University of Illinois at Chicago
Research Information and Parental Consent for Participation in Biomedical Research
"MIND: Mindfulness Intervention to study the Neurobiology of Depression"

You and your child are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: Rachel Jacobs, PhD
Department: Psychiatry
Address and Contact Information: 1747 W. Roosevelt Rd.; rjacobs@psych.uic.edu
Emergency Contact Name and Information: Dr. Jacobs can be reached at 312 413-9178
Sponsor: Klingenstein Third Generation Fund, the University of Illinois at Chicago Campus Research Board, the National Center for Advancing Translational Sciences, and the Mind and Life Institute

Why is my child being asked to participate?

You and your child are being asked to take part in a research study about depression in adolescents sponsored by the Klingenstein Third Generation Fund, the UIC Campus Research Board, the National Center for Advancing Translational Sciences, and the Mind and Life Institute. This study aims to examine how rumination, an unhelpful way of thinking, may contribute to depression. This study is being conducted by Dr. Rachel Jacobs, who is a Research Assistant Professor in the Department of Psychiatry in the College of Medicine at the University of Illinois, Chicago (UIC). Dr. Jacobs can be reached at (312) 413-9178.

You and your child are being asked to participate in the research because your child has been previously diagnosed with major depressive disorder. Please read this form carefully and ask any questions that you may have before giving your consent to participate and your permission for your child to participate in this research study.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 80 subjects will be involved in this research at UIC.

What is the purpose of this research?

The study is being done to examine how unhelpful ways of thinking, such as going over and over something in your mind (rumination), may contribute to ongoing depression. This study will test whether or not helping teenagers to think in different, more helpful ways, will help them stay healthy, instead of experiencing depression again. This study will test Rumination-focused Cognitive Behavior Therapy (R-CBT), which is based on a promising treatment for recurrent depression in adults. The study will evaluate whether R-CBT can prevent relapse of depression among youth. Participants in this study will be assigned randomly (like flipping a coin) to receive either the R-CBT treatment or assessment only. The assessment-only group involves careful monitoring of depression by a clinician, but no treatment. This study will test whether the R-CBT treatment is helpful for teenagers who have had depression. Ultimately, studies like this one will help us figure out how to help teenagers receive the best possible care for depression.

What procedures are involved?

Approximately 80 teenagers (ages 12-18) with a previous diagnosis of major depressive disorder and healthy controls will be involved in this research at UIC. If you and your child agree to participate in this research, we will ask you and your child to do the following:

Part 1: Initial screening interview:

- The screening process and initial testing day will take approximately three hours. This will start with us telling your child about the study and asking if he/she would like to participate. We will encourage your child to let us know at any time (before, during or after completion) if he/she has any questions about the study. We are happy to answer any questions.
- After your child has agreed to participate in the study, a trained clinician will ask you and your child several questions in regard to how they are currently feeling and how they have felt in the past.
- As part of the research, we will be conducting an fMRI (functional magnetic resonance imaging) scan at the beginning and at the end of the study. This is where a large magnet rapidly creates pictures of your child's brain as he/she is performing tasks and thinking. As a result, researchers will know what parts of your child's brain are active when he/she is performing certain tasks. The scanner is a small space. To get your child used to the small space, we will provide time during the screening interview for your child to lie in a simulator.
- Finally, at this time a research coordinator will conduct a short IQ evaluation of your child. This estimation of your child's IQ will only be used for research purposes.

Part 2: Assignment to R-CBT or assessment only:

If researchers determine that they think the study is right for you and your child, then your child will be randomly assigned to a study group (an assessment-only control group or to a group receiving 8 weeks of Rumination-focused Cognitive Behavior Therapy).

1. *Assessment-only control group*: Your child will need to come to lab for a baseline and 8 week assessment. Between these two dates, your child will need to fill out questionnaires every 2 weeks (total of 4 times online or by mail).
2. *R-CBT group*: For those assigned to the R-CBT group, they will need to come to the lab once a week for 8 weeks for each of their R-CBT sessions. During these sessions, a study therapist will target rumination and other unhelpful ways of thinking. Rumination is an unhelpful thought process where a person thinks about something over and over without problem solving. Mindfulness will be used as a key strategy for dealing with these negative thoughts. Mindfulness is a strategy that focuses attention with the goal of reducing stress and promoting well-being.

Sessions will be audio recorded at our offices at 1747 W. Roosevelt Road. These recordings are done so that we can make sure the study staff are doing the interviews and treatment correctly. These audio files will be labeled by subject number only and will be destroyed within one year of study completion. Please check the box and print your initials to demonstrate that you understand sessions will be recorded:

☐ I understand audio recording of my/ my child's treatment session(s)/clinical interviews will occur.
Initials _____.

Your child may remain on medication during this study and continue any other treatment they are already getting. Medication or other treatment does not need to be altered in any way because of participation in this study. **We ask that you keep us informed of any medication or other treatment changes. Additionally, we ask that you provide us with contact information for your child's clinician. Your child's clinician will be notified of their participation. Please keep us updated on any clinician changes.**

This research will be performed in our clinic and research building at 1747 W. Roosevelt Road.

Part 3: fMRI Scan:
All participants will be scanned twice: at baseline and at an 8-week follow-up appointment. An fMRI machine is basically a large, spinning magnet that rapidly creates pictures of the brain. For our study, we will take structural images of your child while they are resting and also, we will have your child perform tasks and think while in the fMRI scanner. By doing this, researchers can look at these pictures of your child's brain and determine what areas are activated while he/she is performing certain tasks. The fMRI scan will last about an hour and throughout that time, your child will perform three tasks (approximately 10-15 minutes each):

1. A task looking at different ways of thinking where they will be asked to think about themselves as well as visualize simple scenes
2. A resting task where they will lie still and let us know what they are thinking about.
3. A self-reflection task where they will repeat resting state while reporting on their thinking patterns

Your child will perform these tasks by responding using a button box that they will hold throughout the fMRI.

Part 4: Questionnaires:
Along with the visits to the study site, your child will be asked to complete questionnaires about how they've been feeling. Questionnaires will be completed at home (online or via mail) every 2 weeks during the treatment and then, once every 3 months during the 24 months following the completion of the 8-week study. These online questionnaires will take your child approximately 20 minutes to complete. Additionally, we ask that you complete some questionnaires and provide information about your child. You will need to complete these at the initial visit, the 8-week follow up visit, and every 3 months throughout the 2 year follow-up. These questionnaires should take you about 20 minutes as well. Some of the questions we ask will be personal and some will be about sensitive topics. In order to protect your privacy and the privacy of your child, we suggest you complete these questionnaires in a private location, but separately from each other. This will help to keep all answers confidential.

Part 5: Follow-up visits:
In addition to filling out questionnaires, after the baseline visit, your child will need to come into lab to meet with a clinician at 6 follow-up dates: 8-weeks (completion of study), 6-months, 12-months, 18-months, and 24-months after the study. These meetings with a clinician will last about two hours.

In summary, your child will need to come to the study site 6 times over the next 2 years. The baseline visit will last approximately 3 hours. The follow-up interviews will last about two hours each. If you are assigned to the R-CBT group, your child will also need to attend 8 clinical sessions during the first 8 weeks. Each of these sessions will be 60-90 minutes long.

If your child turns 18 during the course of the study, they will need to re-consent to this study as an adult.

If your child goes away to college while they are in the follow-up portion of the study, we will make every effort to conduct clinical visits during their school breaks when they are home, but we will also allow for phone interviews, if necessary.

As the parent of your child, you will be asked to participate in clinical diagnostic interviews, complete questionnaires about you and your child, and support your child in attending the clinic for scheduled visits.

What are the potential risks and discomforts?

There are some risks associated with this research. It is possible your child will experience an increase in their depression symptoms. This is a risk whether or not they participate in this study and we hope that the careful monitoring and possible treatment may help teenagers stay well. If your child becomes depressed, we will ensure your child is provided contact information for a doctor, either in our clinic or at a clinic in the community. You may withdraw from the study at this or any other time. If you are willing, we would like your child to continue in the study so that we can see what happens to teens who experience depression again.

In addition, some of the questions you and your child will be asked are personal and can result in embarrassment or strong emotional reactions. Your child is free to refuse any questions that may be uncomfortable. If your child becomes emotionally disturbed, the questioning will be discontinued. If you child continues to experience emotional distress, the interviewer or clinician will provide counseling or other services until the crisis has been resolved. All of your child's answers will be kept strictly private, unless there is a possibility of them hurting themselves, hurting someone else, or we are told of child abuse. In these instances, we will tell you, the parent, the child's clinician (if they have one), and other agencies to make sure your child is safe. If a clinician at IJR/UIC is seeing your child, your child's clinician will be told that you are participating in this study. However, we will not give the clinician any additional information unless you authorize it in writing, except in the instances listed above where safety is a concern.

Your child may feel claustrophobic (or trapped) in the fMRI scanner. Your child may stop at any time if he or she becomes too uncomfortable. If your child feels uncomfortable at any time, they will be told how to communicate this to research staff (by speaking) and research staff will remove them from the scanner.

Your child may experience discomfort associated with the noise of the fMRI scanner. This is minimized by the use of earplugs.

In the fMRI scanner, there is a potential risk of invalidating credit cards exposed to the magnetic field and the attraction of magnetic objects, such as metal, toward the magnet. To minimize the risk that your child has no metal objects in his/her body such as braces, pacemakers, shrapnel, etc., a thorough participant screening will be done at the MR Center and strict operating procedures are used to minimize potential risks.

Boredom and discomfort may be experienced while lying in the magnet during the scan. We try to help with this by regularly providing information about the progress of the examination, and close monitoring by the MR technologist. Individuals with strong anxiety reactions to lying in the magnet are free to withdraw permission or consent for the study. Comfort will be addressed by using foam padding around the head, neck, and under the knees. Also, blankets are available upon request.

There is a minimal potential risk of loss of confidentiality. Others may know you/your child are participating, for example, if they see you at the clinic. Others may find out about your private research information. This risk may lead to emotional distress for you, your child, or your family. However, we will do everything we can to protect against this risk. To protect against this risk, research staff will keep all information secure on password protected computers in the laboratory. Your child's research data will not be stored by name or other identifying information but instead will be given a code number to protect privacy.

What are the reproductive risks?

If your child is female: Participating in the fMRI scan may involve risks to a pregnant woman and/or an unborn baby. To protect against this, we will screen all female participants for pregnancy and, if they are pregnant, they may not take part in this study.

Will I be told about new information that may affect my decision to allow my child to participate?

During the course of the study, you will be informed of any new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be requested again.

Are there benefits to taking part in the research?

There is no direct benefit from participating in this study. The program is designed to try to prevent depression relapse, but there is no guarantee. An indirect benefit of the study is that you and your child's participation may benefit the scientific community as a whole, and you may contribute in part to improving models of brain functioning and improving treatments for adolescents with depression.

What about privacy and confidentiality?

If a clinician at IJR/UIC is seeing your child, your child's clinician will be told that you are participating in this study. However, we will not give the clinician any additional information unless you authorize it in writing, except in the instances listed above where safety is a concern.

No information about you or provided by you during the research will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law (this includes instances in which we determine that your child may be in danger of harming himself or herself or another person, plans to commit a felony, or we learn of severe trauma which is related to daily living problems).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity. Your child's name will never be used when information about this study is published. As soon as your child becomes a participant in this study, your child will be given a number that links your child's tests together. However, the only people who will have access to link the ID number and your child's name are the research staff. All forms filled out for this study will be kept in a locked cabinet in the Institute for Juvenile Research (1747 W. Roosevelt Road). All data stored on the computer is stored under firewall and is password protected. Only those directly related to data collection and management will have access.

All audio recordings in the study will be destroyed no later than one year after you complete the study. These recordings will be used to measure how the clinician is doing the therapy. Until they are destroyed, they will be kept in a confidential and locked storage space and will not be accessible to anyone except study staff. One year after study completion, all private identifiers will be destroyed, including your contact information.

Again, all data obtained from participants will be coded with unique numbers to ensure that only investigators have access to information that can link individual names to data. When presented scientifically, only group averages will be used; these will make no reference to individual participants.

All information will be used only for the purposes of this study unless specific informed consent is documented beforehand.

All records, including audio recordings, will be securely stored and accessible by research team members only. Original records will be destroyed according to federal and state guidelines.

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Will my child be reimbursed for any expenses or paid for participation in this research?

Your child will receive $50 for the diagnostic interview, $50 for the first fMRI scan, and $75 for the MRI scan and diagnostic interview at 8-week follow-up. Those in the R-CBT group will be reimbursed $5 per session to offset travel expenses (given to parent). Those in the control group will receive $10 for completing questionnaires every 2 weeks. No matter which group your child is in, this comes to a total of $215 for participation and completion that your child will receive during the initial 8-week period.

For follow-up visits: the adolescent will be reimbursed $50 each for the 6-, 12-, 18-, and 24-month follow-up evaluations in the lab. Additionally, they will receive $10 for completing the 3-month self-report and $20 for completing the 9-month self-report measures. Your child will receive $25 each for both the 15- and 21-month self-report measures. The total compensation for the follow-up is $280.

Checks will be sent to you as the parent for the MRI visits, and it is up to you and your family to discuss how this reimbursement will be divided between you and your child. Cash will be given directly to your child for the diagnostic interviews.

If you or your child decide to withdraw from the study at any point, your child will be compensated for all participation up to that point.

UIC policies and federal tax laws require that personal information, including Social Security Numbers, be collected when subjects are provided with $100 or more in compensation in a year. This information will be collected for payment purposes only and will be kept separate from any other research information.

Can I withdraw my child or can he/she be removed from the study?

Your child's participation in this research is VOLUNTARY. If you or your child chooses not to participate, it will not affect your relationship with UIC or your right to health care or other services to which you are otherwise entitled. If you and your child decide to participate, you or your child are free to withdraw your child's consent and discontinue participation at any time without affecting you or your child's future care at UIC. If you or your child decides to withdraw from the research, we will still use your child's data unless you or your child request in writing that their data be withdrawn from the study. In this case, we will destroy all research materials related to your child within one week of receiving a written request.

There are several circumstances which may deem your child ineligible for the study. These include:

- If your child has severe psychiatric or neurological symptoms that would interfere with participation in the study
- If your child is currently suicidal
- If your child has difficulty completing study tasks

If your child is not enrolled in the study because of psychiatric symptoms that might interfere with participation, the study staff will help you find additional treatment for your child. Your child may be eligible for the study at a later time if their symptoms change.

The researchers and sponsors also have the right to stop your child's participation in this study without your consent if:

- They believe it is in your best interest;
- You/your child were to object to any future changes that may be made in the study plan
- You/your child do not follow the study procedures
- Your child becomes pregnant during the fMRI portion of the study

You will be informed if such a decision is made. If you or your child are removed or withdrawn from the study, you may continue to receive treatment with your doctors.

In the event you and your child withdraw or are asked to leave the study, you will still be compensated as described above.

Whom should I contact if I have questions?

The researcher conducting this study is Dr. Rachel Jacobs (312-413-9178). You may ask any questions you have now. If you have questions later, you may contact Dr. Jacobs or any of her research assistants.

What are my child's rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Remember:

Your child's participation in this research is voluntary. Your decision whether or not to allow your child to participate will not affect your current or future relations with the University. If your child decides to participate, your child is free to withdraw at any time without affecting that relationship. You will be given a copy of this form for your information and to keep for your records.

Optional Sleep Monitoring Task

You may choose to allow your child to participate in an optional Sleep Monitoring Task. This optional study is part of a collaboration with other researchers at the University of Illinois at Chicago to collect information on sleep patterns in people who experience depression. The goal of this project is to try to understand how sleep relates to mood across all age groups.

If you choose to allow your child to participate in this optional task, they would wear a watch-like device on their wrist for 8 days (7 nights) between the baseline visit and the 8-week scan. This actigraphy device is non-invasive. Actigraphy measures total sleep time in minutes, the period between bedtime and when a person falls asleep, and the amount of interruption of sleep based on physical movement.

Your child would be given this device and instructed how to wear and use it at the baseline visit. They would also complete two sleep questionnaires at the baseline assessment. The actigraph belongs to researchers at the University of Illinois at Chicago. Therefore, after your child wears the actigraph, they will be asked to return it to a study staff member during a study appointment or to mail it back to us, but no later than after the 8-week scan.

There is little foreseeable risk involved in completing this part of the study. Actigraph is a commonly worn non-invasive measure endorsed by the American Academy of Sleep Medicine for assessing sleep patterns. Additionally, the two questionnaires your child will be asked to fill out are considered standard measures of sleep quality, brief to complete, and unlikely to feel burdensome.

Some of our collaborators are collecting information on sleep in studies that involve a higher level of risk to participants. The data we collect on your child's sleep patterns will be pooled and compared with sleep data collected in these studies; however, you and your child will not be exposed to any of the risks involved in the studies our collaborators are conducting. Other than sharing sleep data, our study is completely separate from

those of our collaborators and does not share their higher levels of risk. We recruit participants for this study separately and evaluate whether our study is a good fit for you and your child according to our own guidelines.

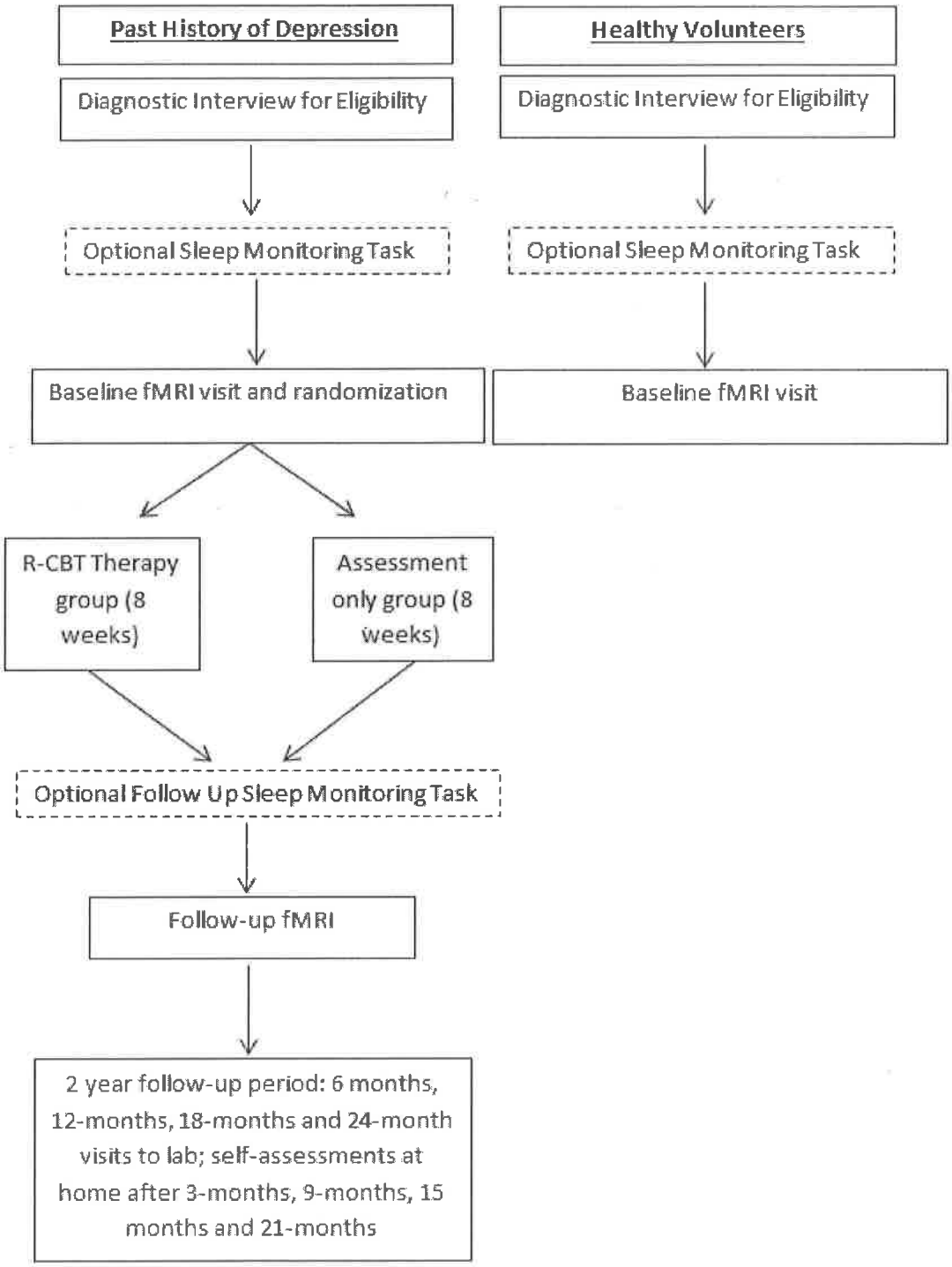
The sleep monitoring task is optional, and if you decide not to allow your child complete it, you and your child may still participate in the current research study.

Your child will receive an additional $15 for participating in the optional Sleep Monitoring Task.

☐ I agree to allow my child to complete the optional Sleep Monitoring Task for the current research study.

☐ I do not agree to allow my child to complete the optional Sleep Monitoring Task.

Initials _____.


Past History of Depression
Healthy Volunteers
Diagnostic Interview for Eligibility
Diagnostic Interview for Eligibility
Optional Sleep Monitoring Task
Optional Sleep Monitoring Task
Baseline fMRI visit and randomization
Baseline fMRI visit
R-CBT Therapy group (8 weeks)
Assessment only group (8 weeks)
Optional Follow Up Sleep Monitoring Task
Follow-up fMRI
2 year follow-up period: 6 months, 12-months, 18-months and 24-month visits to lab; self-assessments at home after 3-months, 9-months, 15 months and 21-months

Signature of Parent/Guardian

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____

Signature of Parent/Guardian Date

_____

Printed Name of Parent/Guardian

_____

Printed Name of Child

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent