

NIMH Database of Cognitive Training and
Remediation Studies
(DCTRS)

Data Submission Agreement

Version 1.5/June 2013

Data Submission Agreement for the NIMH Database of Cognitive Training and Remediation Studies

Definitions

For purposes of this agreement, “data” refers to the information that has been collected and recorded from participants in research studies.

A “Submitter” is defined as a researcher who requests permission to submit data to the National Institute of Mental Health (NIMH).

The “Recipient” Principal Investigator and his/her Organization may be a researcher at a non-profit or for-profit organization or corporation with an approved assurance from the Department of Health and Human Services Office for Human Research Protections. The Recipient Principal Investigator requests access to study data at his or her sole risk and at no expense to the study and NIH.

Description of the NIMH Database of Cognitive Training and Remediation Studies

The NIMH Database of Cognitive Training and Remediation Studies (DCTRS) is an integrated database combining study-level information about the format, targets, duration, and intensity of cognitive remediation interventions for individuals with schizophrenia with participant-level data on cognitive, clinical, and functional measures associated with these interventions. DCTRS is a shared resource available to investigators who propose research questions of interest. DCTRS will allow NIMH staff and interested investigators to examine the ways in which various patient characteristics, intervention approaches and features, and treatment combinations affect responses to remediation. This information will help to identify significant predictors or moderators of therapeutic benefit and will inform the design of studies of personalized approaches to cognitive remediation.

Terms and Conditions

I request approval to submit data to DCTRS for the purpose of sharing data for research purposes. I agree to the following terms:

1. Research Project

These data will be submitted solely in connection with the “Research Project,” specifically indicated and described in the Submitter Information and Certifications section.

Data submitted to DCTRS will be made available by NIMH to qualified investigators for general research purposes, as approved by the DCTRS Data Access Committee.

This Submission Agreement (SA) covers only the Research Project that is identified in the Submitter Information and Certifications section. Submitter will submit a completed SA (this document) for each research project for which submission is requested.

2. Non-transferability of Agreement

This SA is not transferable. Submitter agrees that substantive changes submitter makes to the Research Project requires execution of a new SA, in which the new Research Project is designated. If the submitter changes institutions after a submission agreement is approved but prior to submitting the data to DCTRS, a new SA in which the new institution acknowledges and agrees to the provisions of the SA is necessary.

3. Federal-Wide Assurance

The Submitter's institution or organization must be covered by a Federal-Wide Assurance (FWA) issued by the Department of Health and Human Services (HHS) Office of Human Research Protections, and this FWA number is provided below.

4. Non-Identification of Subjects

Submitter agrees that the data have been 'de-identified' according to the following criterion: the identities of subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (45 C.F.R. 46.102(f)). Submitter further agrees not to disclose the identities of research participants to DCTRS in the future and to verify that data lack identifiers after submission. Submitter agrees to notify NIMH as soon as possible if, upon review of DCTRS data, the Submitter discovers identifying information in that data.

5. Data Disclaimers

Submitter agrees that NIMH does not and cannot warrant the results that may be obtained by using any data included in DCTRS. NIMH disclaims all warranties as to the accuracy of the data in DCTRS or the performance or fitness of the data for any particular purpose.

6. Study Information Form and Supporting Materials

Submitter agrees to provide DCTRS with a completed Study Information Form and supporting materials (listed on the Study Information Form) to enable efficient use of the submitted data by investigators unfamiliar with the data. The form and supporting materials should be submitted together with the SA.

7. Data Accuracy

Submitter certifies to the best of his/her knowledge and belief that the data submitted to DCTRS are accurate. Submitter also agrees to perform quality control activities requested by the DCTRS team within a timeframe agreed upon by the submitter and the DCTRS team. Submitter further agrees to notify NIMH as soon as possible if, upon review of DCTRS data, the Submitter discovers data quality concerns.

8. Data Access for Research

Submitter agrees that data, responses provided on the Study Information Form, and information derived from supporting materials submitted to DCTRS may be accessed by submitting a signed

NIMH Data Access Request and Use Certification (DUC) form (OMB# 0925-0667) and used broadly by qualified researchers for research and other activities as authorized by and consistent with law. This access may result in duplication of research results and findings. With the exception of the name of the Principal Investigator, information about the individuals submitting data (such as contact information) will not be included with the data provided to qualified researchers.

9. Non-Research Access

Submitter acknowledges that data, Study Information Form and supporting materials submitted to DCTRS become U.S. Government records that are subject to the Freedom of Information Act (FOIA). NIMH is required to release Government records in response to (FOIA) requests unless they are exempt from release under one of the FOIA exemptions. Submitter further acknowledges that data, Study Information Form and supporting materials may be used or released consistent with law.

10. Non-Endorsement; Liability

Submitter agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health & Human Services, the National Institutes of Health, or the National Institute of Mental Health of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

11. Submitter's Compliance with Institutional Requirements

Submitter acknowledges that these data were collected in manner consistent with all applicable laws and regulations, as well as institutional policies. Submitter further acknowledges that the data were collected pursuant to an informed consent that is not inconsistent with the data submission, and that the data submitted were collected in accordance with 45 CFR Part 46, or applicable foreign law concerning the protection of human subjects, and other applicable U.S. federal and state laws, if any.

12. Privacy Act Notification

The Submitter agrees that information collected from the Submitter, as part of the SA and submission certification, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the submitter comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0200 (<http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm>) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor

and evaluate the submission of data from clinical, basic, and population-based research activities and to notify submitters in the event a potential error in the dataset is identified or in the event of updates or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Submitter's NIH records. NIH will use the data collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the submitter's permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for submitting data to DCTRS.

13. Amendments

Amendments to this SA must be made in writing and signed by authorized representatives of both parties.

14. Termination

Either party may terminate this SA without cause provided 30 days written notice to the other party. DCTRS will retain a copy of all data already submitted to DCTRS for which data quality activities have been completed, except in the event that research participants withdraw consent for sharing of their data through the DCTRS repository and NIMH is informed by the submitter to withdraw the data. Submitters agree to immediately report violations of DCTRS Policy to the DCTRS team. Additionally, NIMH may terminate this agreement with 5 days written notice if NIMH determines, in its sole discretion, that the Submitter has committed a material breach of this SA. NIMH may, in its sole discretion, provide submitter with 30 days' notice to remedy a breach before termination. Approval to submit may be restored by the DCTRS team upon submission of an updated Submission Request and SA.

Form Approved

OMB Number 0925-XXXX

Expiration Date:

XX/XX/2017

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

Submitter Information and Certifications

1. Submitter Information:

First Name: _____ Last Name: _____

Title: _____ Institution: _____

Telephone: _____ FAX: _____

E-mail Address: _____

2. Certificate of Confidentiality status:

Please check one: Applied Obtained Does not have

If obtained, Certificate of Confidentiality number: _____

3. Attachments

Submit electronic copies of the Study Information Form and supporting materials.

4. Signatures

By signing and dating this SA as part of submitting data to DCTRS, my Institutional Officials and I certify that we will abide by the SA. I further acknowledge that I have shared this document and the NIH policies and procedures with any co-investigators, any research staff who will participate in the submission of data to DCTRS. My Institutional Business Official(s) also acknowledges that they have shared this document and the relevant NIH policies and procedures with appropriate institutional organizations.

Signature: _____

Date: _____

Email address: _____

Institution: _____

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*Authorized Institutional Business Official (as registered in the NIH eRA Commons:
<https://commons.era.nih.gov/commons/>)*

Name: _____

Title: _____ FWA#: _____

Signature: _____ Date: _____

Please submit this form and any inquiries to: nimhdatasets@mail.nih.gov

PI last name:

XX/XX/2017

Form Approved
OMB Number 0925-XXXX
Expiration Date:

Study Information Form

Please send the following information to nimhdatasets@mail.nih.gov:

- **De-identified data** (SPSS, SAS, Excel, TXT or RTF format), including **variable names, definitions and value labels** (this could be incorporated into the data file or in the form of a data dictionary or a codebook).
 - o *Please include all of the variables that you have, even if they weren't primary measures or were not included in published reports.*
 - o *Please include data from all participants who were randomized in the study, regardless of whether they completed the intervention.* Such data will provide maximal utility and flexibility for investigators to study, for example, factors that predict early drop-out.
 - **A complete set of the forms** that were used to collect data
 - **Manuscript(s)** that provide the most complete description of your study
 - **The study protocol**, including an **assessment schedule** showing the assessment time points and the measures that were administered (if this is not available, please complete the schedule summary at the end of this form)
 - **The eligibility criteria** that were used for this study
 - **This study information form**
-

General study information

1. In what year did data collection begin for this study?
2. In what year was data collection completed for this study?
3. In which country (or countries) did data collection take place? Select one:
Select one:
Select one:
4. If "other," please enter name(s) of additional countries where data collection took place:
5. For the purposes of describing your study using this form, please consider the "Cognitive Remediation" (CR) condition to be the condition with the most elaborated intervention and the "Comparison" condition to be the control condition, *even if it also involved cognitive remediation*. For example, if your study compared outcomes in a group of patients who received (1) cognitive remediation plus vocational rehabilitation compared to patients who

received (2) only cognitive remediation, the first condition would be the "Cognitive Remediation" condition and the second is the "comparison" condition.

Please use this table to indicate the intervention(s) that the participants in your study received.

Interventions	Cognitive Remediation condition	Comparison condition
Cognitive Remediation Therapies:		
Attention shaping	<input type="checkbox"/>	<input type="checkbox"/>
Cognitive Enhancement Therapy	<input type="checkbox"/>	<input type="checkbox"/>
Cognitive Remediation Therapy	<input type="checkbox"/>	<input type="checkbox"/>
Integrated Psychological Therapy	<input type="checkbox"/>	<input type="checkbox"/>
Neuropsychological Educational Approach to Rehabilitation	<input type="checkbox"/>	<input type="checkbox"/>
Neurocognitive Enhancement Therapy	<input type="checkbox"/>	<input type="checkbox"/>
Other cognitive remediation (name:)	<input type="checkbox"/>	<input type="checkbox"/>
Comparison/Adjunctive interventions		
Computerized tasks/games without putative cognitive benefit	<input type="checkbox"/>	<input type="checkbox"/>
Cognitive Behavioral Therapy	<input type="checkbox"/>	<input type="checkbox"/>
Putative cognition-enhancing medication (name:)	<input type="checkbox"/>	<input type="checkbox"/>
Social skills training	<input type="checkbox"/>	<input type="checkbox"/>
Supported employment	<input type="checkbox"/>	<input type="checkbox"/>
Vocational rehabilitation (other than supported employment)	<input type="checkbox"/>	<input type="checkbox"/>
General psychosocial rehabilitation (may incorporate >1 of the elements listed above)	<input type="checkbox"/>	<input type="checkbox"/>
Other intervention (please describe:)	<input type="checkbox"/>	<input type="checkbox"/>
Other intervention (please describe:)	<input type="checkbox"/>	<input type="checkbox"/>
Did participants have individualized psychiatric medication and medication management during study participation?	<input type="checkbox"/>	<input type="checkbox"/>

If your study included more than 2 conditions, please describe the third condition:

6. Please identify **up to four primary techniques** that were used in the cognitive remediation (CR) intervention and rank them, with “1” being the most central element to the intervention:

Rank up to 4: Drill and practice (i.e., No explicit input on how tasks might be more effectively completed is provided; More efficient processes are determined as participants try - or do not try - different approaches)

Rank up to 4: Strategy training (i.e., identifying situations that trigger cognitive problems, such as memory lapses, then teaching strategies in therapy and working on transferring these to everyday life)

Rank up to 4: Meta-cognition training

Rank up to 4: Errorless learning

Rank up to 4: Social praise

Rank up to 4: Tangible rewards for performance

Rank up to 4: Rehearsal

Rank up to 4: Habit training

Rank up to 4: Training in compensatory techniques

Rank up to 4: Group processing

Rank up to 4: In vivo practice

Rank up to 4: Other Describe:

7. Please identify **up to four cognitive/behavioral targets** that were the focus of the CR intervention and rank them, with “1” being the primary target of the intervention:

Rank up to 4: General cognition

Rank up to 4: Skill acquisition

Rank up to 4: Work functioning

Rank up to 4: Attention

Rank up to 4: Verbal memory

Rank up to 4: Social cognition (e.g., facial emotion detection, prosody detection, theory of mind reasoning)

Rank up to 4: Social skills (e.g., behaviors related to conversation skills, assertiveness, eye contact)

Rank up to 4: Other Describe:

Rank up to 4: Other Describe:

8. Please provide any **clarifying comments** regarding the study conditions and CR intervention:

9. How was the CR intervention **delivered**?

- Cognitive training tasks were computerized
- Cognitive training tasks were in paper-and-pencil format
- Mix of computerized and paper-and-pencil
- Other Describe:

10. What was the **format** for CR sessions?

- Individual one-on-one sessions
- Group sessions
- Mix of individual and group sessions
- Other Describe:

11. In what **setting(s)** was the CR delivered?

- Outpatient psychiatry/mental health clinic
- Day treatment center
- Inpatient unit
- Home-based
- Other setting Describe:

12. Please check box if CR sessions took place in **more than one setting per participant** (e.g., sessions occurred in a clinic and at a workplace)

13. Please check box if CR sessions took place in **different types of settings for different participants** (e.g., participants were recruited at different types of clinical settings and CR was delivered at recruitment site).

14. What was the typical **duration of a CR session**? minutes

15. What was the **target number of CR sessions**? sessions per week

16. What was the **target duration of the CR intervention**? weeks

17. Please check box if Comparison Condition sessions were similar in duration and frequency to CR sessions

If they were not, please describe the duration and frequency of sessions in the comparison condition:

18. Who administered the CR sessions? Please check all that apply.

- Doctoral level clinicians
- Master's-level therapists
- Trainers without graduate education

19. Please check box if the individuals who administered the CR were employed by the study PI and were primarily research staff members

20. Please check box if the individuals who administered the CR were employed by the clinical institution at which the CR sessions took place and were primarily clinical staff members

21. Please check the box that best describes participant payments:

- All participants were paid for assessment and intervention sessions
Please indicate the amount paid for each intervention session: dollars
- All participants were paid for assessment sessions but not intervention sessions
- Participants were compensated non-monetarily (e.g., vouchers, coupons) for intervention sessions
- Participants in the CR condition were compensated (monetarily or non-monetarily) for completing intervention sessions but participants in the Comparison Condition were not compensated for intervention sessions

22. Please feel free to include any **clarifying comments** regarding the delivery of the CR and comparison interventions:

23. If your study used a cut-off for the number of CR or comparison intervention sessions completed or some other criterion for classifying participants as "completers" and "non-completers," please describe the criteria:

24. Does the database that you will share with NIMH include all participants or only those who were considered "completers"?

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- Data from all participants who were randomized in the study are included in the data that we will share
- Only study “completers” are included in the shared data
- Other Please describe:

25. Was a randomization (or minimization allocation) procedure used to assign participants to study groups? Select one:

26. Was the process of randomization/allocation carried out independently from the trial research team? Select one:

27. Who conducted the study-related assessments? Select all that apply:

- Study staff who were not CR therapists
- Study staff who were CR therapists
- Independent assessors who were not members of study team

28. Were assessors blind/masked to participants' treatment group assignment?
Select one:

29. Was rater blinding verified (e.g., by asking assessors to guess participant group assignment)? Select one:

30. Was a treatment protocol or manual used? Select one:

31. Was adherence to the treatment protocol and/or quality of treatment delivery assessed in an ongoing, standardized way? Select one:

32. Please feel free to add comments about randomization/allocation, assessments and adherence/competence:

33. If you are unable to provide a detailed assessment schedule, please use this table to summarize the timing and types of assessments that were conducted at post treatment and follow-up assessment(s)

	Assessment time point						
	Baseline	1 st Mid-Point	2 nd Mid-Point	Post-treatment	1 st Follow-up	2 nd Follow-up	3 rd Follow-up
Types of measures		Duration of interval between baseline and mid-point assessment: weeks	Duration of interval between 1 st mid-point and 2nd mid-point assessment:: weeks	Duration of interval between baseline assessment and post-treatment assessment: weeks	Duration of interval between end of treatment and 1 st follow-up assessment: weeks	Duration of interval between end of treatment and 2nd follow-up assessment: weeks	Duration of interval between end of treatment and 3rd follow-up assessment: weeks
Cognitive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Functioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

34. Please feel to add clarifying comments regarding the **schedule of assessments**:

Thank you very much for your contribution to the DoCTRS project!

Any inquiries may be sent to: nimhdatasets@mail.nih.gov