OVERVIEW OF CLINICIAN-ADMINISTERED KSADS-COMP
KSADS-COMP LLC

www.KSADS-COMP.com

608-406-2621

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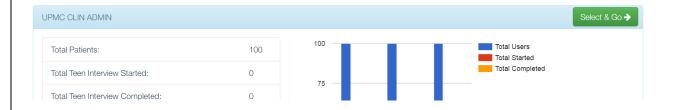
# **OVERVIEW OF CLINICIAN ADMINISTERED KSADS-COMP**

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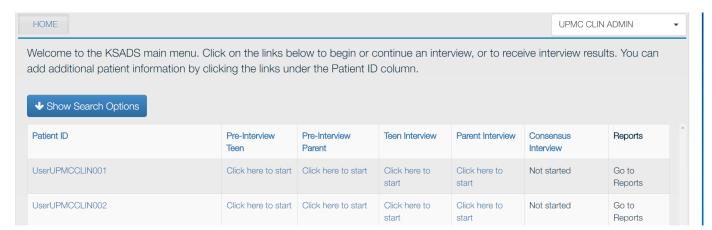
# LOGGING IN

- 1. LOG IN. Once you have purchased the KSADS-COMP, the link to log in is: <a href="www.ksadslogin.com">www.ksadslogin.com</a>. If you are logging into the demonstration site, use the login link provided in the email with your demonstration site userid and password.
- 2. PASSWORDS. The first time you log in, you will be asked to reset your password. If your study has opted for two-factor identification, you will also be asked to provide additional information you would like to use as your second factor identification. For security purposes, you will be asked to change your password every 90 days.
- 3. When you log in, you will see this screen. Most users will see only one 'group' listed. However some users will see more than one, since they may be participating in more than one study, or may be using both the self-administered and clinician administered KSADS in their study. Click 'select and go' to begin.



4. CHOSE THE TYPE OF INTERVIEW AND INTERVIEWEE (TEEN OR PARENT): Once you click "select and go" you will be brought to the main menu (shown below). Here you will choose the type of interview you want to conduct. In the clinician-administered KSADS, there are three 'types' of interviews: *Pre-Interviews, Interviews*, and *Consensus Interviews*. Each is described below.

#### **KSADS Main Meu**

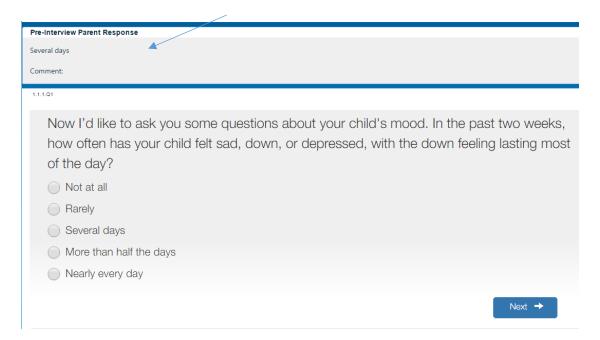


# TYPES OF INTERVIEWS

#### THE PRE-INTERVIEW

The *Pre-Interview* is a brief pre-screen that is completed independently by the patient before they see you. It is not required, but it is strongly recommended as it helps streamline the time it takes you to conduct the clinical interview. The patient's answers to the pre-screen questions are displayed on the screen as you go through the screening modules of clinician interview (see below). This helps to guide your interview, allowing you to simply summarize what they said and move on rather than having to re-ask all the questions verbatim from scratch. The pre-interview consists of all the current questions from the screening modules. There are about 180 questions in the pre-interview, and it should take the patient about 20 minutes to complete. There are both teen and parent versions of the pre-interview.

#### Answers to Patient Pre-interview on clinician's screen

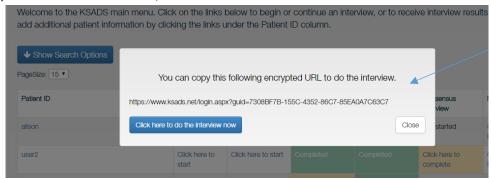


You also have the option of having the patient complete the pre-interview from home before the office visit. To do this, click on "Click here to start" under either the Parent or Teen pre-interview.....



....and the box below will appear. Copy the URL and email or text it to the patient. When the pre-interview is conducted remotely from home, the suicide and homicide items are not included.

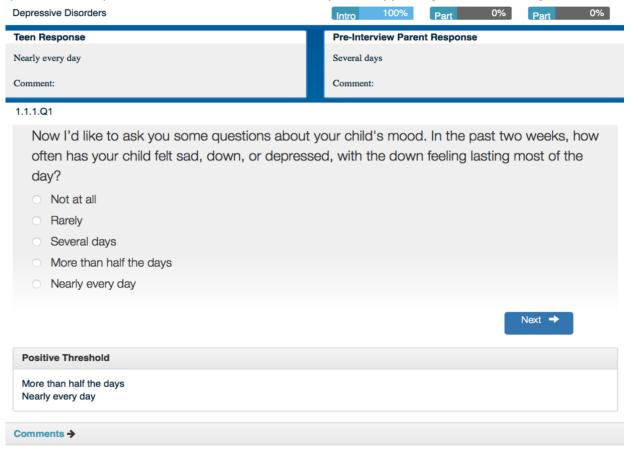
To do the pre-interview in the office, click on 'Click here to do the interview now".



#### **TEEN AND PARENT INTERVIEWS**

The *Teen Interview* and *Parent Interview* are the Teen and Parent versions of the clinician-administered KSADS. Once you have completed a clinician-administered interview with a teen, their answers will be shown on the screen during your interview with the parent (see example below). Similarly, if the parent clinician-administered interview was conducted first, their answers will be shown on the screen during the teen interview. This is done to help guide your thinking and questioning. Also note that the threshold rating for a positive response for each item is shown in the lower left corner.

#### Example of Teen Responses and Parent-Pre-Interview Responses Appearing on Screen During Parent Interview

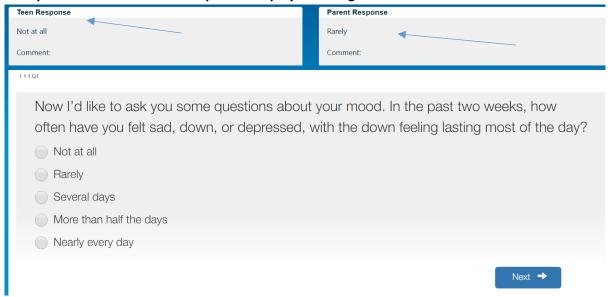


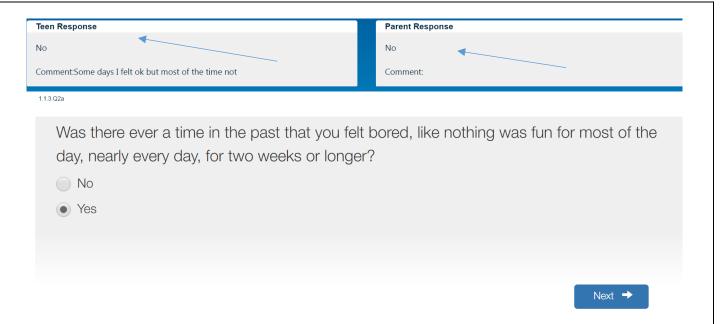
**Introductory Interview**. Each Teen and Parent Interview begins with an Introductory Interview. The parent introductory interview obtains information about the child's health, presenting complaint, social functioning, prior psychiatric treatment, and current and past psychiatric medications. Both the parent and the child introductory interviews ask about the child's school functioning, hobbies, and peer and family relations. Discussion of these latter topics is extremely important, as it provides a context for eliciting mood symptoms (e.g., depression and irritability), and obtaining information to evaluate functional impairment. This section of the KSADS-COMP should be used to establish rapport with the parent(s) and the child, and should never be omitted.

#### THE CONSENSUS INTERVIEW

The *Consensus Interview* is done after you have completed both the parent and teen interviews. It is your chance to use your clinical judgment in weighing both sources of information to come up with a final rating. For each item in the consensus interview, both the teen and parent's responses to that item will appear on the screen, along with any notes you took (see examples below). Use your clinical judgment to pick a final rating; you can even choose a different rating than you originally gave to either the teen or the parent if other information came up to affect your rating. Usually, however, the rating would typically be a rating you gave to either the teen or the parent. Note that the consensus interview will branch based on your consensus rating for each item. Since parent and teen may have answered questions differently, some follow up questions may have only been answered by only one of them, due to branching logic. In that case, only the answers from the person who answered the question will appear.

# **Examples of Teen and Parent Responses Displayed During Consensus Interview**





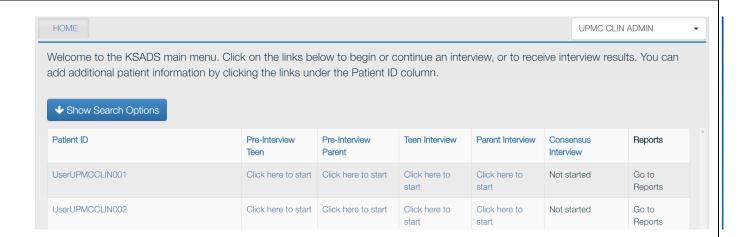
# RENAMING A PATIENT ID.

Once you log in you will see the screen below. We have generated preassigned ID numbers for you. However you have to ability to change the ID's to fit your preferences. Click on the patient ID you want to rename. A window will pop up allowing you to change the Patient ID. Simply delete and/or type over the preassigned patient ID with the ID of your choosing. There is also a line for "additional information". Some clinicians use this field to enter the patient name. Or you can use this filed for your unique ID. The additional information field will show up in the "Overall Report" (described below). Once you start an interview, you will not be able to change the ID. However you can change the ID if you have not entered any data yet for that ID. Remember to click "Update & Close" to save your entries.

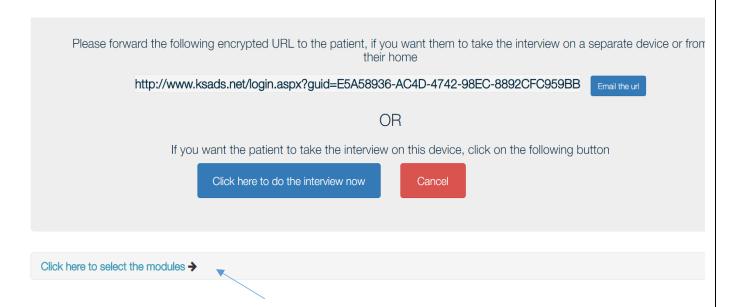


# STARTING AN INTERVIEW

To start an interview (either pre-interview, teen interview, parent interview, or consensus interview), click on the 'click here to start' link under the type of interview you wish to administer.



Once you click 'click here to start' you will come to the screen below. To start the interview immediately, click on "Click here to do the interview now". You also have the option of emailing the link to the patient in order to take the interview from home, or from another location or device. To do this, click "Email the url" and it will open your email application and automatically paste the link in the body of the email. Alternatively, you can copy and paste the link to the interview into your email yourself.



#### **Choosing Modules to Administer**

When you click the link to start the interview, all the modules will be administered by default. However, when we set up your account, we can customize your set-up in one of three ways, depending on your preferences:

Option 1: Standard Option. The standard option will administer all the modules by default. However, you do have the option at the beginning of each interview to select only certain modules to administer to a patient. To do this, click on the "Click here to select the modules" link (see prior screen). The screen below will appear. Click on the modules you want to administer to the patient and then click the blue "Save selected modules". If you don't click this it will not save your choices and all modules will be administered. Note if you choose Mood Disorders, it will automatically select the sleep and suicide modules as well, as they are part of the Mood

'Click here to do the interview now" it will administer all modules by default. Intro Mood Disorders Panic Disorder Psychosis O Social Anxiety Disorder O Specific Phobia Agoraphobia Separation Anxiety Generalized Anxiety Obsessive Compulsive Eating Disorders Enuresis and Encopresis Disorder Disorder Attention Deficit Oppositional Defiant ■ Tic Disorders Conduct Disorder Hyperactivity Disorder Disorder Autism Spectrum Post-Traumatic Stress Alcohol Use Disorder Drug Use Disorders Disorders Disorder ■ Selective Mutism ■ Sleep Problems Suicidality Homicidality Save selected modules

Disorders module. Again, if you don't click the link taking you to this screen to select modules, but instead click

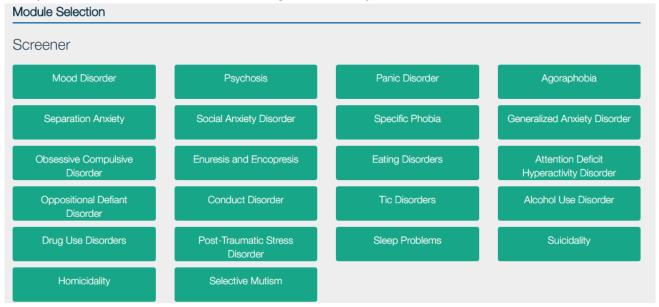
Option 2. Pre-Select Modules. Some research studies only want to administer certain modules as part of their trial. We can set it up so that the default is that only the modules required for the study are administered. This saves time at the beginning of each interview, as you don't have to spend time choosing the modules for each patient. It also helps guard against clinician error, in choosing (or forgetting to choose) the required modules for your study. This is particularly relevant for studies with multiple sites. You still have the option for choosing additional modules on a patient by patient basis before the start of each interview.

#### Example of "Pre-selected" Interview

Intro Mood Disorders **Psychosis** Panic Disorder Agoraphobia Separation Anxiety Social Anxiety Disorder Specific Phobia Generalized Anxiety C Obsessive Compulsive Enuresis and Encopresis Eating Disorders Disorder Disorder Oppositional Defiant Attention Deficit Conduct Disorder ■ Tic Disorders Hyperactivity Disorder ☑ Autism Spectrum Post-Traumatic Stress Alcohol Use Disorder Drug Use Disorders Disorders Disorder ■ Selective Mutism Homicidality Save selected modules

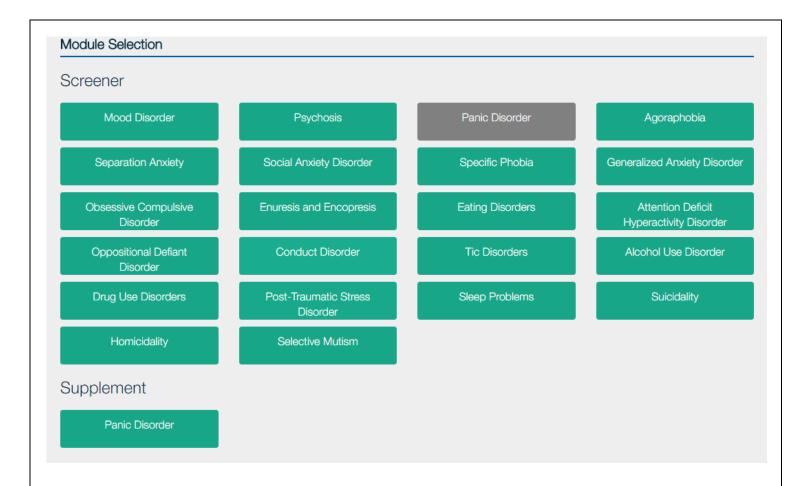
Option 3. Selection During Interview. In this option, clinicians are free to choose "on the fly" during the interview which modules to administer, and in what order. At the beginning of the interview, after the introductory portion of the interview is completed, you are presented with a menu of the screening modules for all the disorders (see below).

#### **Example of Initial Screen for "Selection During Interview" Option**



After completing a screening module for a chosen disorder, the supplement module for that disorder will appear and because accessible *if the patient met criteria for that disorder* in the screen (see below). You are returned to a main menu after each module, and are free to choose another screening module, or go to the supplement for those modules endorsed in screener. While this option allows for greater flexibility, it also opens up the possibility for clinician error in choosing modules that aren't required or forgetting to administer required modules. It also makes the interview longer, as you have to keep picking modules as you go along vs. automatically sent to the right module. This option is more geared for clinical practice, where clinicians are not bound by clinical trial requirements.

Example of Screen After Screening Positive for Panic Disorder. The Panic Disorder Supplement Appears.



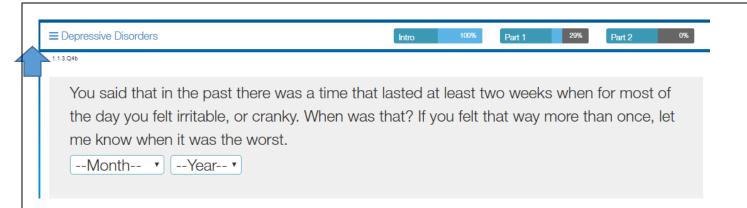
#### **Taking Notes**

You can type in notes on any item by clicking the comments link. Notes can be typed or written in using a stylus.

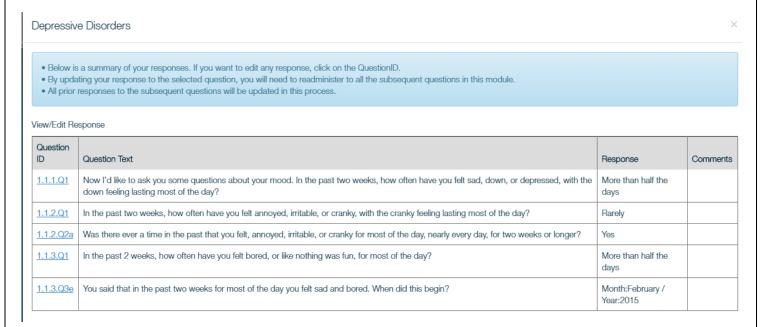


# BACK BUTTON AND CHANGING ANSWERS TO PRIOR QUESTIONS

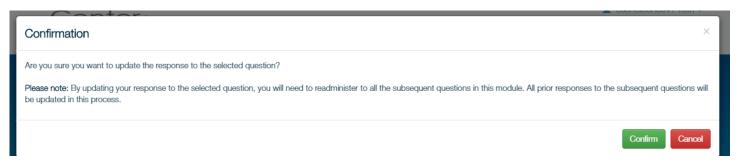
In the **clinician-administered interview**, there is an icon in the upper left corner to press to change an answer to any question in the module you are currently in.



When you press this icon, all the prior questions in the module and answers you gave to them will appear.



To change an answer, click on the question ID for the question you want to change. <u>Since the answer to any question</u> will potentially change the subsequent branching logic for the following questions, you will have to re-administer all the <u>subsequent questions in the module</u>. For example, if you change your answer to 1.1.2.q1 above ("In the past two weeks, how often have you felt annoyed, irritable or cranky....") you will have to re-answer the rest of the questions in the module (and may be asked different questions, depending on your new answer). You will get a 'warning' message alerting you to this fact before you are brought to the question you chose to change.



"One Time Selection Before Interview" vs. "Select Order During Interview" setup

#### **One Time Selection Before Interview Setup**

If your study is set up with the "one time selection before interview" format (i.e., modules are preselected OR you choose which modules you want to administer before each interview, and once the interview starts the order of administration is determined by the KSADS algorithm, with no breaks between modules), you will only be able to change answers in the module you are in.

# **Select Order During Interview Setup**

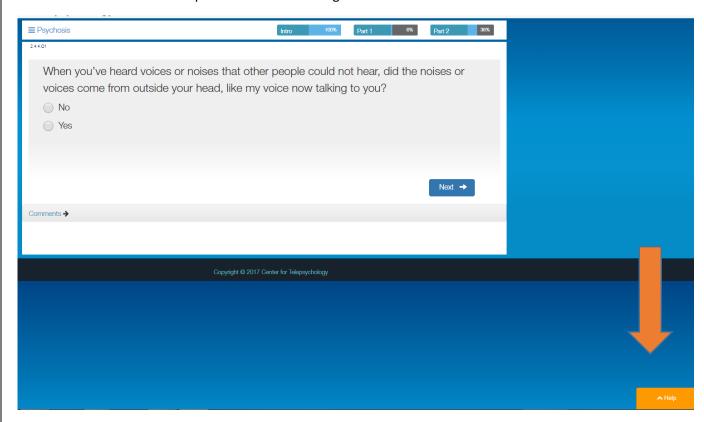
If your study is set up with the "select order during interview" (i.e., you return to a main menu between modules and select the next module to administer as you go along) (see below), you will be able to change answers to questions in other modules, with the following exception: Once you have begun a supplement for a disorder, you cannot edit the screen module for that disorder.

Take a look at the screen shot below. The clinician has completed the mood disorder supplement (coded blue) and thus the mood disorder screener (coded grey) is no longer editable. The mood supplement however is still editable. Supplements are all editable until the user clicks "End Your Interview". The psychosis screen has been completed (coded blue) but is still editable because the psychosis supplement (coded grey) has not begun. If you exit an interview in the middle of a module, it will take you to the place you left off when you log in again.

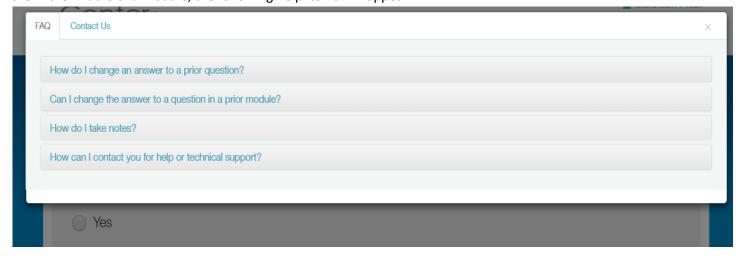


# **HELP BUTTON**

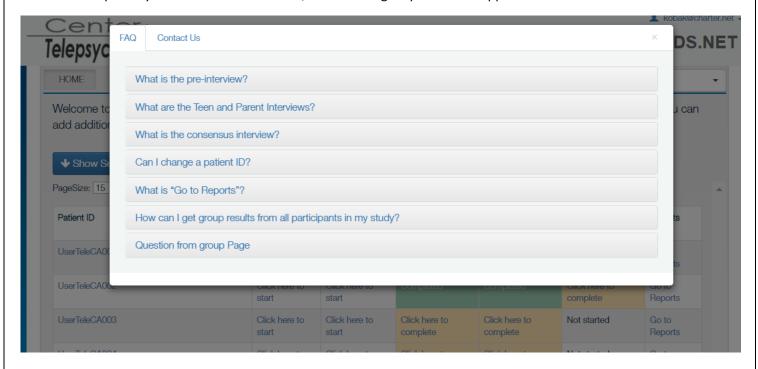
The clinician version has a Help button in the lower right hand corner of the screen.



When you click the help button, a list of FAQs will appear that are relevant to the section you are in. For example, if you are in the middle of a module, the following help items will appear.



Another example: If you are on the main menu, the following help items will appear:



There will also be a link to contact us, where you can ask us a question or provide a comment. It will automatically generate an email sent directly to us.

# **REPORTS**

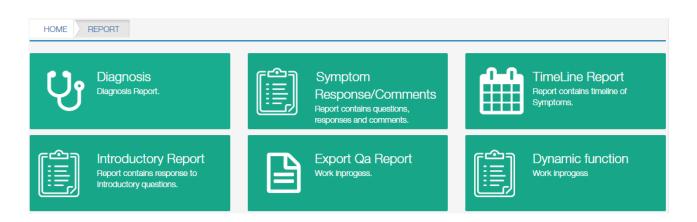
There are two types of reports: results from individual interviews with patients, and study-wide data reports, called Admin Reports.

# REPORTS ON RESULTS FOR INDIVIDUAL PATIENTS

1. To obtain results of an individual interview, click on the "Go to Reports" link on the main page for the patient requested.



2. You will arrive at a menu of types of reports you can view and print.



Once you choose the type of report you want, it will ask you on whom you want the report. The options depend on the type of report you choose. For diagnostic reports, you can choose the parent, the teen, or the consensus interview. For user response reports, you can also get reports on the pre-interviews.



What follows is a description of each type of report.

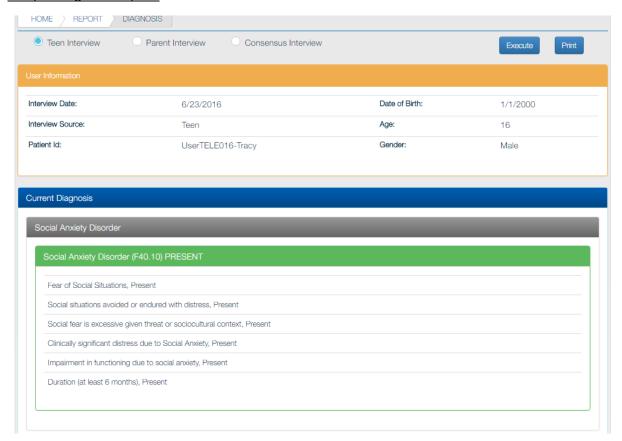
#### Diagnosis Report

This will generate a pdf file that lists the current and past diagnoses for the chosen patient, including the symptoms that they met for each diagnosis. See below for Diagnosis Report screenshot.

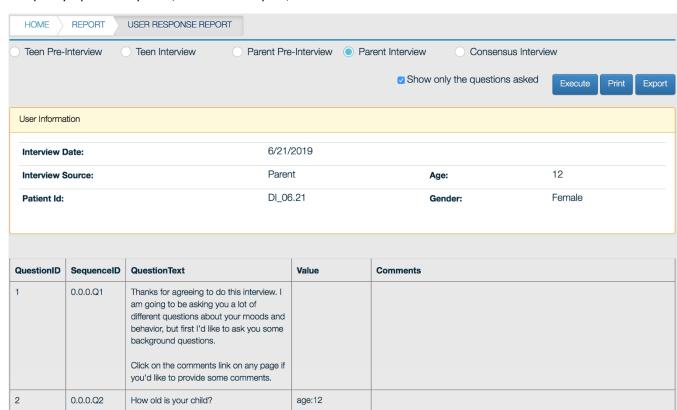
#### Symptom Response/Comments Report:

This will generate an excel file that lists all the individual questions the patient was asked, and their response. It will also include any free text comments they added. There is a box to check if you only want to display the questions that the patient was asked, or if you want the report to also include questions that the patient was not asked, due to branching around them as a result of a negative response. To download the file in excel, click the 'Export' tab. See following page for Symptom Response/Comments Report screenshot.

# Sample Diagnosis Report:



# Sample Symptom Response/Comments Report, Parent:



#### **Timeline Report**

This will generate a report listing all the symptoms the person endorsed in a timeline, starting from the most recent.



#### Introductory Report

This will display the answers to the introductory interview in a separate, stand-alone report.

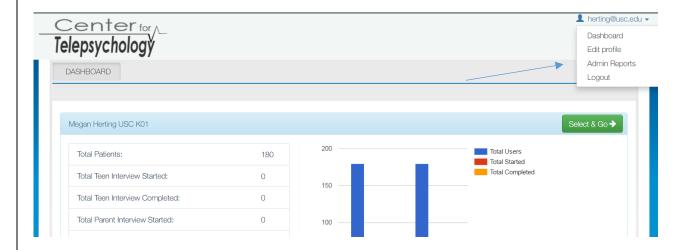


# **Export Qa Report and Dynamic Function Report:**

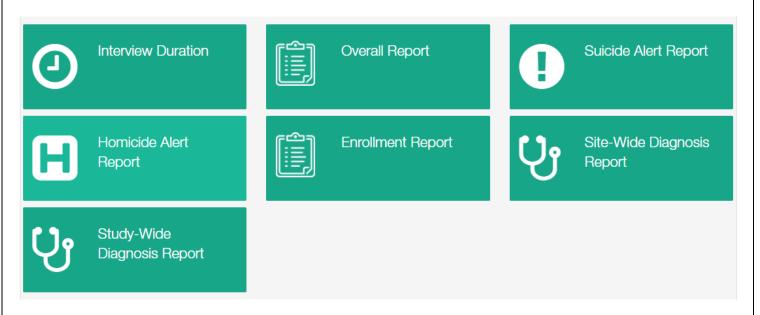
These reports are under development and not currently available.

# GROUP DATA REPORTS (ADMIN REPORTS)

To export all data from all patients at your site into a single data file, click on your username in the upper right hand corner. A drop down menu will appear. Choose "Admin Reports".



The following menu will appear offering you seven types of reports.

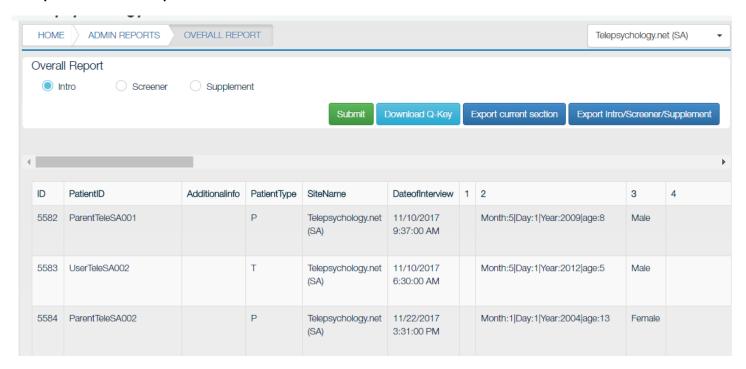


What follows is a description of each of the Admin Reports.

# Overall Report

The "Overall Report" will generate a report with all subjects as rows, and all questions as columns. There are 2,143 columns, representing all the potential questions asked in the KSADS. To manage file size, there are separate downloads for the introductory interview, the screening interview, and the supplements. You can download all three at once by using the 'export intro/screener/supplement' button, but it might take a while. If a question was not asked due to branching logic, that column is blank. You can export the report to excel by clicking the "Export current section" tab.

#### **Example of an Overall Report**



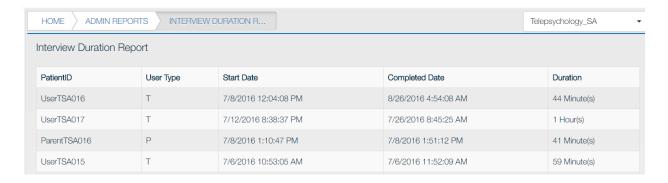
There is also a link to download the "question key" ('download Q-key tab), which provides the text of each question corresponding to each column.

#### **Example of the Question Key**

1	2	3	4	5	6	7	8	9	10	11	12	13
Hello I'm	What is	What sex	Who do	Is your	How old	How	Is your	How old	How	Who in	Is there	What
Dr.	your date	were you	you live	biological	were you	often do	biological	were you	often do	your	anyone in	grade are
Kenneth	of birth?	born?	with?	mother	when she	you	father	when he	you	family or	your	you in?
Kobak.			Click all	still	died?	typically	still	died?	typically	of the	family or	
Thanks			that	living?		see your	living?		see your	people	the	
for			apply.			mom?			dad?	you are	people	
agreeing										living with	you are	
to do this										would	living with	

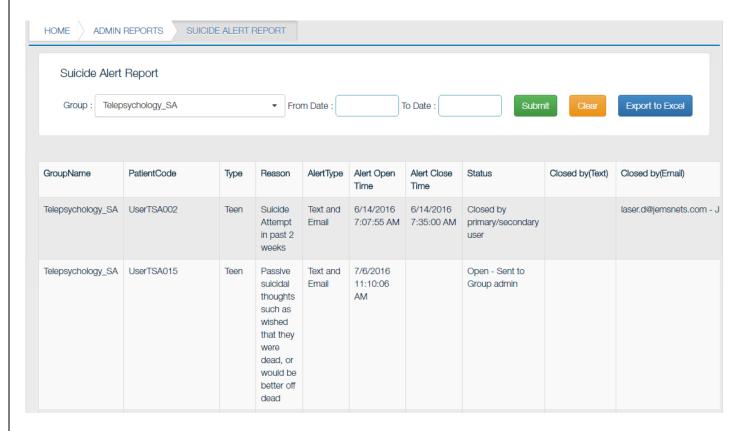
#### Interview Duration Report

The "Interview Duration" report will list the duration of each interview for each patient.



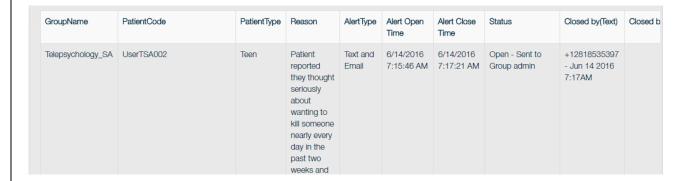
# Suicide Alert Report

The "Suicide Alert" report lists all the suicide alerts that were generated, the reason for the alert (i.e., the item endorsed), who responded to the alert, and the date and time the alert was opened and closed. When sites are initially set up, they have the option to choose whether to receive and respond to alerts by text, email or both. The report indicates the method(s) by which the alerts were sent and responded to, and the mobile phone and/or email of the respondent(s).



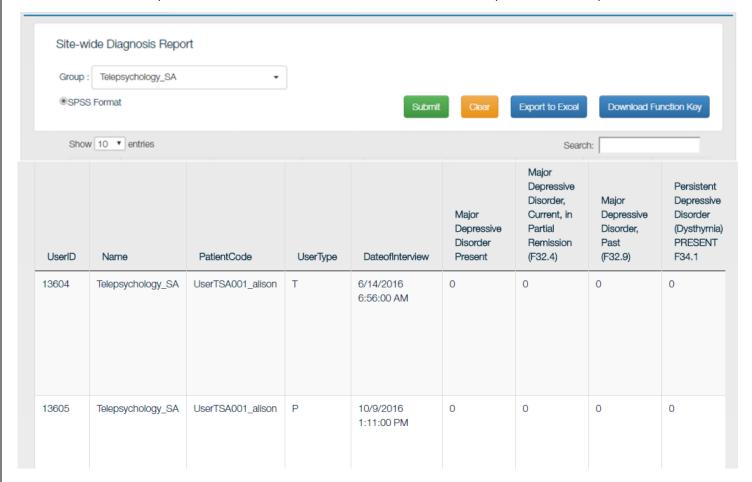
#### Homicide Alert Report

The "Homicide Alert" report is similar to the suicide alert report, i.e., it lists all the suicide alerts that were generated, who the alerts were sent to, the reason for the alert (i.e., the item endorsed) and if the alert was responded to (i.e., closed).



# Site-Wide Diagnosis Report

This report will list all diagnoses and symptoms endorsed for all patients at your *site*. Patients are listed as rows, and diagnoses and symptoms are listed as columns. The report lists first all the diagnoses for a DSM group (e.g., Mood Disorders) followed by the symptoms for these disorders. Diagnoses and symptoms are coded '1' if present, and '0' if absent. You can also download the report as an excel spreadsheet.

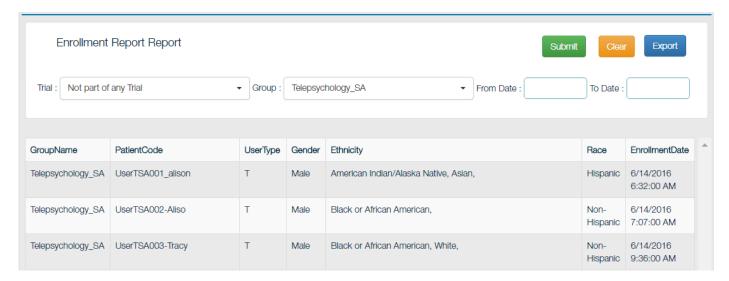


#### Study Wide Diagnosis Report

If you are a multi-site study, this report will list all diagnoses and symptoms endorsed for all patients at *all sites* in your *study*. It is similar in structure to the Site wide Diagnosis Report.

#### Enrollment Report.

This will list all the subjects enrolled at the site, with enrollment date, and statistics required for ongoing NIMH reporting requirements (i.e., gender, race and ethnicity).



#### Automated Electronic Data Transfer.

The KSADS is also equipped with the feature to transfer the data to the calling programs electronically. Sites can have their system programmed to call KSADS at a scheduled time with a requesting JSON (input JSON). This requires the site to program their in-house software to request and import the data from KSADS. KSADS uses REST protocol. The data is exported in a JSON format, which can be ported to any program or databases. We export 2 different data sets:

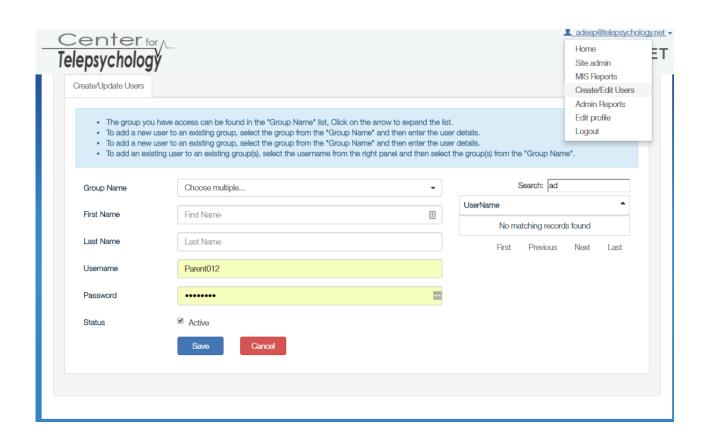
- Raw data
- Diagnosis data

If you are interested in this option, let us know and we will have our IT Department work with your IT Department to arrange for this.

# STUDY ADMINISTRATION FFATURES

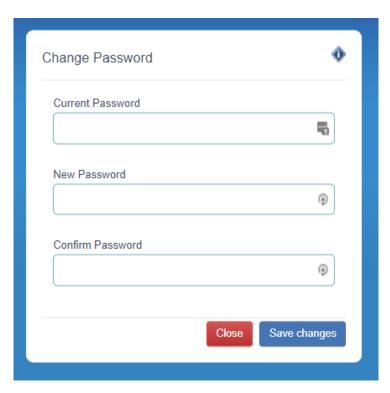
For studies where there are multiple users at each site or multiple sites (such as clinical trials) you can assign someone as "Study Administrator". The study administrator can add or delete users who have access to the KSADS site, reassign users to sites, and change passwords. When we set up your study/site, let us know if you would like to have a study administrator, and we can this person up with these credentials.

The study administrator can add or delete users by clicking on the user name in the upper right corner. A drop down menu will appear. Choose "Create/Edit Users". Then assign the user to a group (or multiple groups, if they are working on more than one study), and add their name, username and password. To delete a user, go to Create/Edit Users, enter the person's username, and remove the check in the "Active" box under "Status.



#### **PASSWORDS**

A password will be assigned to each user when we set up your site. We will need to know the name and email of each user. As a security feature, you will be asked to change your password every 90 days.



If you forget your password, you can click on the Forgot Password link on the Login page. We will send your password to the email address used when setting up your site..

