

QUALITY ASSESSMENT (QA) MANUAL

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Treatment for Adolescents with Depression Study (TADS)

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1.0 TADS Training

To ensure that all sites conduct the protocol in the same manner, quality assurance (QA) procedures that cover administration of both treatments and assessments are critical to the success of a large complex multicenter trial such as TADS. In particular, QA procedures are necessary to guarantee (1) consistent standardized administration of TADS treatments, and (2) reliability defined as consistent standardized ascertainment of the study entry diagnosis and the primary dependent measures. Without QA procedures, the potential for site-by-treatment interactions increases, with no *a priori* guarantee that such differences, if they occur, are not the result of divergent administration of the TADS protocol at the individual site level. Hence, by enhancing reliability of assessment and administration of treatments, QA procedures are essential to securing valid data and, ultimately, to interpreting the findings from the trial.

1.1 Centralized Training. Before enrollment of study subjects commences, the Coordinating Center (CC) trains site principal investigators (PIs), and the supervisors of cognitive behavior therapy (CBT), pharmacotherapy (PT), and of the independent evaluators (IEs) at each study site on the protocol and study procedures. The training includes (1) study materials, (2) a five-day training session held at a location near the CC, and (3) certification of the site IE, CBT, and PT supervisors. Materials provided for review in advance of the group training session include treatment manuals, assessment administration booklets, and data forms. The agenda for the centralized training session includes (1) an overview of the study protocol, study organization, and staffing requirements; (2) detailed training on study procedures, including recruitment and screening, randomization, unblinding, early termination, regulatory requirements, study medication, adverse events, data collection procedures and quality assurance; and (3) training on the delivery of the CBT and PT interventions and administration of the study instruments.

1.2 Training of Trainers Model. The CC uses a “training of trainers” (TOT) model to train and certify site supervisors so that they, in turn, train and supervise the IEs and CBT and PT clinicians at their sites. “Trained trainers” leave the centralized training with an Inservice Manual, IE Manual, CBT Manuals, and Pharmacotherapy Manual (PTM) for use at their sites. By using a TOT model, TADS places QA procedures at the heart of site implementation of the protocol, thereby maximizing site attention and allegiance to QA while at the same time minimizing costs and administrative inefficiencies associated with centralized QA monitoring.

2.0 Cognitive Behavior Therapy (CBT) Quality Assurance

2.1 CBT Supervisor Certification. Trained CBT supervisors send audio recordings of 3 CBT sessions to the CC for review. One of the 3 recorded sessions sent to the CC for review should be a family or parent CBT session. CBT sessions with volunteer patients or subjects from the TADS Feasibility Study are acceptable. While listening to each tape, CC reviewers complete a *CBT - Quality Assurance Form (CBT-QA)* to assess the CBT supervisor’s adherence to session structure and content, competence in implementing CBT, and flexibility. Once performance is rated acceptable according to the criteria described below, the CC formally certifies the CBT supervisor for conducting CBT and for training and supervising the TADS CBT therapists at the study site.

- A copy of the CBT-QA is included in the APPENDIX to this manual.

2.2 Criteria for Judging CBT Adherence, Competence, and Flexibility. *CBT Adherence* is rated in terms of the CBT supervisors ability to (a) adhere to the basic CBT session structure as described in the CBT Manual and engage in the more general tasks of psychotherapy, and (b) maintain an appropriate therapeutic relationship and orientation. Adherence items are rated on 4-point scales (CBT-QA items CB10 and CB11): 4 = very adherent, 3 = adherent, 2 = needs improvement, 1 = not adherent. Ratings of 3 (adherent) or higher are required on both items to meet the TADS criterion for adherence.

CBT Competence is defined in terms of an overall rating of the CBT supervisor's ability to (a) introduce, use or review skills (i.e., Topic Codes) in the session, and (b) integrate skills training with supportive therapy. Ratings also take into consideration the extent to which the CBT supervisor maintained a working relationship, attended to the concerns of the adolescent or family, made "Topic Code" skills or psychoeducation relevant to these concerns, and maintained a CBT framework. Competence is assessed on a 4-point rating scale (CB12): 4 = very competent, 3 = competent, 2 = needs improvement, 1 = incompetent. Ratings of 3 (competent) or higher on item CB12 are required to meet the TADS competence criterion.

CBT Flexibility is defined in terms of the ability of the CBT supervisor to meet the needs of the patient by (a) adapting the session to the adolescent's current state; (b) incorporating event-related issues into the CBT framework; and/or (c) using examples, narratives, and behavioral methods in the services of the session goals. The supervisor's flexibility in implementing the CBT session topics and skill areas is assessed on a 4-point rating scale (CBT-QA item 13): 4 = very flexible, 3 = flexible, 2 = needs improvement, 1 = inflexible. Ratings of 3 (flexible) or higher on item CB13 are required to meet the TADS criterion for flexibility.

2.3 CBT Therapist Training, Certification and Supervision. In order for Supervisors to become familiar with all stages of the protocol, the certified CBT Supervisor will treat the first patient at their site who receives CBT treatment for the full length of the patient's participation. Certified CBT supervisors train and supervise CBT therapists at their sites on the content and procedures for the individual adolescent sessions, conjoint parent-adolescent working therapy sessions, and psychoeducational sessions as described in the TADS CBT Manuals. CBT supervisors certify that CBT therapists completed the following tasks before being assigned their first TADS CBT subject.

- Read the Protocol for the *Treatment for Adolescents with Depression Study (TADS)*.
- Read the TADS CBT Manuals.
- Read Brent, D. & Poling, K. (1997). *Cognitive Therapy Treatment Manual for Depressed and Suicidal Youth*. Pittsburgh, PA: University of Pittsburgh.
- Reviewed and discussed tapes of two exemplary individual CBT sessions and one family session from the TADS feasibility study.

- Completed a minimum of **8** hours of supervision with CBT supervisor that includes review and discussion of the content of TADS CBT modules and the CBT training tapes.
- Passed a *TADS CBT Therapist Qualifying Test* (80% of questions answered correctly).

CBT Supervisors complete a *TADS CBT therapist certification form* that documents that the CBT therapist completed all elements of training and passed the CBT Therapist Qualifying Test.

2.4 QA Recordings and Forms. All TADS CBT sessions are recorded using an audio tape recorder. The only exception is that CBT sessions provided to placebo non-responders after Week 12 (end of Stage 1) are not recorded. Therapists position the microphone so that the voices of both the subject and therapist are heard on the tape. After each CBT session, the therapist completes the CBT Session Checklist (CBTA). The CBT therapist uses the CBTA to document the content areas or skills that were introduced, reviewed, or used in the session. CBT supervisors and CC reviewers complete an expanded version of the CBTA form, the *CBT-Quality Assurance Form* (CBT-QA), when conducting QA reviews of CBT sessions.

2.5 Supervisor Review of CBT Therapist's First TADS Case. The supervisor will review 4 tapes from each therapist's first subject they treat in the TADS study. The sessions reviewed should include Topic Codes MM, PA, CD and one Conjoint Parent-Adolescent (Family) session.

Sessions are selected in such a way as to anticipate problems that arise early in the course of therapy, while at the same time attending to middle and later sessions as well. Supervisors review tapes within two weeks of the session date.

2.6 CBT Supervisor Review of Subsequent TADS Cases. The supervisor will review 3 tapes of the therapist's second subject. The sessions reviewed should include Topic Codes MM, PS, and one Conjoint Parent-Adolescent (Family) session

For the third and subsequent subjects the supervisor will review 2 tapes. The sessions reviewed should include Topic Code PS, and one Conjoint Parent-Adolescent (Family) session

Supervisors review tapes within two weeks of the session date.

2.7 QA Ratings Procedures. While listening to each tape, the CBT supervisor completes the CBT-QA. The CBT supervisor uses the CBT-QA to record the primary topic or skill introduced in the session, as well as other content areas or skills that were reviewed or used in the session. The CBT-QA is also used to assess the supervisor's ratings of the therapist's adherence to CBT session structure, general therapeutic activities, and maintenance of a cognitive-behavioral orientation and working alliance with the subject. In addition, the supervisor uses the CBT-QA to assess fidelity, competence, and flexibility. The CBT supervisor completes the CBT-QA independent of the therapist's rating on the CBTA. A copy of the CBT-QA is included in the Appendix.

2.8 Clinical Supervision. The CBT supervisor meets with the CBT therapist(s) on a regular (weekly or biweekly) basis to discuss issues of adherence to the treatment protocol and questions

about content and flexibility. Supervisors discuss their CBT-QA ratings with therapists with emphasis on identifying and rectifying problems associated with ratings of 2 ("needs improvement") or lower for CBT-QA items summarizing adherence (CB10 and CB11), competence (CB12), or flexibility (CB13). For COMB treatment cases, supervisors and therapists of all treatment arms will meet in additional regularly scheduled team meetings (e.g., bi-weekly).

2.9 CBT Treatment Plan. After the first six weeks of CBT, the therapist develops a treatment plan based on his or her formulation of the case. After the first six weeks of CBT, the CBT therapist will complete and fax to the CC CBT coordinator (Dr. Curry) a one-page summary of the case formulation and treatment plan for the second six weeks of CBT using the CBT Formulation and Treatment Plan (CBTP) form. The CC will conduct a qualitative clinical review of the adequacy of the proposed treatment plan in terms of adherence and flexibility based on the CBT therapist's formulation of the case. A copy of the CBTP is included in the appendix.

2.10 Coordinating Center (CC) Review of CBT Sessions. The CC also reviews a 5% sample of Stage I CBT sessions for content adherence, competence, and flexibility using the CBT-QA. The sample of tapes will include 50% from visits 1 – 4 and 50% from visits 5 and above. To ensure QA review of each CBT session type, the CC will request tapes from the first session of each type used at a site. Sessions to be reviewed by the CC will be identified at the time that subjects are randomized to treatment conditions. Tapes selected by the CC for QA reviewers are sent to the CC no later than two weeks after requested by the CC. The CC reviewer will contact the CBT supervisor to discuss unsatisfactory ratings of adherence or competence as defined below.

2.11 Therapist Performance Criteria. CBT therapists who receive unsatisfactory ratings for adherence or competence by site supervisors or CC reviewers for three sessions are not assigned additional TADS subjects. However, in consultation with the CC, the CBT supervisor may elect not to suspend the CBT therapist from being assigned new treatment cases if the three unsatisfactory sessions are relatively far apart and do not show a clear pattern of poor performance. In such cases, the CBT supervisor and the CC CBT coordinator may develop an individualized plan for improving and rectifying the therapist's performance. When the CBT supervisor decides to suspend a therapist, he/she may not be assigned new TADS cases, but may complete the treatment of ongoing assigned cases with the CBT supervisor providing intensive supervision.

- A satisfactory CBT adherence rating is defined as a rating of 3 {"Adherent"}) or higher on items CB10 and CB11 of the CBT-QA.
- A satisfactory CBT competence rating is defined as an overall rating of 3 ("Competent") or higher on item CB12 of the CBT-QA.

2.12 National Teleconferences. The CC hosts a weekly 1-hour national teleconference call for the CBT supervisors in which questions about the CBT protocol, adherence, flexibility, and other clinical and operational issues are raised and discussed. The CC maintains a written cumulative

operations log that documents decisions that affect the treatment protocol. Attendance is mandatory, although sites will report on cases on alternate weeks.

3.0 Pharmacotherapy Treatment (PT) Quality Assurance

3.1 PT Supervisor Certification. Trained PT supervisors send audio tapes of 2 PT sessions to the CC for review. PT sessions with volunteer patients or subjects from the TADS Feasibility Study are acceptable. While listening to each tape, CC reviewers complete *a Pharmacotherapy - Quality Assurance Form (PT-QA)* to assess the PT supervisor's adherence to session structure and content, avoidance of topics that would contaminate the PT condition with elements of psychological or behavioral interventions, and competence in implementing PT. Once performance is rated acceptable according to the criteria described below, the CC formally certifies the PT supervisor for conducting PT and for training and supervising pharmacotherapists (PTs) at the study site.

- A copy of the PT-QA form is included in the APPENDIX to this manual.

3.2 Criteria for Judging PT Adherence and Competence. *Adherence* is scored dichotomously (Yes/No) on item 17 of the PT-QA. A "Yes" rating for Adherence requires that

- At least seven session content items (items 1 - 9) of the PT-QA (e.g., "Assess compliance with medication?" and "Ask about health problems and other medical events?") are scored "Yes" or "NA" (not applicable).
- All items assessing the absence of potentially confounding elements of psychological and behavioral interventions (i.e., "NOT focus on psychosocial change strategies to target any MDD or other psychiatric symptoms" (items 10 – 16) are scored "Yes."

Competence is scored as an overall rating of the PT supervisor's ability to introduce and implement the components of the PT office visit interview. The supervisor's competence in implementing the PT session topics is assessed on a 4-point rating scale (PT-QA item 18): 4 = very competent, 3 = competent, 2 = needs improvement, 1 = incompetent. Ratings of 3 (competent) or higher on item 18 are required to meet the TADS criterion for competence.

3.3 PT Therapist Training and Supervision. In order for Supervisors to become familiar with all stages of the protocol, the certified PT Supervisor will treat the first patient at their site who receives PT treatment for the full length of the patient's participation. Certified PT supervisors train and supervise PT therapists at their sites on the content and procedures for pharmacotherapy sessions described in the TADS PT Manual (PTM). A description of the professional qualifications required for the PT also appears in the TADS PTM. PT therapists complete the following tasks before being assigned their first TADS PT subject. PT supervisors certify that PT therapists completed the following tasks before being assigned their first TADS PT subject.

- Read the Protocol for the *Treatment for Adolescents with Depression Study (TADS)*.
- Read the TADS PT Manual.

- Reviewed and discussed tapes of two exemplary individual PT sessions from the TADS feasibility study.
- Completed a minimum of **4** hours of supervision with PT supervisor that includes review and discussion of the content of TADS PT manual and the PT training tapes.
- Passed the *TADS PT Therapist Qualifying Test* (80% of questions answered correctly).
- PT Supervisors complete a *TADS PT therapist certification form* that documents that the PT therapist completed all elements of training and passed the *PT Therapist Qualifying Test*.

3.4 QA Recordings. All TADS PT office sessions are recorded using an audio tape recorder. Therapists position the microphone so that the voices of both the subject and therapist are heard on the tape. The only exception is that PT office sessions provided to placebo non-responders after Week 12 (end of Stage 1) are not recorded.

3.5 Supervisor Review of PT Therapist's First TADS Case. For the *first* subject treated by each PT therapist, the PT supervisor reviews three PT sessions: Medication office visits at weeks 1, 4, and 6. Supervisors review tapes within two weeks of the session date.

3.6 PT Supervisor Review of Subsequent TADS Cases. For the second and third subjects treated by each PT therapist, the supervisor reviews two tapes from Stage I: PT office sessions at weeks 2 and 4. For all subsequent subjects treated by each PT therapist, the supervisor reviews one tape from Stage I PT office session. Supervisors review tapes within two weeks of the session date.

3.7 QA Ratings Procedures. While listening to each tape, the PT supervisor completes the Pharmacotherapy Quality Assurance Form (PT- QA). A copy of the PT-QA is in the appendix of this manual. The PT supervisor uses the PT-QA to record coverage of topics that should be discussed or activities that should occur at medication sessions.

Topic 1: Review symptoms on the ADS

Topic 2: Assess compliance with medication

Topic 3: Complete medication count log

Topic 4: Assess severity and improvement (Assign CGI-S and CGI-I scores)

Topic 5: Assess functioning (Assign CGAS scores)

Topic 6: Set medication for next week

Topic 7: Encouragement of the expectation that medication will reduce MDD symptoms

Topic 8: Ask about health problems and other medical events

Topic 9: Maintain a supportive therapeutic relationship

PT supervisors also use the PT-QA as a guide to review session tapes for prohibited actions that would contaminate the medication treatment conditions with elements of CBT or other psychological approaches to treatment, as outlined in the PT Manual.

- Topic 10: NOT focus on psychosocial change strategies to target any MDD or other psychiatric symptoms
- Topic 11: NOT focus on specific psychological themes, especially those associated with cognitive behavioral principles
- Topic 12: NOT provide interpretations related to psychological mechanisms of depression or anxiety
- Topic 13: NOT interpret patient's feelings toward others or toward the therapist
- Topic 14: NOT provide specific behavioral instructions or routines
- Topic 15: NOT recommend reading materials or other resources associated with CBT
- Topic 16: NOT recommend changes in school programming

In addition, PT supervisors use the CBT-QA to assess adherence and competence.

Adherence is scored (Yes/No) on two component ratings of item 17 of the PT-QA. A "Yes" rating for Adherence requires that:

- At least seven session content items (items 1 - 9) of the PT-QA (e.g., "Assess compliance with medication?" and "Ask about health problems and other medical events?") are scored "Yes" or "NA" (not applicable).
- All items assessing the absence of potentially confounding elements of psychological and behavioral interventions (i.e., "NOT focus on psychosocial change strategies to target any MDD or other psychiatric symptoms," items 10 – 16) are scored "Yes."

Competence is scored as the supervisor's overall rating of the PT's ability to introduce and implement the components of the PT office visit interview. The PT's competence in implementing the PT session topics is assessed on a 4-point rating scale (PT-QA item 18): 4 = very competent, 3 = competent, 2 = needs improvement, 1 = incompetent. Ratings of 3 (competent) or higher on item 18 are required to meet the TADS criterion for competence.

3.8 Clinical Supervision. The PT supervisor meets with the pharmacotherapist(s) in all medication conditions, including COMB, on a weekly or bi-weekly basis to discuss issues of adherence to the treatment protocol and to answer questions about dosing and flexibility. For COMB treatment cases, supervisors and therapists of all treatment arms meet in additional weekly or bi-weekly team meetings. Supervisors discuss their PT-QA ratings with therapists with emphasis on identifying and rectifying problems associated with "NO" ratings for PT-QA items summarizing adherence (item 17), and scores of 2 or less on the competence (item 18) ratings.

3.9 Coordinating Center (CC) Review of PT Sessions. The CC also reviews a 5% sample of Stage I PT sessions for content adherence and competence using the PT-QA. The sample of tapes will include 50% for weeks 1,2,4 and 50% for weeks 6, 9, 12. All visits selected will be regular non-ASAP sessions.. Sessions to be reviewed by the CC will be identified at the time that subjects are randomized to treatment conditions. PT supervisors and PTs do not receive advance notice of which tapes will be reviewed by the CC. Tapes selected for CC review are

sent to the CC no later than two weeks after the session date. The CC reviewer will contact the PT supervisor to discuss unsatisfactory ratings of adherence or competence as defined below.

3.10 PT Performance Criteria. PT therapists who receive unsatisfactory ratings for adherence or competence by site supervisors or CC reviewers for three sessions are not assigned additional TADS subjects. However, in consultation with the CC, the PT supervisor may elect not to suspend the PT therapist from accepting new treatment cases if the three unsatisfactory sessions are far apart. In such cases, the PT supervisor and the CC PT coordinator may develop an individualized plan for improving and rectifying the therapist's performance. Suspended PT therapists may not accept new cases, but may complete the treatment of ongoing cases with the PT supervisor providing intensive supervision.

- A satisfactory PT adherence rating is defined as a "YES" rating on both components of item 17 of the PT-QA.
- A satisfactory PT competence rating is defined as an overall rating of 3 (competent) or higher on item 18 of the PT-QA.

3.11 Cross-Site Pharmacology Panel (CSPP). The CSPP will meet once monthly via teleconference to insure high quality clinical care and to decrease the potential for cross-site variability. The CSPP maintains a written cumulative operations log that documents decisions that affect the treatment protocol.

4.0. Assessment Quality Assurance

The Independent Evaluator (IE) will collect data on the study entry diagnosis and the primary outcome variables. She/he will be an experienced clinician capable of gathering all the relevant information from the child and the parents, and formulating scores on the clinical global impression scales. A description of the required qualifications for the IE appears in the TADS IE Manual (IEM). Procedures for administering the TADS diagnostic and dependent measures are also fully specified in the IEM.

At each site, before and during the trial, there will be an ongoing process of monitoring the quality of the IE 's interviewing skills and of the data collected by the IE. This process will include audio taping of the interviews and reviewing a sample of the tapes by the IE Supervisor at each site and by CC QA staff. **The IE is kept blind as to the treatment assignment of the randomized patients for the entire duration of the study.** Specifically, the IE is to remain blind to patient treatment assignment even after the patient has completed the study.

4.1 Certifying the IE Supervisor. The certification process for site IE supervisors on the primary diagnostic and dependent variables requires that each views/listens to two standardized tapes of child and parent interviews and completes the CDRS, associated CGI ratings, and the *K-SADS Affective Disorders Module*. Certification tapes include a combination of video and audio recordings of child and parent interviews. Supervisors' ratings of standardized K-SADS and CDRS interviews and CGI ratings are reviewed by the CC. Supervisor certification on the CDRS and CGI is based on achieving criterion-based levels of agreement between the site supervisor and standardized ratings developed by the CC.

For the CDRS, the CC will contact the IE Supervisor to discuss and resolve disagreements in which total score discrepancies are +/- > 5 points (for video recordings) or +/- > 6 points for audio recordings. IE supervisors must achieve CDRS total score ratings within the ranges specified for the standardized taped interviews in order to be certified to train IE(s) at their sites. Certification on the CGI-S requires that the IE supervisor's CGI-S ratings for each taped interview deviate no more than 1 point from the standard CGI-S ratings. Criteria for supervisor certification on the KSADS Affective Disorders Module requires agreement on at least 80% of the 54 items at the summary symptom level. IE supervisors who meet these criteria for rating the CDRS, CGI-S and KSADS on the first two standardized tapes are certified. IE supervisors who do not meet criteria on the initial two tapes are sent one or more additional video or audio tapes of KSADS or CDRS interviews to review and rate. Ratings on these tapes must also meet predetermined criteria. IE Supervisors who do not meet criteria on a majority of reviewed tapes (e.g., two out of three) are not certified.

4.2 IE Training and Certification. Certified IE supervisors train IEs at their sites to administer CDRS and K-SADS interviews and to rate severity of symptoms and improvement on the CGI. IE training consists of the following elements.

- IE reads the TADS protocol
- IE studies the TADS Independent Evaluator Manual (IEM)
- IE reads the CDRS manual
- IE reads the KSADS Manual
- IE rates two standardized tapes of *K-SADS (Affective Disorders Module)* and CDRS interviews and completes the CGI-S ratings.

The IE supervisor reviews the IE's rating of each K-SADS and CDRS interview and CGI rating, and using the TADS IE Certification Form specific to each training tape, compares the IE's ratings with the standard ratings on the form. A copy of one of the TADS IE Certification Forms appears in the Appendix.

For the CDRS, the IE supervisor discusses with the IE disagreements in which total score discrepancies are +/- > 5 points (for video recordings) or +/- > 6 points for audio recordings. To be certified, IEs must achieve CDRS total score ratings within the ranges specified for the standardized taped interviews. Certification on the CGI-S requires that the IE's CGI-S ratings for each taped interview deviate no more than 1 point from the standard CGI-S ratings. Criteria for IE certification on the KSADS Affective Disorders Module requires agreement on at least 80% of the 54 items at the summary symptom level (KSAAt Tally Sheet). IEs who meet these criteria for rating the CDRS, CGI-S and KSADS on the first two standardized tapes are certified by the IE supervisor. IEs who do not meet criteria on the initial two tapes rate one or more additional video or audio tape of KSADS or CDRS interviews. Ratings on these tapes must also meet pre-specified criteria. IEs who do not meet criteria on a majority of training tapes (e.g., two out of three) are not certified. The IE supervisor signs the TADS IE Certification Form for

each training tape rated by the IE and sends copies of these forms and the K-SADS booklet and tally sheet, CDRS, and CGI-S to the CC to document certification.

4.3 IE Supervision and QA.

- All (excluding Gate B) IE K-SADS and CDRS interviews are taped through the end of the study.
- IE Supervisor observes one of the 1st 2 full K-SADS administered by a newly certified IE at Gate B assessment.
- IE Supervisor observes a Stage I IE assessment every 6 months
- IE Supervisor and IE meet regularly (e.g., biweekly) for supervision to listen to the CDRS interview of an IE session (parent and teen components of CDRS), discuss CDRS interviews in relation to the IE Manual and CDRS Manual, and identify issues for discussion on the national conference calls.
- The IE supervisor will independently complete the K-SADS and CDRS for observed assessments at Gate B and Stages I and III and use these in supervision.
- The IE supervisor and IE will listen to an IE assessment tape at least once a month in clinical case conferences.
- IEs who drift below certification criteria on two consecutive Gate C assessments will be suspended from assessing new TADS patients until re-certified by the IE supervisor in consultation with the CC.

4.4 Coordinating Center (CC) Review of IE Sessions. Over the course of the study, the CC reviews IE sessions from 35% of enrolled subjects. Two-thirds of this sample will be of the CDRS and *K-SADS Affective Disorders Module* interviews and CGI ratings conducted by the IEs at Assessment Gate C; one-third will be from week 12.. CC reviewers provide IE supervisors feedback on IE performance, as needed. IE/CC inter-rater agreement will be examined for the K-SADS, CDRS, and CGI.

5.0. Site Tape and QA Forms Management

5.1 Labeling the Cassette Tapes for Recorded CDRS/KSA, CBT, and PT Sessions.

All medication office visits (PT Office visits), CBT sessions, and CDRS and K-SADS interviews are voice recorded on audiocassette tapes. The project coordinator at each site attaches labels to the cassette tapes.

5.2 CDRS/KSADS Interviews. Tape labels for CDRS and KSADS interviews include the following information, plus the patient ID number:

Volume #: __ of __ (e.g., 1 of 1, 1 of 2, 2 of 2, etc.). This information indicates how many tapes were needed for the session.

Gate C ___ Week 12 ___ Other (specify) _____.

Date = Date of Assessment (mm/dd/yyyy)

IE Code = Interviewer's staff ID code

5.3 CBT Sessions. The labels for the audiocassette recordings of CBT sessions include the following information along with the patient ID number:

Stage Number:

Primary Topic Code: Use abbreviation indicated on the CBTA for that session

Date = Date of Session (mm/dd/yyyy)

CL Code: Treating clinician's staff ID code

Note: CBT sessions that run back to back are considered separate sessions and two tapes are required. For example, teen only and parent sessions that occur on the same day are considered separate CBT sessions.

5.4 PT Sessions. The labels for the audiocassette recordings of PT sessions include the following information:

Stage Number:

Session #: If a regular session, the number corresponds to the regular session # listed on the IPL (Individual Patient Tracking Log). If an ASAP, list the ASAP number recorded on the IPL and print the acronym "ASAP" on the label.

Date = Date of Session (mm/dd/yyyy).

CL Code = Treating clinician's Staff ID code.

6.0 Site and CC Tapes and QA Forms Management

Table 1 lists the CBT, PT, and IE sessions to be taped and reviewed by rater and by TADS stage. A pre-specified 5% sample of CBT and PT session tapes and forms are sent by mail to the CC for QA review. Also, 35% of subjects will be selected to have one IE session (CDRS and K-SADS assessment tape and form) sent to the CC for QA review. All other audiotapes are stored at the sites. Tapes and QA forms are sent to the DCRI and received by a research assistant assigned to the TADS project. The assistant is responsible for:

- Logging in each QA form and tape received from the site;
- Archiving materials in a secure storage cabinet maintained by DCRI;
- Tracking the delivery and return of QA materials to reviewers at the CC.

DCRI develops and maintains a database to track the status of QA materials received from the site. In addition, the QA forms data are entered in a database for analysis purposes (e.g., calculation of Kappa and intra-class correlation coefficients).

Send tapes and forms specified below within two weeks of session date to:

**Duke Clinical Research Institute
TADS- Team 6th Floor
2400 Pratt Street, Room 0311 Terrace Level
Durham, NC 27705**

6.1 Tapes and Forms for Gate C Assessment. An IE assessment from 35% of subjects is randomly selected by the CC for review. 20 % of this sample will be from Gate C1 and 15% of week 12 tapes will be reviewed. For selected IE assessments, send copies of the following materials to the CC.

- KSA Booklet
- Audiotape of CDRS and K-SADS Affective Disorders (KSA) interviews
- Copy of K-SADS Affective Disorders Module Diagnostic Summary Sheet (KSAs)
- Copy of K-SADS Affective Disorders Tally Sheet (KSAt)
- Copy of Children's Depression Rating Scale, Revised (CDRS)
- Copy of Independent Evaluator Battery: Clinical Global Impressions Scale (CGI)

6.2 Tapes and Forms for CBT Sessions. A 5% sample of CBT tapes will be reviewed by the TADS CC. For selected CBT sessions, send the following materials to the CC:

- Audiotape of CBT session;
- Copy of CBT Session Checklist (CBTA)
- Copy of CBT-QA if selected tape was also reviewed by CBT supervisor

6.3 Tapes and Forms for PT Sessions. A 5% sample of PT tapes will be reviewed by the TADS CC. For selected PT sessions, send the following materials to the CC:

- Audiotape of PT session;
- Copy of Pharmacotherapy Office Session Checklist (PTO)
- Copy of PT-QA if selected tape was also reviewed by PT supervisor

**TABLE 1: Quality Assurance Procedures:
Sessions to be taped and reviewed**

Stage 1

Rater	Sessions Taped	Site Supervisor Review		Coordinating Center Review	
		Pre-specified	Flexible	Pre-specified	Flexible
Independent Evaluator	Gate C1 CDRS Gate C1 CGI-S Gate C1 KSA Wk 6 CDRS Wk 12 CDRS + KSA Wk 18 CDRS Wk 24 CDRS Wk 30 CDRS Wk 36 CDRS + KSA				20% from Gate C1 15% from Week 12
CB Therapist	All sessions	<u>First patient</u> 3 sessions: 1 session with each of the following Primary Topic Codes: MM; PA; CD <u>Other Patients</u> 2 sessions: MM, PS	<u>First patient</u> Session from Stage 1 Parent or joint session <u>Other Patients</u> Parent or joint session		5% sample (Stages I) Half from sessions 1-4. Half from sessions 5 and above. 1 st subject randomized to CBT or Combo will be excluded from random sample.
Pharmaco-therapist	All office sessions	<u>First patient</u> Week 1 Week 4 Week 6 2 nd - 3 rd patient Week 2Week 4 <u>Other Patients</u> <u>1 tape</u>			5% sample (Stage I) Half from wks 1, 2, 4 Half drawn from wks 6, 9, 12.

Stage 2

Rater	Sessions Taped	Site Supervisor Review		Coordinating Center Review	
		Pre-specified	Flexible	Pre-specified	Flexible
Independent Evaluator	All sessions				
CB Therapist	All sessions		One session		
Pharmacotherapist	All office sessions				

APPENDIX

CBT-Quality Assurance Form (CBT-QA)
CBT Session Checklist (CBTA)
CBT Formulation and Treatment Plan (CBTP)
Pharmacotherapy – Quality Assurance Form (PT-QA)
Pharmacotherapy Office Session Checklist (PTO)
TADS IE Certification Form