

CIDI

Q x Q Version: 10/02/00 ; (rev. 05/28/02)

Purpose of this form: The CIDI is a computerized, self-administered interview to assess mental disorders by DSM-IV and ICD-10 criteria.

When to complete this form: The CIDI is only administered at the second screening visit (S02) to all patients.

GENERAL INFORMATION

Instructions for using CIDI Auto 2.1

- Setting up the program on the computer:
The CIDI is administered on the computer in DOS format. The interviewer must set up the computer according to procedure outlined in the Instructions for using CIDI Auto 2.1: Set-up procedure.
- Make sure that the patient::
Has privacy to continue the interview.
Understands how to operate the computer.
Has access to the interviewer to answer questions as needed.
- Tutorial:
The first part of the program is a tutorial designed to teach the patient how to answer each type of question s/he may encounter in the interview. If the patient is not able to complete this section, it may be necessary for the interviewer to conduct the interview. (See note under Tutorial Module in Instructions for using CIDI Auto 2.1).
- Viewing the Interview Results:
See page 5 of the Instructions for using CIDI Auto 2.1 for details of the file. As Appendix A, there is a “dummy” hard copy to look at. Notice that the ID # is r0987654 and that at the top are the DSM-IV Diagnostic Scores and then the ICD-10 Diagnostic Scores. Only the DSM-IV Diagnostic Scores are to be entered on Form #4 (Screening Checklist).
- Printing out a hard copy of the results for the patient’s file:
Follow directions on page 5 of the Instructions for using CIDI Auto 2.1 for printing out a hard copy of the patient’s file. This file must be converted into a Word document in order to print.

COMPOSITE INTERNATIONAL DIAGNOSTIC INTERVIEW (CIDI) Interviewer’s Manual

- This describes how to conduct an interview if the patient is not able to complete the CIDI by her/himself.

Instructions for using CIDI Auto 2.1

The CIDI Auto 2.1 is a computerized, self-administered diagnostic interview for the assessment of mental disorders by DSM-IV and ICD-10 criteria. The following instructions are for running the CIDI Auto 2.1 program that has been installed on your computer (See Appendix 1 for installation instructions). If additional questions arise, please refer to the Administrator's Guide and Reference manual.

Set-up procedure

The CIDI Auto 2.1 should be administered on a computer in a quiet, private environment with no distractions. The Respondent and Interviewer should be comfortably seated during the process.

1. Double click on the CIDI shortcut Icon on your computer
2. The program will run through several information screens before the interview set-up data entry screen appears as shown below
3. The row of 4 boxes in the menu panel at the top of the screen identifies possible actions to be taken. When a new interview is to be set up only the **EDIT SETUP**, **CREATE DEFAULT**, and **QUIT** options are available. Pressing [Enter] will cause the highlighted option to be executed. The highlighted option may be changed by pressing either the arrow keys or the tab key.
4. To set-up a new interview, press the highlighted **EDIT SETUP** key. In this window there are two main types of items. The items ID CODE, AGE, BIRTHDATE, INTERVIEWER CODE, and REMARKS all require the administrator to type in information. All of the other items have a limited set of alternatives from which one is selected by using the arrow keys to scroll through the options. Once the information has been entered or selected the administrator may move on to the next field by typing [Tab] or [Enter]. To move to a previous field, type [Tab] while holding down the [Shift] key. The items ID CODE, GENDER, AGE, BIRTHDATE, and INTERVIEWER CODE must have information entered or an alternative selected or else the program will beep and the **RUN AS SHOWN** option will not be made available.
5. The items in the set-up information window are identified below in their forward entry order

ID CODE: Record the 7-digit ID Code as follows:

The first digit starting at the left is the visit # as follows:

Screening (S00) = 0 (If you only put the last 6 digits of the patient ID, a "0" will automatically be added to the left of the patient ID.)

Week 24 (W24) = 1; Month 12 (M12) = 2; Month 24 (M24) = 3; Month 36 (M36) = 4;

Month 48 (M48) = 5; Month 54 (M54) = 6; Week 48 (W48) = 7; Week 72 (W72) = 8;

Randomization Visit (R00) = 9

The last 6 digits are the patient ID number.

GENDER: The interview engine must know the Respondent's GENDER because there are a number of questions within the interview which vary as a function of gender. Using the arrow keys, select either MALE or FEMALE and press [Enter].

AGE: The Respondent's AGE in years on the day of the interview must be entered in this field. This two digit item is entered by the administrator rather than the respondent for accuracy.

BIRTHDATE: The respondent's birthdate must be entered in European format: The day of the month, followed by the month, and then the year, are all entered as two digit numbers. For example, the date

30th of May 1957 would be entered as 300557. The program will not accept dates in any other format.

INTERVIEWER CODE: Any number up to 3 digits in length may be entered in this field. A Default value of 999 will appear if you do not specify an interviewer code. It is suggested that an interviewer code be developed at each center to specify which study coordinator administered the Interview (i.e. at UMich, 001= Amy Randall-Ray, 002= Pam Richtmyer).

5. The preceding 5 items must all have a valid value entered before the program will allow the administrator to run the interview. The remaining items in the set-up are initially set to a default value by the program and may be left or unchanged at the administrator's discretion.

ADMINISTRATION BY: This item has two alternatives: RESPONDENT or INTERVIEWER, either of which may be selected. If the INTERVIEWER option is chosen, some additional text, meant only for the administrator, will be visible on the screen (See Appendix 2). These additional questions should not be asked of the Respondent, so it is important not to choose the INTERVIEWER option if the program is meant to be self-administered by the RESPONDENT.

DEMOGRAPHICS (A): When setting up a new interview this item has only one option, ADMINISTER. Because the demographics section has several questions which control how later questions in other sections of the interview are asked, it is important that it always be administered.

TOBACCO (B) through INTERVIEWER RATINGS (X): These items representing the modules of the CID I have 3 alternatives: ADMINISTER, DO NOT RUN, or RUN LATER. The three alternatives control which sections of the interview are administered. Choosing ADMINISTER or DO NOT RUN controls whether the section will be administered or not. Choosing RUN LATER will result in the section not be administered in the current session, but the section can be administered in a later session.

For the HALT-C trial, only the **ANXIETY DISORDERS (D)**, **DEPRESSION (E)**, **ALCOHOL (J)**, and **DRUGS (L)** modules should be highlighted as ADMINISTER. All of the other modules should be highlighted as DO NOT RUN. (NOTE: Umich and USC will use the **ANXIETY (D) and DEPRESSION (E)** modules at additional test administrations at month 6,12,24, 36, 48,and 54 for Randomized patients, at W48 and W72 for week 20 Responders and at Randomization visit (R00) for Breakthrough/ Relapsers (Communication #28, #29) per the Ancillary Study protocol)

ICD DIAGNOSES: This item has two alternatives: YES or NO. Selecting YES will cause the ICD-10 Scoring program to be run. The type of output asked for is controlled by the REPORT FORMAT item described below and the output will be written to a file having the name R[idnumber].ICD. Note that the scoring program can be run later even if this item is coded as NO when the interview is run. For the HALT-C trial please enter **YES** for this field.

DSM DIAGNOSES: This item has two alternatives: YES or NO. Selecting YES will cause the DSM-IV Scoring program to be run. The type of output asked for is controlled by the REPORT FORMAT item described below and the output will be written to a file having the name R[idnumber].DSM. The initial default value for both ICD DIAGNOSES and DSM DIAGNOSES is **YES**. For the HALT-C trial, please enter **YES** for the DSM DIAGNOSES field.

REPORT FORMAT: This item has two alternatives TEXT or DATA. This item controls the way in which the output from the Scoring programs appears in the scoring files. Selecting TEXT will cause the output to appear as text describing the diagnoses for which the Respondent met criteria. Selecting DATA will cause the output to appear as data which can be read into statistical analyses packages. Please use the **TEXT** format for respondent's in the HALT-C trial.

REMARKS: This item allows the administrator to enter up to 40 characters of free form text. It may also be left blank. For the HALT- C trial , we do not plan to enter any data into this field.

6. The set-up is now complete. If the administrator presses the [Esc] key, all four action options, including **RUN AS SHOWN**, will become available on the menu at the top of the screen. If [Esc] is pressed before having completed entry of the required set-up information, the program will cause the computer to beep and the **RUN AS SHOWN** option will not be available in the menu.

CREATE DEFAULT: At this point the administrator may choose to use the current selection of Sections to be administered and outputs to be created as the default set-up. Pressing [Enter] with the **CREATE DEFAULT** menu option highlighted will cause the program to create a file named **CIDIA.INI** in the current working directory. This file will contain the information about which sections are to be run and what output is to be created. It will not contain any identifying information about the particular respondent for whom the set-up may have initially been created. On starting the CIDI-Auto, the program will look in the current working directory for **CIDIA.INI**, and if it is found, will use its contents to define the default values for the items. Otherwise, it will use the internally defined default set-up.

RUN AS SHOWN: This menu option runs the program as shown in the set-up screen. Selecting this menu option causes the program to create a file named R[idnumber].INI which contains all the set-up information for that Respondent. This file controls the execution of the interview engine and the data transfer programs.

QUIT: This menu option allows you to quit from the program without saving any of the changes that may have been made in the set-up data or creating any other files.

Interview operation

Once the set-up procedures have been completed the program will present a screen carrying the CIDI-A logo. Pressing [Enter] will cause the program to continue. If the interview is to be administered by the INTERVIEWER, the program will skip straight into the **DEMOGRAPHICS (A)** section. If the interview is to be self-administered by the RESPONDENT, the program will next present the Respondent with reassurance about the confidentiality of their responses. This is followed by a relatively detailed tutorial. The study coordinator should remain available to assist with completion of the tutorial and entering numerical and letter data into the computer keyboard or attached keypad as needed.

Tutorial Module

The tutorial has been designed to teach the RESPONDENT how to answer each type of question they may encounter in the interview. Each type of question is described and in some cases the Respondent is given a chance to try entering a response to a question of that type.

The Tutorial warns the Respondent to read onset and recency questions carefully. Upon completing the tutorial which takes ~ 5 minutes, the program continues with the interview itself starting at section A.

NOTE: If a Respondent is unable to complete the tutorial section , they will likely encounter great difficulty with many of the more complex questions in the interview. In such cases the administrator is strongly advised to administer the interview to the RESPONDENT in the INTERVIEWER mode (See Appendix 2).

The Interview

The Study coordinator should leave the area to allow the Respondent to complete the program in privacy. However, the Study coordinator should remain nearby to answer questions or troubleshoot problems that may arise.

It should take **20- 40 minutes** for a Respondent to complete the **ANXIETY DISORDERS (D)**, **DEPRESSION (D)**, **ALCOHOL (J)**, and **DRUGS (L)** modules during Screen 1 of the HALT-C trial..

Types of questions- The following paragraphs describe how responses are entered for each of the different type of questions used in the interview.

Yes/ No questions- Most of the questions asked require a simple yes or no response. Throughout the interview a **5** is used to indicate Yes and a **1** is used to indicate No. In the tutorial, the Respondent is instructed to answer **No** if they are not sure whether their answer should be Yes or No.

The Go Back key- Within a Section of the interview, Respondent can go back to a previous question by entering [-] [Enter] (i.e. typing the minus key followed by the [Enter] key). It is possible to back up from the last to the first question within a module. It is not possible to go back to a question within a previous module.

Numerical Answers- Some questions require users to enter the age of onset or recency of symptoms or to provide some other kind of numerical answer. Answers to such questions are given by typing in the appropriate number followed by [Enter]. These questions also allow users to indicate that they do not know the answer by entering the letters **DK** instead. The program will not accept [Enter] alone. **DK** responses will nearly always be followed with a simple multiple choice question asking the user to choose from a range of broad estimates.

Multilpe Response Answers- A few questions allow users to choose one or more of a number of options as their answer. The most common of these is the question asked about the diagnoses a doctor may have given as the cause of a particular symptom. Users are able to select and deselect options from the list of available options. An option is selected by typing its corresponding letter or number, causing it to be highlighted. To de-select the option, the user types the corresponding letter or number again. Users may select as many of the available options as appropriate.

Text Answers- Some questions request users to enter text as the answer to the question. Users are only allowed to enter one line of text (~ 60 characters). If they attempt to type beyond the end of the input line the computer will “beep” at them and ignore any further input other than [Enter] or [Backspace].

Quitting from a Section or Terminating an Interview

The interview administrator can gain control of the program in order to quit from one section or to terminate the entire interview by typing **[#]** (i.e. [Shift] [3]) from any multiple choice or multiple response questions. Typing **[#]** causes a message to appear at the bottom of the screen that lists 3 options:

- [R]** = Resume the interview and return to the current question
- [Q]** = Quit the current section and go on to the next
- [T]** = Terminate the whole interview

If the administrator chooses **[Q]** to quit from the current section, the data for that section will be saved but a code will be entered in the R[idnumber].INI file marking that section as partially completed. At the end of the interview, the data transfer program will ignore the data from partially completed sections when it concatenates the data files from each section. This allows the administrator to

examine the data but stops the scoring program from making any decisions on the basis of incomplete data.

If the administrator chooses **[T]** to terminate the interview, the data from the current section will not be saved. However, data files from previously completed sections will be concatenated.

Note that a module is complete only after a **5**, indicating move on to the next module, has been entered at the final question of the section. It is only at this point that the results of the Section are written to a file. Terminating the interview at any point within a Section, including the final question of a Section will mean that the results for that Section are not written to a file.

Viewing the Interview Results.

The Scoring programs read the R[idnumber].OUT created at the end of the interview and create their own results files which will be named either R[idnumber].ICD (if ICD Diagnoses had been called for) or R[idnumber].DSM (If DSM Diagnoses had been called for).

The file **R[idnumber].SCS** contains the results of the scoring program and should be printed out in hard copy format. In the HALT-C trial, both the ICD-10 and DSM-IV diagnostic data will appear in this file.

Data files: Two files , R[idnumber].INI and R[idnumber].OUT, contain all the results of the interview and must be kept. When the data transfer program creates the R[idnumber].OUT file it also creates a compacted version suitable for use as a hard copy of the raw data. This file named **R[idnumber].ALL** contains the same data as that found in R[idnumber].OUT however the information is organised in a compacted format. These files can be found in the CIDI folder in your directory. A hard copy **of R[idnumber].ALL** should be printed out and stored in the patients CRF for future reference.

Inputting CIDI data into the HALT-C Trial database

The DSM-IV diagnoses obtained from a Respondent should be transferred on to section **H of Form #4** of the Screening Checklist. The following parameters for each DSM-IV diagnosis should be transferred to Form #4

- a. DSM-IV 5 digit diagnostic code
(e.g 296.32= Major depressive episode, recurrent, moderate)
- b. Number of diagnostic criteria met
Code identifying what level of diagnostic criteria were met.
0= Indeterminate diagnosis
1= Criteria for diagnosis not met
3= The positive criteria for diagnosis are met but exclusion criteria not met
5= All diagnostic criteria are fulfilled
- c. 1 digit onset code
Standard CIDI Onset code
1= within last 2 weeks
2= 2 weeks to less than 1 month ago
3= 1 month to less than 6 months ago
4 = 6 months to less than 1 year ago
5=in the last 12 months, DK when
6 = more than 1 year ago
- d. 2 digit age of onset if Onset is coded
- e. 1 digit recency code
Standard CIDI Recency code

- 1= within last 2 weeks
- 2= 2 weeks to less than 1 month ago
- 3 = 1 moth to less than 6 months ago
- 4= 6 months to less than 1 year ago
- 5= in the last 12 months, DK when
- 6 = more than 1 year ago

f. 2 digit age recency if Recency is coded

g. DSM-IV diagnosis text

DSM-IV diagnosis text and code

The following DSM-IV diagnoses can be generated from the CIDI Auto 2.1 module of ANXIETY, DEPRESSION, ALCOHOL, and DRUGS.

Anxiety disorders

- Specific phobia (300.29)
- Social phobia (300.23)
- Agoraphobia without history of panic disorder (300.22)
- Panic disorder without agoraphobia (300.01)
- Panic disorder with agoraphobia (300.21)
- Generalized anxiety disorder (300.02)

Depressive disorders

- Major depression, single episode mild (296.21)
- Major depression, single episode, moderate (296.22)
- Major depression, single episode, severe (296.23)
- Major depression: recurrent , mild (296.31)
- Major depression, recurrent, moderate (296.32)
- Major depression, recurrent, severe (296.33)
- Dysthymia (300.4)

Alcohol abuse (305.00)

Alcohol dependence (303.90)

Psychoactive substance use disorders; dependence or abuse

- Cannabis abuse (305.20)
- Cannabis dependence (304.30)
- Cocaine abuse (305.60)
- Cocaine dependence (304.20)
- Hallucinogen abuse (305.30)
- Hallucinogen dependence (304.50)
- Inhalant abuse (305.90)
- Inhalant dependence (304.60)
- Opioid abuse (305.50)
- Opioid dependence (304.00)
- Amphetamine or similar-acting substance abuse (305.70)
- Amphetamine dependence (304.40)
- Sedative abuse (305.40)
- Sedative dependence (304.10)
- Stimulants
- PCP abuse (305.90)
- PCP dependence (304.90)
- Other substance abuse (not otherwise specified [NOS]) (305.90)
- Other substance dependence (304.90)

Installation procedure using Windows

1. To install CIDI-Auto, open up your Windows File Manager/ Windows Explorer and create a directory folder for the files (Name this new directory CIDI).
2. Copy the program files from the distribution disk into the directory you have just created by dragging the file icons over to the appropriate directory.
3. Once the installation programs have been copied, simply double-click on each of the **LT.EXE** and **12.EXE** file icons, to execute their installation programs. This will result in the extraction of the 8 program files for each version of the CIDI-Auto.
4. To run CIDI-Auto, merely double-click on the **CIDI2_LT.EXE** file icon in the file Manager/ Windows Explorer for the standard lifetime version of the CIDI-Auto. Or double-click on the **CIDI2_12.EXE** file icon in order to run the 12-months recency version of CIDI-Auto. The CIDI-Auto should then switch the computer to a DOS mode, or open up a DOS window on the screen, which will then run the CIDI-Auto program
5. To setup program access that is more convenient than double-clicking the program icon within the Windows/ Explorer, simply drag the program icon for **CIDI2_LT.EXE** or **CIDI2_12.EXE** from the Windows Explorer directory folder onto the background wallpaper. Note the Explorer will have to be windowed rather than full screen to allow a view of both the Explorer and the Wallpaper. This will automatically generate a shortcut to the program file on your desktop.

Interviewer Adminstered CIDI Auto2.1

The CIDI auto 2.1 may need to be administered by the INTERVIEWER if the RESPONDENT is not capable of performing the self-administered version. Because of the need for stating each question, it is anticipated that an INTERVIEWER administered CIDI will take 30 to 40 minutes to complete.

1. **INTERVIEWER preparation-** Before administering the CIDI- Auto 2.1 to a respondent, it is imperative that the INTERVIEWER be familiar with the format, questions, and content of each module. The INTERVIEWER should read all of the sections in the CIDI 2.1 Interviewers Manual before starting an interview. A copy of the actual questions in each module is available in the CIDI Training Reference Questionnaire.
2. **INTERVIEWER instructions:** When the CIDI Auto 2.1 has been set-up in the INTERVIEWER mode, there will be text and instructions addressed to the INTERVIEWER that are set off in brackets and typed in caps. This text should not be read aloud to the patient. These instructions assist the INTERVIEWER.
3. **Cards-** In some of the modules like ANXIETY (D), ALCOHOL (J), and DRUGS (L), the INTERVIEWER will be asked to give the respondent a card for reference to subsequent questions. In these circumstances, give the requested card to the patient before proceeding. At time you will be asked to circle the patient's response for them and then refer back to the circled text. When finished with the interview, keep the completed cards with the computerized data output in the patient's CRF.
4. **Questions-** The principles of asking questions in the standardized interview are essential to maintain the integrity of the survey data. Questions must be read in their entirety and in the order they appear to ensure comparability across respondents. Even slight deviations from wording have been shown to affect responses. Please review pages 9-13 of INTERVIEWER's Manual for exceptions due to grammatical changes, breaking questions into shorter questions, and verifying responses.
5. **Data entry-** Type the respondents response into the computer as a digit or free text into the computer as appropriate to the question. Verify the respondents answer as needed.

PROBE FLOW CHART- Throughout the CIDI interview, a determination as to whether the reported symptom may or may not be due to a possible Psychiatric condition vs other cause is assessed. The following line of questioning is used regarding many symptoms or situations:

- Did symptom occur ?
 - If Yes:
- Was it severe ?
 - If Yes:
- Was it always due to illness, injury, or medicine drugs, or alcohol ?
 - If No:
- Possible Psychiatric symptom

A psychiatric diagnosis is made when a specified number of positive or inclusion criteria are met and exclusion criteria are eliminated. If a symptom is believed to be due to illness, injury, or medicine, drugs, or alcohol then it will not be classified as a possible psychiatric symptom. To get this information, the PFC is used repeatedly to determine 1) "Did you ever have X symptom ? 2) IF yes, "did you tell a doctor about X symptom ?" 3) If Yes" What was the diagnosis of X symptom ? IF no, "Did you tell another Professional about X symptom ?" 4). "Was X symptom ever the result of physical illness or injury ? " 5) "Was X symptom ever the result of taking medication, drugs, or alcohol ? " 6) If no to 4 and 5,

NOTE: **Doctor** includes psychiatrists, other medical doctors, and osteopaths.

Other Professional includes psychologists, social workers, counselors, nurses, clergy, dentists, chiropractors, healers, and podiatrists .

PRB 1 = DID NOT HAVE SYMPTOM

The respondent denies having the symptom, problem or experience, or doesn't remember having it. No further questions will be asked about this symptom. IF PRB 1 = YES then further questions are asked

PRB 2 = NOT CLINICALLY SIGNIFICANT

The respondent has had the symptom but the symptom was never severe enough for the respondent to seek professional help or take medication for it more than once, and it did not interfere with his/ her life or activities a lot (i.e. it was not clinically significant).

PRB 3 = ALWAYS CAUSED BY MEDICATION, DRUGS, OR ALCOHOL

The respondent has had the symptom and its occurrence met the criteria for clinical significance . Further probing for causes indicated that the symptom was always the result of the respondent's use of medications, drugs, or alcohol.

PRB 4= ALWAYS CAUSED BY PHYSICAL ILLNESS OR INJURY

The respondent has had the symptom and its occurrence met the criteria for clinical significance. Further probing for causes indicated that the symptom was always the result of a physical illness or injury or all occurrences were the result of either a physical condition or using medication, drugs, or alcohol.

PRB 5 = POSSIBLE PSYCHIATRIC SYMPTOM

The respondent has had the symptom and its occurrence met the criteria for clinical significance. Further probing for causes indicated that all occurrences could not be explained by either using medication, drugs, or alcohol or a physical illness or injury. A PRB 5 question will lead to subsequent questions regarding ONSET and RECENCY.

Appendix A for CIDI

DSMIV Diagnostic Scores : r0987654

296.32 5 Major Depressive Disorder, Recurrent, Moderate
 Onset Code 6 Age 37 Recency Code 3 Age 56
 300.23 3 Social Phobia
 Onset Code 2 Age 56 Recency Code 2 Age 56

ICD10 Diagnostic Scores : r0987654

F33.2 5 Recurrent Depressive Episode - Severe - without Psychotic Symptoms
 Onset Code 6 Age 37 Recency Code 3 Age 56
 F41.0 5 Panic Disorder
 Onset Code 6 Age 22 Recency Code 6 Age 45

Example of how to record the CIDI diagnostic scores on Form # 4 , page 3, section H (using the DSM-IV Dx above).

Composite International Diagnostic Interview (CIDI):

H1. CIDI IDCODE: 0 9 8 7 6 5 4 (0 plus 6-digit pt ID #)

	Yes	No
H4. Were any DSM-IV diagnoses made for this patient by the CIDI program?	①	2 (H6)
H5. If yes, how many DSM-IV diagnoses? <u>0 2</u>		

a. Diagnostic Code	b.Diagnostic Criteria	c. DSM-IV Diagnosis		
1.a. <u>2 9 6 . 3 2</u>	b. <u>5</u>	c. major depressive disorder, recurrent, moderate		
	d. Onset Code	e. Age of Onset	f. Recency Code	g. Age of Recency
	d. <u>6</u>	e. <u>3 7</u>	f. <u>3</u>	g. <u>5 6</u>