GA SEED Participant Ascertainment Procedures – November 2008

A. Study Population

Catchment area description:
- Clayton, Cobb, Dekalb, Fulton, and Gwinnett counties
- Demographics of population (see below)

	Georgia 2004
Number of Live Births	51,805
Race/Ethnicity of Mother	
American Indian / Alaska Native	0.22 %
Asian/Pacific Islander	6.52 %
Black/African American	44.38 %
White	
White-Non-Hispanic	32.58 %
White-Hispanic	20.55 %
Unknown/Other	0.47 %
Non-Hispanic	75.72 %
Hispanic	21.37 %
Proportion of children under 18 years living in poverty	13.71 % (1999)
Urban/Rural Distribution	
Urban	98.61 %
Rural	1.39 %

B. Ascertainment Approach

1) CASE group/NIC: Potential case children and children in the neurodevelopmentally impaired group have been ascertained from all the same school sources and clinic sources currently used by the Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP). Most children eligible for GA SEED are either enrolled in special education programs at nine public school systems serving the study area or seen at participating specialty clinics and pediatric hospitals. The nine participating school systems are Atlanta City Schools, Buford City Schools, Decatur City Schools, Clayton County Schools, Cobb County Schools, DeKalb County Schools, Fulton County Schools, Gwinnett County Schools, and Marietta City Schools. The nine participating clinic

sources are Emory Children's Center, Children's Medical Services, The Emory Clinic, Child Neurology Associates, The Marcus Institute, Children's Healthcare of Atlanta, Woodlawn Development Center, Grady Memorial Hospital, and Georgia Department of Human Resources, Division of Mental Health, Developmental Disabilities and Addictive Diseases (DMHDDAD).

Ascertainment strategy – Our site does not have any exceptions to the broad net diagnosis/exceptionality list of conditions used by the sources. We have asked each of the sources to provide us a list of children's names with limited demographic information (birth date, contact information, mother's name, etc.) and diagnosis codes of children within our birth range criteria during the requested service year. The sources limit the list to the subset of eligible children that have any of the diagnoses listed in Appendix E. This list is requested at least one time per year and includes the previous calendar year's service dates. For example, the January 1, 2009 request will include children seen January 1-December 31, 2008. Re-requests are made if the data is incomplete such as lacking dates of birth or unreadable. Requested data from schools are based upon the Full-time Equivalent (FTE) counts the school systems have to provide the Department of Education. The FTE count is reflective of the number of children enrolled in school at that point in time. The data from clinics are based upon if a child has received medical attention at that source within the dates requested. The majority of the sources provide the information via electronic files uploaded onto our secure data network (SDN). The list of potential cases and NIC are generated annually per source. The status of the family's current residence is determined via tracing (see below).

Tracing procedures – The sources provide the lists of children and their data to us for processing and tracing. The GA SEED data manager first matches the children from the clinic or schools source lists against the Georgia birth records and death records. The list of children that match as being born in our catchment area (who are not known to be deceased) is passed to our GA SEED staff members to trace for current addresses. Because the majority of the clinic and school source data do not have addresses or phone numbers, we trace the children's information based on the birth mother and father's names and addresses on the certificate. GA SEED staff uses Accurint location and research tool and the online white pages to collect all possible current mailing addresses and phone numbers. During September through March of most years, we do not have access to Accurint due to funding and close out of fiscal year spending. Because of this, we batch our tracing and will have children traced 4-6 months before they are sent invitation letters.

Process for preparing and sending invitation letters – GA SEED has approval to send invitation letters directly to the families. One source, GA DMHDDAD had requested we include another letter on their letterhead indicating how GA DMHDDAD and CDC are working in collaboration on the study. Our work-study students prepare the packets and keep an ample stock based on source classification – CASE, NIC, or Subcohort. The letters are sent out via the CDC mail system and have CDC return address labels.

Schedule/time frame for sending invitation letters - We select batches of 100 children to send invitation letters every two weeks. The actual number of letters sent is higher since many families have more than one possible current address. If a file is larger than 100, we select the known cases and send those family's letters in the first batch. We invite an entire sources' list of children before moving to the next source list. As of October 15, we have sent letters to children from clinic sources and one school source. We anticipate sending to more school source children in the upcoming months. The data available to our site is listed in the attached document.

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School sources approvals –The school systems each have a research review board that reviews and approves research protocols or defers their approval another system's board. We have obtained approval letters from the majority of the school systems with 3 systems pending approval. A detailed study protocol and a school sponsor's signature is required as part of the board's application.   We have met with each system's special education director to garner support and signature of our applications.

Clinic sources approvals– Each of the clinical sources (specialty clinic, pediatric hospital, and the GA DMHDDAD) has an IRB or defers (accepts) another entity's IRB approval. We have obtained approval letters from the majority of IRBs with 2 entities pending approval. As with our school sources, we require a source sponsor's signature before we can submit our application to the local IRB. We have met with various physicians and heads of pediatric departments to obtain local providers' support and signature of our applications.

2) Subcohort: We have not deviated from the subcohort selection criteria. Subcohort children will be selected from Georgia vital records. The use of birth certificates as a mechanism for obtaining normal controls is possible because Georgia's vital records are maintained electronically within the Department of Human Resources (DHR). Further, CDC has access to the electronic birth certificate files for linkages with MADDSP and MACDP for additional information on child and maternal characteristics. An estimated 50,000 children are born in the five-county metropolitan Atlanta area. Subcohort members will be identified by Georgia state birth certificates on the basis of birth range and residence in the five-county metropolitan Atlanta area at the time of birth. Complete birth certificates have been provided to the CDC. The birth certificate files are linked with Georgia death certificate files to remove any potential members who are deceased. The GA SEED data manager has randomly selected 5000 children from the birth cohort and batched them into files of 100 children each. Each "batched" subcohort file has children of all ages within the birth cohort. The status of the family's current residence is determined via tracing (see below).

Tracing procedures – same as for Case/NIC

Process for preparing and sending invitation letters – same as for Case/NIC

Schedule/time frame for sending invitation letters - same as for Case/NIC; GA SEED alternates between sending letters to Case/NIC and Subcohort. Our proportions are roughly half Case/NIC and half Subcohort letters.

3) First Contact with All Types of Families: Potential study participants will be contacted by the GA SEED staff through an invitation packet. If the potential participant returns the response card indicating interest, then the potential participant will receive an invitation phone call from a GA SEED recruiter. If there is no response from the potential participant within 14 days, the recruiter will place follow up telephone calls as outlined in the protocol (up to 9 attempts). An additional letter will be attempted if the potential participant is not available by telephone. If the potential participant returns the response card indicating no interest, no additional follow-up contact will be made.

C. Birth Certificate Information
The GA SEED data manager first matches the children from the clinic or schools source lists against the Georgia birth records and death records. The list of children that match as being born in our catchment area (who are not known to be deceased) is passed to our GA SEED staff members to trace for current addresses. All data from both the clinic (or school) record and the birth certificate are combined, creating one matched record for the child (per source). This matched record is batch imported into CIS.

SEED Participant Ascertainment Procedures
California Report
November 2008

A.   Study Population

Geographic area

The California catchment area for the study is Santa Clara County and Alameda County, two large counties in the San Francisco Bay Area. These two counties combined have 48,026 births in 2004, are highly urbanized (1.31% rural in 2004) and extremely ethnically diverse. Of the employed adult population, 46% are in management, professional, and related occupations, 11% are in service occupations, 24% are in sales and office occupations and 21% work in manufacturing industries. The adult population is, in general, very well-educated, with 28% having some college education, 38% being college graduates, and only 8% having less than a 9th grade education.

Demographics of population

	California
	2004
Number of Live Births	48,026
Race/Ethnicity of Mother	
American Indian / Alaska Native	0.45%
Asian/Pacific Islander	16.24%
Black/African American	10.85%
White	-
White-Non-Hispanic	37.61%
White-Hispanic	28.39%
Unknown/Other	6.47%
Non-Hispanic	70.71%
Hispanic	29.29%
Proportion of children under 18 years living in poverty	13.84%
Urban/Rural Distribution	
Urban	98.69%
Rural	1.31%

B.   Ascertainment Approach

1. Case group/NIC
   a. Community Sources
   The Case and NIC groups are ascertained from the Department of Developmental Services/Regional Centers (DDS/RC) and Kaiser Permanente of Northern California (KPNC).

i) *Department of Developmental Services (DDS) and Regional Centers (RC):*
The California Department of Developmental Services operates a system of 21 Regional Centers that coordinate services for persons with autism, mental retardation (MR), cerebral palsy (CP), epilepsy (EP), and other developmental disabilities requiring similar services as individuals with mental retardation. DDS is responsible for the implementation of Part B and Part C of the Individuals with Disabilities and Education Act (IDEA) in California. Eligibility is determined and services are provided without regard to citizenship or financial status. The system is widely utilized across different socio-economic levels and racial/ethnic groups. Referrals to the RCs come from pediatricians and other clinical providers, the educational system, friends, and family members.

For this study, recruitment efforts are directed towards children receiving services from San Andreas Regional Center (SARC), which serves residents of Santa Clara County, and from the Regional Center of the East Bay (RCEB), which serves residents of Alameda County.

In November 2006 we identified:

	9/2003-8/2005
Case	68
NIC	93

We have a memorandum of understanding with DDS that allows us to review both centralized statewide electronic records and hard copy files at the 21 RCs throughout the state without the requirement to obtain individual consent.

ii) *Kaiser Permanente of Northern California (KPNC)*:
Kaiser Permanente Medical Care Program of Northern California is a group-model pre-paid, integrated health plan. Most members enroll through employment; many also join through MediCal (a low-income health insurance plan).

Approximately 32,000 births/year take place in KPNC birth facilities, representing ~25% of the live births in the 14-county geographic region served by KPNC. KPNC members are very representative of the general population with regard to sociodemographic characteristics.

In November 2006 we identified:

	9/2003-8/2005
Case	91
NIC	380

With IRB approval, we are allowed to review outpatient databases for Santa Clara County and Alameda County residents using the SEED ICD-9 eligibility list.

b. Describe ascertainment strategy for each source

i) Department of Developmental Services (DDS) and Regional Centers (RC):

DDS maintains a centralized electronic database of diagnostic and identifying information, derived from information provided by the RCs on a standardized, statewide reporting form, Client Development Evaluation Report (CDER). A CDER form is completed at initial enrollment and is updated periodically when new diagnostic information is obtained.

Regional Centers provide services to children with autism, MR, epilepsy, CP, and other DDS-eligible disabilities. Autism is recorded on the CDER as Code 1, Code 2, or Code 9. Code 1 corresponds to the DSM-IV classification of autistic disorder (DSM-IV code 299.00). Code 2 corresponds to the earlier DSM-III classification of Infantile Autism, Residual State. Code 9 is used in cases where a diagnosis of autism is "suspected" but not yet formally determined. We recruited Code 1 autism as cases, Code 2 and Code 9 we included in the NIC. In addition all other clients were recruited as NIC except those with hearing of vision problems.

Both SARC and RCEB have agreed to allow us to recruit clients eligible for the SEED study. SEED study staff pull a list from the DDS database semi-annually. SARC and RCEB review the recruitment list to see if there are families we should not contact for administrative reasons. Letters are generated by the SEED recruitment team; produced on the RC letterhead; and either sent to the RC for signature (SARC) or an electronic signature is used (RCEB).

ii) Kaiser Permanente of Northern California (KPNC):

The KPNC has a number of automated databases including comprehensive inpatient and outpatient records containing detailed information on all diagnoses and procedures associated with hospitalizations and ambulatory visits.

Children currently receiving pediatric services at a KPNC facility in Alameda or Santa Clara County who have a diagnosis of ASD or one of the diagnoses included in the NIC group after 24 months are identified from KPNC electronic outpatient files.

We must get the Primary Care Provider (PCP) approval before recruiting any children identified through the KPNC database. Letters including lists of case, NIC, and sub-cohort children identified for inclusion in the study are sent to the PCPs. If PCP approval was not obtained, we do not recruit those children. This includes when no response is received. The numbers listed above only include cases and NIC with PCP approval. PCPs approved 81% of requests for cases and 51% of NIC requests.

iii) Recruitment for both DDS and KPNC identified children is the same.
   a) We generate the recruitment list from the source databases.
   b) The recruitment list is linked to the birth records prior to recruitment process to obtain demographic data and verify birth residence. Children

that did not link to the birth records or linked outside of our ascertainment area are excluded from the recruitment list.

c) Tracing is not needed for case/NIC because we receive current addresses from the sources and I-Packs with incorrect address are returned to us. We will trace those families for whom letters are undeliverable if the source can not provide an updated address.

d) I-packs are mailed by SEED recruitment staff. Families who do not return a response call are called after 3 weeks. Families who return a response card indicating interest in the study are called within 2 days. Families returning a negative response card are not contacted by phone.

e) Lists have been pulled annually, but could be generated more frequently if needed. SEED staff schedule I-Pack mailings based on staffing and recruitment goals. We mail on average 10 to 15 I-Packs per week.

f) Demographic information from the birth certificated is available on all case and NIC children. In addition we have ICD-9 diagnoses on all children recruited from KPNC and some of the children from DDS. Both KPNC and DDS also provide some demographic information.

2. Subcohort

a. Describe ascertainment strategy

First, SEED staff at CDPH link the live birth files to infant death files and exclude children who died before age one. We expected approximately 10% of all invited children in the sub-cohort will enroll in the study. Therefore, our initial sample was for 1500 children and was selected randomly from the cohort of survivors to age one for recruitment into the study.

Our first random sample of 1500 was drawn in November 2006 from all live births who survived to age one, born between 1/1/2003 and 12/31/2005 in Alameda and Santa Clara counties. This list was linked to the KPNC membership, and children who were members were included on lists sent to the KPNC PCPs for approval to invite into the study. This was done so that we could use the current address information recorded in KP databases. Children, who linked to KPNC or DDS, and had language, vision, hearing issues, were excluded. Children were also excluded if PCP refused or did not respond. This reduced the list by 250 children. After birth date range was narrowed to 9/1/2003-8/31/2005, we had 922 available to recruit.

Our response rates were lower than projected and we selected a second random sample of 1500 in July 2008.

All sub-cohort families are traced for a phone number. If we are unable to identify a phone number, the family is not recruited. The first contact with the sub-cohort is a telephone invitation call. An I-Pack is only sent if the respondent requests more information on the I-Call. The number of I-Calls is based on our recruitment goals and staffing available. We recruited on averaged 50 sub-cohorts per month.

Demographic information from the birth certificated is available on all sub-cohort children. In addition we have ICD-9 and addition demographic information on those children that also linked to KPNC and DDS.

3. Describe "first contact" with potential case or NIC or subcohort by site staff

Recruitment of all 3 study groups is carried out by the SEED recruiters at CDPH. Recruitment is carried out in batches in order to minimize the time between initial contact and completion of the study protocol while maintaining a steady stream of participants in each phase of data collection. Batch size is determined by the number of that study group in the process and the time it takes to recruitment. For example, the sub-cohort families require nine calls and with a simple 4.5% response rate (9.8 adjusted for ineligible) we process those in much larger batches.

First contact for case or NIC group is a letter produced by SEED staff on the source organization's letterhead. If the family does not respond to the letter in three weeks, SEED staff will conduct the I-Call. A positive response card is not needed for us to trigger a call. SEED recruiters will call all traceable sub-cohort families.

C. Birth Certificate Information

Case and NIC children are linked to the birth certificate records prior to enrollment.

Colorado Seed Participant Ascertainment Procedures Report – November 2008

A. **Study Population - 2004**

Catchment area description:
- The seven-county Denver Metropolitan area: Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson counties.

Table 1. Population Demographics, 2004 Birth Year

	California	Colorado	Georgia	Maryland	North Carolina	Pennsylvania
Number of Live Births	47,454	40,410	49,966	35,037	34,000	37,217
Race/Ethnicity of Mother						
American Indian / Alaska Native	0.34%	0.67%	-	0.32%	1.00%	0.24%
Asian/Pacific Islander	26.32%	4.52%	-	4.86%	2.00%	3.95%
Black/African American	7.10%	5.51%	41.01%	33.20%	31.00%	28.08%
White	-		-	-	-	64.62%
White-Non-Hispanic	34.39%	55.79%	39.40%	55.19%	61.00%	-
White-Hispanic	29.55%	33.49%	13.90%	6.48%	5.00%	-
Unknown/Other	30.64%	0.01%	6.63%	0.32%	-	3.11%
Non-Hispanic	69.36%	-	-	-	-	93.49%
Hispanic	30.64%	-	-	-	-	6.51%
Proportion of children under 18 years living in poverty	14.75% (1998)	10.67% (1999)	16.3%	10.1% (1999)	33.0% (2002)	24.75%
Urban/Rural Distribution						
Urban	98.59%	95.35%	93.90%	86.07%	78.0%	97.00%
Rural	1.41%	4.65%	6.10%	13.93%	22.0%	3.00%

B. **Ascertainment Approach**

    1. Sources - Case group/NIC
        a. Itemize community sources for potential case/NIC identification (i.e., children with a previous ASD clinical dx/spec ed exceptionality or broad net dx/spec ed exceptionality)
            i. If the list excludes some potential community sources (e.g, relative to an ADDM list of sources for the same population), provide rationale for selection of each source and exclusion of each source for SEED purposes.

   ii. Where possible, provide quantitative data to support selection/exclusion of a specific source (e.g., estimated number/proportion of all ASD cases in the study population served by source, sociodemographic profile of ASD cases served by source, etc.).
   iii. Describe approval from each source

  b. Describe ascertainment strategy for each source – specifically
   i. Describe any exceptions to the broad net dx/exceptionality list of conditions used by the source
   ii. Participant selection criteria that the source uses
   iii. How does the source generate the list of potential cases and NIC (based on what data?)
   iv. How often is the list of potential cases and NIC generated?
   v. Tracing procedures for contact info (is tracing performed, who does it, what tracing resources are used, etc)
     1. if tracing is not done, what information is shared with site re: returned invitation letters, individuals with no valid contact info, etc.
   vi. Process for preparing and sending invitation letters
   vii. Schedule/time frame for sending invitation letters
   viii. What kinds of data are available to the sites re: characteristics of the potential case and NIC pool (e.g., sample size, age distribution, ethnic distribution, broad net dx distribution, etc.)

Included

JFK Partners (affiliated program with the University of Colorado Denver)
- For the ADDM 2002 SY, JFK Partners was the largest contributor of cases among health sources with nearly a quarter of the cases having an evaluation performed at JFK Partners.
- Approval: Permission from JFK Partners Director.
- Ascertainment Strategy: Queried database for children in the birth cohort (9/1/2003 - 8/31/2005) with at least one diagnostic code from the Broadnet list. The list was only generated once.
- Tracing and Tracking: Letters returned as undeliverable are not traced, however, the source does share the number of returned invitation letters and the number of individuals who are not interested.
- Process for Sending Letters: A letter from the source (on their letterhead) is sent with the SEED Invitation Letter and response card. The response cards are addressed to SEED. A second Invitation Letter and response card is sent approximately 4 weeks from the date the first letter is mailed.
- Schedule/Timeframe: Letters sent in December 2007 and January 2008. Additional letters will be sent in July and August 2009.
- Data Available: Sample size and possibly distribution by age, ethnicity and broad net diagnosis.

The Children's Hospital (TCH)
- For the ADDM 2002 SY, TCH was the next largest contributor of cases among health sources with 13% of the cases having an evaluation performed at TCH.

- Approval: Permission from the Child Development Unit Director.
- Ascertainment Strategy: Queried database for children in the birth cohort (9/1/2003 - 8/31/2005) with at least one diagnostic code from the Broadnet list. The list was only generated once.
- Tracing and Tracking: Letters returned as undeliverable are not traced, however, the source does share the number of returned invitation letters and the number of individuals who are not interested.
- Process for Sending Letters: A letter from the source (on their letterhead) is sent with the SEED Invitation Letter and response card. The response cards are addressed to SEED. A second Invitation Letter and response card is sent approximately 4 weeks from the date the first letter is mailed.
- Schedule/Timeframe: Letters sent in May and August 2008. Additional letters will be sent in December 2008 and then in July, August and September 2009.
- Data Available: Sample size and possibly distribution by age, ethnicity and broad net diagnosis.

Part C

- In Colorado, eligibility for Part C Services is defined as:
  i. developmental delay in the areas of cognitive development (thinking and learning skills), physical development (moving, seeing and hearing), communication development (understanding and using sounds, gestures and words), social-emotional development (responding to and developing relationships with others), or adaptive development (taking care of one's self when doing things like feeding and dressing); OR
  ii. has a diagnosed physical or mental condition which has a high probability of resulting in developmental delay.
- Part C data in Colorado is not coded with ICD-9 diagnoses. However, in 2000-2001, there were 914 children with an indication of adaptive delays, cognitive delays, communication delays, physical delays, and social delays.
- Community Centered Boards (CCBs) manage and deliver the services for persons with developmental disabilities. CO SEED is working with county Part C agencies through the CCBs.
- Approval: Permission from the county CCB Directors.
- Ascertainment Strategy: Because Part C is not as reliable by eligibility category, we ask that the agency only query by birth year (9/1/2003 - 8/31/2005). The CCBs have the Part C database representing children 2-3 years of age and the Family Support Service database that contains children who are 3-5 years of age who were eligible for Part C. SEED is requesting that the CCBs only select those children who were both Part C and Part B eligible. Children who were ONLY eligible for Part C do not qualify. The sample is generated based on an estimated 15% response rate. The list was only generated once for each CCB.
- Tracing and Tracking: Letters returned as undeliverable are not traced and the source does not share the number of returned invitation letters, however, the sources do share the number of individuals who are not interested.

- Process for Sending Letters: A letter from the source (on their letterhead) is sent with the SEED Invitation Letter and response card. The response cards are addressed to SEED. A second Invitation Letter and response card is sent approximately 4 weeks from the date the first letter is mailed.
- Schedule/Timeframe: Please see attached spreadsheet for schedule and timeframe.
- Data Available: Sample size and possibly distribution by age, ethnicity and broad net diagnosis.

Excluded at present time

Part B/Special Education

- The Part B agency is administered under the Colorado Department of Education (CDE) and is called the Colorado Preschool Program. In Colorado, Part B serves approximately 5000 children 3-5 years of age.
- Part B data in Colorado is not coded with ICD-9 diagnoses. Children with the following categories of conditions are eligible for Part B: mental retardation, hearing impairments (including deafness), speech or language impairments, visual impairments (including blindness), serious emotional disturbances, orthopedic impairments, autism, traumatic brain injury, other impairments or specific learning disabilities. The specific diagnosis (i.e. autism, etc.) is not always indicated. In 2000-2001 there were 58 children with autism, 3425 with speech and language delays, and 86 with multiple delays in Part B.
- Approval: Part B requires approval from each district Special Education Director and their district IRB. There are 15 school districts in the seven county Denver Metropolitan area.
- Rationale for Exclusion: The school districts are already working with CO ADDM for autism monitoring. Given the delicate relationships with the schools, CO SEED decided to work with Part C first and then, if needed, to solicit participation from the school districts.

Other ADDM Sources
- The following sources were not included as recruitment sources for CO SEED:
  - Boulder Community Hospital
  - Denver Health Medical Center
  - Developmental Disability Consultants
  - Kaiser Permanente
  - Sewall Child Development Center
  - Hospital Discharge and Billing Databases
- These sources required an immense amount of resources to yield cases that also had overlap with JFK Partners, TCH or the school districts. Approximately 12% of the total cases solely came from these sources. CO SEED expects that many of these children will be captured by the CCBs.

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2. Subcohort
   a. Describe ascertainment strategy – specifically
       i. Describe any deviations from the SEED subcohort selection criteria
       ii. How does the source generate the list of potential subcohort?
       iii. How often is the list generated?
       iv. Tracing procedures for contact info (is tracing performed, who does it, what tracing resources are used, etc)
           1. if tracing is not done, what information is shared with site re: returned invitation letters, individuals with no valid contact info, etc.
       v. Process for preparing and sending invitation letters
       vi. Schedule/time frame for sending invitation letters
       vii. What kinds of data are available to the sites re: characteristics of the potential subcohort pool (e.g., sample size, age distribution, ethnic distribution)

   a.   The Vital Records Section in the Colorado Department of Public Health and Environment issues and maintains the birth certificates for the state of Colorado. In the seven-county Denver Metropolitan area there were an estimated 40,000 live births reported in 2002 and 2003.
   b.   Deviations from SEED selection criteria: CO SEED chose to oversample by birthdate in order capture the older children who would otherwise age out of the study. Please see attached sampling plan.
   c.   List Generation: The sample of 1349 children was generated by HSVR, based on an estimated 4.5% response rate. The monthly samples are pulled from this list.
   d.   Tracing: HSVR matches children with the Women, Infants and Children (WIC) database prior to sending out letters to search for a most recent address. Letters that are returned as undeliverable are traced using Accurint.
   e.   Process for sending letters: A letter from HSVR (on their letterhead) is sent with the SEED Invitation Letter and response card. The response cards are addressed to SEED. A second Invitation Letter and response card is sent approximately 4 weeks from the date the first letter is mailed.
   f.   Schedule/Timeframe: A sample of letters is sent each month by HSVR with the exception of May and November. In order to accommodate staffing changes, letters were not sent during these two months.
   g.   Data Available: HSVR will be able to share sample size, age distribution, ethnic distribution.

3. Describe "first contact" with potential case or NIC or subcohort by site staff
   a. What is the trigger for the contact (e.g. positive response card, no response card, etc)
   b. Time frame/schedule for the first contact

c. *Who performs the first contact (staff person)*
d. *Process for carrying out first contact (focus on idiosyncratic deviations from protocol, if any)*

- Families who indicate interest in the study by returning the response card will be contacted via telephone by study staff (Jen Baltz (PC), Ann Ribe (resigned), Katy Ridge, Andrea Cantarero or Leovi Madera). Spanish-speaking families are contacted by Leovi Madera and Andrea Cantarero.
- The families are typically contacted within 10 days of receiving the response card. However, during the early months of enrollment CO SEED was understaffed and not expecting a high response so many of the families waited longer for the Introductory Call.

C. Birth Certificate Information
Describe when linkage with the birth certificate will occur/does occur for enrolled CASE, NIC and Subcohort.

- The original agreement with HSVR is to match the enrolled families to the birth certificate to confirm birth county of residence on a yearly basis. However, CO SEED and HSVR recently agreed to a quarterly match.

Seed Participant Ascertainment Procedures – Site-specific Report – November 2008
Maryland

A.   Study Population
Catchment area description:
- Geographic area, e.g. counties
  - o   Howard County
  - o   Baltimore City
  - o   Baltimore County
  - o   Cecil County
  - o   Anne Arundel County
  - o   Carroll County
  - o   Harford County

	California	Colorado	Georgia	Maryland	North Carolina	Pennsylvania
Number of Live Births	47,454	38,342	49,966	**35,057 (2004)**	34,000	37,217
Race/Ethnicity of Mother						
American Indian / Alaska Native	0.34%	0.84%	-	**0.23%**	1.00%	0.24%
Asian/Pacific Islander	26.32%	4.02%	-	**4.84%**	2.00%	3.95%
Black/African American	7.10%	5.78%	41.01%	**32.67%**	31.00%	28.08%
White	-	-	-	**-**	-	64.62%
White-Non-Hispanic	34.39%	60.23%	39.40%	**57.58%**	61.00%	-
White-Hispanic	29.55%	29.07%	13.90%	**4.49%**	5.00%	-
Unknown/Other	30.64%	0.07%	6.63%	**0.19%**	-	3.11%
Non-Hispanic	69.36%	-	-	**95.32%**	-	93.49%
Hispanic	30.64%	-	-	**4.68%**	-	6.51%
Proportion of children under 18 years living in poverty	14.75% (1998)	10.67% (1999)	16.3%	**10.8% (2005)**	33.0% (2002)	24.75%
Urban/Rural Distribution						
Urban	98.59%	95.35%	93.90%	**89.82%**	78.0%	97.00%
Rural	1.41%	4.65%	6.10%	**10.18% (2000)**	22.0%	3.00%

4.   Case group/NIC

   a.   Recruitment Site Approvals -
       The Maryland site has two recruitment locations that we are currently
       working with for CASE and NIC referrals. The Maryland State

Department of Education (MSDE) and the Kennedy Krieger Institute (KKI) are both actively assisting us in reaching these populations.

The approval process for the Maryland State Department of Education was multifaceted. Because we must obtain data from each of the seven school districts, which correspond to the counties in our catchment area, we had to receive individual agreements from each directing official. MSDE also had to obtain a letter of approval from the state Attorney General which provided them the authority to use student data for research purposes. Furthermore, MSDE received a Federalwide Assurance number to meet the CDC requirements.

The approval process for KKI included review of the protocol and agreement of the terms from both parties. Additionally, KKI agreed to release their patient contact information to Johns Hopkins University (JHU) study staff. A waiver for recruitment was signed giving JHU authority to use the data for research purposes.

b. Ascertainment Strategies –
   i. Maryland State Department of Education - MSDE categorizes their special education population using a more specific criterion. After reviewing and comparing their categories to the ICD-9 diagnostic codes agreed upon for SEED, the following were included in the selection criteria:

NIC	CASE
01 = Mental Retardation	14 = Autism
04 = Speech or Language Impairment	
06 = Emotional Disturbance	
08 = Other Health Impairment	
10 = Multiple Disabilities	
15 = Developmental Delay	

In order to select individuals that may qualify for the study, MSDE performs queries on early intervention and pre-school special education databases to screen eligible children based on age, special education code and zip code. Information from this source is generated semi-annually.

Once eligibility is confirmed, study staff prepares and mails an invitation packet to the homes. Each packet includes an introductory letter on MSDE letterhead signed by the Assistant Superintendent for Special Education Services. Invitation letters are generally sent out on a monthly basis in quantities of 100.

Second mailings will be sent if no response is received within two weeks of the initial mailing. Two weeks after the second mailing, study staff will attempt to call the families to introduce the study and encourage them to

return their response card. If the response card is not returned after the first two mailings, and phone calls, a final invitation packet will be sent six months after the initial mailing, after which no further contact will be attempted.

If a mailing is returned indicating an incorrect address, MSDE will check with the local school district to determine if contact information has been updated for the student. If the local school district is unable to provide updated information, MSDE personnel will access a CD directory to locate a current mailing address. If an address is available, the packet will be re-sent. If there is no updated information there are no additional contact attempts made to the family.

ii. Kennedy Krieger Institute - KKI participants are selected based on the agreed upon ICD-9 codes. Intermittent queries are performed on patient billing databases to screen for eligible children based on age, last address and ICD-9 diagnostic code. Information from this source is generated semi-annually. Prior to each new pull, the data is checked for new families who may have elected not to participate in research studies.

Once eligibility is confirmed, study staff prepares and mails an invitation packet to the homes. Each packet includes an introductory letter on KKI letterhead signed by the Director of their Center for Autism and Related Disorders. Invitation letters are generally sent out on a monthly basis in quantities of 100.

Similar to MSDE, second mailings will be sent if no response is received within two weeks of the initial mailing. Two weeks after the second mailing, study staff will attempt to call the families to introduce the study and to conduct the invitation call. If the response card is not returned after the first two mailings, and phone calls, a final invitation packet will be sent six months after the initial mailing, after which no further contact will be attempted.

If a mailing is returned indicating an incorrect address, staff will access either a CD directory or an online database system to locate a current mailing address. If an address is available, the packet will be re-sent. If there is no updated information there are no additional contact attempts made to the family.

Both recruitment sources use the eligibility criteria stipulated in the study protocol. The criterion includes the following:

- Child was born between September 1, 2003 and August 31, 2005
- Child was born and currently lives within one of the catchment areas

- Child has a diagnosis that coincides with the agreed upon ICD-9 diagnostic codes

Additionally, both recruitment locations will provide the following broad net demographics regarding the populations that are being contacted;

Age
Zip code (catchment area)
Diagnostic code

5. Subcohort
    i. Ascertainment Strategy -
    We have also developed a relationship with The Maryland State Department of Health and Mental Hygiene (DHMH) in order to reach our subcohort population. Subcohort children are identified from birth certificates maintained by the Division of Vital Records at DHMH. Because birth certificate data cannot be released without consent in Maryland, DHMH has agreed to contact subjects for potential enrollment in the study subcohort. A file was created of all potentially eligible births based on birth date and residence in the catchment area at the time of birth. Birth records were first linked to death certificate files to remove any children from the file who are deceased, and then linked with internal DHMH information on past research refusers so that any family who has requested to never be contacted for research will not be included. These lists are generated quarterly at which time approximately 375 invitation packets are mailed. To achieve our goal of 150 sub-cohort children, this quantity per quarter may be increased during the enrollment period.

    Tracing is performed by Vital Statistics personnel and occurs prior to the mailing of the first invitation packet. A CD directory is used to verify and/or update addresses.

    Invitation packets are prepared by JHU study staff and mailed by Vital Statistics. Each packet includes an introductory letter on DHMH letterhead and is signed by the Director of Vital Statistics. A modified version of the response card is also included in these packets.

    Families who do not respond to the initial mailing, by returning the response card or otherwise initiating contact with study staff, are sent a second invitation packet 4 weeks after the first mailing and again after 6 months. Modified versions of the letter are used for the successive mailings. Upon request Vital Statistics will provide the following demographics regarding the populations that are being contacted;

    Age
    Race

19

Zip code (catchment area)

6. Staff Procedures for First-Contact with Potential Participants
     i. Maryland State Department of Education - Participants must return a positive response card before the staff can contact them to conduct the invitation call. Part-time Research Assistant, Maria Stacy, would place cold calls to the families if there is no response four weeks after the initial mailing. During this call, Ms. Stacy provides information about the study and strongly encourages the family to return the response card if they are interested in participating. Upon receipt of the response card, JHU staff contacts the family to conduct the invitation call.

    ii. KKI – Participants will generally return a positive response card before the staff would contact them to conduct the invitation call. With this group we do have the option to place cold calls if there is no response four weeks after the initial mailing. Full-time Research Assistant, Jasina Wise, would be responsible for placing the cold calls to the families.

   iii. DHMH - Participants must return a positive response card before the staff can contact them to conduct the invitation call. We do not have the option of placing cold calls to this group.

         It is our goal to contact a family within two weeks of their returning a positive response card. If we have a back-log of response cards, all families are contacted to acknowledge receipt and to schedule their invitation call.

C. Birth Certificate Information

     i. We will receive birth certificate data from the Maryland State Department of Health and Mental Hygiene (DHMH) on a quarterly basis. We are requesting data for participants upon completion of their caregiver interview. We are requesting that DHMH match on the following variables:
          a. Mom first and last name
          b. Child first and last name
          c. Mom maiden name
          d. Mom DOB
          e. Child DOB

    ii.   DHMH will confirm that mom gave birth to index child, on identified date and in one of the zip codes within our catchment area. If DHMH is unable to provide birth certificate data, we are requesting the information from the family.
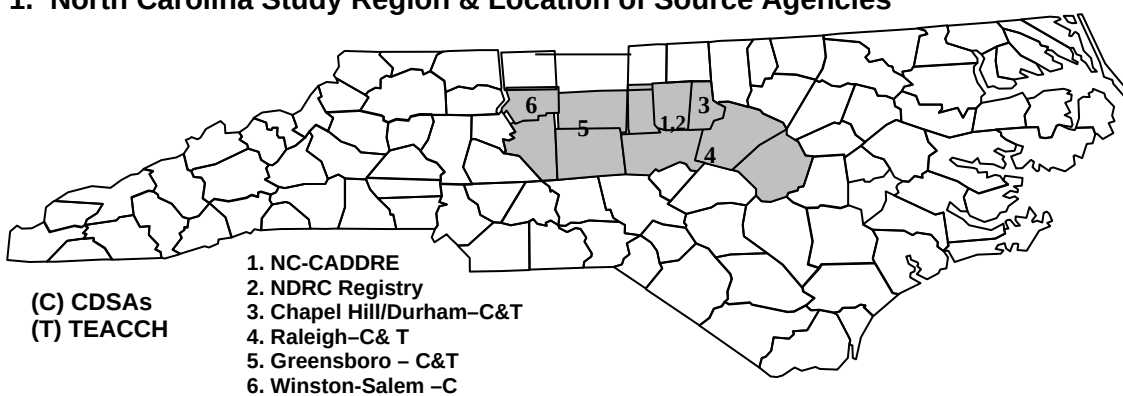
SEED Participant Ascertainment Procedures
Site-specific Report for <u>North Carolina</u>
November 2008

  A. Study Population
          a. Catchment area description

Approximately 131,000 children were born in North Carolina in 2007. That's up 7% from the approximately 122,000 births in 2004. Racial distribution of births in 2004 for the study catchment area is in the table below. The study's catchment area (Figure 1) includes 10 counties in central North Carolina, which together yielded about 38,000 live births in 2007. The target counties are Alamance, Chatham, Davidson, Durham, Forsyth, Guilford, Johnston, Orange, Randolph, and Wake. They represent both urban and rural regions with sociodemographic variability. All have regional access to health care and educational services.

Figure 1. North Carolina Study Region & Location of Source Agencies

(C) CDSAs
(T) TEACCH

1. NC-CADDRE
2. NDRC Registry
3. Chapel Hill/Durham–C&T
4. Raleigh–C& T
5. Greensboro – C&T
6. Winston-Salem –C

        i. Geographic area
       ii. Demographics of population

	California	Colorado	Georgia	Maryland	North Carolina	Pennsylvania
Number of Live Births per year in catchment area	47,454	38,342	49,966	35,037	33,323	37,217
Race/Ethnicity of Mother for catchment area						
American Indian / Alaska Native	0.34%	0.84%	-	0.32%	0.25%	0.24%
Asian/Pacific Islander	26.32%	4.02%	-	4.86%	4.23%	3.95%
Black/African American	7.10%	5.78%	41.01%	33.20%	23.56%	28.08%
White	-	-	-	-	-	64.62%
White-Non-Hispanic	34.39%	60.23%	39.40%	55.19%	54.34%	-
White-Hispanic	29.55%	29.07%	13.90%	6.48%	17.49%	-
Unknown/Other	30.64%	0.07%	6.63%	0.32%	0.13%	3.11%
Non-Hispanic	69.36%	-	-	-	82.37%	93.49%
Hispanic	30.64%	-	-	-	17.63%	6.51%
Proportion of children under	14.75%	10.67%	16.3%	10.1%	20.8.0%	24.75%

18 years living in poverty	(1998)	(1999)		(1999)	(2005)	
Alamance					16.6%	
Chatham					16.0%	
Davidson					18.6%	
Durham					19.4%	
Forsyth					21.5%	
Guilford					20.9%	
Johnston					16.8%	
Orange					11.6%	
Randolph					21.1%	
Wake					12.9%	
Urban/Rural Distribution					(2000)	
Urban	98.59%	95.35%	93.90%	86.07%	78.0%	97.00%
Rural	1.41%	4.65%	6.10%	13.93%	22.0%	3.00%

B. Ascertainment Approach
 a. CASE/NIC sources

North Carolina has a statewide network of diagnostic and referral agencies for children with developmental delays. The three primary agencies are the Division of Treatment and Education of Autistic and related Communication-handicapped CHildren (TEACCH), the Children's Developmental Services Agencies (CDSAs) under the Department of Health and Human Services (NC DHHS), and the Department of Public Instruction. These agencies work independently and together to identify, evaluate and provide treatment or referrals for children with special needs and their families. TEACCH and CDSA clinics, which are often the first point of entry for evaluation and service of preschool age children, receive referrals from the majority of pediatricians in the state when developmental concerns arise among young children. Three TEACCH centers are located in the target study area. Consequently, TEACCH clinics and CDSAs are the primary sources for cases and NIC controls in this study. The NC Department of Public Instruction receives children from the CDSA service centers for continued service over age 3 and also evaluates and treats children age 3 and above with developmental issues.

We received approval from the Children's Developmental Service Agency and from the NC Department of Public Instruction to use our study materials to approach potential subjects. We also use the UNC Autism Research Subject Registry (IRB # 01-0843), to reach families of children with ASD.

Case Invitation
The caregivers of children evaluated by TEACCH centers are offered an opportunity to register their child with the Autism Research Registry, which is managed by the Neurodevelopmental Disorders Research Center's Research Registry through the Department of Psychiatry at UNC. This registry informs families of opportunities to become involved in research conducted at UNC. The Research Registry is used by NC-CADDRE to recruit families for SEED. The Registry Administrator sends SEED Invitation Cover Letter and brochure with a Registry-specific cover letter and Registry-specific response card to families living in the catchment area with children born during the cohort range. Only one packet is mailed. If no response card is received after two weeks, Registry staff calls the families to obtain an interest decision. No tracing of undeliverable packets or bad phone numbers is done. All positive response cards are forwarded to study staff. Basic data are provided on invitee demographics: how many sent, how many with positive and negative responses, how many with bad address and phone number, how many with no response, unclear if reached.

Due to extremely high response rate from the first batch in this group, we have elected to as the Registry Director to invite batches only twice per year and keep the batch size down around 40 to 50 per batch.

We do not receive the ICD-9 codes for any of the children in the Autism Research Registry potential pool. However, all children in the registry have been evaluated and treated for autism or ASD at a TEACCH center. We can obtain aggregate age distribution and county of residence for the children in the potential pool.

NIC Invitation
Staff at the Children's Developmental Services Agencies in central North Carolina obtained a pool of potential families to invite. Five CDSAs serving the ten counties in the North Carolina catchment area agreed to allow one CDSA to be the location from which invitation packets are mailed and to which response cards are returned. Our first step was to provide the central data repository at DHHS with our Exceptionality and ICD-9 inclusion codes and have them identify children potentially eligible for the study (i.e. receiving services or evaluations for developmental disabilities or autism, living in the catchment area, and born between September 1, 2003 and August 31, 2005). DHHS then pulled the contact and demographic data for these families and made it available to the CDSA taking responsibility for inviting families. We developed an Access tracking system for the CDSA staff to use to pull batches of families from the DHHS data file, track mailings and calls, and produce reports for us to track demographics.

Unfortunately the first attempt to pull the five CDSA's data revealed that there were extremely few or no children with the Broadnet ICD-9 or Exceptionality codes to be included. Further investigation uncovered a change in documentation policy that allows the local CDSAs to send data to DHHS without ICD-9 codes if the families do not have private insurance covering their services (i.e. diagnostic codes are only needed for insurance billing and are thus only input into the state-wide system if they are required in order to receive payment). Thus three of the five CDSAs had 0 or fewer than 200 families meeting our ICD-9 criteria thus drastically reducing the potential subject pool and leaving only higher SES families in the pool. We discussed the situation with DHHS and the relevant CDSA directors and arranged varying means for obtaining additional families who probably meet our ICD-9 or Exceptionality inclusion criteria. Most CDSAs have "referral reasons" in their local data bases. Referral reasons are linked to an older method of assigning children to Eligibility Categories for reporting purposes that was used prior to July 2006. For two of the under-represented CDSAs in our pool, we reviewed the categories and their sub-codes, selected the categories most clearly representing the SEED ICD-9 and Exceptionality inclusion codes and asked them to pull datasets for those families meeting our study inclusion criteria and in the selected Eligibility Categories.

The old Eligibility Categories are
- Developmental Delay (delays in cognitive, gross or fine motor function, communication, social-emotional, or adaptive development);
- Atypical Development (significantly atypical behavioral, socio-emotional, motor or sensory development – does include substantiated physical abuse, exploitation or neglect);
- Risk Established (diagnosed with physical or mental conditions know to result in developmental delay or atypical development as the child matures – does include two codes that are not really within the Broadnet); and
- High Risk Potential (documented presence of indicators associated with development which have high probability of resulting in development delay or atypical development as the child matures).

Given the specific conditions under the four categories, we elected to include Developmental Delay, Atypical Development, and High Risk Established but exclude High Risk Potential.

For the fifth CDSA for whom no families had ICD-9 codes entered at DHHS, discussion with the CDSA director revealed that his site kept no single database that contained contact information plus Eligibility Categories plus demographics. That director reviewed our Broadnet list and reported that these codes represented about 90% of the referrals seen by his agency. He also reported insufficient staffing available to concatenate his local datasets to provide an appropriate pool and opted instead to have the DHHS office release ALL families referred to his CDSA whose child was born in our cohort dates and whose address was in one of our catchment area counties. Thus, for one of our sources (covering two of our ten counties), we have included a small set of children who probably do not meet any of our Broadnet criteria.

Those local datasets were then pooled with the DHHS data set and made available to the staff person responsible for sending Invitation Packets to families. This database creation resulted in approximately 5500 potential subjects. We have permission to repeat the pull during early 2009 to capture any younger children who would not yet have been in the system at the time of this initial database creation. However, completion of this additional pull will be dependent on availability of resources at the local sources who had to provide data from their local databases. We may not be able to add any more children to this pool.

The same Invitation Packet as used for the Subcohort is used by the CDSA staff but includes an agency-specific cover letter assuring families of their identity protection unless they grant permission to forward it to the study via the response card. The first Invitation Packet is mailed, if no response card is received within two weeks, a second Invitation Packet is mailed. If there is still no response card received two weeks after the second Invitation Packet is mailed, CDSA staff call each family and document their outcome status (unable to contact, moved out of the area, negative interest, positive interest, etc) in the Access tracking system. No tracing of undeliverable packets is done. CDSA staff calls families whose packets were returned undelivered if a phone number is available. All positive response cards are forwarded to study staff to attempt Invitation Calls.

The CDSA invites batches of 100 to 180 children approximately every other month. This year, because we had a delay in starting, there will be only 5 batches sent out.

We do not receive the Referral Reasons, ICD-9 or Eligibility Categories for any of the children in the CDSA potential pool. Nor do we receive aggregate statistics on age distribution or county of residence on the potential pool. We might be able to get aggregate statistics on the pool if the CDSA sponsoring this work is willing to allocate programmer resources to do so.

We have a similar agreement with the NC Department of Public Instruction for contacting children served who meet the initial eligibility criteria but they do not have staff to support the mailing and receipt of response cards nor do they have a central database of contact information. The central office can pull IDs of individuals meeting our Exceptionality categories but either study staff or DPI staff must go to each county's central DPI office to link those IDs with contact information and then send Invitation Packets. We do not have funding to provide staff to do this amount of travel and could not secure staff at DPI to receive the response cards, track any response demographics, and forward any positive response cards to us. Thus we have not implemented this method of inviting families but will if we are unable to recruit sufficient numbers of NIC through the CDSAs.

b. Subcohort source

We have obtained approval from the Registrar of the NC State Center for Health Statistics to obtain birth records for the appropriate general population pool and were given names, addresses, and demographic information from birth certificate records for children born in the appropriate time window (Sep 2003 through Aug 2005) in the 10-county catchment area. The NC Electronic Birth Certificate database has randomly sampled 4500 live births for us to contact to recruit the subcohort. SAS was used to create batches

of approximately 100 children to import into CIS at regular intervals in order to send Invitation Packets. Sampling in small batches allows reasonable time to trace, recruit, and process identified subjects. If response rates differ from expected, the number of samples in each subsequent batch will be altered to ensure recruitment goals are met but not exceeded.

Subcohort Invitation
Tracing via Accurint is done on each batch prior to importing into CIS. Best address is used for mailing the Invitation Packet. If no updated contact information is obtained from tracing, parent contact information from the birth records is used to send the Invitation Packet. Local study staff sends Invitation Packets to these families. If no response card is received after two weeks, a second Invitation Packet is mailed. If no response card is received one month after the second packet is mailed, families are coded out in CIS as appropriate. Packets returned as undeliverable are traced again and, if new contact information is obtained, an additional packet is mailed. No calls are made if no positive response card is received.

We invite batches of 100 to 200 children approximately every 3 months (quarterly). This year our first batch was only 100 but all subsequent batches have been larger. We can obtain aggregate statistics on any birth certificate data obtained including age and county of residence and compare enrollees with non-enrollees.

        c. Self-referral source
Due to the interaction of ASD parents through autism organizations or common clinical care sites, it is possible that families not initially identified by the above procedures will learn about the study and want to participate. Parents or legal guardians who initiate contact with the study, have a child with a previous ASD or ASD-related diagnosis, and are interested in having their child participate, will be considered Self-Referrals if their child meets the eligibility criteria and parents are willing to provide us with a copy of the diagnosis.

        d. First Contact with subject by site staff
CASE/NIC sources
Invitation Packets are mailed by sources. Once positive response cards are sent to study staff, Invitation Calls are attempted. Messages are left after 1st, 3rd, 5th and 9th calls.

Subcohort source
Invitation Packets are mailed by study staff. Once positive response cards are received, Invitation Calls are attempted. Messages are left after 1st, 3rd, 5th and 9th calls.

C. Birth Certificate Information
CASE/NIC sources
We have obtained approval from the Registrar of the NC State Center for Health Statistics to confirm county of residence on birth records for the children enrolled in the study but not obtained via birth records. Twice each year we can send spreadsheets of specific identifying information (mother's full name including maiden, child's full name, DOB and gender) for the individuals needing confirmation. They will then confirm that county of residence was one of the 10 counties in our catchment area. We have not yet attempted this confirmation. We do, however, have consent via the study consent form, "to obtain a copy of your child's birth records from the North Carolina State Center for Health Statistics". Thus, if we can get approval from the NC SCHS, we might be able to obtain the same data we obtained on the Subcohort.

Subcohort source
We have already obtained birth certificate data for all 4500 potential children in the Subcohort.

Pennsylvania Seed Participant Ascertainment Procedures
November 2008

A.   Study Population

Catchment area description:
Pennsylvania

The catchment area will include three counties in Pennsylvania: Chester, Montgomery and Philadelphia counties.
- Demographics of population
  - update table below - indicate census year used for estimates

	California	Colorado	Georgia	Maryland	North Carolina	Pennsylvania
Number of Live Births	47,454	38,342	49,966	35,037	34,000	36,674
Race/Ethnicity of Mother						
American Indian / Alaska Native	0.34%	0.84%	-	0.32%	1.00%	-
Asian/Pacific Islander	26.32%	4.02%	-	4.86%	2.00%	6.19%
Black/African American	7.10%	5.78%	41.01%	33.20%	31.00%	32.26%
White	-	-	-	-	-	50.95%
White-Non-Hispanic	34.39%	60.23%	39.40%	55.19%	61.00%	-
White-Hispanic	29.55%	29.07%	13.90%	6.48%	5.00%	-
Unknown/Other	30.64%	0.07%	6.63%	0.32%	-	10.6%
Non-Hispanic	69.36%	-	-	-	-	93.21%
Hispanic	30.64%	-	-	-	-	6.79%
Proportion of children under 18 years living in poverty	14.75% (1998)	10.67% (1999)	16.3%	10.1% (1999)	33.0% (2002)	18.5%
Urban/Rural Distribution						
Urban	98.59%	95.35%	93.90%	86.07%	78.0%	97.00%
Rural	1.41%	4.65%	6.10%	13.93%	22.0%	3.00%

B.   Ascertainment Approach

7. Case group/NIC
   a. Itemize community sources for potential case/NIC identification (i.e., children with a previous ASD clinical dx/spec ed exceptionality or broad net dx/spec ed exceptionality)
      i.   Elwyn, Incorporated
      ii. Chester County Early Intervention Program
      iii. Montgomery County Early Intervention Program
      iv. Chester County Intermediate Unit
      v.   Montgomery County Intermediate Unit
      vi. Children's Hospital of Philadelphia
   b. If the list excludes some potential community sources (e.g, relative to an ADDM list of sources for the same population), provide rationale for selection of each source and exclusion of each source for SEED purposes.

i. Sources being utilized for recruitment for the SEED project best represent our population age demographic. The Early Intervention Programs (EIP) of Chester, Montgomery and Philadelphia counties provide services to children ages 0-3 years. The agencies are: Elwyn, Inc. (Philadelphia), Chester County Early Intervention Program, and Montgomery County Early Intervention Program. A diagnostic code is not necessary to receive services, and many children in the 0-3 age range are identified as having a "developmental delay." Eligibility criteria are a 25% delay and/or and established condition with a high probability of developmental delay. Data for all children receiving services through the Early Intervention Programs is located in the Early Intervention Reporting System (EIPS). Once in the system the child's diagnoses, disability categories etc are assigned EIPS codes.

ii. The Intermediate Units (IU) of The Pennsylvania Department of Education oversee preschool and school age educational services. The Philadelphia county Intermediate Unit has a contract with Elwyn, Inc. to provide services to children ages 3-5. Children eligible for these services in Pennsylvania have been identified as having an exceptionality from the list of thirteen. ICD-9 codes may also be used to identify children who are eligible for special accommodations covered by Section 504 of the Americans with Disabilities Act. Chester and Montgomery County IUs oversee pre-school and special education services for ages 3-5. The IUs serves the educational needs of children ages 3-18 (grades preschool to grade 12). Each county maintains the special education records of children in the county as well as socio-demographic information on children receiving special education services.

c. Where possible, provide quantitative data to support selection/exclusion of a specific source (e.g., estimated number/proportion of all ASD cases in the study population served by source, sociodemographic profile of ASD cases served by source, etc.).

i. Approximately 180 potential cases are expected from the I.U.s. The IUs are: Chester County Intermediate Unit #24, Montgomery County Intermediate Unit #23, and Philadelphia County Intermediate Unit #26.

ii. Approximately 100 potential cases are expected from the Children's Hospital of Philadelphia

d. Describe approval from each source

b. Describe ascertainment strategy for each source – specifically
    i. Describe any exceptions to the broad net dx/exceptionality list of conditions used by the source N/A
    ii. Participant selection criteria that the source uses
        1. All sources glean records from their databases based on SEED exceptionality/ICD-9 eligibility codes and cohort birth date ranges. In order to receive services from the source the child must be currently residing in the county.
    iii. How does the source generate the list of potential cases and NIC (based on what data?) See above
    iv. How often is the list of potential cases and NIC generated? As needed
    v. Tracing procedures for contact info (is tracing performed, who does it, what tracing resources are used, etc)
        1. if tracing is not done, what information is shared with site re: returned invitation letters, individuals with no valid contact info, etc.
            a. Sources are not tracing addresses and phone numbers. Sources are providing Penn staff with number of returned packets.
    vi. Process for preparing and sending invitation letters
        1. Packets are prepared at Penn and mailed to sources.
    vii. Schedule/time frame for sending invitation letters

1. Every two to three weeks a Penn staff person goes to the source location and send out an initial mailing. At this time the second mailing is also sent for the previous mailing.
        viii. What kinds of data are available to the sites re: characteristics of the potential case and NIC pool (e.g., sample size, age distribution, ethnic distribution, broad net dx distribution, etc.)
                    1. After the entire mailing list has been exhausted, it will be deidentified and sent to Penn. At that time we will be able to provide aggregate level statistics on demographics and exceptionality/ICD-9 codes for those who were interested in learning more, not interested and did not respond.

8. Subcohort
   a. Describe ascertainment strategy – specifically
        i. Describe any deviations from the SEED subcohort selection criteria
        ii. How does the source generate the list of potential subcohort?
                    1. Penn applied for and received the birth record file for our birth cohort. A random sample of 5000 was generated from the initial birth record file which was subsequently divided into 10 random samples of 500 using Excel's random sample generator.
        iii. How often is the list generated?
                    1. Once the first list of 500 is exhausted we will move on to the next list of 500.
        iv. Tracing procedures for contact info (is tracing performed, who does it, what tracing resources are used, etc)
                    1. if tracing is not done, what information is shared with site re: returned invitation letters, individuals with no valid contact info, etc.
        v. Process for preparing and sending invitation letters
                    1. Packets are prepared and sent from Penn. CIS will be used for our second batch of subcohort mailings since PA batch import is now working!
        vi. Schedule/time frame for sending invitation letters
                    1. Initial letters are sent out with a second letter being sent 4 – 6 weeks later
        vii. What kinds of data are available to the sites re: characteristics of the potential subcohort pool (e.g., sample size, age distribution, ethnic distribution)
                    1. All birth certificate variables

9. Describe "first contact" with potential case or NIC or subcohort by site staff
   a. What is the trigger for the contact (e.g. positive response card, no response card, etc)
        i. Invitation calls are triggered by a positive response card
   b. Time frame/schedule for the first contact
        i. Invitation call attempts begin as soon as a response card is received
   c. Who performs the first contact (staff person)
        i. Suzanne Smith and Kathleen Lesko are currently making invitation calls. Brooke Levenseller is being trained on the invitation call protocol.
   d. Process for carrying out first contact (focus on idiosyncratic deviations from protocol, if any)

C. Birth Certificate Information
Describe when linkage with the birth certificate will occur/does occur for enrolled CASE, NIC and Subcohort.

Birth certificate linkage occurs before mailings are sent to any family on the mailing lists at the sources