UNC SCHOOL OF MEDICINE

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

TEACCH—ADMINISTRATION AND RESEARCH

Office Address
100 RENEE LYNNE COURT
CARRBORO, NC 27510

T 919.966.2174
F 919.966.4127

Mailing Address
CAMPUS BOX 7180
CHAPEL HILL, NC 27599-7180

Dear TEACCH Client:

One of the missions of the TEACCH Autism Program is to support research on the treatment and cause of autism and related disorders. Therefore, we are enclosing information on research at TEACCH for you to consider. **Please note that research at TEACCH is completely separate from the services offered at TEACCH, and you do not have to give consent to participate in research to use any TEACCH services. We encourage you to call us (local center or the Registry office 1-866-744-7879) if you have any questions about this research information.**

In the consent form that is attached to this letter, we are inviting you to participate in a research study/project that has two components. First, we are asking your permission to review records and information obtained as part of your services at TEACCH (referred to as the Records Review component). Second, we are asking you to participate in a registry of possible subjects for researchers who are interested in studying autism spectrum disorder (referred to as the Research Registry component). You may consent to one, both, or none of the components. You may withdraw at any time from either component by calling me (919-966-2174).

If you agree to participate in the Record Review component, information already obtained by TEACCH will be used to answer research questions of interest to our program or individual researchers. This information will only be used by researchers in or approved by the TEACCH Autism Program. You or your child will not have to do anything extra to participate in the Record Review component.

If you agree to participate in the Research Registry component, you agree to let us add your name and contact information to a list of families who want to be notified when there are UNC research projects that are recruiting participants. The Registry office would send information about a research study for you to review and a response form for you to send to the researcher to indicate whether you are interested in participating. You are under no obligation to participate in any of the research studies that you receive information about. The Registry office would also contact you by phone, email, or mail once per year to verify/update your contact information.

Please review the consent form that is attached and carefully consider participation in these research projects. You may return this form at any time. Your participation will allow researchers to learn more about autism spectrum disorder that may eventually lead to improved services and intervention for children and families. I will appreciate your consideration of this request.

Sincerely,

Laura Klinger

Laura Grofer Klinger, Ph.D.
Executive Director, Associate Professor, Psychiatry

University of North Carolina at Chapel Hill
Research Consent Adult Client *(who is own guardian)*

Consent Form Version Date: 12/19/2019
IRB Study # 69-0001
Title of Study: UNC Research Program for Autism and Related Disorders
Principal Investigator: Laura Klinger
Principal Investigator Department: Psychiatry

Study Contact: Renée Clark, M.S.W.
Study Contact telephone number: Toll-free 1-866-744-7879
Study Contact email: rdclark@email.unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH) and The State of North Carolina

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We are asking you to take part in the UNC Autism Research Program. There are two parts. You can be in one or both parts, or you don't have to be involved at all.

Part 1 is the Records Review. The purpose of the Records Review is to make the records of people who have been treated at TEACCH available for other research studies.

Part 2 is the Research Registry. The Registry is a list of individuals with autism spectrum disorders who agree to be contacted about research studies on autism and related conditions.

The purpose of the Research Registry is to help researchers who study autism and autism treatments find participants for their studies. By agreeing to be in the Registry, you are NOT agreeing to be in a study. You are agreeing to let us send you information (by mail or email) about studies in the future. Your name, address, and other basic information from your records at TEACCH will be put in the Registry's records. Someone from the Registry office will contact you once each year to see if your phone number and address are correct. The Registry will also send you information about a specific study if you may be eligible. You can then decide whether or not you want to participate.

You may not benefit directly by participating in the Records Review or Research Registry, but your participation will help us learn more about how to diagnose and treat autism. Sometimes research studies involve risk. You will be informed about the possible risks (and benefits) for any research study. The risk involved in being in the Registry is low because we protect your personal information by using security procedures designed to safeguard your privacy and prevent disclosure of information.

Enrolling in the Records Review or Research Registry is voluntary. If you agree, this means we will keep information about you to share with other researchers for Records Review or in order to contact you in the future about any research studies that may be of interest to you as part of the Research Registry. We will contact you annually to confirm your contact information.

We will keep you in the Records Review and/or Registry until you ask us to remove your information. You may change your mind at any time in the future and request to have your name removed. There is no penalty for withdrawing from the Records Review or Research Registry.
You have the right to ask, and have answered, any questions you may have about this Records Review and Research Registry. If you have questions or complaints, you should contact Dr. Laura Klinger at TEACCH by phone at 919-966-2174 or Renee Clark by phone toll-free 1-866-744-7879 or email rdclark@email.unc.edu.

To keep information about research participants private, TEACCH follows rules for security and confidentiality of medical records from the state and federal government and the UNC Health Care System. Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research

information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB_ subjects@unc.edu.

This research is funded by the National Institutes of Health (NIH) (the sponsor). This means that the research team is being paid by the sponsor for doing the study. In addition, Christina Corsello, a researcher on this study, has an ownership interest in a training guide for a diagnostic measure that is commonly used for clinical evaluations, including for those individuals who might enroll in this registry. Christina Corsello may receive financial benefits if clinicians purchase the training guide. If you would like more information, please ask the researchers listed in the first page of this form.

CHECK √ ONE STATEMENT IN THIS BOX to show if you want to be in the Records Review.

COMPONENT #1 - RECORDS REVIEW

_____**Yes,** I agree to participate in the Records Review component of this research study.

OR

_____ **No,** I choose not to participate in the Records Review component of this research study.

AND

CHECK√ ONE STATEMENT IN THIS BOX to show if you want to be in the Research Registry.

COMPONENT #2 - RESEARCH REGISTRY

_____ **Yes,** I agree to be on the Research Registry list. Please notify me of ALL studies for which I am eligible (OR indicate a specific number if preferred. Limit notices about studies to _____ (number) per year.)

OR

_____ **No,** I do not want to be on the Research Registry list.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 69-0001

Title of Study: UNC Research Program for Autism and related Disorders
Principal Investigator: Laura Klinger
Mailing Address for UNC-Chapel Hill Department: CB:7180 TEACCH , 100 Renee Lynne Court , Chapel Hill, NC 27599-7180 , USA

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, diagnostics centers, including but not limited to the UNC Health Care System, and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Other information includes:

Questionnaires or medical history forms completed for the purpose of evaluation at TEACCH; Diagnosis of an Autism Spectrum Disorder or a developmental disability, including DSM diagnoses and the most recent available assessment results from the following domains: 1) cognitive testing; 2) adaptive behavior ratings; 3) academic and vocational assessments; and 4) autism evaluation measures such as the Childhood Autism Rating Scale, the ADOS, and the ADI-R.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the university or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Print Name of Research Subject Date

_____

Signature of Research Subject (Adult who is own guardian)

For Personal Representative of the Research Participant, if applicable : (e.g., parent, legal guardian, etc.)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Research Subject

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative Date