**Initial Clinic Visit (Clinic or Home)**

1. Review & sign written informed consent (10)
2. Obtain signed medical records release forms (10)
3. Review completed questionnaires & assist with buccal collection if necessary
4. Complete other data collection components if scheduled

**Tracing Procedures**

- Invitation Letter
  1. Letter
  2. Study brochure
  3. Response card
  4. $1.00 incentive (beach ball, magnet, etc)

- Response Card Received

- Invitation Phone Call/Screener (may consist of 2 separate phone calls)
  1. Introduction to study
  2. Eligibility screen (10)
  3. Verbal consent for the SCQ
  4. SCQ (10)
  5. Overall verbal consent to participate in the study
  6. Inform participant of enrollment packet

- Follow Up Call
  1. Q & A on the study
  2. Schedule Caregiver Interview.
  3. Complete Pregnancy Reference Form.
  4. Explain Questionnaire Packets.
  5. Schedule First Questionnaire Packet.

- Caregiver Interview**
  Verbal consent for interview obtained by interviewer

- Enrollment Packet (mailed)
  1. Introductory Letter
  2. Copy of consent to review
  3. Study bill of rights
  4. Study flow sheet
  5. Prep Guides for data collection
  6. Picture Story
  7. Questionnaire Checklist
  8. HIPAA checklist & medical records release forms
  9. Buccal Swab Kit
     a. Buccal Instructions
     b. Buccal Consent Forms
     c. Buccal Collection Materials

- Follow Up Call
  1. Schedule Clinic Visits
  2. Schedule Second Questionnaire Packet

- Questionnaire Packet I (interview or self-administered)
  1. Paternal Medical Hx (10)
  2. Maternal Medical Hx (10)
  3. Autoimmune History Worksheet (20)
  4. GI questionnaire (10)
  5. Paternal Occupational Exposure Questionnaire (5)
  6. Services & Treatments Q (Cases Only) (5)
  7. Early Development Questionnaire (Cases Only) (20)

- Subcohort/NIC Child Clinic (Clinic or Home)
  1. Mullen * (45)
  2. Dysmorphology exam (15)
  3. Biosamples (20)
     - blood, hair (buccal if needed)

- Third Questionnaire Packet
  1. 3 day diet diary (20)
  2. 7 day stool diary (40)

- Parent Biosamples (Clinic or Home)
  1. Blood (Buccal if needed) (15)

- Questionnaire Packet II (interview or self-administered)
  1. CBCL (15)
  2. Carey Temperament Scale (10)
  3. Sleep Habits Questionnaire (10)
  4. Child Social Responsiveness Scale (15)
  5. Parent Social Responsiveness Scale (30)

- Follow Up Call
  1. Answer questions about clinic visits.
  2. Remind about clinic visits.

**CLINIC VISIT**

- Initial Clinic Visit (Clinic or Home)
  1. Review & signed written informed consent (10)
  2. Obtain signed medical records release forms (10)
  3. Review completed questionnaires & assist with buccal collection if necessary
  4. Complete other data collection components if scheduled

- Enrollment Packet (mailed)
  1. Introductory Letter
  2. Copy of consent to review
  3. Study bill of rights
  4. Study flow sheet
  5. Prep Guides for data collection
  6. Picture Story
  7. Questionnaire Checklist
  8. HIPAA checklist & medical records release forms
  9. Buccal Swab Kit
     a. Buccal Instructions
     b. Buccal Consent Forms
     c. Buccal Collection Materials

- Follow Up Call
  1. Q & A on the study
  2. Schedule Caregiver Interview.
  3. Complete Pregnancy Reference Form.
  4. Explain Questionnaire Packets.
  5. Schedule First Questionnaire Packet.

- Caregiver Interview**
  Verbal consent for interview obtained by interviewer

- Enrollment Packet (mailed)
  1. Introductory Letter
  2. Copy of consent to review
  3. Study bill of rights
  4. Study flow sheet
  5. Prep Guides for data collection
  6. Picture Story
  7. Questionnaire Checklist
  8. HIPAA checklist & medical records release forms
  9. Buccal Swab Kit
     a. Buccal Instructions
     b. Buccal Consent Forms
     c. Buccal Collection Materials

- Follow Up Call
  1. Schedule Clinic Visits
  2. Schedule Second Questionnaire Packet

- Questionnaire Packet I (interview or self-administered)
  1. Paternal Medical Hx (10)
  2. Maternal Medical Hx (10)
  3. Autoimmune History Worksheet (20)
  4. GI questionnaire (10)
  5. Paternal Occupational Exposure Questionnaire (5)
  6. Services & Treatments Q (Cases Only) (5)
  7. Early Development Questionnaire (Cases Only) (20)

- Subcohort/NIC Child Clinic (Clinic or Home)
  1. Mullen * (45)
  2. Dysmorphology exam (15)
  3. Biosamples (20)
     - blood, hair (buccal if needed)

- Third Questionnaire Packet
  1. 3 day diet diary (20)
  2. 7 day stool diary (40)

- Parent Biosamples (Clinic or Home)
  1. Blood (Buccal if needed) (15)

- Questionnaire Packet II (interview or self-administered)
  1. CBCL (15)
  2. Carey Temperament Scale (10)
  3. Sleep Habits Questionnaire (10)
  4. Child Social Responsiveness Scale (15)
  5. Parent Social Responsiveness Scale (30)

- Follow Up Call
  1. Answer questions about clinic visits.
  2. Remind about clinic visits.

**Subcohort/NIC Child Clinic (Clinic or Home)**

- 1. Mullen * (45)
- 2. Dysmorphology exam (15)
- 3. Biosamples (20)
  - blood, hair (buccal if needed)
- 4. ADOS (40)**

**Case Child Clinic**

- Administered to Child (Clinic or Home): (Subcohort/NIC members who score <1.5 std. dev. Below average on the Mullen. This outcome is expected to be rare, but if it occurs, the vineland will be administered AFTER the mullen as a follow up telephone call.)

- Administered to Parent (clinic, home, or telephone)
  1. ADI-R (120)
  2. Vineland (45) *

**Follow Up Call**

- Schedule Clinic Visits
- Schedule Second Questionnaire Packet

**Follow Up Call**

- Q & A on the study
- Schedule Caregiver Interview.
- Complete Pregnancy Reference Form.
- Explain Questionnaire Packets.
- Schedule First Questionnaire Packet.

**Parent Biosamples (Clinic or Home)**

- Blood (Buccal if needed) (15)

**Third Questionnaire Packet**

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

**Key**

<table>
<thead>
<tr>
<th>TOTAL TIME:</th>
</tr>
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<tbody>
<tr>
<td>CASE: 11 hours</td>
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<tr>
<td>NIC/Subcohort: 7 hours</td>
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</tbody>
</table>

**Figure 9. Study Flow Diagram**

- * Vineland will be administered to subcohort and NIC members who score <1.5 std. dev. Below average on the Mullen. This outcome is expected to be rare, but if it occurs, the vineland will be administered AFTER the mullen as a follow up telephone call.

- **ADOS will be administered to subcohort children who score positively on SCQ**