Official Title: Improving Adherence in Adolescents and Young Adults With Bipolar Disorder (IGNITE)

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
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Project Title: Improving Adherence in Adolescents and Young Adults with Bipolar Disorder - RCT

Principal Investigator: Martha Sajatovic, MD

Introduction:

This form gives you information to help you decide if you want to be in a research study. Research studies are a way to find out new information about something. This form will tell you about this research study. You can ask the doctor or staff any questions you may have.

Why are you being asked to be part of this research study?

You are being asked to be a part of this research study because you are an adolescent or young adult (age 13-21), have been diagnosed with bipolar disorder, and have missed some doses of your medication in the past week or month.

Why is the study being done?

The results of the study will help us to understand if an educational and behavioral intervention (or learning opportunity), called Customized Adherence Enhancement for Adolescents and Young Adults (CAE-AYA), helps patients with taking their medication and missing fewer doses compared to a standard educational program about bipolar disorder.

You will be one of 40 participants that will be a part of this study, from 2 study sites in Ohio. Around 20 participants from Case Western Reserve University/University Hospitals and around 20 participants from the University of Cincinnati will be a part of this study.

If you join the study what will you have to do?

We think that you will be in this research study for about 6 months. During that time you will be asked to do 5 study assessment visits and 5 educational session visits (4 sessions over 4-6 weeks and then one more about 4 weeks later). Members of the study staff will also call you about 2 weeks after the fourth educational session.

Your first visit will be about 2 hours long and will help the researchers see if you will be able to be a part of the study.

- You will sign this assent form, and your parent or caregiver will sign the consent form saying that you want to be a part of this study
- You will be asked questions about your basic information, like age and gender
- You will be asked about your past and current experiences with different mental health symptoms, your medication, and other questions related to your mental health
- You will be given a special pill box called a SimpleMed device to use with your bipolar medication(s), and research staff will help you set it up and show you how to use it. You will be asked to use this pill box the whole time you are in the study, which will help track whether you are taking your medication on time.

The next visit will be about 1 ½ hours long and you will be asked to answer questions that will tell researchers more about you, your mental health, and how you are taking your medication. You will also be placed in one of the two different educational sessions; this will be random, similar to how a flip of a coin is random. Neither you nor the study staff will get to choose the group you are placed into, but study staff will tell you which one you are in once it has been randomly decided.

Will any part of the study be upsetting or uncomfortable?

It is possible that some of the questions you are asked may be upsetting, or might make you may feel uncomfortable answering them. If you do not want to answer a question, you can skip it and go to the next question. You do not have to answer questions you are uncomfortable with. You might also feel tired after completing all the questionnaires.

Will the study help you?

We cannot promise any benefits to you or others that might happen from you being a part of this research, but you might think the educational sessions were helpful.

Will the study help others?

This study might find out things that will help children, adolescents, and young adults with Bipolar Disorder someday.

Who will see the information collected about you?

The information collected about you during this study will be kept safely locked up. Nobody will be able to see your information except the people doing the research and the people making sure the researchers are doing their jobs by protecting your information.

Study information about you will be given to your parents.

The research assistance will ask you if you have thoughts or have made plans to harm yourself (suicidal thoughts). They will talk to you about these thoughts to better understand and to help keep you safe. If they are concerned for your safety, that you may hurt yourself, plan to or intend to harm yourself, they will share this information with your parent.

What do you get for being in the study?

You will get $25 for each assessment visit you complete. There are 5 assessment visits. You will

also get another $10 when you return the SimpleMed pillbox at the end of the study. The total amount of money you can earn for being a part of this study is up to $135.

If you decide you do not want to continue with the study or are removed from it by the research team, you will still get the payments for the visits that you have already done. Your payments will be made by a check mailed to you and your parent or caregiver after the meeting is completed. If you do not have a bank account to cash the check, the research assistant will talk about other possible payment methods with you.

Depending on what intervention session you are placed in, you might also be given small items (e.g., $5 gift card, pens, notebooks, key tags, lanyards, mini calendars, etc.) for meeting goals you set during the sessions.

Do you have to be in the study?

You do not have to be in the study. If you don't want to be in this study, you just have to tell us. It's up to you.

You can also take more time to think about being in the study if you don't know yet if you want to be in the study.

What if I have any questions?

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call 216-844-2102

You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

What choices do you have if you say no to this study?

There are other ways to help your Bipolar Disorder if you don't want to be in this study. You can continue to see your pediatrician or another doctor.

This study is extra, so if you don't want to do it, nothing else will change.

Contact for Future Research

Our study team might have other research studies in the future. We would like your permission to get in touch with you in the future if we think you could be a potential participant in one of our

studies. Please check one of the boxes below that tells us your choice to be contacted for future research.

- ❑ Please contact me by _____ (email, phone, etc.) for future research opportunities.
- ❑ Please **do not** contact me for future research opportunities.

Permission to Contact Parent or Caregiver

Our study team might want to ask your parent or a caregiver how you are doing with taking your medication at 4 times throughout the study. Please check one of the boxes below that tells us whether or not we can contact them.

- ❑ Yes, you can ask my parent or a caregiver how I am doing with taking my medication.
- ❑ Please **do not** contact my parent or a caregiver.

Other information about the study.

If you decide to be in the study, please write your name below.

You can change your mind and stop being part of it at any time. All you have to do is tell the person in charge.

You will be given a copy of this paper to keep.

_____
Write your name

_____ _____ _____
Person Obtaining Assent Date Time