STANFORD UNIVERSITY Research Consent Form	IRB Use Only
Protocol Director: Dennis P Wall	Approval Date: June 7, 2023 Expiration Date: February 21, 2024
Protocol Title: Evaluating Efficacy of GuessWhat Mobile System	

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Protocol Director: Dr. Dennis Wall 1265 Welch Rd X141, Stanford, CA 94304. (650) 497-9214

Are you participating in any other research studies? _____ Yes _____No

SUMMARY: Consent is being sought for participation in a study where you and your child will test and play a mobile based charades game, "GuessWhat." Participation is voluntary and you can leave the study at any point in time. The purpose of the study is to understand if regular use of the GuessWhat App between parent and child can improve social communication among children with autism. A secondary goal of this study is to understand if gameplay data and videos submitted by the parent after gameplay can allow researchers to develop Artificial Intelligence based technology to automatically detect, improve treatment, and track behaviors associated with autism (this research is covered by IRB Protocol 39562). **Your participation will last 4 to 5 months if you decide to participate in the GuessWhat Clinical Trial.** As part of this research project, the GuessWhat app will make recordings of you and your child during gameplay and will ask after *each session* to share or delete the recording. You will be able to choose which uses of this shared video you are willing to consent to by selecting up to three options below. We will only use the video in ways that you agree to. There is a risk of loss of confidentiality if you agree to share your video. If you agree to share with the public or other researchers or other players, we cannot guarantee that your child will not be recognized by another GuessWhat player or researcher. **This GussWhat Trial study includes** answering several questionnaires about your family and child that could cause discomfort due to length and nature of the questions. You will complete these questionnaires at enrollment, 4 weeks after, and 8 weeks following the date you enroll in the study. There will be follow-up at 12-, 16-, and 20-weeks following enrollment too. We do not guarantee any benefits to you or your child. Your participation will help us further researcher into developing mobile tools for treatment that could help other children with autism in the future. There are no alternative treatments offered, the alternative is to not participate in this study. National Science Foundation, National Institutes of Health, and Stanford MediaX are providing financial support and/or material for this study.

RESEARCH: You and your child are invited to participate in a research study. This study seeks to recruit adult parents and their child with autism who is between the ages of 3-12 years. Your participation is completed remotely. We aim to understand the ability of the mobile charades play app, "GuessWhat," to improve social communication skills in children with autism spectrum disorder through gamified mobile-based social interaction. This mobile app is not currently approved by the Food and Drug Administration (FDA). Participants will use their own personal phone to download our study app. The app will walk participants through a variety of games and questionnaires that are relevant to the tracking and treatment of autism. The interactive games will be video recorded and all data are transferred securely to the Wall Lab for analysis.

We will recruit up to 2000 parents and their child for this study.

Your participation is completely voluntary. We aim to test the efficacy of this mobile application to see if it can improve social communication skills among children with autism. This clinical trial seeks to recruit parents of children with autism and their child between the ages of 3-12 years who:

1. whose autism diagnosis has been provided by a clinical professional and can be confirmed by parent report measures and a video-based analysis measure.
2. You, the parent, must be able to speak and read in English.
3. You, the parent, has an iOS smartphone--the app will be available on Android after further development and we will notify interested families when it becomes available.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

TIME INVOLVEMENT: You and your child's participation in this experiment will take approximately 8-12 weeks. If you are randomized to the treatment condition you will be asked to use the GuessWhat system, for at least three sessions per week, for 8 weeks. You will also be asked to complete questionnaires about your child at study start, 4 weeks later, and 8 weeks after beginning the study. These questionnaires will take about 1.5 hours to complete. There will be another round of questionnaires at 12, 16, and 20 weeks following enrollment.

GROUP ASSIGNMENT: Participants will be randomized to treatment or control conditions using a 1:1 randomization model, where half of participants will be randomized to treatment and half randomized to control condition. Treatment participants will receive the GuessWhat Mobile App system for 8 weeks after completion of baseline assessment, and control participants will have the option to receive GuessWhat system 8 weeks after completion of baseline assessment, along with completion of all study measures. Participants randomized to the control condition will not download the GuessWhat app and will instead maintain treatment as usual.

COSTS: There is no cost to you for participating in this study.

PAYMENT: GuessWhat Trial study participants will receive $50 for completing baseline, intervention, and post-test study procedures. Participants will receive an additional $20 gift card for completing additional rounds of measures following initial 8 week period measure collection. If you decide to withdraw from the study or are withdrawn from the study, your payment will be prorated for your participation for the procedures you complete. Participants randomized to the control condition will not download the GuessWhat app, and will instead maintain treatment as usual. Participants randomized to the CONTROL condition who download the GuessWhat App during the study period will be withdrawn and ineligible for gift card.

WITHDRAWAL FROM STUDY

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

VIDEO SHARING OPTIONS AND CONFIDENTIALITY:

As part of this research project, the GuessWhat app will make recordings of you and your child during gameplay, and will ask after *each session* to share or delete the recording. Please choose what uses of this shared video you are willing to consent to by selecting up to three options below. We will only use the video in ways that you agree to. In any use of this video, you and your child's name will *not* be identified. We may use segments of the video to create short video clips (including, but not limited to GIFs, JPEG images, etc.). If you agree to share your child's video data with the public, these clips may be viewed in the GuessWhat app by other app players or by adult raters who may rate the video on a set of behavioral features that can be used to train new machine learning models to detect faces, emotion, eye gaze, etc. as well as presence or absence of developmental delays (covered by Stanford IRB Protocol 39562)

Clinical Trial Participants randomized to the treatment conditions are required to submit at least 1 video each game session, this means each time you play with your child, we ask you submit at least 1 video after playing GuessWhat (so at least 3 vides per week). This allows us to analyze behavior change using video, in addition to gameplay usage data, and parent reports.

We do not limit the number of consented participants who can view and analyze your video. We want to understand if by using crowdsourcing methods to acquire and analyze home videos of children, if the power of the crowd can identify core features of autism.

Videos shared with the public, other research participants, or the Wall Lab Team will be hosted on a secure password protected rating portal and will include gender age, video and audio of your child on a secure analyst portal that will be accessed securely with unique username and password. Video raters approved by you (see below) will watch the video and respond to a survey about what they see in the video. The study team reviews and monitors all activity in the analyst portal and takes your privacy and confidentiality into consideration. The videos will be kept indefinitely for use by The Wall Lab on a secure server.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

You may receive text messages from a third-party service. Standard message and data rates could apply. There will be no personal health information included in the texts. These text messages will be used to remind parents to play with their child and notify parents of new app features. *You can opt out if you choose to not receive these text messages.* You will receive no more than 2 text messages per week if you are a GuessWhat Trial study participant, and no more than 2 text messages per month if you are a regular GuessWhat app user.

Risks
Your participation in this study is entirely voluntary. You have the right to refuse to answer any question. If you provide your email (optional), the research team will contact about future studies. We cannot and do not guarantee or promise that you will receive any benefits from this study. This is a low-risk and all data are stored on secure and encrypted servers, approved by Stanford University. The Wall Lab has taken every measure to ensure data confidentiality; however, there is always a small probability that the database may be hacked. If this occurs, the Wall Lab will notify you immediately. If you agree to share your video with "the public" or "other research participants," we cannot guarantee that you or your child will not be recognized or that the video will not be shared with someone you know. Additionally, if the content of the video recordings and/or responses to study surveys raise suspicion of child abuse, child neglect, or a child being in a dangerous situation, the research staff is required by law to report such issues to the appropriate authorities. If your phone does not meet the device requirements listed when you download the app, it may not perform correctly and could lead to you and/or your child feeling frustrated. Please test the app on your device by yourself first before playing with your child to prevent undue stress or harm.

PARTICIPANT'S RIGHTS:
You can decide to participate now but withdraw your consent later. If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.If you decide to withdraw, please inform the study coordinator immediately at the-wall-lab@stanford.edu.

As a participant, your responsibilities include:
- Follow the instructions the Protocol Director and study staff have set forth on this website
- Complete the phases that you consent to, as instructed
- Ask questions as you think of them

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and any other personally identifiable data will not be disclosed except as authorized by you or as required by law**.** Patient information may be provided to Federal and other regulatory agencies as required. It is important to note that, as always, there is some risk that even de-identified information might be re-identified.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including the level of video sharing option you select below.

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Authorization To Use Your Health Information For Research Purposes:

Because information about you and your child's health is personal and private, it generally cannot be used in this research study without your authorization. If you continue to participate in this study, it will provide that authorization. The form is intended to inform you about how you and your child's health information will be used or disclosed in the study. Information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before agreeing.

What is the purpose of this research study and how will my and my child's health information be utilized in the study?: We aim to understand the ability of gamified and crowd-powered systems to aid in the treatment of autism spectrum disorder through mobile-based gamified therapy, and in the evaluation of autism through unstructured home videos provided by families. The videos you choose to submit of your child after playing GuessWhat will be shared with Dennis Wall IRB Protocol 39562 and be used to identify core features of autism, and we aim to use these videos to see if crowd-powered systems can be used to identify and possibly screen for autism. You choose which videos you wish to share of your child, and who you give the Wall Lab permission to share the video with for research purposes. We will also collect questionnaires about your family and child to understand if GuessWhat is correlated with improvements on social skills in children with autism. We will also examine players' gameplay data (duration of play, right answers, game mode choices).

Do I have to agree with this authorization form?: You do not have to give your authorization. But if you do not, you will not be able to participate in this research study.

If I give my authorization, can I revoke it or withdraw from the research later?: If you decide to participate on behalf of you and your child, you are free to withdraw your authorization regarding the use and disclosure of you and your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dennis Wall at: ATTN: Dennis Wall, Stanford University,

1265 Welch Rd, X143, Stanford, CA 94305. You may also email at dpwall@stanford.edu.

What Personal Information Will Be Obtained, Used or Disclosed?: Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to:

- Participants' email, name, phone number
- Information on the child of the participant:
- State and Zipcode
- Name (first, last)
- Date of birth
- If applicable, developmental delay medical diagnosis (and when)
- If possible, picture of medical diagnostic report of developmental delay to confirm disclosed medical diagnosis
- Gender
- Ethnicity
- Other diagnoses
- If they have any siblings
- Video image data
- Voice audio data
- Age of child in the home video
- Behavioral questionnaire data

Who May Use or Disclose the Information?: The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Dr. Wall
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?: The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- National Science Foundation

- StanfordMediaX
- The Wall Lab research protocols
- **ACES**
- Collaborating institutions approved by Stanford University.

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?: Your authorization for the use and/or disclosure of your health information will end on September 1st, 2050 or when the research project ends, whichever is earlier. All data collected in this study will be securely kept until this date and then properly destroyed.

CONTACT: If you have any questions, concerns or complaints about this research study, its procedures, or risks and benefits, you should ask the Protocol Director, Dr. Dennis Wall. You may contact him now or later at 650-497-9214. If you cannot reach the Protocol Director, please contact the research coordinator at the-wall-lab@stanford.edu.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

For participants residing in the EU:
As described elsewhere in this informed consent form, during the study, data pertaining to your participation in the study will be generated and recorded. In addition, we will collect from you your personal data and sensitive personal data, including health-related data. We refer to all such data as "Your Study Data," which will be specifically regulated in the EU/EEA under the General Data Protection Regulation (the "GDPR"). Your Study Data may be processed or used for the following purposes, which we refer to, collectively, as "Data Processing":

- *to carry out the study;*
- *to confirm the accuracy of the study;*
- *to monitor that the study complies with applicable laws as well as best practices developed by the research community;*
- *to make required reports to domestic and foreign regulatory agencies and government officials who have a duty to monitor and oversee studies like this one; and,*
- *to comply with legal and regulatory requirements, including requirements that data from this study, without information that could directly identify you, be made available to other researchers not affiliated with the study sponsor or with the study team. It is possible, for example, that as part of efforts to make research data more widely available to researchers, regulatory authorities in some countries may require that Your Study Data, without information that could directly identify you, be made publicly available on the internet or in other ways.*

The following entities and organizations may engage in Data Processing of Your Study Data:
-the study team, including other people who, and organizations that, assist the study team.

- the study sponsor
- *the ethics committee or institutional review board that approved this study; and*
- *domestic and foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one.*

We may conduct the study in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. In addition, we may disclose Your Study Data for Data Processing to entities and individuals located in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. However, all reasonable steps will be taken to protect your privacy in accordance with the applicable data protection laws.

The GDPR gives you certain rights with regard to Your Study Data. You have the right to request access to, or rectification or erasure of, Your Study Data. You also have the right to object to or restrict our Data Processing of Your Study Data. Finally, you have a right to request that we move, copy or transfer Your Study Data to another organization. In order to make any such requests, please contact The Wall Lab at +001 650-497-9214 or the-wall-lab@stanford.edu

There is no limit on the length of time we will keep Your Study Data for this research because it may be analyzed for many years. We will also retain your Study Data to comply with our legal and regulatory requirements. We will keep it as long as it is useful, unless you decide you no longer want to take part. You are allowing access to this information indefinitely as long as you do not withdraw your consent.

You may withdraw your consent at any time. If you withdraw your consent, this will not affect the lawfulness or our collecting, use and sharing of Your Study Data up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use Your Study Data that has been anonymized so that the data no longer identifies you. In addition, we may use and share Your Study Data that has been pseudonymized (by removal of your name and certain other identifiers so that the data does not directly identify you) as permitted by applicable law for purposes of: (a) public health (e.g., ensuring high standards quality and safety of health care and/or of medicinal products or medical devices), (b) scientific or historical research or statistical analysis as permitted by applicable European Union or European Union Member State laws and (c) archiving in the public interest. Further, we will maintain Your Study Data in fully identifiable form if required by law.

You consent to the collection, use and transfer of Your Study Data, which includes health and other sensitive personal data, for the purpose of carrying out the research study and know that you can withdraw your consent at any time, and we will stop processing your personal data, except as described above.

Please download and/or print a copy of this consent form for your records.

(Selected on mobile app)

By selecting an option below, you are consenting to participate in the study, that you understand this consent form, and are at least 18 years old. You are also consenting to participate on behalf of your child.

_____ My video(s) can be shown to the public. This means that video-based images of my child may be shared with, used, and/or viewed by anyone including but not limited to: members of the media and their audiences for sharing information about Wall Lab research for future study recruitment, other researchers, research participants, and GuessWhat app users.

_____My video(s) can be shown to the Wall Lab team and other Wall Lab research participants. This means that video based images of my child may be viewed by

researchers and research participants in both GuessWhat app and other Wall Lab research studies (e.g. other current or future video rating projects)

_____My video can be studied by the Wall Lab team. This means that the video based images of my child will be viewed only by members of the Wall Lab Research team and will not be shared with anyone outside our team.