University of North Carolina-Chapel Hill
Consent to Participate in a Research Registry
Adult Participants
Social Behavioral Form

IRB Study # 01-0843
Consent Form Version Date: 3/3/2014

Title of Study: Research Registry for the Carolina Institute for Developmental Disabilities
Principal Investigator: Renée D. Clark
UNC-Chapel Hill Department: Carolina Institute for DD
UNC-Chapel Hill Phone number: (919) 966-5232
Email Address: rdclark@email.unc.edu
Funding Source: National Institute of Child Health and Human Development

Study Contact telephone number: Toll-free (866) 744-7879
Study Contact email: Research_Registry@unc.edu

What are some general things you should know about research studies?
You are being asked to join a research registry which is a list of people who will be contacted about opportunities to take part in research studies on development and learning.

The Registry is for children and adults with developmental conditions or disorders including (but not limited to) language delays, cognitive delays, or motor delays; autism spectrum disorders; genetic conditions (e.g. Down syndrome, Fragile X syndrome, Turner syndrome, Williams syndrome, Prader Willi syndrome, Rett syndrome, and others); and other developmental conditions.

Joining the Registry is voluntary. You may refuse to join, and if you do join, you may withdraw your consent to be in the Registry at any time and for any reason without penalty.

Details about the Research Registry are discussed below. It is important that you understand this information so that you can make an informed choice about joining this Registry. You will be given a copy of this consent form. Please ask the researchers named above, or staff members who may assist them, any questions you have about joining the Research Registry.

What is the purpose of the Research Registry?
The purpose of the Registry is to help research investigators who study developmental disabilities find potential participants in a systematic and organized manner that preserves and protects the confidentiality of Registry members. The Registry is a database used to inform members about research studies for which they may be eligible. Registry members are NOT obligated to participate in studies.

How many people will take part in the Registry?
About 700 people each year join the Registry each year.

How long will your participation in the Registry last?
Participation in the Registry is voluntary. If you give consent, you will be in the Registry until you request to be removed. You may change your mind at any time and request to have your name
removed. There is no penalty for withdrawing from the Registry.

What will happen if you take part in the Registry?
If you agree to be listed in the Research Registry:
1. Your name, contact information, and information about you (such as birthday, gender, developmental test results, diagnosis of condition) will be put in the Registry’s database. This information will be requested from your developmental care provider. Our only use of this information will be to determine whether you may qualify for a research study.

2. We will send you a referral for any study that you may be eligible to participate in. Members of the Research Registry are NOT required to participate in any particular study. Our study referrals will include a study brochure and a reply form that you will use to indicate whether you may be willing to participate. Your response is confidential, and your name will only be forwarded to the research project if you give explicit written or verbal consent to be contacted by the research project. On average, Registry participants receive 2 study referrals per year (range 0-4).

3. If you don’t return a reply card to accept or decline participation, we may contact you to verify that you received the notice. If you want more information, we will offer to provide your name and number to the researcher so that he or she can contact you to answer any questions that will affect your decision to participate. This call does not obligate you to participate in a study.

4. You will receive a report summarizing the findings for any research study in which you participate. You may also receive a newsletter from the Registry describing results and progress from various UNC studies.

5. We will make an annual contact to verify that your telephone number and address are correct and to confirm that you still want to be in the Research Registry.

What are the possible benefits from being in the Registry?
Research on developmental disabilities is designed to benefit society by gaining new knowledge that is relevant for diagnosis and treatment. The Registry provides a way to learn about new studies. You may or may not benefit personally from being in the Registry.

What are the possible risks or discomforts involved from being in the Registry?
There are no risks (dangers) involved in joining the Research Registry. Any study to which the Registry refers you will inform you of the risks for that particular study.

How will your privacy be protected?
The Registry has privacy safeguards that exceed the standards required by the law for protected health information. Records are housed on secure computer systems and in offices that are accessible only to trained and certified Registry personnel. No identifying individual information (such as names or addresses) is ever released to any recruiting research project without your explicit written or verbal consent.

Participants will not be identified in any report or publication about this Registry or in any study. Although every effort will be made to keep research records private, federal or state law could require the disclosure of some information. Legal disclosure is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take appropriate steps to protect the privacy of personal information. It is also possible that information in the Research Registry could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.
Will you receive anything for being in the Registry?
You will not receive anything for joining the Registry.

Will it cost you anything to be in the Registry?
There will be no costs for joining the Registry.

What if you have questions about this Registry?
You have the right to ask, and have answered, any questions you may have about joining the Registry. If you have questions, or concerns, you should contact the Registry Associate Director, Renée Clark by email rdclark@email.unc.edu or toll-free phone 1-866-744-7879.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by an Institutional Review Board that works to protect each research participant’s rights and welfare. If you have questions or concerns about the rights of a participant in our Registry or in any research project, you may contact personally or anonymously the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant’s Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

________________________________________________________________________________
Printed Name of Research Participant

________________________________________________________________________________
Signature of Legally Authorized Representative Date

________________________________________________________________________________
Printed Name of Legally Authorized Representative

________________________________________________________________________________
Signature of Research Team Member Obtaining Consent Date

________________________________________________________________________________
Printed Name of Research Team Member Obtaining Consent
We are asking you to take part in our Research Registry. Our Research Registry is a list of names of people who have a developmental condition such as autism, Down Syndrome, and others, and who want to know about opportunities to participate in research studies.

If you agree, we will tell your parents about research studies that you might want to participate in. With your parents’ help, you will decide if you want to participate in any of these studies.

You do not have to be in our Research Registry or participate in any research study. No one will be mad at you if you decide not to be in the Registry. Even if you say yes to being in the Registry now, you can remove your name from the Registry at any time if you want. You may ask questions about the Registry before agreeing to participate.

Signing here means that you have read this form or heard it read to you and that you are willing to have your name included in our Research Registry.

Signature of Registry participant

Participant’s printed name

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

IRB Study # 01-0843

Title of Study: Research Participant Registry for the Carolina Institute for Developmental Disabilities

Principal Investigator: Renée D. Clark
Mailing Address for UNC-Chapel Hill Department: CB:3366, Chapel Hill, NC 27599-3366

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 (described in #2 below) about you:
Any health care providers or health care professionals that have provided health services or diagnostic evaluations for you such as physicians, clinics, hospitals, diagnostics centers, laboratories, including but not limited to the UNC Health Care System.

2. If you sign this HIPAA authorization 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:
Diagnostic testing for an Autism Spectrum Disorder or a Developmental Disability, including genetic testing, DSM diagnoses codes and the most recent available assessment results from the following domains: 1) cognitive testing; 2) adaptive behavior ratings, 3) autism evaluation measures such as the Childhood Autism Rating Scale, the ADOS, and the ADI-R, and 4) language and educational testing.

3. The people or groups listed in #1 on this form may give this health information to the researcher listed at the top of this form (UNC-Chapel Hill Principal Investigator) or to another researcher working on this research study. This information may also be shared with, used by or seen by the sponsor of the research study, the sponsor’s representatives, officials of the IRB, and certain employees of the university or government agencies if needed to oversee the research study.

4. The HIPAA rules that apply to your medical records will not apply to your information in the research study records. The informed consent document describes the procedures in this research study 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.

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 #1 on this form to give access to the information about you that is listed in #2 on this form. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study but 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. HIPAA rules are that if you want to stop this HIPAA authorization, you must do that in writing. You may give your written stop of this HIPAA authorization directly to the people or groups listed in #1 on this form or you may give it to the researcher 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.

__________________________  __________
Signature of Research Subject    Date

__________________________
Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

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
# REGISTRY PARTICIPANT INFORMATION FORM

## FOR AN ADULT WITH A GUARDIAN OR LEGALLY AUTHORIZED REPRESENTATIVE

(Please Print)

## PARTICIPANT’S INFORMATION

<table>
<thead>
<tr>
<th>First Name</th>
<th>Middle</th>
<th>Last</th>
<th>Suffix</th>
<th>Nick Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Gender:**
- [ ] Male  
- [ ] Female

**Birth date:** / /

**Vocational and Educational Status (check all that apply):**
- [ ] Full or part time student
- [ ] Employed full-time
- [ ] Employed part-time
- [ ] Day program
- [ ] Other, specify:

**Race (check all that apply):**
- [ ] American Indian or Alaskan Native
- [ ] Asian
- [ ] Black, African American
- [ ] Hawaiian, Pacific Islander
- [ ] White, Caucasian
- [ ] Other, specify:

**Ethnicity:**
- [ ] Hispanic or Latino, descended from Spanish-speaking countries
- [ ] NOT Hispanic or Latino

**Participant lives with:**
- [ ] Both biological parents
- [ ] Biological mother
- [ ] Biological father
- [ ] Adoptive parents
- [ ] Mother and stepparent
- [ ] Father and stepparent
- [ ] Other, specify:
- [ ] Joint custody

## Participant’s Diagnostic and Medical History

**Which term best describes the participant’s autism diagnosis?**
- [ ] Asperger’s disorder or High Functioning Autism (HFA)
- [ ] Autism, Autistic disorder, or Autism Spectrum disorder
- [ ] Pervasive developmental disorder-NOS (PDD-NOS)

**What type of professional made this diagnosis?**
- [ ] Pediatrician
- [ ] Psychologist
- [ ] Neurologist
- [ ] Psychiatrist
- [ ] Other:

**Date of ASD diagnosis?** / /

**Other psychiatric conditions (ADHD, anxiety, depression, OCD, etc)?**

**Has participant been diagnosed with an intellectual disability?**
- [ ] No
- [ ] Mild
- [ ] Moderate
- [ ] Severe
- [ ] Profound
- [ ] Not sure of level

**History of seizures:**
- [ ] None
- [ ] Current (including controlled by medication)
- [ ] Past, not present

**Sensory Impairments:**
- [ ] None
- [ ] Visually impaired (VI)
- [ ] Blind
- [ ] Hearing impaired (HI)
- [ ] Deaf
- [ ] VI and HI

**Any known genetic syndromes or other medical/neurological conditions?**

**Does participant have relatives who have been diagnosed with an autism spectrum disorder? (check all that apply)**
- [ ] None
- [ ] Sibling
- [ ] A parent
- [ ] First cousin
- [ ] An aunt or uncle
- [ ] Other, specify

**Has participant received services at a TEACCH Center?** (in Chapel Hill/Raleigh, Greenville, Asheville, Charlotte/Gastonia, Fayetteville, or Wilmington)
- [ ] Yes
- [ ] No
- [ ] I’m not sure

**Has participant received services at the UNC Center for Development and Learning (CDL) or Carolina Institute for Developmental Disabilities (CIDD)?**
- [ ] Yes
- [ ] No
- [ ] I’m not sure
# PARENT/GUARDIAN INFORMATION

**PRIMARY CONTACT for study referrals (in addition to the Participant)**

<table>
<thead>
<tr>
<th>First name</th>
<th>Middle or Maiden</th>
<th>Last</th>
<th>Suffix</th>
<th>Preferred</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Jr. III Sr. IV</td>
</tr>
</tbody>
</table>

**Date of birth** / / Relationship to participant:

**Mailing Address/ Street or PO Box Number:**

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
<th>NC County:</th>
</tr>
</thead>
</table>

**Phone:** ( )

**Alternate phone:** ( )

**Email:**

**Race (check all that apply):**

- American Indian or Alaskan Native
- Asian
- Black, African American
- Hawaiian, Pacific Islander
- White, Caucasian
- Other, specify:

**Ethnicity:**

- Hispanic or Latino (descended from Spanish-speaking countries)
- NOT Hispanic or Latino

**Is English your primary language?**

- YES
- NO
- English
- Spanish
- Other, specify:

**Education completed:**

- No high school diploma or GED
- High school diploma or GED
- Some college, but no degree
- Associate or technical degree
- BA, BS or 4-year college degree
- Graduate degree

**When is it most convenient for you to receive phone calls?**

- Mornings
- Afternoons
- Evenings
- Specify:

**How many studies per year would you like to be notified about?**

- All studies for which I may be eligible.
- Three, max
- Five, max
- Other, specify

**Any other relevant information about the participant which may impact research participation**

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# 2ND PARENT/GUARDIAN INFORMATION

**ADDITIONAL CONTACT FOR STUDY REFERRALS**

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Middle or Maiden</th>
<th>Last</th>
<th>Suffix</th>
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<td></td>
<td>Jr. III Sr. IV</td>
</tr>
</tbody>
</table>

**Date of birth:** / / Relationship to participant:

**Mailing Address (if different from P1 above):**

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
<th>NC County:</th>
</tr>
</thead>
</table>

**Phone:** ( )

**Alternate phone:** ( )

**Email:**