RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Online Evaluation of the Diagnostic Accuracy of BlinkLab's Digital Assessments for Autism

PROTOCOL NO.: 08012025
WCG IRB Protocol #20250163

SPONSOR: BlinkLab Ltd.

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STUDY-RELATED PHONE NUMBER(S): 908-824-3471 (24 hours)

Your child's participation in this study is voluntary. Your child may decide not to participate, or your child may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which your child is otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt your child, talk to the research team at the phone number(s) listed in this document.

A person who takes part in a research study is called a research or study subject. In this consent form "your child" always refers to the research subject.

The BlinkLab Device is a non-invasive, smartphone-based application that functions as a diagnostic aid to healthcare providers that supports the evaluation of neurodevelopmental conditions in children 2 to 11 years. This study specifically concerns children for whom either the parents/caregivers or the pediatrician have developed concerns for the subject's developmental progress.

As the parent/caregiver you are a legally authorized representative, please remember that "your child" means the research (study) subject.

SUMMARY

Your child has been selected to participate in a research study. The purpose of this consent form is to help you decide if you want your child to participate in the research study.

Your child should not join this research study until you (the parent/caregiver) have read all of the information contained in this consent form, and all of your questions have been answered.
This study aims to enroll 400 participants.

Participants must be willing to be videotaped during the diagnostic assessments by the BlinkLab app.

Things to know before deciding to take part in a research study:

- The primary purpose of a research study is to gather information that may help improve care for patients in the future, rather than providing direct medical benefits to those who participate.
- The main goal of regular medical care is to help each patient.
- Your child's participation is voluntary; the decision to join or not join the research study will not cause your child to lose any medical benefits. If your child decides not to take part in this study, your child's doctor will continue to treat your child.

- Parts of this study may involve experimental (investigational) procedures that are being tested for a certain condition or illness. An investigational device is one that has not been approved by the U.S. Food & Drug Administration (FDA).
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your child's medical records may become part of the research record. If that happens, your child's research related medical records may be looked at and/or copied by the sponsor of this study and health authorities or other groups associated with the study.
- This study requires you to send us your child's diagnostic report following a recent neurodevelopmental assessment

PURPOSE OF THE STUDY
The purpose of this study is to evaluate how well the BlinkLab mobile app (BlinkLab Dx app) can help identify signs of autism in children, compared to a doctor's diagnosis. The study will use expert opinions based on DSM-5 guidelines as the reference for diagnosing autism.

The BlinkLab Dx app is being developed as a tool to assist healthcare providers in diagnosing autism in children aged 2-11 years. It is specifically for children whose parents, caregivers, or pediatricians have concerns about the child's developmental progress, which might suggest autism.

In this study, children who have undergone an assessment for any neurodevelopmental condition are eligible to participate; the assessment does not need to have resulted in an autism diagnosis. Your child may participate regardless of whether the outcome of the assessment indicated a neurodevelopmental condition or not. This will help us evaluate how reliably the App can assist in the diagnostic process for autism, including in cases where other neurodevelopmental conditions are present or suspected.

In this study, your child will watch short movies on a smartphone. These movies include audio sounds, and the app uses the phone's camera to measure the child's reactions to the sounds. This means that your child's face will be recorded during the study. The goal is not to diagnose autism but to collect data that may help improve the app, which could later be used to assist healthcare providers in autism evaluations.

The data collected from the phone will be stored securely on an online system, where only the research team can access it to ensure your child's privacy. The videos and other information will be de-identified, meaning no personal details will be linked to the data. The research team will use this platform to track the study's progress and review the results.

The BlinkLab Dx app is not intended to provide a diagnosis of autism but is being developed to support the diagnostic process, particularly in the early screening stages. In addition to using the app, we will also ask parents and caregivers to complete questionnaires and have interviews about your child's medical and developmental history.

Who is conducting the study
This study is being conducted by BlinkLab, which serves both as the sponsor and the lead investigator. This means that BlinkLab is responsible for funding the study and overseeing its design and conduct.

WHO CAN PARTICIPATE
To participate in this study, your child must meet the following inclusion criteria and must not meet any of the following exclusion criteria.

Inclusion Criteria
Your child may be eligible for this study if they meet all of the following conditions:

- **Age:** Your child is between the ages of 2 and 11 years old.
- **Parent/Caregiver/Healthcare Provider Concern:** Your child is scheduled for a neurodevelopmental assessment within 30 days of enrollment or has already received a neurodevelopmental assessment based on DSM-5 criteria within the past 12 months.

- **Language Proficiency:** You and your child must have functional English capability at home (e.g., understanding and communicating in English).
- **Informed Consent:** You (as the parent or caregiver) must be able to read, understand, and voluntarily sign the Informed Consent Form (ICF).
- **Videotaping:** Your child must be willing to be videotaped during the diagnostic assessment using the BlinkLab App.

Exclusion Criteria
Your child will not be eligible for the study if any of the following conditions apply:

- **Severe Auditory or Visual Impairments:** Your child has significant visual impairments (e.g., congenital nystagmus, cataracts), substantial hearing deficits, including deafness or blindness, or any suspected auditory or visual hallucinations.
- **History of Neurological Conditions:** Your child has a history or suspicion of brain malformation, injury, or insult requiring medical interventions (e.g., surgery or chronic medication), or has a history of audiogenic seizures.
- **Acute Illnesses:** Your child is currently experiencing acute illnesses or acute exacerbations of chronic conditions (e.g., conjunctivitis, uncontrolled allergy symptoms) that may interfere with the study.
- **Medication Use:** Your child is currently receiving therapies that could affect their vision, hearing, nervous system, or the ability to focus on the study videos (e.g., CNS stimulants, CNS depressants, anticonvulsants), unless they have had a sufficient washout period before participation.
- **Device Compatibility:** You do not have access to a smartphone that is compatible with the BlinkLab app.
- **Previous Enrollment:** Your child has previously enrolled in any BlinkLab clinical study.
- **Location of Testing:** Your child is unable to complete all remote at-home study visits within the United States.

STUDY PROCEDURES
This study consists of five parts, one of which is optional, in which you and your child take part. All parts of the study will be completed from home:

1. **Screening Phase:** This phase will start with an online screening survey. If you pass the screening survey, we will schedule a phone call with you to determine if your child is eligible for the study. This call will take about 15 minutes. If you and your child choose to participate and sign the informed consent form, we will ask you to provide details about your child's recent neurodevelopmental assessment, including sending us the diagnostic report. Next, you will receive instructions on how to install the BlinkLab app on your mobile device. You will also be asked to complete an online form to provide demographic and medical history information.

2. **First BlinkLab Video Session**: This session includes your child watching a 15-minute video in the BlinkLab app on your mobile device at home. You can watch a video about using our app on our website: https://www.blinklab.org/participate (scroll down to “How it Works”).

3. **Second BlinkLab Video Session**: After successfully completing the first video session, you’ll receive instructions via email for the second 15-minute video session. This session will be completed on a separate day from the first video session.

4. **Questionnaires**: You will be asked to complete four standardized questionnaires about your child’s behaviors and traits. These can be completed online at your convenience between the first and second video sessions and will take approximately 30 minutes in total. Links to the questionnaires will be sent to you via email.

5. **Optional Computer-Based Tasks:** If your child is 5 years or older, you and your child will be asked to complete three short tasks. This optional session will take approximately 15 minutes and will be performed from home using both the BlinkLab app and your own computer.

The total time you are expected to spend participating in this study is approximately 1 hour and 15–30 minutes. Your child's participation will take about 30–45 minutes in total. The study activities will be scheduled over a period of 1 week to about 1 month, depending on your availability and coordination with our study team.

SUBJECT AND PARENT RESPONSIBILITIES
If your child participates in the study, it is important that you and your child be prepared to do the following:

- Inform the study staff of any changes in your child's health or medications that they are taking.
- Inform the study staff if you wish to stop your child's participation in this study at any time.

Before the first BlinkLab video session, the parent/caregiver is responsible for providing the study investigator with the child's diagnostic record of their most recent neurodevelopmental assessment, medical history and demographics through an online form. Between the two video sessions, the parent is responsible for completing the online questionnaires via the link provided by the study staff.

RISKS AND DISCOMFORTS
The anticipated risks associated with this study are minimal. The device is non-invasive. However, your child might experience some discomfort during the presentation of the auditory stimuli while wearing the provided headphones. If your child is uncomfortable and chooses not to continue with the experiment, they may stop at any time during the video watching sessions.

If you believe your child may have been injured or gotten sick as a result of being in this study, or if you have questions regarding your child's treatment, please contact the study doctor. The study doctor will help your child receive appropriate medical treatment.

It is important to note that there may also be additional side effects or risks that are not known or are not currently foreseeable at this time.

NEW INFORMATION
If any new information about the BlinkLab Dx App or this research study that might change your decision on your child's participation becomes known – especially considering risks and discomforts associated with the device – while they are participating in the study, the study team will inform you. You may be asked to sign a new consent form if this occurs.

POTENTIAL BENEFITS
This is an investigational study designed to test how well the BlinkLab Dx app works as a diagnostic aid. It is, therefore, not expected that your child will receive any medical benefits from being in this study.

ALTERNATIVE TREATMENT
This is not a treatment study. The BlinkLab Dx App is not intended to be a standalone diagnostic tool but serves as an addition to the diagnostic process.

Your child does not need to be in this study to be assessed for autism. The standard of care diagnosis method used by clinicians rely on screening tools and subjective behavioral assessments

COSTS
BlinkLab will provide the study BlinkLab Dx App and materials package free of charge during this study.

PAYMENT FOR STUDY PARTICIPATION
You will be paid $200 in the form of an Amazon Gift Card for your child's participation in this study. If your child is 5 years or older, you may also choose to complete an optional session with your child. For completing this additional session, you will receive an extra $75 Amazon gift card ($25 per each additional task).

The results from this study may lead to new commercial products or tests. If this happens you will not receive any additional payment

CONFIDENTIALITY
As required by the federal Health Insurance Portability and Accountability Act (HIPAA) we will take reasonable measures to safeguard the confidentiality of information that identifies your child and relates to their past, present, and future physical and mental health conditions (protected health information) collected, used and shared as part of this research.

Information from this study will be given to the sponsor. “Sponsor” includes any persons that are contracted by the sponsor to have access to the research information during and after the study. Information on your child collected for this study will be de-identified.

Medical records which identify your child, and the consent form signed by you will be looked at and/or copied for research and regulatory purposes by the Sponsor's study team.

Your child’s private information and medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration and other countries where the study BlinkLab App may be considered for approval
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Any information collected will not be sold to any unauthorized third-party vendors.

Confidentiality Risks
Absolute confidentiality cannot be guaranteed because of the need to give information to the above listed parties. Breach of confidentiality is a potential risk in all research that collects or maintains personally identifiable information.

STUDY RESULTS
The results of this research study may be presented at meetings or in publications. Any time that the results are presented, the Sponsor will take measures to ensure that the data is presented in a manner that does not disclose your child’s identity.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your child’s participation in this study is voluntary. You may decide for your child not to participate, or you may remove your child’s participation from the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your child’s participation in this study may be stopped at any time by the study team without your consent for any reason, including:

- if it is advisable for your child’s health and wellbeing
- if you do not consent for your child to continue in the study after being told of changes in the research that may affect your child.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, BlinkLab is paying the study team for the conduct of this research study.

QUESTIONS
Contact Henk-Jan Boele at 908-824-3471 (24 hours) for any of the following reasons:

- if you have any questions about your child's participation in this study,
- if you feel your child has had a research-related injury, or
- if you have questions, concerns or complaints about the research.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to have your child participate in this study, you will receive a signed and dated copy of this consent form for your records.

If you have questions about your child's rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Institutional Review Board (IRB)/Independent Ethics Committee (IEC)
WCG IRB at 855-818-2289 or email: clientcare@wcgclinical.com

The Institutional Review Board/Independent Ethics Committee is a group of people who independently review research.

The IRB/IEC will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB/IEC if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

STATEMENT OF CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my child's participation in it have been answered to my satisfaction. I freely consent to my child being in this research study.

I authorize the release of my child's medical and research records for the purpose of this study. I understand that I am giving permission to collect, use and share my child's health information.

I understand that by signing this consent form, I have not given up any of my child's legal rights.

- Assent of children aged 2-6 is not required.
- Assent of children aged 7-11 is required.
- If assent is obtained, have the person obtaining assent document assent on the consent form

Your signature below documents your permission for you, or the individual named below to take part in this research:

Printed Name of Subject

Signature of Child Subject's Parent, or Individual Authorized Under State or Local Law to Consent to the Child Subject's General Medical Care

Signature Date (DDMMMYYYY)

Printed Name of Child Subject's Parent, or Individual Authorized Under State or Local Law to Consent to the Child Subject's General Medical Care

Signature Time (AM/PM)

Signature of Person Obtaining Consent

Signature Date (DDMMMYYYY)

Printed Name of Person Obtaining Consent

Signature Time (AM/PM)

The section below is to record your child's assent:

- I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of Person Obtaining Assent	Signature Date (DDMMMYYYY)
Printed Name of Person Obtaining Assent	Signature Time (AM/PM)

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Participant Name: _____

What is the purpose of using and sharing your child's protected health?
We are asking you and your child to take part in the research study described in the attached informed consent form. We need to be able to collect, use and share your child's protected health information in order for you to participate in this research study.

What protected health information about your child may be collected, used and shared with others?

- Demographic information, such as, but not limited to, your child's name, date of birth, address and other contact information such as telephone or email address and gender.
- Past and present medical records.
- Research records.
- Records about phone calls made as part of this research.
- Records about your study visits.
- Results of medical tests, questionnaires and interviews.

The above listed health information will all be collected through you, so you will always be aware what information is collected. We will not directly collect health information from one of your child's health care providers.

Who may use and give out information about your child?
Designated persons that are working for or with the sponsor that part of the research team:

- Principal Investigator
- Clinical Research Manager
- Members of the research team you speak directly to about your child's medical and developmental history.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons that are working for or with the sponsor.

Why will this information be used and/or given to others?
- To do the research,
- To study the results, and
- To confirm the research was done right.

If the results of this study are made public, information that identifies your child will not be revealed.

For how long will protected health information about your child be collected, used or shared with others?
If you sign this form, we will collect, use and share your child's protected health information until the end of this research study, which may be after your direct participation in the research project ends.

Your child's protected health information may also be useful for other studies. We can only use the health information collected for this research study again if the WCG IRB gives us permission. The WCG IRB may ask us to talk to you again before using or sharing the health information collected for this research study for other research purposes. However, if we meet certain requirements established by law, the WCG IRB may also let us use and share your health information collected for this research study for additional research without talking to you again.

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

What if I decide not to give permission to use and give out my child's health information?
Then you will not be able to be in this research study.

May I review or copy my child's information?
To maintain the integrity of the research study, you generally will not have access to your child's protected health information related to this research until the study is complete. At the conclusion of the research and at your request, you will have access to your health information.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your child's health information at any time. You do this by sending a written letter to the Principal Investigator. The letter needs to say that you have changed your mind and do not want the sponsor to collect, use and share your child's health information. If you withdraw your permission, your child will not be able to stay in this study.

When you withdraw your permission, no new health information identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my child's health information protected after it has been given to others?
After your health information is collected and given to others, there is a risk your child's health information will be given to others without your permission.

Summary of privacy rights:
If you sign this form, you are giving us permission to collect, use and share your child's health information. If you decide not to sign this form, your child cannot be in the research study. You need to sign this form and the attached informed consent form in order for your child to participate in the research study. Whatever your decisions you make about this research study will not affect your access to medical care. You will be given a signed copy of this form.

Signature, Date, and Identity of Person Signing:

The health information about _____ can be collected, used and shared by the sponsor for the research study as described in this form and the attached informed consent form.

Signature of Parent or Subject's Personal Representative	Signature Date (DDMMMYYYY)
Printed Name of Parent or Subject's Personal Representative	Signature Time (AM/PM)