARP as instructed – DataFax forms are bolded above
Remember to use the Counseling checklist.

Once the participant reaches a daily dose of zero, they will follow the regular schedule of visits including weekly counseling (until week 12, followed by monthly visits until week 52). Safety Phase participants should continue the weekly laboratory and social impact assessments as noted above even after dosing stops.

Full Phase

Week 1 (starting at Day 4) – Week 4

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
<i>(Week 4 only)</i>		Update Locator Form <i>(Week 4 only)</i>
		Assess use of drugs in the last 24 hours
		Complete Suboxone administration, Weekly Dosing Record (DR-1), continue to reduce dose by 2 mg per day until 0 mg is reached. Detoxification is to be completed by Day 18. <i>(Daily through Day 18)</i>
		Concomitant Medications Log, if needed (CM-1)
<i>(Week 4 only)</i>		Collect Urine for testing for Pregnancy (UTR-1) <i>(Week 4 only)</i>
		Complete Specimen Tracking Sheet (non-DataFax) (optional)
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX.
		Confirm next visit
		QA/QC checks on all documents

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Remember to use the Counseling checklist.

Once the participant reaches a daily dose of zero, they will follow the regular schedule of visits including weekly counseling (until week 12, followed by monthly visits until week 52). Safety Phase participants should continue the weekly laboratory and social impact assessments as noted above even after dosing stops.

Follow-up Visit

Weeks 26 and 52

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
		Review participant's progress, explain procedures to be completed at this visit, confirm willingness to continue; get consent for specimen storage, if applicable
		Administer Risk Assessment Form (RA-1); review form for completeness and accuracy
		Provide HIV pre-test and risk-reduction counseling; document in source file
		Collect urine for testing for Opiates and Other Drugs (UTR-1)
		Collect blood for platelet count, CBC, bilirubin, creatinine, and ALT and HIV rapid test (LLF-1) (HTR-1)
		Complete Specimen Tracking Sheet (optional)
		Update Locator Form
		Administer Acceptability Assessment (AA-1)
		Complete Social Impact Assessment (SIA-1)
		Complete Social Impact Log (SIL-1), if necessary
		Provide HIV post-test and risk-reduction counseling; document in study source documents
		Conduct interim medical history by assessing changes since last history Complete Medical History form (non-DataFax)
		Conduct symptom directed physical exam. Complete Physical Exam form. (non-DataFax)
		Update Concomitant Medications Log (CM-1). Include over-the-counter medications, street drugs, vitamins, herbal remedies and other traditional preparations
		Review, assess and grade any adverse experiences. Record on the Adverse Experience Log (AE-1)
		Complete DAIDS EAE Form and fax to RCC within 3 days of site awareness for all events that meet the criteria for expedited reporting
		Offer and administer hepatitis B vaccine, if appropriate. Record in the source documents
		Document and other procedures in the study source documents
		Schedule next appointment
		Perform QA/QC

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Remember to use the Counseling checklist.

Follow-up Visit

Weeks 78, 104, 130 and 156

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
		Review participant's progress, explain procedures to be completed at this visit, confirm willingness to continue; get consent for specimen storage, if applicable
		Administer Risk Assessment Form (RA-1); review form for completeness and accuracy
		Provide HIV pre-test and risk-reduction counseling; document in source file
		Collect urine for testing for Opiates and Other Drugs & Pregnancy (UTR-1)
		Collect blood for HIV rapid test (HTR-1)
		Complete Specimen Tracking Sheet
		Update Locator Form
		Complete Social Impact Assessment (SIA-1)
		Complete Social Impact Log (SIL-1), if necessary
		Provide HIV post-test and risk-reduction counseling; document in study source documents
		Review, assess and grade any adverse experiences. Record on the Adverse Experience Log (AE-1)
		Complete DAIDS EAE Form and fax to RCC within 3 days of site awareness for all events that meet the criteria for expedited reporting
		Offer and administer hepatitis B vaccine, if appropriate. Record in the source documents
		Document and other procedures in the study source documents
		Schedule next appointment
		Perform QA/QC

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Second Detoxification

Week 26

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Document participant's interest in second detoxification
		Document participant's eligibility for a second detoxification based on the eligibility criteria listed in section 3.2.1 of the BUP/NX Treatment Manual
		Complete the DSM-IV Diagnostic Worksheet
		Confirm all laboratory results from the Week 26 visit. Provide results to the participant
		Complete Second Detoxification Eligibility Checklist

Second Detoxification

Day 1 of Second Detoxification

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Collect urine specimen for pregnancy testing from all females and document results on the Urine Results Form (UTR-1). If pregnant, stop; participant is ineligible for detoxification. Provide counseling and make appropriate referrals
		Provide results of laboratory tests to participant
		Update Concomitant Medication Log (CM-1), if needed
		Explain process of second detoxification to participant and his/her willingness to receive detoxification. Document in the participant's source file.
		Assess participant's use of drugs and alcohol over the previous 24 hours, especially the time when an opiate was last used. Record on COWS.
		Administer COWS. Regardless of last use of drugs, observe for visible and objective signs of withdrawal. If COWS score is less than 8, repeat COWS in one hour. Continue repeating at one-hour intervals until the score is 8 or greater. If the participant fails to develop objective signs of withdrawal while under observation, she/he will be given an appointment for the next day when induction will be performed.
		Offer participant sip of water before giving the BUP/NX tablets. No liquids should be taken while the tablets are dissolving
		Using the Induction Guidelines in Table 2 of the BUP/NX Treatment Manual, administer dose of BUP/NX ensuring that tablets are placed under tongue correctly. Observe participant until tablets are dissolved completely. Record on the Induction Record (IR-1)
		Repeat the COWS in one hour. Following the <i>Induction Guidelines</i> and based on current COWS, administer another dose of BUP/NX if needed. Maximum total dose for Day 1 is 8 mg. Record on the Induction Record (IR-1)
		Observe the participant for another 30-60 minutes to ensure that withdrawal symptoms have resolved and that participant does not appear sedated
		Assess adverse events if any. Record on the Adverse Experience Log (AE-1)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills or other drugs while on BUP/NX
		Schedule appointment for the next morning (or at the same time that the first dose was administered today).
		Provide participant with phone number for emergency contact
		Document all procedures in signed and dated chart notes

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Second Detoxification

Day 2 and 3 of Second Induction

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Update Concomitant Medication Log (CM-1), if needed
		Assess participant's use of drugs and alcohol over the previous 24 hours, especially the time when an opiate was last used. Record on COWS
		Administer COWS
		Offer participant sip of water before giving the BUP/NX tablets. No liquids should be taken while the tablets are dissolving
		Using the Induction Guidelines in Table 2 of the BUP/NX Treatment Manual, administer dose of BUP/NX ensuring that tablets are placed under tongue correctly. Observe participant until tablets are dissolved completely. Record on the Induction Record (IR-1)
		Assess adverse events if any. Record on the Adverse Experience Log (AE-1)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills or other drugs while on BUP/NX
		Schedule appointment for the next morning (or at the same time that the first dose was administered today).
		Provide participant with phone number for emergency contact
		Document all procedures in signed and dated chart notes

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Second Detoxification

Day 4 to 18 of Second Induction

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant identity and PTID
		Review concomitant medication (CM-1)
		Review withdrawal symptoms, adverse experiences and other drug use since yesterday. Record any SAE or EAE on the Adverse Experience Log (AE-1)
		Instruct participant about the dose reduction plan and the possible emergence of mild withdrawal symptoms
		Offer participant sip of water before giving the BUP/NX tablets. No liquid should be taken while the tablets are dissolving
		Administer the previous day's dose minus 2 mg each day until dose is 0. Ensure that the tablets are placed under tongue correctly and dissolved completely. Record on Weekly Dosing Record (DR-1)
		Treat withdrawal symptoms as necessary. Record on Concomitant Medications Log (CM-1)
		Instruct the participant about the dangers of using opiates, benzodiazepines, alcohol, sleeping pills or other drugs while taking BUP/NX
		Schedule appointment for next day at the same time unless it is the last dose. Instruct participant to use no other drugs prior to appointment
		Ensure that the participant has counseling appointment and make referrals if needed
		Document the visit in a signed and dated chart note.

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Substitution Arm

Safety Phase

Week 1 (starting at Day 4) – Week 4 (Dosing Visits)

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant’s identity
<i>(Week 4 only)</i>		Update Locator Form <i>(Week 4 only)</i>
		Assess use of drugs in the last 24 hours
		Concomitant Medications Log, if needed (CM-1)
		Administer Suboxone, Weekly Dosing Record (DR-1) , Daily until stabilizing dose reached (to be completed by Day 21), then 3 times weekly dosing
<i>(Weekly)</i>		Complete Medical History Form (non-DataFax) <i>(Weekly)</i>
<i>(Weekly)</i>		Complete Physical Exam (non-DataFax) <i>(Weekly)</i>
<i>(Weekly)</i>		Collect Blood for platelet count, CBC, bilirubin, creatinine, and ALT (LLF-1) <i>(Weekly)</i>
<i>(Weekly)</i>		Collect Urine for testing for Opiates and Other Drugs (UTR-1) <i>(Weekly)</i>
<i>(Week 4 only)</i>		Collect Urine for testing for Pregnancy (UTR-1) <i>(Week 4 only)</i>
		Specimen Tracking Sheet (non-DataFax), as needed
<i>(Weekly)</i>		Complete Social Impact Assessment (SIA-1) <i>(Weekly)</i>
<i>(Weekly)</i>		Complete Social Impact Log (SIL-1) , if necessary <i>(Weekly)</i>
<i>(Week 4 only)</i>		Acceptability Assessment (AA-1) <i>(Week 4 only)</i>
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX
		Confirm next visit
		QA/QC checks on all documents

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Remember to use the Counseling checklist.

Full Phase

Week 1 (starting at Day 4) – Week 4 (Dosing Visits)

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
<i>(Week 4 only)</i>		Update Locator Form <i>(Week 4 only)</i>
		Assess use of drugs in the last 24 hours
		Administer Suboxone, Weekly Dosing Record (DR-1), Daily until stabilizing dose reached (to be completed by Day 21), then 3 times weekly dosing
		Concomitant Medications Log, if needed (CM-1)
<i>(Week 4 only)</i>		Collect Urine for testing for Pregnancy (UTR-1) <i>(Week 4 only)</i>
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX
		Confirm next visit
		QA/QC checks on all documents

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Remember to use the Counseling checklist.

Full Phase

Week 5 – Week 46 (Dosing Visits Only – Excludes Week 26 Follow-up Visit)

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
<i>(Every 4 weeks)</i>		Update Locator Form <i>(Every 4 weeks)</i>
		Assess use of drugs in the last 24 hours
		Complete Suboxone administration, Weekly Dosing Record (DR-1)
		Concomitant Medications Log, if needed (CM-1)
<i>(Every 4 weeks)</i>		Collect Urine for testing for opiates and other drugs and pregnancy (UTR-1) <i>(Every 4 weeks)</i>
<i>(Weeks 12 & 40 only)</i>		Collect blood for ALT and bilirubin <i>(Weeks 12 and 40 only)</i>
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX.
		Confirm next visit
		QA/QC checks on all documents

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Remember to use the appropriate Follow-up visit checklist for Week 26 and Counseling checklist.

Full Phase

Week 47 – Week 52 (Dosing Visits Only – Excludes Week 52 Follow-up Visit)

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
<i>(Every 4 weeks)</i>		Update Locator Form <i>(Every 4 weeks)</i>
		Assess use of drugs in the last 24 hours
		Complete Suboxone administration, Weekly Dosing Record (DR-1) . Dose tapering begins at Week 47. Follow instructions for dose tapering in the Treatment Manual
		Concomitant Medications Log, if needed (CM-1)
<i>(Every 4 weeks)</i>		Collect Urine for testing for opiates and other drugs and pregnancy (UTR-1) <i>(Every 4 weeks)</i>
		Adverse Experience Log, if needed (AE-1)
		Complete EAE form, if necessary
		Signed and dated chart notes (non-DataFax)
		Instruct participant about the danger of using opiates, benzodiazepines, alcohol, sleeping pills, or other drugs while on BUP/NX.
		Confirm next visit
		QA/QC checks on all documents

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Remember to use the appropriate Follow-up visit checklist for Week 52 and Counseling checklist.

Follow-up Visit

Weeks 26 and 52

Participant ID

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
		Review participant's progress, explain procedures to be completed at this visit, confirm willingness to continue; get consent for specimen storage, if applicable
		Administer Risk Assessment Form (RA-1); review form for completeness and accuracy
		Provide HIV pre-test and risk-reduction counseling; document in source file
		Collect urine for testing for Opiates and Other Drugs & Pregnancy (UTR-1)
		Collect blood for platelet count, CBC, bilirubin, creatinine, and ALT and HIV rapid test (LLF-1) (HTR-1)
		Complete Specimen Tracking Sheet (optional)
		Update Locator Form
		Administer Acceptability Assessment (AA-1)
		Complete Social Impact Assessment (SIA-1)
		Complete Social Impact Log (SIL-1), if necessary
		Provide HIV post-test and risk-reduction counseling; document in study source documents
		Conduct interim medical history by assessing changes since last history Complete Medical History form (non-DataFax)
		Conduct symptom directed physical exam. Complete Physical Exam form. (non-DataFax)
		Update Concomitant Medications Log (CM-1). Include over-the-counter medications, street drugs, vitamins, herbal remedies and other traditional preparations
		Review, assess and grade any adverse experiences. Record on the Adverse Experience Log (AE-1)
		Complete DAIDS EAE Form and fax to RCC within 3 days of site awareness for all events that meet the criteria for expedited reporting
		Offer and administer hepatitis B vaccine, if appropriate. Record in the source documents
		Document and other procedures in the study source documents
		Schedule next appointment
		Perform QA/QC

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The appropriate dosing visit checklist must be used in conjunction with this follow-up visit checklist.

Follow-up Visit

Weeks 78, 104, 130 and 156

Participant ID:

DATE	STAFF NAME	PROCEDURE
		Confirm participant's identity
		Review participant's progress, explain procedures to be completed at this visit, confirm willingness to continue; get consent for specimen storage, if applicable
		Administer Risk Assessment Form (RA-1); review form for completeness and accuracy
		Provide HIV pre-test and risk-reduction counseling; document in source file
		Collect urine for testing for Opiates and Other Drugs & Pregnancy (UTR-1)
		Collect blood for HIV rapid test (HTR-1)
		Complete Specimen Tracking Sheet
		Update Locator Form
		Complete Social Impact Assessment (SIA-1)
		Complete Social Impact Log (SIL-1), if necessary
		Provide HIV post-test and risk-reduction counseling; document in study source documents
		Review, assess and grade any adverse experiences. Record on the Adverse Experience Log (AE-1)
		Complete DAIDS EAE Form and fax to RCC within 3 days of site awareness for all events that meet the criteria for expedited reporting
		Offer and administer hepatitis B vaccine, if appropriate. Record in the source documents
		Document and other procedures in the study source documents
		Schedule next appointment
		Perform QA/QC

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