Screening & Study Visits

IMPAAACT 2013
RSV D46/NS2/N/ΔM2-2-HINDIII

IMPAAACT 2013
INVESTIGATOR’S MEETING
MARCH 10, 2017
RECRUITMENT

- Consent
- Screening
- Enrollment
- Vaccination
- Study Visit
- RSV Seasonal Surveillance
Multi-site study

Outpatient clinics

Domestic IMPAACT sites selected

Sites will create IRB approved recruitment materials
RSV Vaccine Study

RSV (Respiratory Syncytial Virus)
- Most common cause of viral pneumonia and bronchiolitis in children
- Contagious virus that can be spread by coughing or sneezing, or contact with nasal or oral secretions
- Occurs in late Fall, Winter and early Spring
- Researchers are working to develop RSV vaccines

WE NEED YOUR HELP!

- Physicians at Johns Hopkins University are evaluating a Nose Drop vaccine developed by scientists at the National Institutes of Health.
- Participants must be 6 – 59 months of age & in good health.

Ask your pediatrician for more information on RSV vaccine studies

Contact JOHNS HOPKINS UNIVERSITY - Center for Immunization Research
(410) 502-3333 - or - (301) 490-3767

PRINCIPAL INVESTIGATOR: Ruth A. Karron, M.D.

This study is voluntary. The nose drop vaccine is given at no cost to you. You will receive compensation for participation.
RECRUITMENT STRATEGY

- Face to face recruitment
  - IMPAACT clinic
  - Local pediatric practices

- Previous participants

- Referrals

- Posting flyers

- Employees (depending on local IRB procedures)
2015 JHU PEDIATRIC RSV STUDY RECRUITMENT

- **Families Approached**: 1045
- **Potential Interest**: 891
- **Screened**: 21
- **Inoculated**: 14

1.1 approached : 1 interested
42 potential interest : 1 screened
1.5 screened : 1 inoculated
75 approached : 1 inoculated

Source: JHU, Center for Immunization Research, 2015 Pediatric RSV Recruitment
CONSENTING

Recruitment  Screening  Enrollment  Vaccination  Study Visit  RSV Seasonal Surveillance
Parental consenting requirements at each site will depend on the IRB/IBC risk determination (IMPAACT2013, Protocol, V1.0, Section 12.2, 14 February 2017)

Informed consent process

- Detailed discussion
- Assessment of understanding
- Potential risks, benefits, alternatives
- Emphasize unproven efficacy
- Storage of specimen for future testing but if declined no impact on other aspects of the study or care
HANDBOOKS

- PEDIATRIC COMPREHENSION ASSESSMENT
- FAQ

Source: IMPAACT2011, MOP, Appendix IV, v0.4, 21Apr2016
SCREENING PROCESS

ACUTE AND POST-ACUTE PHASE

Nasal wash
Clinical assessment: inoculation & 8 visits
Acute Phase

Blood and nasal wash collection

Scheduled In-person Visit

RSV Season

Screening/blood collection within 42 days of enrollment
Nasal inoculation

day 0 3 5 7 10 12 14 17 28 29 56

Post- Acute Phase
## ACUTE PHASE

### Screening

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<th>In person visit</th>
<th>Non-visit contact</th>
<th>Informed consent</th>
<th>History</th>
<th>Interim History</th>
<th>Physical exam (full)</th>
<th>Clinical assessment (focused PE)</th>
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<th>Blood for: cellular immune assay (viable PBMCs)</th>
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### POST-ACUTE PHASE

- Day 56
- Day 57
- Day 58
- Day 59
- Day 60
- Illness Visit
- Early DC

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Source: IMPAACT2013, Protocol, Appendix II, V1.0, 14February2017
Within 42 days of planned inoculation
- Last routine immunizations
- Upcoming routine immunizations or medical referrals
- Household circumstance
- Childcare circumstance
- Travel
- Current medication

Source: IMPAACT2013, Protocol, Section 6.1, V1.0, 14February2017
SCREENING PROCESS
OVERVIEW

Medical history intake, Medical record review, Physical exam, Obtain a serum
↓
Process & Ship lab specimens per IMPAACT2013 Lab Processing Chart
↓
CIR Lab will email results to Site Study Coordinator and the Clinical Trial Specialist
SCREENING PROCESS
PHYSICAL EXAM

- Temperature, heart rate, respiratory rate
- Weight & length
- HEENT
- Lungs
- Heart
- Abdomen
- Musculoskeletal
- Skin
- Age appropriate neurological

Source: IMPAACT2013, Protocol, Section 6.1, V1.0, 14February2017
## Screening Supplies

### Venous Blood Draw

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<th>Distributor</th>
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<td>LMX 4% topical anesthetic cream</td>
<td>15 gram</td>
<td></td>
<td>LMX</td>
<td>Drugstore.com</td>
<td></td>
<td><a href="http://www.drugstore.com">www.drugstore.com</a> 888-548-0900</td>
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<td>Sorbaview Shield dressing, small</td>
<td>SV254</td>
<td>50/pack</td>
<td>Sorbaview Shield</td>
<td>Centurion Medical Products</td>
<td><a href="http://www.centurionmp.com">www.centurionmp.com</a> 800-248-4058</td>
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<td>Gloves, latex free</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reclosable bag 8&quot;x10&quot;</td>
<td>1</td>
<td>S-1700</td>
<td>1000/carton</td>
<td>Uline</td>
<td>Uline</td>
<td><a href="http://www.uiline.com">www.uiline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Kimtech 12&quot;x12&quot; task wipes</td>
<td>1</td>
<td>S-13045</td>
<td>100/pack</td>
<td>Kimtech Science</td>
<td>Uline</td>
<td><a href="http://www.uiline.com">www.uiline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Reclosable bag 4&quot;x6&quot;</td>
<td>1</td>
<td>S-1294</td>
<td>1000/carton</td>
<td>Uline</td>
<td>Uline</td>
<td><a href="http://www.uiline.com">www.uiline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Tourniquet, latex free</td>
<td>1</td>
<td>71369</td>
<td>25/roll</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>Alcohol wipes, 2 ply Large</td>
<td>4</td>
<td>5110</td>
<td>200/box</td>
<td>Covidien Webcol</td>
<td>Express Medical Supply</td>
<td><a href="http://www.EXMED.net">www.EXMED.net</a> 800-633-2139</td>
</tr>
<tr>
<td>Syringe 3mL</td>
<td>1</td>
<td>309385</td>
<td>100/pack</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>Syringe 5mL</td>
<td>1</td>
<td>309647</td>
<td>100 pack</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>BD vacutainer safety-lok blood collection 23g butterfly w12&quot; tubing (without luer adapter)</td>
<td>1</td>
<td>02-664-7: BD 367297</td>
<td>50/pack</td>
<td>BD</td>
<td>Fisher Scientific</td>
<td><a href="http://www.fishersci.com">www.fishersci.com</a> 800-640-0640</td>
</tr>
<tr>
<td>Band-Aid (strip 3/4x3) flexible fabric</td>
<td>1</td>
<td>J00434</td>
<td>100/bag</td>
<td>Band-Aid</td>
<td>Atlantic Medical Supply</td>
<td><a href="http://www.atlanticmedsupply.com">www.atlanticmedsupply.com</a></td>
</tr>
<tr>
<td>Tube, red top (no additive) or SST 4mL vacutainer</td>
<td>2</td>
<td>367812</td>
<td>100/pack</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>2.0 ml cryovial tubes</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>See LPC</td>
<td></td>
</tr>
<tr>
<td>Container, sharps 1qt portable</td>
<td>500006-469</td>
<td>Each</td>
<td>Impact</td>
<td>VWR</td>
<td></td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>Finger/Heel Stick</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lancet, incision devices</td>
<td>1 or 2</td>
<td>TF50I</td>
<td>50/pack</td>
<td>Tenderfoot</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
</tbody>
</table>

Source: IMPAACT2013, MOP, Appendix II, V0.2, 4February2017
### Section 3 (SCREENING, ACUTE, AND POST-ACUTE): Specimen Processing & Shipping Instructions

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF # DMC Test Code</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV Ab)</td>
<td>NON or SST</td>
<td>Must be collected prior to vaccine administration.</td>
<td>CRF: F3008 DMC Test Code: ABRSVQT</td>
<td>Allow to clot for at least 30 mins. Spin blood at 1000xg for 10 mins; remove serum and save at least 3 X 0.50 mL aliquots and freeze at -80°C.</td>
<td>Screen-Ship ONE aliquot real time M-Th to JHU. Retain the remaining aliquots on site. They will be batched shipped at the end of study or when requested by team.</td>
</tr>
</tbody>
</table>

- Ship samples on dry ice priority overnight, **M-Th only**
## SCREENING
### PBMC AND PLASMA STORAGE

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF #</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBMC and Plasma Storage</td>
<td>EDTA</td>
<td>Invert tubes 8-10 times to ensure mixing of anticoagulant and Blood</td>
<td>F3008</td>
<td>Plasma: Centrifuge blood at 400xg for 10 minutes. Transfer plasma to a new centrifuge tube and centrifuge @ 800xg for 10 minutes. Freeze 3 x 0.50 mL aliquots. Store at -70°C or lower. LDMS Code BLD/EDT/PL2</td>
<td>Send to local processing lab All samples will be stored and batch shipped. See detailed shipping instructions at the end of the LPC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Process samples within 8 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PBMC  
See Cross-Network PBMC Processing SOP.  
Store viable PBMCs in 2 aliquots of 3-5 x 10^6 per vial  
Record cell # in LDMS.  
Store at -150°C or in LIQ N2 vapor phase  
LDMS Code: BLD/EDT/CEL/DMS

---

Source: IMPAACT2011, LPC, Appendix III Section 3, v0.4, 20Apr2016
## Section 4 APPENDIX II (SCREENING, ACUTE AND POST-ACUTE PHASE):

### SCREEN: (no more than 42 days prior to enrollment) (Day 0).

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV AB)</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3 X 0.50 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NOTE: One screening serum aliquot must be shipped to JHU real time.</td>
</tr>
<tr>
<td>Blood for: cellular immune assay (viable PBMC) and Plasma</td>
<td>3 ml EDTA</td>
<td>F3008</td>
<td>PBMC: Save 2 aliquots of 3-5 million viable PBMC</td>
<td>BLD/EDT/CEL</td>
<td>Store at -150 °C or in LIQ N2 vapor phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Plasma: Save 3 x 0.50 ml aliquots</td>
<td>BLD/EDT/PL2</td>
<td>Store at -80 °C until end of study</td>
</tr>
</tbody>
</table>

Visit Code: 0 Scr

Source: IMPAACT2011 ,LPC, Appendix II Section 4, v0.4, 20Apr2016
Ship samples to Johns Hopkins University (JHU) **only on** Monday, Tuesday, Wednesday, Thursday

Friday preceding the screening by 2pm EST notify by email
- Bhavin Thumar, Kim Wanionek, and Jen Oliva CIRLab@jhu.edu

Results will be emailed to CTS and IMPAACT Site Coordinator

---

Source: IMPAACT2013, MOP, Section 3.3, V0.2, 24February2017
SCREENING
EXPECTED RESULTS

Samples shipped

Mondays or Tuesdays
Results the following Monday

Wednesday or Thursdays
Results the following Tuesday

Source: IMPAACT2013, MOP, Section 3.3, V0.2, 24February2017
DAIDS policy for Essential Documents

A screened subject is defined as having signed the study consent

- Screening and enrollment logs
  - Document all subjects that were screened
  - Including screening failures
- Logs may be separate or combined
- Maintained in the Investigator study files

Source: IMPAACT2013, MOP, Section 3.2.1, V0.2, 24February2017
Logs should include the following information:

- Initials of the subject
- Participant ID number (PID)
- Date screened
- Race
- Gender
- Status of screening (e.g., pass/fail)
- Screen failures, indicate ineligibility reason
- Date randomized
- If not randomized, indicate reason
ASSIGNMENT OF PARTICIPANT ID NUMBERS (PID)

- PID is assigned at the site
  - List that is generated by the DMC and sent to sites

- If a subject has been on another IMPAACT or ACTG (AIDS Clinical Trials Group) study, that PID is carried with them
  - New PID number would not be assigned

Source: IMPAACT2013, MOP, Section 3.2.2, V0.2, 24February2017
INOCULATION - DAY 0

- Recruitment
- Consenting
- Screening
- Inoculation
- Study Visit
- RSV Seasonal Surveillance
INOCULATION DAY – DAY 0

Blood and nasal wash collection
# Schedule of Events

## Day 0

<table>
<thead>
<tr>
<th>Source: IMPAACT2013, Protocol, Appendix II, V1.0, 14February2017</th>
</tr>
</thead>
</table>

| In person visit | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Non-visit contact | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Informed consent | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Physical exam (full) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Clinical assessment (focused PE) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Administer study product | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Blood for: Immunologic assays | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL | 5mL |
| Blood for: cellular immune assay (viable PBMCs) | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL | 3mL |
| Nasal wash for: RSV antibody | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Nasal wash for: viral detection & quantification | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Request adventitious agent assay | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Total blood volume | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL | 8mL |
## Inoculation Visit: Day 0 Supplies

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity per Kit</th>
<th>Item Number</th>
<th>Quantity Supplied</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stethoscope</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otoscope</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal wash kit</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporal thermometer</td>
<td>1</td>
<td>each</td>
<td></td>
<td>Exergen</td>
<td>Walmart</td>
<td><a href="http://www.walmart.com">www.walmart.com</a></td>
</tr>
<tr>
<td>Digital, flexible tip rectal thermometers</td>
<td>1</td>
<td>each</td>
<td></td>
<td>MABIS</td>
<td>Walmart</td>
<td><a href="http://www.walmart.com">www.walmart.com</a></td>
</tr>
<tr>
<td>Viral transport media</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.uline.com">www.uline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Reclosable bag 4”x6”</td>
<td>1</td>
<td>S-1294</td>
<td>1000/carton</td>
<td>Uline</td>
<td>Uline</td>
<td><a href="http://www.walmart.com">www.walmart.com</a> or <a href="http://www.target.com">www.target.com</a></td>
</tr>
<tr>
<td>Syringe, 3mL</td>
<td>1</td>
<td>309385</td>
<td>100/pack</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>2.0 ml cryovial tubes, virology</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.impaact2013.org">See LPC</a></td>
</tr>
<tr>
<td>2.0 ml hinged cryovial tubes, antibody</td>
<td>At least 3 and up to 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.impaact2013.org">See LPC</a></td>
</tr>
<tr>
<td>Infant’s Acetaminophen 160mg/5ml</td>
<td>1</td>
<td>each</td>
<td></td>
<td>Tylenol</td>
<td>Walmart or Target</td>
<td><a href="http://www.walmart.com">www.walmart.com</a> or <a href="http://www.target.com">www.target.com</a></td>
</tr>
<tr>
<td>Playmate Pal 7 qt. personal size cooler</td>
<td>1</td>
<td>34223058975</td>
<td>each</td>
<td>Igloo Products Corp</td>
<td>Walmart or Target</td>
<td><a href="http://www.walmart.com">www.walmart.com</a> or <a href="http://www.target.com">www.target.com</a></td>
</tr>
<tr>
<td>Dry Ice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature card</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schedule of visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study contact information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study product on wet ice with temperature monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.impaact2013.org">See LPC</a></td>
</tr>
<tr>
<td>CoolBox System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.impaact2013.org">See LPC</a></td>
</tr>
</tbody>
</table>

Source: IMPAACT2013, MOP, Appendix II, V0.2, 24February2017
# IMPAACT NON-STANDARD SUPPLIES

## Protocol-Required Non-Standard Reagents and Supplies

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Reagent or Supply</th>
<th>Manufacturer part #</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CoolBox 30 System</td>
<td>BCS-166</td>
<td></td>
</tr>
<tr>
<td>Nasal Wash</td>
<td>Viral Transport Media (VTM)</td>
<td>N/A</td>
<td>JHU see mop for ordering instructions</td>
</tr>
</tbody>
</table>
## Nasal Wash Kit Supplies

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity per Kit</th>
<th>Item Number</th>
<th>Quantity Supplied</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL sterile polypropylene tubes</td>
<td>2</td>
<td>430290</td>
<td>25/rack</td>
<td>Corning</td>
<td>Fisher Scientific</td>
<td><a href="http://www.fishersci.com">www.fishersci.com</a> 800-640-0640</td>
</tr>
<tr>
<td>Lactated Ringers 1000 mL for injection</td>
<td>40 mL</td>
<td>NDC#0409-7953-09</td>
<td>1000mL/bag</td>
<td>Hospira</td>
<td>JHH Central Supply</td>
<td>877-946-7747</td>
</tr>
<tr>
<td>Parafilm M sealing film</td>
<td>8&quot;</td>
<td>EW-06270-50</td>
<td>2&quot; x 250'/roll</td>
<td>Parafilm</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>Reclosable bag 8&quot;x10&quot;</td>
<td>1</td>
<td>S-1700</td>
<td>1000/carton</td>
<td>Uline</td>
<td>Uline</td>
<td><a href="http://www.uline.com">www.uline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>4 oz. sterile specimen container</td>
<td>1</td>
<td>16-320-730</td>
<td>100/case</td>
<td>Fisherbrand</td>
<td>Fisher Scientific</td>
<td><a href="http://www.fishersci.com">www.fishersci.com</a> 800-640-0640</td>
</tr>
<tr>
<td>1 oz. bulb syringe</td>
<td>1</td>
<td>7148</td>
<td>50/case</td>
<td>LSL Healthcare, Inc.</td>
<td>LSL Healthcare, Inc.</td>
<td><a href="mailto:customerPO@lslhealthcare.com">customerPO@lslhealthcare.com</a> 773-878-1100</td>
</tr>
<tr>
<td>Kimtech 12&quot;x12&quot; task wipes</td>
<td>1</td>
<td>S-13045</td>
<td>100/pack 5 pk/case</td>
<td>Kimtech Science</td>
<td>Uline</td>
<td><a href="http://www.uline.com">www.uline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Wooden tongue depressor, sterile</td>
<td>1</td>
<td>23-400-121</td>
<td>100/pk</td>
<td>Fisherbrand</td>
<td>Fisher Scientific</td>
<td><a href="http://www.fishersci.com">www.fishersci.com</a> 800-640-0640</td>
</tr>
<tr>
<td>Reclosable bag 4&quot;x6&quot;</td>
<td>1</td>
<td>S-1294</td>
<td>1000/carton</td>
<td>Uline</td>
<td>Uline</td>
<td><a href="http://www.uline.com">www.uline.com</a> 800-295-5510</td>
</tr>
<tr>
<td>Syringe 3mL</td>
<td>1</td>
<td>309385</td>
<td>100/pack</td>
<td>BD</td>
<td>VWR</td>
<td><a href="http://www.us.vwr.com">www.us.vwr.com</a> 800-932-5000</td>
</tr>
<tr>
<td>2.0 ml cryovial tubes virology</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>See LPC</td>
</tr>
<tr>
<td>Specimen labels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gloves, latex-free</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gowns</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masks</td>
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</tr>
<tr>
<td>Chux pads</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: IMPAACT2013, MOP, Appendix II, V0.2, 24February2017
INOCULATION VISIT - DAY 0

- April 1st – Oct 14th
- Randomization preferably day of inoculation
  - within 3 days of inoculation
  - Screening sample confirms infant is RSV seronegative
  - Infant meets all other inclusion/exclusion criteria
- > 3 day window contact protocol team via email: impaact.psrt2013@fstrf.org

- Confirm study consent signed and dated
- Confirm sample authorization consent obtained
- Confirm Inclusion/Exclusion eligibility

Source: IMPAACT2013, Protocol, Section 6.2, V1.0, 14February2017
Focused clinical assessment: Temperature, heart rate, respiratory rate, HEENT, lung, heart, lymph nodes
- Acute illness: Defer randomization
- Chronic illness. Examples of chronic illnesses that would not be considered exclusionary are as follows:
  - Mild Gastroesophageal Reflux Disease (GERD)
  - Iron deficiency anemia
  - Constipation
  - Other conditions should be reviewed with the protocol team
- Evaluate child’s growth
- Evaluate child’s medications

Rule of thumb: if you find that you will be entering a sign/symptom or diagnosis at baseline, reconsider the child’s eligibility.

Source: IMPAACT2013, Protocol, Section 6.2, V1.0, 14February2017
INOCULATION VISIT - DAY 0
PROCEDURES

- Obtain nasal wash for viral culture and antibody assays
  - prior to administering study product

- Administer study product
  - appx. 0.25 mL per nostril

- Maintain subject supine for 60 seconds

- Observe for 30 minutes after inoculation

- Provide parental/guardian teaching and supplies

- Provide study contact information

Source: IMPAACT2013, MOP, Section 5.9, V0.2, 24February2017
TEMPORAL TEMPERATURE MONITORING

- Provide temporal and rectal thermometers
  - Phillips Sensor Touch or similar temporal artery thermometer
  - The use of rectal thermometers should be minimized and used only to verify the elevated temporal readings

- The method of taking temperature readings should be documented

- Daily for Days 0-28 following inoculation

Source: IMPAACT2013, MOP, Section 2.2.1, V0.2, 24February2017
Daily for first 28 days

During this period, avoid acetaminophen (Tylenol) or ibuprofen (Motrin) unless he/she has a fever or pain
  - Take temperature prior to administering medication

Use temporal thermometer as directed by the manufacturer

Source: IMPAACT2013, MOP, Appendix I, V0.2, 24February2017
Take the temporal temperature, following manufacturer’s instructions, THREE times and write down the highest temperature on the card.

If 100.0°F or higher

Take a rectal temperature. Do this within 20 minutes.

If the rectal temperature is lower than 100.4°F
- No fever
  - Write the rectal temperature on the card

If the rectal temperature is 100.4°F or higher
- Fever
  - Contact study staff and write the rectal temperature on the card

Source: IMPAACT2013, MOP, Appendix I, V0.2, 24February2017
Instruct parent or caregiver to contact study nurse for the following:

- Trouble breathing
- Wheezing
- Runny nose
  - Not associated with crying or climate change
- Cough
  - 3 episodes within 15 minute period or
  - Awakens child from sleep and
  - Not associated with crying or feeding
- Any condition that concerns parent or caregiver
- Document medication
  - name
  - indication
  - dose
  - start and stop date
**TEMPERATURE CARD**

**Rectal Temperature**
1. Place probe cover thermometer, lubricate with K-Y Jelly or plain water, and turn ON.
2. Beep sounds, display changes to last temperature taken & displays – °F.
3. Spread buttocks & gently insert silver tip no more than ½ inch into the rectum.
4. Comfort & gently keep child from moving.
5. When highest temperature reached (about 1 min), °F will stop flashing & thermometer will beep.
6. Remove from rectum.

**Temporal Temperature**
1. Place sensor right above eyebrow & press and hold button.
2. Move thermometer slowly across skin until you reach the top of the ear. You will hear beeps and light flash during the reading.
3. Make sure sensor is in proper contact with the skin.
4. Read temperature on the display.
5. Repeat steps 1-4 (3 times), record highest reading.

<table>
<thead>
<tr>
<th>Call Study Nurse before giving any medications</th>
<th>Name of Medication</th>
<th>Dose</th>
<th>Start Date</th>
<th>Stop Date</th>
</tr>
</thead>
</table>

**Temperature Card**

**SERONEGATIVE**

Study staff are available 24 hours a day.
Do you have a question or concern that cannot wait until your next visit?

**Call:**
- Betty Schappell, RN, BSN 410 307-6221
- Nicole Bysma, RN, BSN 410 960-8500
- Milena Gatto, RN 410 800-7907
- Karen Loehr, RN, BSN 410 627-6069
- Jocelyn San Mateo, CRNP 410 935-2740

Principal Investigator: Ruth A. Karzon, MD

**JOHNS HOPKINS CENTER FOR IMMUNIZATION RESEARCH**

Source: JHU, CIR, RSV Seronegative Temperature Card Sample
### TEMPERATURE CARD (CONTINUED)

**Take Temperature Daily**

Place decimal point in the correct place. Example: 100.3, instead of 103.

1. If highest **TEMPORAL** reading is below 96.5°F or is 100.0°F or higher, confirm with **RECTAL** temperature within 20 minutes & write on chart.
2. If **RECTAL** temperature is 100.4°F or higher contact the on-call nurse.

<table>
<thead>
<tr>
<th>Day of Study</th>
<th>0</th>
<th>1</th>
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<th>3</th>
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<td>C</td>
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</table>

**When to Contact Study Nurse**

- **Fever** – Rectal temperature 100.4°F or higher (see #2 above)
- **Wheezing** or **trouble breathing** at any time.
- **Any condition** which concerns the parent.
- **2 or More Consecutive Days of**
  - **Cough** - 3 or more episodes in a 15-minute period, not associated with crying or feeding. Any coughing which awakens child from sleep.
  - **Runny nose** not associated with crying or outside wind/cold.

Source: JHU, CIR, RSV Seronegative Temperature Card Sample
STUDY VISITS

- Recruitment
- Consenting
- Screening
- Enrollment
- Vaccination
- RSV Seasonal Surveillance
ACUTE PHASE
D0 TO D28

Blood and nasal wash collection
## SCHEDULE OF EVENTS
### ACUTE PHASE

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<th>Day 13</th>
<th>Day 14</th>
<th>Day 15</th>
<th>Day 16</th>
<th>Day 17</th>
<th>Day 18-27 (contact each day)</th>
<th>Day 28</th>
<th>Day 29</th>
<th>Day 30-55</th>
<th>Day 56</th>
<th>Day 66</th>
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Source: IMPAACT2013, Protocol, Appendix II, V1.0, 14February2017
ACUTE PHASE
D0 TO D28

- Study Visit Schedule (based on Friday Inoculation)
  - Monday, Wednesday, Friday
    - Week 1: Study Day 3, 5, 7
    - Week 2: Study Day 10, 12, 14
    - Week 3: Study Day 17
  - Friday
    - Week 4: Study Day 28

- Study visit window +/- 1 day

Source: IMPAACT2013, Protocol, Section 6.3, v1.0, 14February2017
## STUDY VISIT SUPPLIES

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<tr>
<th>Study Visit Day</th>
<th>Item</th>
<th>Quantity per Kit</th>
<th>Item Number</th>
<th>Quantity Supplied</th>
<th>Manufacturer</th>
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<td>JHU – CIR Lab</td>
<td>JHU – CIR Lab</td>
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Source: IMPAACT2013, MOP, Appendix II, v0.2, 24February2017
# ACUTE PHASE

**D0 TO D28**

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Study Visit D3
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Study Visit D4
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Study Visit D5
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Study Visit D6
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Study Visit D7
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Study Visit D8
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Study Visit D9
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Study Visit D10
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11

Study Visit D11
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12

Study Visit D12
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13

Study Visit D13
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Study Visit D14
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Study Visit D15
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Study Visit D16
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Study Visit D17
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Study Visit D18
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Study Visit D19
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Study Visit D20
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Study Visit D21
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Study Visit D22
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Study Visit D23
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Study Visit D24
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Study Visit D25
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Study Visit D26
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Study Visit D27
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Study Visit D28
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Study Visit D29
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Study Visit D30
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ACUTE PHASE
SCHEDULED STUDY VISIT

- Obtain illness and temperature history
- Obtain concomitant medication history
- Clinical assessment
  - Vitals
    - Temperature
    - Heart Rate
    - Respiration
  - HEENT
  - Heart and lung
  - Lymph nodes
- Nasal wash
  - Virology

Source: IMPAACT2013, Protocol, Section 6.3.1, V1.0, 14February2017
Non-visit contacts will be via phone or email
  - Obtain illness and temperature history
  - Obtain concomitant medication history

Non-Visit Study Days
  - Saturday, Sunday, Tuesday, Thursday
    - Week 1: Study Day 1, 2, 4, 6
    - Week 2: Study Day 8, 9, 11, 13
    - Week 3: Study Day 15, 16, 18, 19, 20, 21
  - Saturday - Thursday
    - Week 4: Study Day 22, 23, 24, 25, 26, 27

Window +/- 1 day to correspond with study visits
# ACUTE PHASE
## DAILY HISTORY

<table>
<thead>
<tr>
<th>Study Day</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
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<td><strong>Day of Week</strong></td>
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<tr>
<td>Temporal Temperature (≥100°F - rectal temp needed)</td>
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</tr>
<tr>
<td>Rectal Temp. (≥100.4°F)</td>
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</tr>
</tbody>
</table>

### Has your child taken:
- Any OTC medication
- Any prescription medication
- Any herbal remedies

### Has your child been sick since you last spoke to study staff?
- Y/N

**Answer Y = Yes, N = No**  
If No, do not proceed with questions below.

1. Nasal Discharge (runny nose)
   - If yes, illness criteria met?
2. Sore Throat
3. Cough
   - If yes, illness criteria met?
4. Hoarseness
5. Wheezing
6. Difficulty Breathing
7. Other

**Initials**

Y/N = Yes/No;
Y = Symptom present within 24 hour time period of 12am – 11:59pm;
N = Symptom not present within time period of 12am – 11:59pm on date specified.

Daily history information is obtained from the parent for the previous day’s 12am – 11:59 pm. (Ex: Day 0’s history is obtained on day 1)
ILLNESS VISIT
ACUTE PHASE

- Fever
- Otitis Media
- Respiratory Illness

Criteria for a solicited AE (see Section 7.33 and Appendix IV)
- Grade 1 event, the assessment will occur within 3 days
- Grade 2 or higher event, the assessment will occur within 2 days
- LRI, with any grade, the assessment will occur within 1 day

Source: IMPAACT2013, Protocol, Section 6.10, v1, 14February2017
Obtain illness and temperature history
Obtain concomitant medication history
Clinical assessment
  - Vitals
    - Temperature
    - Heart Rate
    - Respirations
  - Heart and Lung
  - ENT
Nasal wash
  - Virology
  - Request for Adventitious

Source: IMPAACT2013, Protocol, Section 6.10, v1, 14February2017
If illness criteria met or suspected request an adventitious assay

Send to JHU with next available batch

If illness meets criteria for Pausing and Stopping Rules (Protocol 8.2) then send to JHU ASAP

Contact via mail that adventitious assay requested
- Bhavin Thumar, Kim Wanionek, Jen Oliva
- CIRLab@jhu.edu
- Email should include PID, date of collection, and CRS number. Include copy of F3008 with shipped samples
# Acute Phase Screening

**Day 0**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

**Days 1-14**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

**Days 15-28**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

**Days 29-55**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

**Early DC**
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

---

**Post-Acute Phase**

**Day 27**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

**Days 28-55**
- In person visit
- Informed consent
- Physical exam (full)
- Clinical assessment (focused PE)
- Administer study product
- Blood for: immunologic assays
- Blood for: cellular immune assay (viable PBMCs)
- Nasal wash for: RSV antibody
- Nasal wash for: viral detection & quantification
- Request adventitious agent assay
- Total blood volume: 8mL

---

Source: IMPAACT2013, Protocol, Appendix II, V1.0, 14February2017
**DAY 28**

- Day 28 visit – collect NW for RSV antibody assay and viral detection and quantification
- Review SAE criteria and how do contact personnel during post-acute phase

Source: IMPAACT2013, Protocol, Section 6.4, 14February2017
POST ACUTE PHASE
D30 TO D56

Blood and nasal wash collection
POST ACUTE PHASE

- Begins at 12:01am on the 29th day after inoculation and ends at midnight on the 56th day after inoculation

- Parents/Guardians monitor and contact study site if infant symptoms are suggestive of any Serious Adverse Event (SAE)

Source: IMPAACT2013, Protocol, Section 6.5, 14February2017
POST ACUTE PHASE
D56

Blood and nasal wash collection
DAY 56 FOLLOW-UP VISIT

- Window +7 days (D56-D63)
- Serum
- PBMC
- Nasal Wash Antibody
- Compensation per IRB
- Review RSV Surveillance monitoring instructions

Source: IMPAACT2013, Protocol, Section 6.5.1, V1.0, 14February2017
POST DAY 56 – OCTOBER 31ST

Blood and nasal wash collection

ACUTE AND POST-ACUTE PHASE

Screening/blood collection within 42 days of enrollment
Nasal wash
Clinical assessment: inoculation & 8 visits
Acute Phase

Scheduled In-person Visit
Post-Acute Phase

RSV Season
POST DAY 56 – OCTOBER 31ST

- No clinical data will be recorded on case report forms (CRFs)

- Except for data related to an AE with onset date during Day 0 to the Day 56 Visit or

- Grade >3 AE or SAE that is probably or definitely related to Pre-RSV Season Study Visit procedures

Source: IMPAACT2013, Protocol, Section 6.6, V1.0, 14February2017
RSV SEASONAL SURVEILLANCE

- Recruitment
- Consenting
- Screening
- Enrollment
- Vaccination
- Study Visit
RSV SEASONAL SURVEILLANCE

ACUTE AND POST-ACUTE PHASE

Nasal wash
Clinical assessment: inoculation & 8 visits

Acute Phase

Blood and nasal wash collection

Scheduled In-person Visit

RSV Season

Blood and nasal wash collection

Nasal inoculation

Screening/blood collection within
42 days of enrollment
# RSV Seasonal Surveillance Schedule

<table>
<thead>
<tr>
<th>Pre-RSV season</th>
<th>Weekly contact</th>
<th>Post-RSV season</th>
<th>Illness Visit</th>
<th>Early DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Period</td>
<td>Oct 1&lt;sup&gt;st&lt;/sup&gt; to Oct 31&lt;sup&gt;st&lt;/sup&gt;</td>
<td>Nov 1&lt;sup&gt;st&lt;/sup&gt; to Mar 31&lt;sup&gt;st&lt;/sup&gt;</td>
<td>Apr 1&lt;sup&gt;st&lt;/sup&gt; to Apr 30&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Clinical assessment (focused PE)</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Interim history</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

## Laboratory Evaluations

| Blood for: immunologic assays | 5 mL | 5 mL | 5 mL |
| Blood for: cellular immune assay (viable PBMCs) | 3 mL | 3 mL | 3 mL |
| Nasal wash for antibody | X | | X |
| Nasal wash for viral detection & quantification | | | X |
| Request adventitious agent assay | | X |

## Total Blood Volume

<table>
<thead>
<tr>
<th>Pre-RSV season</th>
<th>Weekly contact</th>
<th>Post-RSV season</th>
<th>Illness Visit</th>
<th>Early DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 mL</td>
<td>–</td>
<td>8 mL</td>
<td>–</td>
<td>8 mL</td>
</tr>
</tbody>
</table>

*Source: IMPAACT2013, Protocol, Appendix III, V1.0, 14February2017*
RSV SEASONAL SURVEILLANCE

- **Pre-RSV Surveillance Phase**
  - October 1st – October 31st
    - One visit to obtain blood specimen and NW Antibody
    - Visit and sample not required if Study Day 56 occurs on or after October 1st

- **RSV Seasonal Surveillance**
  - November 1st – March 31st
    - Weekly contact and illness visit as needed
    - Study visit within 72 hours if child has a medically attended illness of the following types: fever, upper or lower respiratory illness, or otitis media occurring between November 1st until March 31st

- **Post-RSV Seasonal Surveillance**
  - April 1st – April 30th
    - One visit to obtain blood specimen and NW Antibody

Source: IMPAACT2013, Protocol, Section 6.8, V1.0, 14February2017
Assemble required nasal wash supplies

Pour 15–20 mL of room temperature lactated ringers into a sterile specimen cup

Label outside of sterile container with subject number (PID), date, specimen type, and visit day (Day 0)

Position subject in sitting position in an adult’s lap in chair

Instruct parent/guardian:
- Hug child with one arm holding both of child’s arms at his/her sides
- Place other hand on child’s forehead and gently position child’s head facing forward and back of head against parent/guardian’s chest
- Sit slightly forward so child’s neck does not flex back as this may cause the child to swallow some of the nasal wash (NW) solution

Place paper towel in front of subject
Compress and release bulb to create a vacuum
Draw entire volume of NW solution into sterile bulb
Place sterile specimen cup under both nostrils
Assist child to position head forward to minimize solution draining to back of throat
Gently compress the bulb syringe to expel the NW solution
Gently release pressure on bulb syringe to collect effluent from around the bulb syringe and from nostril
If the child is able to cooperate, have him/her tip head forward to help expel solution
If age-appropriate, provide a snack to remove NW solution taste from mouth
NASAL WASH PROCEDURE

- Nasal Wash Video

- Specimen Processing
  - Nasal Wash Virology and Nasal Wash Antibody Specimen

- Children’s Hospital Colorado
  
  https://www.youtube.com/watch?v=giE580avMj4&feature=youtu.be
RSV quickly loses infectivity if allowed to sit in nasal wash fluid without Viral Transport Media (VTM)

- Immediately transfer 6 mL of nasal wash effluent into a vial containing 1.5 mL cold (2-8°C) VTM
  - If only 5 mL collected, only use 1.25 mL of VTM
  - If only 4 mL collected, only use 1 mL of VTM
  - If < 4 mL collected, repeat wash

Gently mix contents to assure even distribution of specimen in VTM

- Keep on wet ice until snap-freezing

- Process and snap freeze within 30 minutes of collection

Source: IMPAACT2013, Protocol, Section 7.4, V1.0, 14February2017
Label 7 Cyrovials
- Preprinted LDMS or labels capable of being stored at -80°C
- PID
- Protocol #: IMPAACT 2013
- Specimen collection date
- Specimen type: NW/VTM
- Visit Day or SCK (i.e., 0, 3, 5, 7, 9, etc.)
- Vial #1, 2, 3, 4, 5, 6, 7

Aliquot approximately 1 mL of the combined NW and VTM mixture

Seal caps tightly
- CO2 from dry ice will affect VTM pH and inactivate virus

RSV loses infectivity if freezing is not performed rapidly
- Process and snap-freeze within 30 minutes of collection
- Snap freeze specimen aliquots per BioCision CoolBox ® manufacturer’s -78°C instructions
  - At least 20 minutes prior to snap freezing specimen, place CoolRack directly onto dry ice to reach appropriate temperature
## VIROLOGY NW SPECIMEN PROCESSING (CONTINUED)

### Section 3 (SCREENING, ACUTE, AND POST-ACUTE): Specimen Processing & Shipping Instructions

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF # DMC Test Code</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>After collection, keep Nasal wash refrigerated or on wet ice until processed and frozen. See 2011 MOP for detailed NW collection instructions.</td>
<td>CRF: F3008 DMC Test Code: CXRSVQT and/or ADVENTTS</td>
<td>Sterilely Transfer 6mL of Nasal Wash into vial containing 1.5 mL cold (2-8°C) VTM. Gently mix to assure even distribution of specimen in VTM. Aliquot into 7 X 1.0mL aliquots (Sarstedt 2ml cryovials) Be sure cap is on tight, and then flash freeze in Biocision Coolbox, for a minimum of 15 min. Transfer frozen aliquots immediately to -80 °C freezer.</td>
<td>Shipping: ACUTE Phase Ship FOUR aliquots to JHU at the end of the acute phase, on dry ice priority overnight, M-W only. Retain 3 aliquots on site until requested by team. Multiple patient samples can be batched and shipped within 2 weeks of the time points, unless directed to ship sooner by team.</td>
</tr>
<tr>
<td>Nasal Wash for RSV viral detection must be mixed with Viral Transport Media (VTM), aliquoted and snap frozen within 30 min of collection.</td>
<td></td>
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<td></td>
<td>Shipping: Illness Visits Complete Adventitious Agent Assay request for rRT/PCR on nasal wash for adventitious agents. Ship these samples with the next batch to JHU. Include a copy of F3008. However, if illnesses meet criteria for Pausing and Stopping Rules (protocol section 8.1.3), specimens should be shipped REAL-TIME to JHU. Please notify JHU of any changes made to LDMS or the F3008 form after the sample has been shipped.</td>
</tr>
</tbody>
</table>

**NOTE:** Lab must enter comment in LDMS for all aliquots that have a different time on label than in the LDMS (for example: “LDMS time is actual sample time as noted on CRF. Time on label is not correct.”)
Day 0, 28, 56, Pre-Surveillance, and Post-Surveillance Visits

- Use cryovials
  - external thread
  - 2.0 mL hinge tubes

- Label 3 Cyrovials
  - Preprinted LDMS or labels capable of being stored at -80°C
  - PID
  - Protocol #: IMPAACT 2013
  - Specimen collection date
  - Specimen type: NW
  - Visit Day (i.e., 0, 28, 56, etc.)
  - Vial #1, 2, 3...

- NW antibody specimen is not mixed with VTM
- Aliquot the nasal wash fluid 1.5ml per vial, max 8 vials
- Secure cap tightly and snap freeze within 30 min of obtaining specimen

Source: IMPAACT2013, Protocol, Section 7.4, V1.0, 14February2017
### Nasal Wash Antibody Specimen Processing

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF #</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash (NW) for RSV Antibody</td>
<td>Nasal Wash</td>
<td>After collection, keep Nasal wash refrigerated or on wet ice until processed and frozen. See 2011 MOPS for detailed NW collection instructions</td>
<td>CRF: F3008 DMC Test Code: ABRSVQT</td>
<td>Measure and save 6 mL NW from total sample to be used for Viral Detection and Quantification</td>
<td>Day 0 At the End of acute phase (Day 0-28): batched shipment(s) of TWO aliquots per participant. Batch ship the remaining aliquots when directed by team or at the end of the study</td>
</tr>
<tr>
<td></td>
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<td>Aliquot all remaining NW in three equal (1.5 mL) aliquots for RSV Ab assay. If volume exceeds 5 mL, prepare additional aliquots</td>
<td>Day 56 Ship TWO aliquots per participant to JHU, multiple patient samples should be batched and shipped within 2 weeks of DAY 56, unless directed to ship sooner by team.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Nasal Washes for RSV Antibody should be snap frozen within 30 minutes of collection and transferred to a -80°C freezer. Store at -80°C</td>
<td>Retain the remaining aliquots on site. They will be batched shipped at the end of study or when requested by team.</td>
</tr>
</tbody>
</table>

**NOTE:** Nasal wash aliquots for RSV Antibody do not contain VTM.

Ship all samples on dry ice priority overnight, M-W only.

Source: IMPAACT2011, LPC Appendix III Section 3, v0.4, 20Apr16
THANK YOU!!

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