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

University of North Carolina at Chapel Hill
Research Consent for Parent/Guardian of Adult Client

Consent Form Version Date: 12/19/2019

IRB Study # 69-0001

Title of Study: UNC Research Program for Autism and related Disorders Spectrum Disorders

Principal Investigator: Laura Klinger

Principal Investigator Department: Psychiatry

Principal Investigator Phone number: (919) 966-8183

Study Contact telephone number: Toll-free 1-866-744-7879

Study Contact email: rdclark@email.unc.edu

You are being asked to be part of a two-component research program at The TEACCH Autism Program at UNC. One component 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 is the Executive Director of The TEACCH Autism Program, and she has staff members who assist her with the Research Program.

Participation in research is voluntary. You may decide to be in both, one, or neither of these two research components at TEACCH after you have read more about them below.

Purpose of the Records Review and Research Registry

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 Division TEACCH available for other 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.

Records Review Procedures

If you agree to participate in the Records Review Component, then records from your TEACCH evaluations and services may be viewed for other approved research studies conducted by TEACCH staff, faculty, students and trainees, and university research investigators. For the protection of your 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.

Research Registry Procedures

If you agree to be on the Registry list, the following things may happen:

1. Your name, address, and other basic information from your records at TEACCH (such as your birthday, your gender and whether you have autism) will be put in the Registry's records.
2. The Registry office will send information about all studies for which you might be eligible when researchers need to recruit participants. 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.

3. First, the Registry office would send you a letter or brochure about a study. It would tell you how to call or write the researcher if you wanted to be in the 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.
4. 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.

3. Someone from the Registry office would contact you once each year to see if your phone number and address are correct on the list.

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

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

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 are discovered, TEACCH would notify you.

Enrolling and Withdrawing from the Records Review and/or the Research Registry

Your participation in the both the Research Program is voluntary. You do not have to be in either research component to receive services at TEACCH.

If you decide to be in the either component, you will stay in until you ask for your name to be removed. If you sign up to be in the Records Review or the Research Registry, you may change your mind any time and take your name out of either component. You 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. 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.

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 Renée Clark at Research Registry office (toll-free 866/744-7879) if you have questions.

Who is sponsoring this study?

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 above.

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

COMPONENT #1 - RECORDS REVIEW

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

Yes, I have read the information provided on the previous pages and I voluntarily 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

COMPONENT #2 - RESEARCH REGISTRY

CHECK ONE STATEMENT IN THIS BOX to show whether you want to be in the 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 TEACCH Client

Date

Printed Name of TEACCH Client

For Personal Representative (guardian) of the Research Participant (if applicable)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Research Participant: _____

I am giving permission by signing this research consent form on behalf of the Research Participant.

Signature of Personal Representative

Date

University of North Carolina at Chapel Hill

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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.

