UNC SCHOOL OF MEDICINE

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

TEACCH—ADMINISTRATION AND RESEARCH

Office Address
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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.**

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
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: 1/27/2016
IRB Study # 69-0001
Title of Study: UNC Research Program for Autism and related Disorders
Principal Investigator: Laura Klinger
Principal Investigator Department: Psychiatry
Principal Investigator Phone number: (919) 966-8183

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

You are being asked to allow your child (or ward) to participate in a two-component research program at The TEACCH Autism Program at UNC. One is a Records Review where records from evaluation and treatment services at the TEACCH Center are made available for research studies. The other is a Research Registry, which is a list of people who have given permission to receive information about research studies on autism. Dr. Laura Klinger Executive Director of The TEACCH Autism Program. She has staff members who assist her with the Research Program.

Participation in research is voluntary. You may give permission for your child to participate in both, one, or neither of these two research components at TEACCH after you have read more about them below.

Purpose of the Research Program at TEACCH
The goal of our Research Program is to assist in the discovery of information about autism spectrum disorders (ASD) that will help doctors and therapists understand more about ASD and how to take care of individuals with autism and related disorders.

The purpose of the Records Review is to make existing records of individuals who have been evaluated and treated at the TEACCH Autism Program available for approved research studies by qualified researchers.

The purpose of the Research Registry is to notify individuals and families of opportunities to participate in research studies about autism in a way that protects their privacy.

Size of the Records Review and Research Registry
About 750 people each year sign up for the Research Program at TEACCH Centers in North Carolina.

Procedures: Records Review Component
If you allow your child to participate in the Records Review Component, then records from your child's TEACCH evaluations and services may be viewed for approved research studies conducted by TEACCH staff, faculty, students and trainees, and university research investigators. For the protection of your family's privacy, only the minimum necessary information needed for the study will be provided, and whenever possible, identification numbers will be used in place of names.

Procedures: Research Registry Component
If you agree for your child to be in the Research Registry, the following things may happen:

1. Your name and contact information and limited information from your child's records at TEACCH (such as his/her birthday, gender and diagnostic test results) will be put in the Registry's records. This information would be used to determine eligibility for research studies.

2. When studies are recruiting participants, the Registry office would send information (brochure or flyer) for all reviewed and approved studies for which you or your child might be eligible. The number of notices you might receive will vary. Based on the last two years of operation, we estimate that you might receive information about zero to four studies per year.

- First, the Registry office would send you a letter or brochure about a study. You are NOT required to be in any study, and each time you receive information about a study, you will be able to choose whether or not you want to participate.
- Someone from the Registry office might call you to see if you received information in the mail about a study. If you wanted, they would help you contact the researcher to find out more about the study so you could decide if you want to participate. The Registry would not release your name or number without your explicit verbal or written consent.

3. Someone from the Registry office would contact you annually to see if your address information is correct.

4. For any study you decide to be in, the researcher would send you a newsletter when the study is finished to describe what they learned.

Benefits of the Research Program
Both the Records Review and the Research Registry help researchers who are studying autism and related disorders. Research may lead to new information about autism that will help doctors and therapists understand more about autism and how to take care of people with autism.

Risks of the Research Program Being in the Research Program is safe. There are no risks (dangers) involved in being in the Records Review or the Research Registry. If any risks were discovered, TEACCH would notify you.

Enrolling and Withdrawing from the Records Review and/or the Research Registry
Participation in Research Program is voluntary. You do not have to be in either the Records Review component or the Research Registry to receive services at TEACCH.

If you give consent for a component, your child will be enrolled in that component until you request to be removed. You may change your mind any time and request to have your child's name removed from either component. You and your child will still be able to receive services at TEACCH and there is no penalty for withdrawing or not being part of the research components.

Protection of Privacy
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.

Cost and Payment
It does not cost anything participate in either the Records Review or Research Registry, nor is there any payment for participating in either component.

Contact for Questions about the Records Review or Research Registry
You can call Dr. Laura Klinger at TEACCH (919/966-2174) or call the Research Registry office (toll-free 866/744-7879) if you have questions.

Contact for Questions about Violations of Rights During Research
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.

Research Program Agreement to Participate

Please make checks √ in both boxes and sign at the bottom. Return all pages to TEACCH in the envelope provided. You will be given a copy.

_____

Printed Name of TEACCH Client

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

COMPONENT #1 - RECORDS REVIEW

____**Yes,** I have read the information provided on the previous pages and I voluntarily agree for my child to participate in the Records Review component of this research study.

OR ____ **No,** I choose not to let my child participate in the Records Review component of this research study.

AND

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

COMPONENT #2 - RESEARCH REGISTRY

____ **Yes,** I have read the information provided on the previous pages and I voluntarily 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 Parent or Legal Guardian of TEACCH Client **Date**

_____

Printed Name of Parent or Legal Guardian of TEACCH Client

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 , CB 7180 , 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 by parents 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