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 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 families. The Registry is a database used to notify individuals or parents 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 join the Registry each year.

How long will your child’s participation in the Registry last?
Participation in the Registry is voluntary. If you give consent, your child will be in the Registry until you request to be removed. You may change your mind at any time and request to have your child’s name removed. There is no penalty for withdrawing from the Registry.
What will happen if your child takes part in the Registry?
If you agree to allow your child to be listed in the Research Registry:

1. Your name, contact information, and information about your child (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 child’s developmental care provider. Our only use of this information will be to determine whether your child may qualify for a research study.

2. We will send you a referral for any study that your child or your family 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 will allow your child or your family 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 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 your child participates. 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 for parents to learn about new studies. Your child or family 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 child’s privacy be protected?
The Registry has privacy safeguards that exceed the standards required by 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 information identifying you or your child (such as names or addresses) would ever be 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 your child receive anything for being in the Registry?
You will not receive anything for taking part in the Registry.

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

What if you or your child has questions about the 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 or your child have questions about your child’s 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.

Parent’s Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

______________________________________________________
Printed Name of Research Participant (child)

______________________________________________________
Signature of Parent                          Date

______________________________________________________
Printed Name of Parent
Signature of Research Team Member Obtaining Permission   Date

Printed Name of Research Team Member Obtaining Permission
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 INFORMATION FORM**

**FOR A MINOR PARTICIPANT**

(Please Print)

### CHILD’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>

- Jr.  
- III  
- Sr.  
- IV.

<table>
<thead>
<tr>
<th>Gender:</th>
<th>Birth date:</th>
<th>Age:</th>
<th>Classroom setting:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race (check all that apply):</th>
<th>Ethnicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaskan Native</td>
<td>Hispanic or Latino, descended from Spanish-speaking countries</td>
</tr>
<tr>
<td>Hawaiian, Pacific Islander</td>
<td>NOT Hispanic or Latino</td>
</tr>
<tr>
<td>White, Caucasian</td>
<td></td>
</tr>
<tr>
<td>Other, specify:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Child lives with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both biological parents</td>
</tr>
<tr>
<td>Biological mother</td>
</tr>
<tr>
<td>Biological father</td>
</tr>
<tr>
<td>Adoptive parents</td>
</tr>
<tr>
<td>Mother and stepparent</td>
</tr>
<tr>
<td>Father and stepparent</td>
</tr>
<tr>
<td>Other, specify:</td>
</tr>
<tr>
<td>Joint custody</td>
</tr>
</tbody>
</table>

### Child’s Diagnostic and Medical History

**Which term best describes your child’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:

<table>
<thead>
<tr>
<th>Approximate date of ASD diagnosis?</th>
<th>Other psychiatric conditions (ADHD, anxiety, depression, OCD, etc)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

**Has your child 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 your child 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 your child received services at a TEACCH Center? (Chapel Hill, Greenville, Asheville, Charlotte, Gastonia, Wilmington, Greensboro, Raleigh, or Fayetteville)

- Yes
- No
- I’m not sure

Has your child received services at the UNC Center for Development and Learning (CDL) or the Carolina Institute for Developmental Disabilities (CIDD)?

- Yes
- No
- I’m not sure

**PARENT/GUARDIAN INFORMATION**

(PRIMARY CONTACT FOR STUDY REFERRALS)

<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.</td>
</tr>
</tbody>
</table>

Date of birth: / / Relationship to child: 

Mailing Address/ Street or PO Box Number:

City: State: ZIP Code: NC County:

Phone: ( ) Alternate phone: ( )

Email:

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

- American Indian or Alaskan Native
- Asian
- Black, African American

**Ethnicity:**

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

Hawaiian, Pacific Islander

White, Caucasian

Other, specify:

Is English your primary language? All Languages spoken

- 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.
- Five, max
- Three, max
- Other, specify number

Any other relevant information about your child/family which may impact research participation (travel, transportation, type of study preferences, etc.)
## 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>
<th>Preferred:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date of birth: / / Relationship to child:

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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Phone: ( ) Alternate phone: ( )

Email:

Race: | Ethnicity:

- American Indian or Alaskan Native
- Asian
- Black, African American
- Hawaiian, Pacific Islander
- White, Caucasian
- Other, specify:
- Hispanic or Latino, descended from Spanish-speaking countries
- NOT Hispanic or Latino

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