# WHO Drug Injecting Study - Phase II Operations Manual Version 4

This is by no means a comprehensive document, but should serve as a guide to various aspects of the study.  Periodic additions will be made to the Master Codebook at the end of this manual. The current Codebook is Version 4(1).  Each time new codes are added to the Master Codebook, it will be reissued to all participating project sites with an incremented number, e.g., Version 4(2), etc.

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Communication with NYC is probably best done by email, or fax if necessary. Except where otherwise specified please send all communications to Theresa Perlis. Note that our fax machine serves about 200 people, so the recipient's name and the number of pages should be clearly indicated.

# Contents

## **Overall Study Operations**

Prior to the start of recruitment, each Project Site should prepare the questionnaire for local use (see Questionnaire Preparation below).  This <u>may</u> involve addition of new questions, addition of new items into multi-item questions, deletion of local option questions, and translation, although sites may use the Questionnaire in unmodified form if so desired.  Project Sites with sufficient resources may set up their own data entry programs to produce data sets in SPSS or SAS provided that variable names conform to the guidelines in this manual.  If other software will be used, please consult with NYC first.  Upon request, NYC will prepare data entry programs in EPI INFO for Project Sites lacking the resources to create their own.  However, all data entry must be done by the Project Site.  Data sets should be submitted to NYC within 3 months of completion of data collection.  It is highly recommended that Project Sites submit a small "test" batch of data early in the project to ensure that all procedures are fully understood.

Each project site should submit their study protocol for review by a local Ethics Board.  Each Site should prepare it's own Informed Consent Information Sheet to show (or read) to subjects so that they are made fully aware of possible implications of participation in the research project before they consent to take part.  Unless the Ethics Board recommends that oral consent is sufficient, written consent should be obtained.

Additionally, it may be helpful to prepare a "Screener".  This is usually a one-page series of questions designed to determine the eligibility of a potential recruit, and to screen out unsuitable candidates.

Data collection should be completed within one year of start date.

## **Study Eligibility and Recruitment**

**Current Injectors**
The primary focus of the study is on injecting drug use, therefore <u>a minimum of 400</u> injecting drug users (IDUs) should be recruited; 200 of these should have been recently admitted to treatment and should be recruited from treatment locations, while the other 200 should be recruited from non-treatment locations as follows:

a) In-treatment. A subject should have been admitted to treatment within the last 30 days and be currently still in the treatment program. Apart from the current course of treatment, the subject should not have been in that same treatment program or any other treatment program during the last 6 months. Thus, transfer patients would not be eligible. Much of the questionnaire asks about drug use and risk behaviors during the last 6 months (preceding interview) and we want to be ensure that for <u>most</u> of that period the subject was not in treatment. Where possible, subjects should be randomly selected from new admits. If that is not feasible, consecutive admissions over a specific time period would be adequate. It is vitally important to avoid any selection bias on the part of the investigators, data collectors, or subjects.

b) Non-treatment. Recruitment of these subjects should take place in non-treatment settings, although after recruitment it may turn out that the subject is (or has recently been) in some form of treatment. Ideally recruitment should be street-based, utilizing such techniques as peer-referral, snowball sampling, targeted sampling, etc. It would be preferable to avoid recruiting in the vicinity of any service location, including needle exchange programs, jails, etc. Random selection of subjects will not be possible here, although some attempt should be made to obtain a sample representative of the non-treatment population in the area.

Within each In-treatment and Non-treatment sample all IDU recruits must:
a) Have injected during the <u>last 2 months</u>
b) Not have been previously interviewed on this study during the preceding 12 months.

**Ex-Injectors and Never-Injectors**
Depending on local conditions, a Project Site may decide to recruit some persons who have replaced injection drug use by non-injection, and/or some persons who have never injected, <u>in addition</u> to the 400 Current Injectors. These can be recruited from In-treatment or Non-treatment settings as desired, must not have been previously interviewed on the study during the preceding 12 months, and must additionally satisfy the following criteria:

a) Ex-Injectors. Persons who used to inject but who have not injected during the last 6 months. However they must have used non-injection methods for "injectable" drugs during the <u>last 2 months</u>.
b) Never-Injectors. Persons who have <u>never</u> injected during their entire lifetime. However, the subject must have used non-injection methods for "injectable" drugs during the <u>last 2 months</u>.

**Subject Classification**
Some parts of the questionnaire apply only to selected groups of subjects, depending on their classification as Current Injectors, Ex-Injectors, or Never-Injectors. Although

the injection status of the subject should be determined by screening at the recruitment stage, the subject's responses during the interview may indicate that he/she actually belongs in a different group.  The interviewer should ask the subject to clarify any inconsistency, and should re-classify the subject if necessary, so that the appropriate questions may be asked.

During the course of the interview the following situations would be cause for terminating the interview:

a)  The subject refuses to give the month and year of his/her birth date.

b)  A subject refuses to give enough information to determine his/her injection status.

c)  A subject says that he/she has not used "injectable" drugs during the last 2 months. If the project site is only recruiting injectors (not ex-injectors or never-injectors) then the interview would be terminated if the subject has not injected during the last 2 months.

## Questionnaire Preparation

Individual Project Sites are encouraged to use all of the Core questions in the Questionnaire (see below), unless resources are so limited that the only way to conduct the study is to cut out parts of the questionnaire.

The questionnaire has been designed to permit insertion by individual Project Sites of additional questions and items (in multi-item questions) of local interest. Detailed instructions are provided below. Additional questions should be issued a unique question number. Most additional items must be numbered using Core Codes obtained from the Master Codebook (see below) or requested from NYC, to permit cross-site comparisons. These Core Code numbers should be pre-coded in the questionnaire – an example is provided at the end of this section. For a few questions, items of purely local interest (not for inclusion in cross-site comparisons) may be added; these will use codes created at the local level.

Each project site is responsible for finalizing its own questionnaire (and for creating additional interviewer instructions where needed for the local items) prior to preparing the questionnaire for use at the local site. If a site decides not to add any new items unused options should be eliminated from the questionnaire (discussed below), to avoid interviewer confusion.

### Translation and Interpretation

The section on Questionnaire Administration provides some extra clarification for questions that might not be self-explanatory. As far as possible please prepare the questionnaire in a similar format to the one provided by NYC. Do not change the meaning of any questions. Under no circumstances should question order be rearranged, or question numbers changed. **In particular do not change the numbers preceding the items or categories in multi-part questions. These serve to identify separate variables for computer data-entry.** However, local option questions (see below) may be omitted. Please send a copy of your questionnaire to NYC. If possible, project sites which are able to provide back-translation (from the native language back into English) should also send a copy of the translated English questionnaire to NYC for checking of translation adequacy.

In translation, substitute appropriate colloquial terms where appropriate. E.g., if the term "primary partner" is not understood, substitute a term such as "regular partner/steady partner".

### Core and Local Option Questions

The questionnaire contains "core questions" which must be included in each project site's questionnaire, and "local option" questions which may be included if they appear to be of local interest. Core question numbers begin with "Q", and local option questions begin with "X". If a project site does not plan to use some or all of the local option questions, these may be omitted from the questionnaire.

The multi-part question on non-injected drug use in the last 6 months (XD56) is a local option. However if substantial non-injected drug use exists in your area, you should include this question in the questionnaire.

## The Master Codebook

The Master Codebook contains core codes.  Use of a uniform coding system permits cross-country comparisons for analysis.  The Codebook will get updated every time project sites request codes for new categories or items.  Updated versions of the Master Codebook will be sent out to each site as soon as a modification occurs.  The Master Codebook will henceforth be referred to as MCB.

Codes from the MCB are used for three purposes:

i) As the item number for a Local Item added by an individual Project Site.  These are pre-coded into the questionnaire during questionnaire preparation.  Using a core code from the MCB as the item number will permit us to match items across sites for analyis.

i)  For responses to certain types of open-ended questions (see Questionnaire Format, below).  If the appropriate code does not appear in the response set on the questionnaire, it should be looked up and coded after the interview.

ii) To identify write-in "Other" items in multi-part questions.  These should be looked up and coded after the interview.

For some purposes, individual project sites will create and maintain local code lists for categories or items that do not have core codes and that are of purely local interest.  These local code lists can be added to the site copy of the MCB .  A copy of the local codes should be sent to NYC at the end of the study.

## Local Item Substitution Using Core Codes

Some multi-part questions have room for additional question items which may be chosen locally by individual project sites and incorporated into their questionnaire at the local level, but which will allow for the possibility of cross-national comparisons..  These are identifiable by the presence of "**## LOCAL ITEM (use core code as item ##)**" (or sometimes, due to space limitations, just  "**..core code…**") in the version of the questionnaire which you receive from NYC.  We recommend a maximum of five additions, but more can be added if desired.  Questions QC02-QC03, QC12, QD10-QD12, QD17, QD19, XD25, XD34, XD54, QD55-XD56, QD60, QE23, XH07, QJ06, QK02-QK03, QK06, QK14, QM03, QM05, QM07, XO14 are of this type. In these questions the text "**LOCAL ITEM**" indicates that you should substitute an item text of your choice and the item number ( indicated by the preceding "**##**") should be replaced by the appropriate code from the MCB.  The item number will become part of the variable name when the data is entered into a computerized data set.  If the item does not appear in the MCB, please request NYC for a code for that item so we may maintain comparability between project sites. **Please do not make up your own codes or we will lose the ability to do cross-site analyses.** The appropriate item text and item number must be inserted into the questionnaire by each project site at preparation time (see  "Example of Local Item Substitution" at the end of this section, in which PCP, Ecstasy, and Poppy milk balls have been supplied by a project site).  In all multi-part questions the categories listed should be mutually exclusive.

These additional "fill-in" items are provided for your convenience - you are not required to use them.  However, to avoid confusing the interviewer, any unused "LOCAL ITEM" lines should be deleted from the questionnaire.

Note that the "Other" lines are for items supplied by the respondent during the interview, and filled in by the interviewer, so the text and format of these lines should not be changed during questionnaire preparation.

**Local Items and Codes to be Created by Project Sites**

a) Interviewers' code numbers (QA03).  These are of purely local interest and should therefore be created locally.  Use any 2-digit codes except 95 through 99 (see Reserved Codes below).

b) Recruitment location (QA05A).  This is a 2-digit code, created locally to identify the specific treatment center, or the geographic location in the community where recruitment took place.  Use any 2-digit codes except 95 through 99.

c) Recruiter (QA05B).  This is a 2-digit code, created locally to identify the person who recruited the subject into the study.  Use any 2-digit codes except 95 through 99.

d) Respondents' race/ethnicity (QA09).  Each project site should identify major population "groups" found in the area.  Use 2-digit codes 01, 02, 03, ... etc.  The first code should be used for the dominant ethnic group in the population of that country, and so on in order of decreasing group size.

e) Vocational training, certificates, licences etc. (XB04).  Any participating site wishing to gather this information should create appropriate items (maximum of five) to incorporate into the questionnaire.  In these questions the text "**LOCAL ITEM**" indicates that you should substitute an item text of your choice.  N.B. High school, college, or other academic diplomas, certificates, etc. would not typically be included here.  However, if there is a particular need to obtain more information on academic education than provided by QB03, one or more items could be included in XB04.

f) Types of places in which respondent initiated another person into injecting (XD45).  This information could be of critical intervention importance but is likely to be site-specific.  (Items listed in XD32 may give you ideas.)  Any participating site wishing to gather this information should create appropriate items (maximum of six) to incorporate into the questionnaire.

g) "Other" categories in questions which do not use Core Codes.  (See list of question numbers under Local Codes in the MCB.)  Sites which desire to retain response details that do not fit the provided codes will need to create and continually update code lists for all possible "other" responses.  Alternatively, any non-listed response can be coded as a generic other with the code "96", but a list of question numbers to which this option applies should be added into your local version of the MCB.

**Social Class Questions and Coding Categories**

We would like to include two questions on social class as follows:

QB11  What was the social class of the family that raised you?