The Research Participant Registry Core

Mission Statement

The Research Participant Registry Core assists with recruitment for research studies focused on developmental disabilities and child development. The Core maintains registry databases to provide an organized and confidential resource to identify and contact potential participants on behalf of studies. The RPRC has a strong commitment to maximizing efficiency by providing high quality referrals, coordinating research efforts among Core users, and fostering collaboration.

The RPRC seeks to make participation in the Registry and research studies a positive, educational experience that aids research while protecting the privacy and dignity of participants. Our goal is to establish and maintain long-lasting relationships with Registry members and to emphasize our appreciation for their willingness to volunteer for research studies.

Personnel

Gabriel Dichter, Ph.D. Core Director

Renée Duffee Clark, M.S.W. Associate Director

Elizabeth Kunreuther, M.S.W. Family Recruitment Coordinator

Services

Human participant recruitment

Public relations and referral source development

Assist investigators with grant preparation

Policies and Procedures

I. Funding and Oversight

A. Funding
The Registry Core is a component of the Intellectual and Developmental Disabilities Research Center (IDDRC) funded by the National Institute of Child Health and Human Development. The RPC Core operates with funds from the IDDRC and contributions from the grants of investigators who access the Registry Core.

B. Organizational Affiliation
The UNC IDDRC operates within the Carolina Institute of Developmental Disabilities (CIDD) at the University of North Carolina School of Medicine.

C. Institutional Review Board
Registry activities are reviewed and approved by the UNC IRB, Study #01-0843, #69-0001 and Study #07-0279

D. Advisory Panel
The Registry Core depends upon the successful collaboration of a wide range of stakeholders with differing perspectives. To assist the Registry staff in making informed decisions on a wide range of issues, an Advisory Panel composed of the following individuals is available:
1. a TEACCH representative (for autism registry)
2. the parent of an individual with autism and/or FXS
3. the IDDRC director at UNC and Waisman Center (for FXS registry users)
4. the RPR core director at UNC and Waisman Center (for FXS registry users)
4. a knowledgeable IRB resource, and
5. a bio-behavioral research scientist

This panel is contacted as needed for consultation on a wide range of issues such as human subject rights protection and resource management.

II. Recruiting Registry Members

A. The Autism Spectrum Disorders (ASD) Registry recruits residents of North Carolina who have a confirmed ASD diagnosis. It is populated primarily through a collaboration with the UNC TEACCH Autism Program, a statewide agency specializing in ASD and clinics at the Carolina Institute for Developmental Disabilities. Individuals are also referred to the Registry by advocacy organizations, service providers, and the Registry website cidd.unc.edu/registry/autism. Registry members are asked provide records confirming their diagnosis of an autism spectrum disorder.

B. The Fragile X Syndrome (FXS) Registry is a national database for individuals with a confirmed diagnosis of FXS. It is jointly owned and operated with the Waisman Center (University of Wisconsin) IDDRC Research Participant Core. Individuals can enroll through a public web site fragilexregistry.org and are referred by advocacy organizations, genetic clinics, and other service providers. Participants must provide

records confirming their diagnosis of FXS.

C. The Child Development Research Registry is a database of children residing within an hour drive of the UNC Chapel Hill campus. Recruitment letters are sent to families of 4-6 month old infants who were born in the region inviting them to enroll their infants and other children. Most of these children are aged one to eleven years. Parents may also enroll their children via the RPRC website. Cidd.unc.edu/registry/Child-Development. Parents are asked to provide basic demographic information and disclose any known medical disorders.

III. Enrollment Data Collected

A. The information in the Registry is used to select and notify potential participants of approved studies, and it is not released to research projects without written consent from the member. The Registry Enrollment Information sheet, completed by families who elect to join, includes the following data for each focal individual:
1. name, address, and telephone number of Registry member and/or custodial parent
2. date of birth
3. gender and ethnicity
4. general diagnostic information

B. A parent or legal guardian signs Registry participation consent forms for minor children and adults with impaired decision-making capabilities. Adults with disabilities who are capable of giving informed consent sign their own consent forms.

IV. Contacting Registry Members

A. According to procedures approved by the UNC IRB for the Registry, contact with registry families are made by Registry staff by mail, email, or telephone. Contacts from the Registry office to participating families meet the following constraints:
1. are limited to the number of contacts per year specified by the consenting party on the Registry participation consent form.
2. include two follow-up phone contact attempts after each recruitment letter to confirm receipt and determine interest in participation
3. include an annual mail and phone contact to update records

B. The individual or family decides whether or not to participate in any research study. Families who participate in a research study may not be contacted for another study until their participation in the first study has ended or until Registry staff is assured that:
1. participation in the next study will not negatively impact data collected for either study, and
2. the annual limit for number of contacts has not been exceeded.

C. Members remain active in the Registry until they ask to be removed. The Registry associate director may also withdraw a member, if necessary.

V. Participant Tracking and Coordination of Recruitment Efforts

A. In order to document the demand and use of Registry services, and to monitor and limit

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the number of recruitment contacts made annually to each participant, the Registry electronically tracks the following information:

1. studies approved to recruit from the RPRC
2. individual referrals to studies
3. the decision of members regarding whether or not to participate
4. the status of the participant in each study
5. the measures and data collected by each study

B. To avoid making duplicate contacts to families for research studies, investigators should use the Registry before advertising through local organizations (e.g., local ASNC chapters, UNC list-serve). The Registry provides the advantage of referring individuals who have confirmed clinical diagnoses to meet the studies inclusion criteria. Public recruitment requires additional screening by project staff.

C. UNC investigators should NOT contact the regional TEACCH Centers to recruit for autism studies. TEACCH clients have already been asked for permission to recruit for studies through the Registry. Those who have declined should not be contacted by investigators.

VI. Investigator Access to Core Services

A. The following investigators are eligible to use the Research Registry:
1. IDDRC investigators who are approved IDDRC administrator and/or RPR Core Advisory Panel and the NICHD program officer.
2. TEACCH investigators and UNC Chapel Hill trainees who have been recommended by the TEACCH Director.

B. Permission to recruit from the Registry is granted for a specific project/study for the duration of that project's funding while the project/PI remains at UNC. Investigators may have simultaneous approval for multiple studies. Projects continuing at another institution may not continue to contact participants recruited through the Registry.

C. Priority for resources is determined by the representatives of the RPRC Advisory Panel based on the following factors:
1. Source of funding, in order by priority: NIH/NICHD funded projects, federally funded grants by agencies of the US government, grants funded by national private organizations, other sources.
2. Application date for Registry services
3. Demand on participant pool—sample size, duration of use
4. Demand on families—intensity and invasiveness that participation in the study will entail
5. Ability for core resources to benefit the most projects possible

VII. Steps for Investigators to Access RPR Core Services

A. To obtain approval to access Registry Core services, investigators must:
1. Submit an Application for Core Services for each grant proposal (available on the

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IDDRC website)

2. Submit a Registry Core Service Request form for each grant proposal from the RPRC webpage. cidd.unc.edu/registry/researchers

3. Include the Registry in the personnel line of the project budget and provide a copy to the Registry core manager

4. Sign an agreement to terms for Core use. The Registry manager will send investigators a written notice of approval and provide a letter of support and a written description of the Research Registry that investigators can submit as a component of their grant proposal.

VIII. Obligations of RPR Core Users

A. To maintain eligibility to use RPR Core services, assist the Core in operating at optimal efficiency, maximize the Core's resources for the good of all IDDRC projects, and comply with IRB requirements, investigators and/or project staff will:

1. Provide a current copy of the study's approved UNC IRB application and the signed approval notice.
2. Provide the current grant account number and the accounting specialist managing the grant.
3. Meet with Registry manager at the start of a project and periodically during the course of the study to review study protocol and inclusion and exclusion criteria, and monitor recruitment progress.
4. Advise the Registry manager of changes in study protocol or procedures.
5. Contact the Registry manager to request recruitment mailings.
6. Provide the Registry with brochures and recruitment materials for mailings. Postage (outgoing and reply) is paid by the Registry Core. Project fees cover this and other recruitment expenses incurred by the Core.
7. Respond promptly to families who have returned study referral reply forms.
8. Notify the Registry of changes in contact information or status of a Registry member. Registry will provide updated information if available to study staff also.
9. Collaborate with other studies when possible on data collection and sharing.
10. Provide regular (monthly) updates on the status of Registry-referred participants in each study. It is critical to notify the Registry when a member has completed a study so that the member may be referred to other projects.
11. Obtain prior approval from the Registry manager before re-contacting Registry members who participated in prior studies. Individuals are referred to participate in the *current study only* and may not be contacted for other studies except through the Registry. This constraint applies even if the registry member agreed to future contacts by the investigator's study. Using the Registry as a central clearinghouse allows us to coordinate research efforts and resist overburdening families with requests and honor the contact preferences on their research consent form. Coordination can also prevent comprising data collection if the member is participating in another study.
12. Contribute project information for the annual research update newsletter to Registry families.
13. Provide a summary of findings for families at the conclusion of the study. The Registry will mail the summary to participating families.

IX. Obligations of the Registry Core

A. To provide high quality services for core users, protect the rights and dignity of Registry members, and facilitate best use of resources, the Registry core will:

1. Consult with projects on grant preparation, recruitment feasibility.

2. Offer feedback if requested on study recruitment materials.

3. Maintain current, accurate Registry participant records.

4. Conduct database queries when requested to identify potential participants for studies.

5. Foster collaboration among studies—especially for those with overlapping recruitment criteria.

6. Prepare recruitment mailings. The Registry provides a cover page (using an IRB approved template) introducing the study to potential subjects, a reply form (with yes and no response options) and a postage-paid reply envelope addressed to the Registry to enclose with the brochure or fact sheet provided by the research study.

7. Forward referral reply forms to the study staff immediately. To comply with privacy regulations, referrals will be sent by secured methods only. Email is not a secure method of data transfer.

8. Make follow-up contacts to individuals referred to studies to confirm that the member received the referral packet. Members may give verbal consent to be contacted by the research project staff. The names and contact information for these individuals will be passed to the study.

9. Address concerns and feedback from investigators and Registry participants.

10. Publicize and promote IDDRC research projects at exhibits and conferences, at presentations, in the community, and in printed materials. The Registry pays conference exhibit fees, designs and staffs an exhibit booth representing UNC studies. Individual projects are encouraged to send recruitment materials for distribution and staff members if available.

XI: Evaluation of RPR Core

A. Researchers are given the opportunity to evaluate Registry services using the IDDRC core services evaluation form.

B. Families are given the opportunity to evaluate Registry and research experiences during annual contacts.