discomfort or other reactions from use of the Study Drug. If you decide that participation may be right for you or a loved one, the study staff will explain the potential risks to you before any study procedures are conducted.

What are the potential benefits of participating?

Participants may or may not receive any benefit from taking part in this study. It is possible that participants may get better, stay the same, or get worse. However, the information learned from this study may help find new treatment options for people diagnosed with autism spectrum disorder in the future.

What are the next steps?

If you or your loved one would like to take the next step toward possible participation or if you have more questions, please contact us as directed on the back of this brochure. Contacting us does not obligate you to participate in this study. Participation is entirely voluntary, and you may withdraw your consent at any time for any reason.

Bloorview RESEARCH INSTITUTE

For more information about the IRIS study, please contact:

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DOES AUTISM AFFECT YOUR LIFE OR THE LIFE OF SOMEONE YOU LOVE?

iRiS

Learn about participating in the IRIS study, a research study of an investigational medication for adolescents and adults with autism spectrum disorder (ASD).

We understand the many ways that autism spectrum disorder (ASD) can impact the lives of those who have ASD and their loved ones. Difficulties with communication and social interaction are some of the core symptoms of ASD. Unfortunately, there are no approved medications for the ASD symptoms that make communication and social interaction such a challenge.

This is why finding new and better treatments for autism spectrum disorder is so important.

What is being researched in the IRIS study?

In the IRIS study, we are looking to find out whether the investigational "Study Drug", designated ML-004, will help alleviate some of the symptoms that interfere with communication in those with autism spectrum disorder.

The Study Drug comes in the form of a tablet taken by mouth. The Study Drug is designed to release some medication immediately and to also release additional medication slowly throughout the day in order to maintain the correct levels of medication in the body. The Study Drug is investigational because it has not been approved for the treatment of ASD symptoms.

Who can participate in the IRIS study?

To join this study, potential study participants must:

- be 12 to 45 years of age
- have a diagnosis of autism spectrum disorder (ASD)
- have a care/study partner* willing to assist during the study

*The care/study partner is someone who lives with or has frequent contact with the study participant (parent, spouse, friend, etc.) and is willing and able to provide information about the participant and attend some study visits.

Additional requirements to participate must also be met. The staff at the study center will explain the complete list of requirements.

Approximately 150 adolescents and adults will participate in the IRIS study. This study will be conducted at about 28 study sites in the United States, Canada, and Australia.

What will happen during the IRIS study?

The study doctor's staff will first give a detailed explanation of the IRIS study and its potential risks and benefits. This explanation will be made verbally and in writing. Only after obtaining written Informed Consent from the potential participant will any study-specific procedures take place.
If the potential participant is a minor or incapable of fully understanding the decision to take part in the study, a legally authorized representative (such as a parent or guardian) must sign the Informed Consent form, and the potential participant will sign another form saying they agree to participate.

Next, the study doctor and the doctor's staff will review medical records and conduct a series of study-related examinations and tests to see if the participant satisfies the requirements to enroll in this study. This process is called "screening."

After screening, potential study participants who satisfy all requirements will begin the treatment period of the study. At some point during the treatment period, all participants will receive a placebo. (A placebo is a substance that looks like the Study Drug but has no active medication.) At other times during the treatment period, participants are assigned to take either the Study Drug or a placebo. This assignment is made randomly by a computer, and the chance of receiving either the Study Drug or placebo is 50/50, like flipping a coin. At no time will study participants be told whether or not they are taking placebo.

The treatment period will last approximately 16 weeks.

Approximately 30 days after the last dose of study medication, participants will receive a safety follow-up telephone call to check their overall health.

In total, participation in the IRIS study will take up to 26 weeks and includes up to 10 visits to the study clinic, plus the safety follow-up call.

Does it cost anything to participate?

There is no cost to participate. Qualified participants receive the study medication (either the Study Drug or placebo) and all required study-related medical assessments and examinations at no cost. Compensation is available for those who satisfy applicable study requirements and reimbursement for expenses related to study participation is also available.

Are there any risks to participating in this study?

There may be potential risks to participating in this study. All drugs and medical procedures carry a risk of side effects; therefore, it is possible that participants may experience some