Specifics of each site's ascertainment and recruitment methodologies for the ASD, DD, and POP study groups were collected in July 2016 and are provided in this document.

STUDY POPULATION

The study population for each site is described below using the 2014 year estimates. A description of the catchment area below is followed by a table describing the number of live births reported in 2014, the racial composition and education of the mothers, and proportion of children under the age of 18 years of age living in poverty. In 1989, the National Center for Health Statistics adopted the use of race/ethnicity of the mother for birth data, rather than race/ethnicity of the child, as a standard classification. Thus, the race/ethnic composition reported below is the race/ethnicity of the mother. Due to differences in reporting ethnicity among the states, race is categorized as White-Non-Hispanic and White-Hispanic and also as a general category of Hispanic and Non-Hispanic.

Colorado

The catchment area will in the seven-county Denver metropolitan area (Arapahoe, Adams, Boulder, Broomfield, Denver, Douglas and Jefferson counties) and El Paso county which includes the city of Colorado Springs.

Georgia

The catchment area will include the five-county metropolitan Atlanta area: Clayton, Cobb, DeKalb, Fulton, and Gwinnett counties.

Maryland

The catchment area will include the nine-county area in Maryland: Anne Arundel, Baltimore County, Baltimore City, Carroll, Cecil, Harford, Howard, Montgomery, and Prince George counties.

<u>Missouri</u>

The catchment area will include the following 22 counties along the Interstate 70 corridor from St. Louis to Kansas City: Boone, Callaway, Cass, Clay, Cole, Cooper, Franklin, Gasconade, Howard, Jackson, Jefferson, Johnson, Lafayette, Moniteau, Montgomery, Osage, Pettis, Saline, St. Louis, St. Louis City, St. Charles, and Warren.

North Carolina

The catchment area will include the fourteen-county area around central North Carolina: Alamance, Davidson, Durham, Chatham, Forsyth, Franklin, Guilford, Johnston, Nash, Orange, Person, Randolph, Rockingham, and Wake counties.

Wisconsin

The catchment area will include a 20-county area that encompasses the 10 counties of southeastern Wisconsin that make up the Wisconsin ADDM Network catchment area: Dane, Green, Jefferson, Kenosha, Milwaukee, Ozaukee, Racine, Rock, Walworth and Waukesha counties, and an extension of 10 counties in south central Wisconsin: Adams, Chippewa, Clark, Columbia, Eau Claire, Juneau, Marathon, Portage, Sauk and Wood counties.

Population Characteristics of SEED Phase 3 Catchment Areas

(Note: 4 sites provided birth data from 2014: CO, GA, NC, and WI; the other 2 sites provided birth data from 2013 because 2014 data was not available at the time this information was collected: MD and MO).

	SITE CO	SITE GA	SITE MD*	SITE MO	SITE NC	SITE WI
Catchment Area						
Live Births/yr (N)	46,686 (2014)	49,303 (2014)	58,747 (2013)	45,345 (2013)	40,106 (2014)	41,015 (2014)
Maternal Race/ Ethnicity (%)						
Black/African American	7.4	41.22	36.17	22.84	26.3	15.8
White	81.8	38.14	55	71.45	54	
Non-Hispanic	62.58	29.9	40.09		51.3	64.7
Hispanic	22.86	8.24	29.82		2.7	11.8
Other/Unknown	4.4	16.59	8.45		19.7	7.7
Non-Hispanic	72.3	82.62	83.93	93.85	95	88.2
Hispanic	26.4	17.38	16	5.72	5	11.8
Maternal Education						
< 12 years	11.3	13.41	5.32*	12.16	15.6	12.3
12 years	19.1	23.59	26.03*	20.65	19.4	23.7
>12 and < 16 years	28.5	17.72	26.21*	31.84	27.2	29.1
>= 16 years	39.9	38.72	37.08*	35.02	37.4	34.9
Unknown				0.32	0.3	
Proportion of children under 18 years living in poverty (%)	14.1		12.9		18	14.5**

^{*}Education data for Maryland is provided for all adults 25 or older in their catchment area. Maternal education data for the birth cohort is not available.

^{**}For the Wisconsin site, the % of children under 18 years living in poverty is based on 2009-2013 American Community Survey data.

ASD AND COMPARISON GROUP ASCERTAINMENT

A. Ascertainment Methodology from Part C (0-3 years)

Colorado

Potential ASD children and children with other developmental delays or disorders (DD) will be ascertained from Community Centered Boards (CCBs), which provide Part C early intervention in the Denver metropolitan area and El Paso County. Responses are the same as for Educational sources (see below).

Background: NA

Obtaining Approvals: NA

Ascertaining Probable Cases: NA

Ascertaining Comparison Group: NA

Contacting Families: NA

Screening Method: NA

Georgia

No plan to use Part C.

Maryland

Background: We plan to recruit children from the Part C dataset available through Maryland State Department of Education (MSDE). We plan to request all children with a Part C code that meet criteria for a 25% delay in one or more of the categories identified through the Early Intervention program to allow for the child to receive special education services. This pool of children will be queried at the same rate as the children accessed through Part B.

Obtaining Approvals: Research approvals will be obtained from the Johns Hopkins Bloomberg School of Public Health IRB, as well as the Department of Health and Mental Hygiene (DHMH) IRB. The MSDE will allow our JHSPH IRB to function as their approval board. We will gain approval to access student data through MSDE, and then each county will grant permission to share their identifiable data with the MSDE data programmers, who will in turn allow our study team to access contact information to send invitation packets. Currently, no data can be taken out of MSDE offices or moved from their secure servers, and only study staff can access the server using secure passwords.

Ascertaining Probable Cases: While some of these children may become CASEs after the eligibility screening call, if they do not have a formal diagnosis code in the Part C dataset we will consider them a DD source. They

will only be put into the CASE group workflow once the invitation call has been completed and the mother indicates that the child has a formal ASD diagnosis or the child scores an 11 or greater on the SCQ.

Ascertaining Comparison Group: Because the children in this group will be mostly 2-3yrs old and will not be in the Part B dataset, they will be less likely to have a formal diagnostic code in their education records, so we will be tracking these children as part of our DD group.

Contacting Families: The study coordinator will request data one to two times per year from the MSDE data programmers. The programmer will query the county schools in SEED 3 catchment and they will send back all potentially eligible children that our staff can recruit. Once the data are put onto the MSDE server, JHU staff will go to MSDE offices to prep and mail invitation packets to the identified families. For families who do not respond to the first mailing, a second invitation packet will be mailed 30 days later. If there is no response after that mailing, a third and final invitation packet will be mailed to them at the 4-month mark. If no response after 14 days, study staff stationed at the MSDE offices will make up to 4 calls to the family at the MSDE-provided phone numbers to attempt to reach the family and determine interest and eligibility. If there is no response after 4 attempts (once per week for 4 weeks), the family will be removed from the contact list and listed as a passive refusal. Study staff will track responses and contact those families who have indicated interest in learning more about our study either through our mail-in response card or our secure online response system. The families will be contacted by phone or email, depending on what information the family has indicated. Within 7 to 14 days of receiving a response, we will call the mother to screen her for eligibility. If she is eligible and interested, we will do the SCQ, determine what workflow her family will be assigned, and the process of enrollment will begin.

Screening Method: We will conduct the screening via a telephone interview with the biological mother of the recruited child. If the mother is eligible, she will be consented to complete the SCQ, and if interested, she will enroll in the full study. If she is not eligible, or not interested in enrolling, staff will send her a \$10 incentive thanking her for her time, and her family will be removed from future contact lists. After we receive the response card or online data information, study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

Missouri

No plan to use Part C.

North Carolina

Background: Potential ASD children and children with other developmental delays or disorders (DD) will be ascertained from Part C service providers serving the NC catchment area. Part C of Individuals with Disabilities Education Act (IDEA) ensures that early intervention services and supports are available for infants and toddlers, birth to age three, with disabilities and their families. In North Carolina, the Part C system of IDEA is led by the Early Intervention Branch of the Women's and Children's Health Section in the North Carolina Division of Public Health. There are 16 Children's Developmental Services Agencies (CDSAs) across the state that provide access to

Part C services. This network of CDSAs serves all 100 counties of North Carolina in single or multi -county catchment areas. As a result, many children eligible for NC-SEED are evaluated by Part C service providers in 5 CDSAs serving the study area. The five CDSAs serving the NC-SEED catchment area are Durham (Chatham, Durham, Franklin, Orange, Person counties), Greensboro (Alamance, Guilford, Randolph, Rockingham counties), Raleigh (Wake county), Rocky Mount (Johnston, Nash counties), Winston-Salem (Davidson, Forsyth counties).

Obtaining Approvals: Early Intervention Director and associated HIPAA Compliance officer have given verbal approval to operate as done in past waves of SEED, pending their agency IRB approval. CDSA IRB approval cannot be obtained until UNC IRB approval is obtained.

Ascertaining Probable ASD: Children who were served by the participating CDSAs at any time, obtaining one of the broadnet ICD9 or ICD10 codes indicating autism spectrum diagnoses, with residence in a catchment county, birth in the cohort range (2014-2017) will be considered potential cases. The Project Coordinator for NC-SEED will make one data request per year to the NC Department of Health and Human Services who manages the CDSA client data. Data requests will be made in Sept/Oct each year. We will make a request to the HHS programmer assigned to SEED to conduct a database query of all children served by relevant CDSAs, with residence in any catchment county who have any allowable ICD9 or ICD10 code (see Appendix E. ICD DSM Code Spec ED Lists SEED 3 for codes to be provided to HHS programmer). The HHS programmer will place deduplicated data containing contact information (child name, parent name when available, child mailing address, all available phone numbers), child DOB, child race, child ethnicity, preferred language, CDSA ID last utilized, system ID (to be used for linking to birth cert data), and up to 12 associated ICD9/10 codes on a secure server at the Greensboro CDSA in a folder dedicated for this purpose [all invitations for all relevant CDSAs will be done through the Greensboro CDSA]. The NC-SEED Invitation System data manager will merge new data pulls into existing master table of potential contacts for use in an Invitation Tracking system built for use in inviting all NC-SEED source families. A stand-alone version of this Invitation Tracking system will be used by the CDSA-SEED liaison under the terms of data security agreement with the Greensboro CDSA. Before contacting families of potentially eligible children, the Invitation Tracking system will allow selection of batches by IDC9/10 codes that INCLUDE codes indicating autism. The mothers of families will be sent a Preliminary Notice postcard alerting them to the arrival of a packet. One to two weeks after mailing Preliminary Notice, SEED invitation materials including a source-specific cover letter assuring families that the research office has not yet received any information about them will be mailed to families. Invitation Packets will provide families with multiple options for indicating interest in the study, including contacting the study office directly, using a web form submitted to the study office, returning a postcard to the CDSA office. Two to three weeks after invitation materials are mailed, the CDSA-SEED liaison will begin phone contact for those non-responders for whom phone numbers were provided. If no phone number was available or phone number(s) are found to be 'bad', subsequent mail and email contact attempts will be made (up to 4 attempts). Some ineligibility may be determined during these contact attempts (e.g. packets that are returned to sender with forwarding outside of catchment, calls that uncover language barriers, child deceased, etc). These will be tracked by the Invitation Tracking system. Children with an Autism ICD9/10 Code: Mothers of children with an autism ICD code who indicate interest in hearing about the study will be contacted by the study office staff and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. Children with a non-Autism Exceptionality Code: Mothers of children with a non-autism ICD code will be

contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through Part C services will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the CDSA-SEED liaison through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the study staff. If there potential participant does not respond to the invitation packet within 14 days, the CDSA-SEED liaison will place follow up telephone calls and/or emails depending on information available for the participant. We will be allowed to trace individual family information if initial contact attempts produce no response or when packets are returned to sender. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: if referred to the study office, the families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Wisconsin

No plan to use Part C.

B. Ascertainment Methodology from Educational Sources

Colorado

Background: Potential ASD children and children with DD will be ascertained from educational sources - Community Centered Boards (CCBs), which provide Part C early intervention and other programs dedicated to the education of young children with ASD and other developmental disabilities are located in the Denver metropolitan area and El Paso County.

Obtaining Approvals: Research approvals will be obtained from each of the participating CCBs and other educational programs.

Ascertaining Probable ASD: Each CCB and other education source will query their database annually for all service recipients within birth cohort dates that are resident in this study's catchment area.

Ascertaining Comparison Group: As described above, some children ascertained through CCB sources will be placed in the workflow for the DD comparison group.

Contacting Families: Each education source will send an introductory letter on its own letterhead with an Invitation Packet (prepared by CO SEED staff) to each sampled family. Study flyers and contact information will be provided to staff at these sites to give to interested families. Education source staff ("source staff") will track

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and attempt to trace any letters returned as undeliverable. To protect privacy and confidentiality, experienced source staff with bilingual capacity will make the initial and subsequent follow-up calls to reach non-responding families, attempt to trace incorrect phone numbers as needed, and track all calls and their outcomes. If the family is successfully contacted, source staff will briefly explain the study and ask for permission to forward the family's contact information to CO SEED staff, who will then contact, screen for eligibility and enroll eligible families. In Year 1, the CO SEED O/R Coordinator will train source staff to implement contact, referral and tracking procedures, and will continue to provide support and training as required. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: CO SEED staff will conduct screening of children from educational sources by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Georgia

Background: Potential ASD children and children with other developmental delays or disorders (DD) will be ascertained from school sources and clinic sources currently used by the Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP). The ascertainment methodology relies on the consequences of Part B of Public Law 94-142 as amended, the Individuals with Disabilities Education Act (IDEA)(6), which mandates that the public schools provide a free and appropriate education for all children with disabilities between the ages of 3 and 21. As a result, many children eligible for GA-CADDRE are either enrolled in special education programs at nine public school systems serving the study area or enrolled in other Georgia Department of Education programs for children who have developmental disabilities. The nine school systems participating in MADDSP 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.

Obtaining Approvals: Research approvals will be obtained from each of the nine participating school systems. A detailed study protocol is required to be submitted to the Research Guidelines Department of each system

Ascertaining Probable ASD: Children who were served by the participating school systems at any time and who meet the study's eligibility criteria will be considered potential cases. The Project Coordinators for GA SEED and MADDSP will make one data request per year to each of the participating school systems. Data requests will be made October 5. The data request date is based on the date when the school systems have to provide the Department of Education with the Full-time Equivalent (FTE) counts. The CDC program project coordinators will ask the Data Request Coordinator in each system to conduct a database query of all children 3 to 10 years of age who are in the select exceptionality categories (see Appendix E for categories used in SEED). The Data Request Coordinators will provide the data to the GA SEED/MADDSP Data Manager. The GA SEED data manager will subset the school lists to children potentially eligible for SEED (based on education codes and birth years). Before contacting families of potentially eligible children, the list of potential SEED participants will be linked to the Georgia Birth Certificate files. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the five-county GA SEED study area, will be removed as

ineligible from the SEED invitation mailing list. The mothers of the remaining families will be sent SEED invitation materials and further screened for eligibility and autism at first contact. *Children with an Autism Exceptionality Code*: Mothers of children with an autism exceptionality code will be contacted and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. *Children with a non-Autism Exceptionality Code*: Mothers of children with a non-autism exceptionality code will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through school sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the Centers for Disease Control and Prevention (CDC) through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Maryland

Background: Potential ASD children and children with other developmental delays or disorders (DD) will be ascertained from sources currently used by MSDE (as stated above for the Part C group as well). The ascertainment methodology relies on the consequences of Part B of Public Law 94-142 as amended, the Individuals with Disabilities Education Act (IDEA)(6), which mandates that the public schools provide a free and appropriate education for all children with disabilities between the ages of 3 and 21. As a result, many children eligible for MD SEED are enrolled in special education programs at the public schools associated with our catchment counties: Anne Arundel, Baltimore, Baltimore City, Harford, Howard, Carroll, Cecil, Montgomery, and Prince George counties.

Obtaining Approvals: Research approvals will be obtained from the Johns Hopkins Bloomberg School of Public Health IRB, as well as the Department of Health and Mental Hygiene (DHMH) IRB. The MSDE will allow our JHSPH IRB to function as their approval board. We will gain approval to access student data through MSDE, and then each county will grant permission to share their identifiable data with the MSDE data programmers, who will in turn allow our study team to access contact information to send invitation packets. Currently, no data can be taken out of MSDE offices or moved from their secure servers, and only study staff can access the server using secure passwords.

Ascertaining Probable ASD: We will receive data on the children who carry a disability code in the MSDE system consistent with receiving services in the school system (via an IEP) related to an ASD diagnosis. These children will be considered CASE workflow. Their mothers will be mailed invitation packets, and when reached by study staff, will be screened for eligibility and enrollment into the study if they express interest. The mothers will complete an SCQ about the child on the screening call, but because the children were already slotted as a CASE source, they will remain in the CASE workflow regardless of SCQ score.

Ascertaining Comparison Group: As described above, children ascertained through school sources will be placed in the workflow for the DD comparison group if they do not have a disability code in the Part B dataset consistent with an ASD diagnosis, and if, when reached for the eligibility screening call, do not disclose an ASD diagnosis or score an 11 or greater on the SCQ.

Contacting Families: The study coordinator will request data one to two times per year from the MSDE data programmers. The programmer will query the county schools in SEED 3 catchment and they will send back all potentially eligible children that our staff can recruit. Once the data are put onto the MSDE server, JHU staff will go to MSDE offices to prep and mail invitation packets to the identified families. For families who do not respond to the first mailing, a second invitation packet will be mailed 30 days later. If there is no response after that mailing, a third and final invitation packet will be mailed to them at the 4-month mark. If no response after 14 days, study staff stationed at the MSDE offices will make up to 4 calls to the family at the MSDE-provided phone numbers to attempt to reach the family and determine interest and eligibility. If there is no response after 4 attempts (once per week for 4 weeks), the family will be removed from the contact list and listed as a passive refusal. Study staff will track responses and contact those families who have indicated interest in learning more about our study either through our mail-in response card or our secure online response system. The families will be contacted by phone or email, depending on what information the family has indicated. Within 7 to 14 days of receiving a response, we will call the mother to screen her for eligibility. If she is eligible and interested, we will do the SCQ, determine what workflow her family will be assigned, and the process of enrollment will begin. Study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

Screening Method: As mentioned above, we will conduct the screening via a telephone interview with the biological mother of the recruited child. If the mother is eligible, she will be consented to complete the SCQ, and if interested, she will enroll in the full study. If she is not eligible, or not interested in enrolling, staff will send her a \$10 incentive thanking her for her time, and her family will be removed from future contact lists. After we receive the response card or online data information, study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

<u>Missouri</u>

Background: There are over 130 public school districts in our SEED 3 catchment area. Therefore, establishing formal agreements with all of these districts is prohibitive. However, we anticipate working with several key districts in study area. We have a written commitment from the Lee's Summit R-7 School District in the

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metropolitan Kansas City area. We also have a verbal commitment from the Special School District (SSD) of Saint Louis County. We also anticipate collaborating with Columbia Public Schools (CPS) in Columbia, Missouri.

Obtaining Approvals: NA

Ascertaining Probable ASD: Children who were served by the participating school systems at any time and who meet the study's eligibility criteria will be considered potential cases. The relevant Project Coordinator for MO SEED will make one data request per year to each of the participating school systems. We will ask each school system to conduct a database query of all children 3 to 5 years of age who are in the select exceptionality categories (see Appendix E for categories used in SEED). Our education sources will not provide MO SEED any identifiable student data. Therefore, district staff will notify the MO SEED Project Coordinator of the number of students that meet the criteria mentioned above. MO SEED staff will then prepare the appropriate number of invitation packets (including postage). The packets will then be returned to the school district where they will be addressed and mailed. The Invitation packet will provide contact information for MO SEED so interested families will communicate directly with MO SEED staff. We plan to send out at least one follow-up mailing (using the same procedure) to families that do not respond to the first mailing. Potential participants that respond to the MO SEED invitation will be linked to the appropriate MO birth certificate file. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the MO SEED study area will be notified they are ineligible for the study. The mothers of the families that meet the residency at birth requirements will be further screened for eligibility and autism. Children with an Autism Exceptionality Code: If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. Children with a non-Autism Exceptionality Code: If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through school sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the participating school district, on behalf of MO SEED, through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

North Carolina

No plan to use Part B.

Wisconsin

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Background: There is no plan to ascertain eligible participants directly through Part B/Special Education providers in Wisconsin. The Waisman Center's *K-12 Registry* will be used to ascertain potentially eligible participants receiving Part B/Special Education services. This registry of school-age children (3-21 years) is maintained collaboratively by the Clinical Translational Core, the Wisconsin Center for Education Research, and the Madison Metropolitan School District. Over 1,500 students are enrolled in this registry; 26% are members of under-represented minority groups; and 14% receive special education services. Thus, it can support ascertainment and recruitment of children with and without ASD and other developmental disabilities (DDs). Parents of all children in the registry have consented to be contacted and invited to participate in research.

Obtaining Approvals: Research approval to use the *K-12 Registry* for the SEED 3 protocol will be obtained from the University of Wisconsin-Madison Health Sciences IRB. This IRB has already approved the operation of the *K-12 Registry*.

Ascertaining Probable ASD: Children in the K-12 Registry who meet the study's eligibility criteria will be considered potential cases. The Project Coordinator (PC) based at the Waisman Center will make quarterly data requests for contact and disability information on all children born between January 2014 and December 2017. The WI SEED Waisman Center PC will subset the school lists to children potentially eligible for SEED (based on education codes and birth years). Before contacting families of potentially eligible children, the list of potential SEED participants will be linked to the Wisconsin Birth Certificate files. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the 20-county WI SEED study area, will be removed as ineligible from the SEED invitation mailing list. The mothers of the remaining families will be sent SEED invitation materials and further screened for eligibility and autism at first contact. Children with an Autism Exceptionality Code: Mothers of children with an autism exceptionality code will be contacted and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. Children with a non-Autism Exceptionality Code: Mothers of children with a non-autism exceptionality code will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. Children screening positive will be placed in the potential ASD workflow group. Children screening negative on the SCQ will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through school sources via the K-12 Registry will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the University of Wisconsin (UW) Survey Center through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone calls from a member of the project staff of the UW Survey Center. If UWSC is unable to reach the potential participant within 14 days, project staff will place follow up telephone calls and/or emails or text messages depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

C. Ascertainment Methodology from Clinics/Private Providers

Colorado

Background: Clinical sources that provide diagnostic and intervention services for children with developmental disabilities will be used to ascertain children for this study. These sources are the University of Colorado JFK Partners and Developmental Pediatrics (JFK/DP) clinics, which offer assessment and treatment services to children from metro Denver and El Paso County.

Obtaining Approvals: The Director of JFK/DP, who is a co-investigator on SEED 3, has provided written confirmation of JFK/DP's participation in SEED 3 as described in this section.

Ascertaining Probable ASD: The Project Coordinator for CO SEED will initiate a data request with each clinical source. Each clinical source will send Invitation Packets to parents of children meeting study requirements who have received at least one International Classification of Diseases (ICD) code indicating that they received an ASD or related diagnosis of one or more select conditions associated with ASD (e.g., intellectual disability, language delay) from a clinical provider.

Ascertaining Comparison Group: As described above, some children ascertained through clinical sources will be placed in the workflow for the DD comparison group.

Contacting Families: Colorado SEED 3 clinical sources will mail potential study participants an invitation to participate in SEED 3. If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the CO SEED staff. If there is no response from the potential participant within 14 days, SEED project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: Screening will be done by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Georgia

Background: In addition to school sources, clinical sources will be used to ascertain children for this study. These sources include metro-area pediatric tertiary care centers and clinics that provide diagnostic or intervention services for children with developmental disabilities – Egleston Children's Hospital, Grady Memorial Hospital, Scottish Rite Children's Medical Center and their associated clinics, and Marcus Autism Center. The clinical sources represent diverse socio-demographic subgroups of the population; they include a public, inner-

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city teaching hospital, serving a predominantly low SES, minority population and private hospitals and clinics in suburban and urban areas serving a broader SES range including mid-high SES populations. Insurance policies varies across these facilities.

Obtaining Approvals: A formal agreement will be made with each clinical source to obtain data and contact potential SEED participants. In some instances the sources might defer to Emory University, as the umbrella organization.

Ascertaining Probable ASD: The Project Coordinators for GA SEED and MADDSP will initiate a data request with each clinical source. The data requests will be made at the same time the data requests are made with the school sources (See Appendix E for the ICD codes that will be used in the query for GA SEED). The Data Request Coordinators at each clinical source will provide the data to the GA SEED/MADDSP Data Manager. The GA SEED data manager will subset the clinic lists to children potentially eligible for SEED (based on ICD codes and birth years). Before contacting families of potentially eligible children, the list of potential SEED participants will be linked to the Georgia Birth Certificate files. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the five-county GA SEED study area, will be removed as ineligible from the SEED invitation mailing list. The mothers of the remaining families will be sent SEED invitation materials and further screened for eligibility and autism at first contact. Children with an ICD code indicating a previous diagnosis of an Autism Spectrum Disorder: Mothers of children with ASD code will be contacted and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. Children with a non-Autism ICD Code: Mothers of children with a non-autism ICD codes will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through clinical sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the Centers for Disease Control and Prevention (CDC) through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Maryland

Background: In addition to school sources, a clinical source will be used to ascertain children for this study. The main clinical source is the Kennedy Krieger Institute (KKI) Center for Autism and Related Disorders (CARD), a renowned Maryland-based clinic that provides diagnostic and intervention services for children with

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developmental disabilities. The main clinic is located about 15 minutes from JHSPH, and is where the majority of our families enrolled will go for developmental assessments. There is a campus located in Odenton, MD that some families can request if the travel time to the main clinic site is too burdensome. This site offers many of the same resources and services as the main clinic site.

Obtaining Approvals: A formal agreement will be made with KKI to obtain billing record data on all children who were assessed in their system based on our specific study criteria (i.e. child's DOB, catchment area). While KKI has their own IRB, they have agreed to allow our JHSPH IRB to be the lead monitor for the SEED 3 study, so all approvals will be granted through our IRB. The MD Project Coordinator (PC) will have access to the billing data for children via a working agreement with a KKI data programmer who will release the data to the coordinator when requested.

Ascertaining Probable ASD: The PC for MD SEED will initiate a data request with KKI. The data requests will be made at similar times as the data requests are made with the school source. The data programmer at KKI will provide the data to the MD SEED project coordinator via encrypted files. The SEED data manager will subset the clinic lists to children potentially eligible for SEED (based on ICD codes, birth year, and current zip code). The mothers of these remaining families will be sent SEED invitation materials and further screened for eligibility once a response is received and study staff have been able to reach them via telephone. Mothers of children with ASD code will be contacted and screened for eligibility. If they consent, they will be given the SCQ, but will remain in the ASD CASE group regardless of score since they have already been given an ASD diagnosis code. Mothers of children with a non-autism ICD codes will be contacted and screened for eligibility. If the child is eligible for participation and the mother consents, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through the clinical source will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the MD SEED staff via an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. For families who do not respond to the first mailing, a second invitation packet will be mailed 30 days later. If there is no response after that mailing, a third and final invitation packet will be mailed to them at the 4-month mark. If no response after 14 days, study staff at KKI will make up to 4 calls to the family at the phone numbers provided to attempt to reach the family and determine interest and eligibility. If there is no response after 4 attempts (once per week for 4 weeks), the family will be removed from the contact list, and listed as a passive refusal. After we receive the response card or online data information, study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

Screening Method: As mentioned above, we will conduct the screening via a telephone interview with the biological mother of the recruited child. If the mother is eligible, she will be consented to complete the SCQ, and if interested, she will enroll in the full study. If she is not eligible, or not interested in enrolling, staff will Appendix C Site Specific Ascertainment for SEED 3

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send her a \$10 incentive thanking her for her time, and her family will be removed from future contact lists. After we receive the response card or online data information, study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

Missouri

Background: In addition to school sources, clinical sources will be used to ascertain children for this study. These sources include 3 pediatric tertiary care centers and clinics that provide diagnostic or intervention services for children with developmental disabilities – Washington University School of Medicine – Department of Child and Adolescent Psychiatry (St. Louis), Thompson Center for Autism and Developmental Disabilities – University of Missouri (Columbia) and Children's Mercy Hospital (Kansas City). These clinical sources are located in the 3 largest population centers in the study area and their geographic distribution results in largely non-overlapping patient populations that cover the entire study area. Additionally, all three institutions have been designated Missouri Autism Centers of Excellence and the Thompson Center and Children's Mercy are the predominate diagnostic centers for ASD and DD in their respective regions.

Obtaining Approvals: A formal agreement and IRB approval will be obtained from each clinical source to obtain data and contact potential SEED participants.

Ascertaining Probable ASD: The Project Coordinators for MO SEED will initiate a data request with each clinical source (See Appendix E for the ICD codes that will be used in the query for GA SEED). The Data Request Coordinators at each clinical source will provide the data to the MO SEED project coordinators. The MO SEED data manager will subset the clinic lists to children potentially eligible for SEED (based on ICD codes and birth years). Before contacting families of potentially eligible children, the list of potential SEED participants will be linked to the Missouri Birth Certificate files. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the five-county GA SEED study area, will be removed as ineligible from the SEED invitation mailing list. The mothers of the remaining families will be sent SEED invitation materials and further screened for eligibility and autism at first contact. Children with an ICD code indicating a previous diagnosis of an Autism Spectrum Disorder: Mothers of children with ASD code will be contacted and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. Children with a non-Autism ICD Code: Mothers of children with a non-autism ICD codes will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through clinical sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by MO SEED staff through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential

participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

North Carolina

Background: In addition to Part C sources, clinical sources will be used to ascertain children for this study. These sources include area pediatric clinics and family practice care centers that provide diagnostic or intervention services for children with developmental disabilities – UNC Healthcare system and TEACCH Autism Centers. The clinical sources represent diverse socio-demographic subgroups of the population; they include facilities operating across the entire catchment area under the UNC Healthcare system umbrella with data available in a central warehouse and the TEACCH-operated Research Registry. Insurance status varies across these facilities.

Obtaining Approvals: A formal Data Use agreement will be made with the Carolina Data Warehouse for Health under the existing UNC Healthcare System privacy policy which allows access to PII for invitation into research studies by UNC academic departments conducting IRB-approved research. A formal agreement will be made with the Research Registry to invite potential participants meeting birth year/age and residence criteria. We currently have letters of support for the study from both of these entities but formal agreements cannot be made until study IRB approval is received.

Ascertaining Probable ASD: The Project Coordinator for NC-SEED will initiate a data request agreement with the data warehouse. The data requests will be submitted twice each year (see Appendix E. ICD DSM Code Spec ED Lists SEED 3 for codes to be provided to data warehouse programmer). Names, contact information including email, birth date, gender, ICD9/10 code for each individual, and date of last service for those in the birth cohort with residence in any catchment county who have any allowable ICD9 or ICD10 code (see Appendix E. ICD DSM Code Spec ED Lists SEED 3) will be requested. The Carolina Data Warehouse for Health (CDW-H) programmer will provide the data for the UNC Sheps Center Data Manager who maintains the SEED Invitation Tracking system. The CDW-H programmer will transfer data containing contact information and up to 12 associated ICD9/10 codes to a secure server at the UNC Sheps Center for Health Services Research. The Invitation Tracking System data manager will merge new data pulls into existing master table of potential contacts for use in the Invitation Tracking system built for use in inviting all NC-SEED source families. This version of the Invitation Tracking system will be used by NC SEED staff to invite clinical and birth record source families. Before contacting families of potentially eligible children, the Invitation Tracking system will allow selection of batches by IDC9/10 codes that INCLUDE codes indicating autism. The mothers of families will be sent a Preliminary Notice postcard alerting them to the arrival of a packet. One to two weeks after mailing Preliminary Notice, SEED invitation materials, including a source-specific cover letter informing families they are being contacted because they are patients of the UNC system, will be mailed to families. Invitation Packets will provide families with multiple options for indicating interest in the study, including contacting the study office directly, using a web form submitted to the study office, returning a postcard to the study office. One to two weeks after invitation materials are mailed, study staff will begin phone contact for those non-responders for whom phone numbers

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were provided. If no phone number was available or phone number(s) are found to be 'bad', subsequent mail and email contact attempts will be made (up to 6 attempts). We will trace individual families for whom provided contact information indicates "bad" contact information or produces no response. Some ineligibility may be determined during these contact attempts (e.g. packets that are returned to sender with forwarding outside of catchment, calls that uncover language barriers, child deceased, etc). These will be tracked by the Invitation Tracking system. *Children with an Autism ICD9/10 Code*: Mothers of children with an autism ICD code who indicate interest in hearing about the study will be screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. *Children with a non-Autism Exceptionality Code*: Mothers of children with a non-autism ICD code will be screened for eligibility. If the child is eligible for participation, the parent will receive the Social about them they will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through clinical sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the NC SEED study office through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 7 to 14 days, project staff will place follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or DD workflow group.

Wisconsin

Background: Ascertainment of potential children with ASD and other DDs will take place primarily at two sites, the Waisman Center located in Madison and the Marshfield Clinic in Marshfield, Wisconsin, based on multiple sources. We will seek to recruit approximately two thirds of these children from the Waisman Center's Clinical Translational Research Core's registries and clinics, and the remaining one third from the Marshfield Clinic's pediatric neurology and behavioral health clinics.

Obtaining Approvals: A formal agreement will be made with each clinical source to obtain data and contact potential SEED participants. The protocol will be submitted for approval to the UW-Madison Health Sciences IRB.

Ascertaining Probable ASD: The PCs located at the Waisman Center and the Marshfield Clinic will initiate a data request with each clinical source, respectively. The PCs will subset the clinic lists to children potentially eligible for SEED (based on ICD codes and birth years). Before contacting families of potentially eligible children, the list of potential SEED participants will be linked to the Wisconsin Birth Certificate files. Children without a link to the birth certificate and children with a link but with indication of maternal residence at birth outside the 20-county WI SEED study area, will be removed as ineligible from the SEED invitation mailing list. The mothers of the remaining families will be sent SEED invitation materials and further screened for eligibility and autism at first contact. Children with an ICD code indicating a previous diagnosis of an Autism Spectrum Disorder: Mothers of

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children with ASD code will be contacted and screened for eligibility. If the child is eligible for participation and the parent consents, the child will be placed in the potential ASD workflow group. *Children with a non-Autism ICD code*: Mothers of children with a non-autism ICD codes will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. Children screening positive will be placed in the potential ASD workflow group. Children screening negative on the SCQ will be placed in the DD workflow group.

Ascertaining Comparison Group: As described above, some children ascertained through clinical sources will be placed in the workflow for the DD comparison group.

Contacting Families: Potential study participants will be contacted by the UW Survey Center through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: Telephone contact with the mother will be attempted to screen for residential and child birth year eligibility. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or remain in the DD workflow group.

D. POP Ascertainment

Colorado

Background: Population control children will be identified by randomly sampling Colorado birth certificates for children who were potentially eligible based on birth date and maternal residence. CO SEED staff will prepare invitation packets, which will be mailed directly to sampled families by the Health Statistics Program (HSP) of the Colorado Department of Public Health (CDPHE). HSP staff will trace returned letters using Accurint®, a searchable database of public and proprietary information for residence searches.

Obtaining Approvals: CDPHE has provided a letter of support indicating its willingness to enter into a contract for the purpose of recruiting POP families.

Ascertaining POP and Probable ASD: Every month, HSP will randomly sample birth certificates of children born in the catchment area within the defined birth cohort. If the mother agrees and the child is eligible for participation the child will be screened for ASD.

Contacting Families: CDPHE will mail potential study participants an introductory letter on its own letterhead with an Invitation Packet (prepared by SEED staff) to each sampled family. Telephone follow-up will be implemented by CDPHE's Survey Research Program (SRP), housed in the same Health Statistics and Evaluation Branch as HSP. If the potential participant responds indicating interest, then the potential participant will receive

a screening phone call conducted member of the CDPHE's staff. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: Screening of families from the birth records group will be done by telephone by a CDPHE staff member. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or POP workflow group. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the POP workflow group

Tracking and Tracing: Approaches for tracing are described in Appendix D.

Georgia

Background: POP children will be selected from Georgia vital records. Georgia's vital records are maintained electronically within the Department of Public Health (DPH). The CDC, National Center on Birth Defects and Developmental Disabilities has developed a Memorandum of Understanding to access to the electronic birth certificate files for use on surveillance and research projects, including SEED. An estimated 50,000 children are born per year in the five-county metropolitan Atlanta area.

Obtaining Approvals: CDC will obtain a DPH sponsor and IRB approval from DPH.

Ascertaining POP and Probable ASD: Complete birth certificates will be provided to the CDC. Potential POP children will be randomly selected from Georgia state birth certificate files subset to all children born in the SEED 3 birth cohort years with maternal residence in the five-county study population area. The birth certificate files will be linked with Georgia death certificate files to remove any potential members who are deceased. The family's current residence will be determined by tracing procedures outlined in Appendix D and confirmed prior to enrollment. Mothers of sampled children will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the POP workflow group

Contacting Families: Potential study participants will be contacted by the Centers for Disease Control and Prevention (CDC) through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or POP workflow group.

Tracking and Tracing: Approaches for tracing are described in Appendix D.

Maryland

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Background: POP children will be selected from Maryland vital records. Maryland's vital records are maintained within the Department of Health and Mental Hygiene (DHMH).

Obtaining Approvals: MD SEED will obtain DHMH IRB approval before recruitment or enrollment of POP families can begin.

Ascertaining POP and Probable ASD: DHMH will run queries on their birth certificate databases to pull potentially eligible children for recruitment into the SEED 3 study. They will only pull children based on child's DOB and zip code at the time of birth listed on the birth record. These data will be housed in a database at the DHMH offices, which MD SEED study staff person will access when mailings are to be sent out. About 30 days before formal invitation packets are mailed to potentially eligible families, study staff will be sending out a "Coming Soon!" postcard, to enhance response rates of this group. MD SEED plans to mail invitation packets to new families one to two times per year

Contacting Families: As noted above, potential study participants will be sent a "coming soon" postcard prior to the invitation packet. They will then be sent an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. For families who do not respond to the first mailing, a second invitation packet will be mailed 30 days later. If there is no response after that mailing, a third and final invitation packet will be mailed to them at the 4-month mark. We are not able to contact non-responding families from the DHMH pool after the 3rd mailing is sent, so they will be removed from our contact database if they do not respond to the 3rd and final mailing. After we receive the response card or online data information, study staff will attempt to reach the family up to 8 times (once per week for 8 weeks), to complete the eligibility screening call. If after 8 attempts the family does not respond, they will be removed from our contact list and marked as a passive refusal in our tracking databases.

Screening Method: Mothers responding to the invitation will be contacted and screened for eligibility. We will conduct the screening via a telephone interview with the biological mother of the recruited child. If the mother is eligible, she will be consented to complete the SCQ, and if interested, she will enroll in the full study. If she is not eligible, or not interested in enrolling, staff will send her a \$10 incentive thanking her for her time, and her family will be removed from future contact lists. If the recruited child fails the SCQ, he/she will enter the CASE workflow. Otherwise, he/she will enter the POP workflow.

Tracking and Tracing: Approaches for tracing are described in Appendix D.

Missouri

Background: POP children will be selected from Missouri vital records. Missouri's vital records are maintained electronically within the Department of Health and Senior Services (DHSS), Division of Community and Public Health, Section of Epidemiology for Public Health Practice. Washington University in St. Louis has received a written commitment from DHSS to access the electronic birth certificate files for use on in the SEED project. An estimated 45,000 children are born per year in the MO SEED study area.

Obtaining Approvals: Washington University will obtain IRB and Application for Vital Records Data for Research Purposes approvals from DHSS.

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Ascertaining POP and Probable ASD: DHSS will provide selected elements from the birth certificate for all children born in SEED 3 – eligible birth years that meet the following criteria: 1) Mother's address at time of birth is within one of MO SEED's study area counties and 2) the child did not match to a record in the death certificate file. In addition to variables that will assist with contacting the family (child and mother's name, mother's address at birth, etc.) it will also contain child sex, maternal race/ethnicity, maternal age at birth, and maternal education. Potential POP children will be randomly selected from these birth certificate files. The family's current residence will be determined by tracing procedures outlined in Appendix D and confirmed prior to enrollment. Mothers of sampled children will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the POP workflow group

Contacting Families: Potential study participants will be contacted by MO SEED staff through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will receive a screening phone call from a member of the project staff. If there is no response from the potential participant within 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or POP workflow group.

Tracking and Tracing: Approaches for tracing are described in Appendix D.

North Carolina

Background: POP children will be selected from North Carolina's Vital Records. NC's Vital Records are maintained electronically within the Department of Health and Human Services. UNC has a formal agreement with the Vital Records office to obtain a random selection of 6000 births to use for inviting potential POP families, to submit annual datasets of non-POP enrollees for matching and provision of full birth record data, and for working with our Part C and clinical sources to perform matching on invitees to provide limited birth record data on unconsented individuals. An estimated 40,000 children are born per year in the fourteen-county central North Carolina area.

Obtaining Approvals: NC will finalize the agreement with the Vital Records office upon receipt of UNC IRB approval for the study.

Ascertaining POP and Probable ASD: Complete birth certificates will be provided to UNC for a random selection of 6000 births in the cohort years to mothers resident in the catchment area at the time of birth. The 6000 records will be prescreened by DHHS programmers to eliminate deaths in the first year of life. The family's current residence will be determined by tracing procedures outlined in Appendix D and confirmed prior to invitation. Mothers of sampled children will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the Social Communication Questionnaire (SCQ) to screen for ASD. If the

child is positive based on this screening tool they will be placed in the potential ASD workflow group. If the child screens negative on the SCQ, they will be placed in the POP workflow group

Contacting Families: Potential study participants will be contacted by the NC SEED office through an invitation packet (regular mail). If the potential participant responds indicating interest, then the potential participant will be screened via phone by a member of the project staff. If there is no response from the potential participant within 7 to 14 days, project staff will place a follow up telephone calls and/or emails depending on information available for the participant. If the potential participant responds indicating no interest, no additional follow-up contact will be made.

Screening Method: The families will be contacted by telephone. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or POP workflow group.

Tracking and Tracing: Approaches for tracing are described in Appendix D.

Wisconsin

Background: POP children will be selected from Wisconsin vital records. Wisconsin's vital records are maintained electronically within the Department of Health Services (DHS). The UW-Madison's Waisman Center WI SEED team has developed a Memorandum of Understanding to access to the electronic birth certificate files for use on SEED, and has agreed to provide access once IRB approval is obtained. An estimated 41,000 children are born per year in the 20-county Wisconsin study area.

Obtaining Approvals: Approval to access birth records in accordance with the WI SEED protocol has been obtained from the WI DHS. Research approval to use the birth records for the SEED 3 protocol will be obtained from the University of Wisconsin-Madison Health Sciences IRB.

Ascertaining POP and Probable ASD: Program staff at DHS will select a random sample of births from each study birth year (2014-2017) from the 20-county Wisconsin SEED catchment area, following the SEED 3 protocol. The birth certificate files will be linked with Wisconsin death certificate files to remove any potential members who are known to have died. The family's current residence will be determined by tracing procedures outlined in the SEED 3 protocol and confirmed prior to enrollment. Mothers of sampled children will be contacted and screened for eligibility. If the child is eligible for participation, the parent will receive the SCQ to screen for ASD. Children screening positive based on this screening tool will be placed in the potential ASD workflow group. Those screening negative on the SCQ will be placed in the POP workflow group.

Contacting Families: Potential study participants will be contacted by the UW Survey Center through an invitation packet sent by regular mail. If the potential participant responds indicating interest, then the Survey Center will contact the potential participant by telephone to screen for eligibility. If there is no mailed response from the potential participant within 14 days of the invitation mailing, the UW Survey Center will place up to 9 follow up telephone calls to contact the potential participant. If email contact information is available, the project coordinator will attempt contact by email. If the potential participant responds indicating no interest, no additional follow-up contact will be made. If a child of a mother interested in participating in the study is eligible for participation, the parent will receive the SCQ to screen for ASD. Children screening positive will be placed in

the potential ASD workflow group. Those screening negative on the SCQ will be placed in the POP workflow group. Potential study participants will be contacted by the WI SEED team.

Screening Method: Telephone contact with the mother will be attempted to screen for residential and child birth year eligibility. If the child meets the eligibility criteria and the family provides verbal consent to participate, then the SCQ will be administered to determine whether the child is eligible to be assigned to the ASD workflow group or remain in the POP workflow group.

Tracking and Tracing: Approaches for tracing are described in Appendix D.