DATA COLLECTION FLOW OUTLINE

These data collection steps begin following case ascertainment procedures. The outline reflects the points of contact with participants. Completion time for each instrument is indicated in minutes (m). Totals for a component indicated in hours and minutes (h.m).

Abbreviations:
CASE - ASD Case Group,
NIC - Neurodevelopmentally Impaired Comparison Group
SUB - Randomly sampled population Comparison Group

Participant Identification
Before intro letter is sent, sites will collaborate with sources to identify individuals to contact and invite for participation. CASE/NIC will be screened by record review at one site (CA).

1. **Introductory letter** - to prospective participants in all groups – sent from the identifying source or from the study center. Potential subcohort members at one site (CA) will skip this step and begin with the invitation phone call.
    1. Intro letter & brochure to describe study
    2. Site specific brochure and fact sheet.
    3. Sealed response card to return indicating interest in participation (positive response is required for some sites to continue).
    4. Two weeks will be allowed for postcard to be returned before continuing protocol. A second mailing (and 2 week wait) may be necessary for some sites before proceeding. One site (CA) will wait 3 weeks for the response card to be returned before proceeding with the invitation phone call.
    5. Incentive (value of approximately $1.00)

2. **Invitation Phone Call/Screener (phone: 20m)**
    1. Overall verbal consent (for all components) – agree to participate/be called again.
    2. Eligibility screen & collection of contact information for all respondents (10m).
    3. SCQ Screen (10m).
    4. Inform participant that Enrollment Packet is coming, that they should complete the instruments in the packet, and that they will be contacted again in one week to schedule a home/clinic visit and to review the material in the enrollment packet.

3. **Enrollment Packet (mail)** Packet mailed to participant upon acceptance of invitation. Instructions indicate subjects should read the Yellow folder, complete the Green folder, and the Blue packet. They will be instructed to return packet by mail or have available for the first in-person visit (in home or clinic). The letter will indicate that they will be contacted in one week to review, answer questions and schedule remaining data collection. Because of variability in geographic dispersion among sites and variability in participants' preferences, methods for collecting enrollment packet materials may vary.

    a. Yellow folder - Instruction letter & Information packet- "Things you keep." Material to be retained by the participant including: information/letter, Overall Consent Form, Study bill of rights, study flow sheet, prep sheets for data collection, social story & $10 incentive.

b. Green Folder – Self Administered Questionnaires – "Forms to return." Data collection components completed by participant at home, which will be collected by home visit staff, or returned by mail. (2h 20m)

1. Paternal Medical History (10)
2. Maternal Medical History (10)
3. CBCL (15)
4. Carey Temperment Scale (10)
5. Sleep Habits (10)
6. Social Responsiveness Scale (45)
7. Autoimmune worksheet (20)
8. GI Questionnaire (10)
9. Paternal Occupational Exposure Questionnaire (5)
10. HIPAA authorization/Medical Record Release forms

c. Blue Folder– "Cheek Swab Kit" –Complete and return by mail or with aid of staff during home/clinic visit. (20m)

1. Overall study consent
2. Buccal kits (instructions, written consent form, & complete) (20m)

4. Follow-Up Phone Call - (phone) -1week after Enrollment packet mailed.

1. Answer initial questions about the study.
2. Review overall consent.
3. Answer questions about self-administered Q and encourage return.
4. Schedule remaining components, attempting to schedule the initial visit first to consent individual in person, and all other components according as convenient. ***If in person visit is not scheduled, additional follow-up phone calls will occur to encourage mail return of self-administered instruments or to schedule a time to pick them up at the home.*

5. **Caregiver Interview – (phone: 60 m)** Etiologic Interview: prenatal-child health & lifestyle history. Supplemental questions will be added to the Interview if medical record release has not been obtained at the time of the interview.

This is where protocol begins to change by group

6. Initial Clinical Visit – (clinic or home: 30m++). Scheduled as soon as possible in order to facilitate in-person consent and enhance the personal rapport. Visit content will vary for Subcohort/NIC vs. Case groups and by parent preference. *****Scheduling options below.

1. Review protocol & sign informed consent (10m)
2. Obtain signed medical record release & self administered questionnaires (10m)
3. Review completed instruments (10m)

7. Child Clinical - (In person at clinical or home: Case 5 hours 10 min, Subcohort 1 hour, 20 min))

Administered to Child (Clinic or Home) Case- 2 hours, NIC/Subcohort 1hour, 20 min):

1. Mullen * (45)
2. Dysmorphology Exam (15)
3. Biosamples (blood, hair, buccal if needed) (20)

4. ADOS (Case only)** (40)

**Vineland will be administered to Subcohort and NIC members who score <1.5 standard deviation below average on the Mullen. This outcome is expected to be rare; but if it occurs, the Vineland will be administered by phone AFTER the administration of the Mullen.*

***The ADOS will be administered to Subcohort members who receive a positive score on the SCQ.*

Parent Interviews- Clinic visit, home, or telephone. Case group only. 3 hours, 10 min.

1. ADI-R (120)
2. Vineland (45)
3. Early Development Questionnaire (20)
4. Services and Treatments Questionnaire (5)

8. Parent Clinical - (In person at clinical or home: 15 m)

1. Biosamples (blood, buccal if needed) (15)

9. Self Administered Packet 2 (1 hour)

Forms will be provided and explained during the clinical visit.

1. 3 day diet diary (20)
2. 7 day stool diary (40)

10. Medical Record Review – Begins as soon as signed MR release is obtained.

11. Possible Follow-Up Visit - IF participant does not complete any clinical in person components and fails to return self-administered instruments by mail, we will call to encourage mail return of self-administered questionnaires or schedule a follow-up visit to their home to collect these components.