

Appendix Z. Detailed Breakdown of Participant Burden Hours

We estimate that we will be able to successfully trace and send a recruitment letter to a 2,458 potential participants during the remainder of the study implementation period (Table A.12.A). Potential participants are identified through schools and clinics that serve children with developmental problems and through state birth certificate registries. After the introductory letters are sent, sites conduct an invitation phone call with any potential study participant who responds indicating interest in the study or, when possible, with potential participants who have not returned the invitation response card. This phone call includes an eligibility screen and autism screen as well as an introduction to the study and a verbal consent for the study. We estimate that 1,008 (41%) participants will return a response card indicating interest and be called or be contacted by phone and be screened for the study (Table A.12.B).

Of the potential participants who receive the invitation phone call, we estimate 423 (42%) potential participants will be eligible to participate, based on the criteria defined/described in Section B-1. This is the number of potential participants who will satisfy the autism screen and selection criteria for enrollment into one of 3 subject groups and who also agree to continue in the study. These 423 participants will be sent the enrollment packet.

The next step for the study participants will be to complete a telephone interview. We expect 402 of the participants will complete this interview (Table A.12.D).

The next steps are to complete two questionnaire packets (Table A.12.C). The participant will be given the option to complete these in person with study staff, over the telephone, or as a self-

administered packet. We expect 347 participants will complete these packets.

The final step of the study will be to complete a clinical visit, including a child development exam, parent interviews, biosampling, and dysmorphology exam. We expect 76% (322) of all participants to complete the components of the clinical visit. The burden for cases (5 hours, 50 minutes) is longer than the burden for the NIC and Subcohort groups (2 hours, 5 minutes). See Tables A.12.F-J.

Table A.12.A. Burden Hours and Cost for Respondents: Mailed Invitation Packet

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Response Card (M)	2,458	1	10/60

We expect to mail the Invitation Packet (Appendix M), which contains the Introductory Letter, Study Brochure, and response card, to 2,458 people and we expect 1,008 people to respond or accept a follow-up contact.

Additional Supplementary Documents

- Invitation Letter (M.1)
- Study Brochure (M.2)
- Study Poster (M)

Table A.12.B. Burden Hours and Cost for Respondents: Invitation Telephone Call

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Social Communication Questionnaire (J)	1,008	1	10/60
Invitation Phone Call (N)	1,008	1	20/60

Table A.12.C. Burden Hours and Cost for Respondents: Questionnaire Packets

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Self-Administered Consent (E3.1 or E3.2)	347	1	10/60
HIPAA Release forms	347	1	15/60
Autoimmune Disease Survey (E.9)	347	1	20/60
Carey Temperament Scales (E.10)	347	1	10/60
Child Behavior Checklist (E.11)	347	1	15/60
Survey of Gastrointestinal Function (E.12) see next page	347	1	10/60
Maternal Medical History (E.13)	347	1	10/60
Paternal Medical History (E.14)	347	1	10/60
Paternal Occupational Questionnaire (E.15)	347	1	10/60
Child's Sleep Habits Questionnaire (E.16)	347	1	10/60
Social Responsiveness Scale (Adult & Child versions) (E.17)	347	1	45/60
3-Day Diet Diary (H.1)	347	1	20/60
7-Day Stool Diary (H.2)	347	1	20/60

Additional Supplementary Documents

- Cover letter (E.1)
- Cover Sheet (E.2)
- Clinic Visit Prep Guide (E.4)
- Caregiver Interview Prep Guide (E.5)
- Glossary of Medical Terms (E.6)
- Rights of Research Subjects Fact Sheet (E.8)
- Checklist of Questionnaire Packets (E.23)

Table A.12.D. Burden Hours and Cost for Respondents: Caregiver Interview

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Telephone Script (C.1)	402	1	30/60
Primary Caregiver	402	1	1.0

Interview (C.2)			
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Table A.12.E. Burden Hours and Cost for Respondents: Follow-Up Telephone Calls

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Follow-Up Phone Calls (O.1)	347	3	20/60

Table A.12.F. Burden Hours and Cost for Respondents: Biosamples (cheek swab and blood)

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Biosample Informed Consent (E.20)	1,041	1	20/60
Cheek Swab Sample Record Sheet (E.21)	1,041	1	20/60
Blood Draw Information Form (R.2)	966	1	15/60

We expect 1,041 index children and their parents (or 347 families) to provide a cheek swab sample. We expect 966 index children and their parents (or 322 families) to provide a blood sample.

Additional Supplementary Documents

- Frequently Asked Questions on Biosampling (E.7)
- How to Collect Cheek Cell Samples (E.19)
- Summary of Biosample Shipping, Processing, and Storage (R.1)

Table A.12.G. Burden Hours and Cost for Respondents: Clinic Visit – Control Children

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Mullen Scales of Early Learning (G.2)	214	1	45/60
Dysmorphology Exam Data Collection Form (P)	214	1	30/60

Additional Supplementary Documents

- Dysmorphology Exam Protocol (P)

Table A.12.H. Burden Hours and Cost for Respondents: Clinic Visit – Control Parent

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Vineland Adaptive Behavior Scales (F.4)	80	1	45/60
Written Informed Consent Document	214	1	10/60

The Vineland is administered to parents of subcohort and NIC children who score less than 1.5 standard deviations

below the mean on the Mullen. This outcome is expected to be extremely rare, but if it occurs, the Vineland will be administered as a follow-up telephone interview.

Additional Supplementary Documents

- Administration of the Vineland in the Subcohort Telephone Script (Q)

Table A.12.I. Burden Hours and Cost for Respondents: Clinic Visit – Case Child

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
ADOS (G.1)	107	1	40/60
Mullen Scales of Early Learning (G.2) see next page	107	1	45/60
Dysmorphology Exam Data Collection Form (P)	107	1	15/60

Additional Supplementary Documents

- Dysmorphology Exam Protocol (P)

Table A.12.J. Burden Hours and Cost for Respondents: Clinic Visit – Case Parent

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
ADI-R (F.1)	107	1	2.0
Early Development Questionnaire (F.2)	107	1	20/60
Services and Treatments Interview (F.3)	107	1	10/60
Vineland Adaptive Behavior Scales (F.4)	107	1	45/60
Written Informed Consent Document	107	1	10/60

Table A.12.K. Burden Hours and Cost for Respondents: Medical Record Abstraction

	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Medical Record Request Script and Fax Letter (S.1)	347	5	3/60

Additional Supplementary Documents

- Prenatal Chart Abstraction Form (S.2)
- Labor & Delivery Chart Abstraction Form (S.3)
- Neonatal Medical Record Abstraction Form (S.4)
- Pediatric Chart Abstraction form (S.5)

Supplementary Documents to the Supporting Statement

- Authorizing Legislation and Other Relevant Laws (A)
- 60 Day Federal Registry Notice (C.1)

- Public Comment Received (C.2)
- Data Flow Diagram (D.1)
- Data Collection Instruments Summary Table (D.3)
- Research Domains by Data Collection Activity (D.4)
- CDC IRB Approval Letter (I)
- Case, Comparison, and Subcohort Ascertainment Methodology (K)
- ICD-9 Codes/Part B School Eligibility Criteria (L)
- Study Hypotheses and Data Collection Tools (T)
- Data Sharing Approval Process (U)

Total (Annualized):

4,948 hours

\$92,132