Site Training

The MARC-35 Age 6-Year Exam: Airway microbiome, nasal microRNA, and age 6-year asthma phenotypes in the MARC-35 cohort
Outline of Presentation

1. Overview
2. Exam Procedures
3. Deviations & Adverse Events
4. REDCap
5. Questions
Wheezing Index (WIND) Study

PI: Carlos Camargo, MD DrPH – Mass General Hospital / Harvard

Aim: To investigate the role of respiratory viruses, microbiome, and host immunity in the pathogenesis of childhood asthma

Study population: Infants (age <1y) hospitalized for bronchiolitis
- 1016 enrolled at 17 sites over 3 fall/winter seasons (2011-2014)
- 921 children are being followed for long-term outcomes

Main early life exposure: index NPA + multiple nasal swabs

Main outcomes:
- Age 3y recurrent wheezing
- Age 5y doctor-diagnosed asthma
- Age 6y asthma phenotypes
Age 3-Year Exam

- To examine the relation of infant sIgE type and longitudinal pattern to the risk of incident asthma at age 5 years.

- To examine the association between RV-C bronchiolitis and risk of incident asthma at age 5 years.

- To test for an interaction between sIgE and RV-C bronchiolitis in relation to the risk of incident asthma at age 5 years.

645 exams done to date! (70% of participants)
Scientific Significance

- The role of airway microbiome in the etiology of asthma and inflammatory diseases is largely unknown.

- Small cohort studies (n<20) collectively implicate microRNAs in asthma pathogenesis.

- The relationship between nasal airway microRNAs during infancy and their longitudinal patterns to incident asthma, has not been previously examined.

- Longitudinal studies have not previously explored the development of different asthma phenotypes or endotypes in children.
Scientific Aims

- To investigate the relation of the airway microbiome to risk of childhood asthma among infants with severe bronchiolitis

- To identify nasal airway microRNAs that are prospectively associated with asthma at age 6y

- To compare asthma cases vs non-cases on downstream NFkB signaling mediators and outcomes associated with nasal airway microRNAs

- To derive asthma endotypes at age 6y
MARC-35 Sites \( (n=17) \)
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Inclusion Criteria

- Previously enrolled in MARC-35.

- Age 6.0 to 7.9 years at the time of the in-person exam. _Ideal age_ at time of exam is 6.0 to 6.9 years.

- Ability of the parent/legal guardian to give informed consent at the time of the in-person exam.
Exclusion Criteria

- Parent/legal guardian who does not agree to the possible future use of specimen(s).

- Parent/legal guardian who does not agreed to sign a medical record release authorization form.
Study ID Number

Each child retains their unique study ID number from the original MARC-35 study.

Patient number

```
011
```

Site-specific 3-digit number

For example MGH = ‘011’

```
201
```

Study year child was enrolled

(either 1, 2 or 3)
Specimen Labels

Specimen labels included:

- 2 x red top research blood
- 1 x blue top cryo-vial for blood pellet
- 1 x white top cryo-vial for blood serum
- 1 x lavender top for CBC/diff
- 1 x nasal swab specimen
- 1 x saliva swab specimen
- 1 x stool sample specimen
- 2 x extra labels
Participant Remuneration

- Families will receive $125 via check for their time and travel expenses (for example, public transportation costs or parking costs).

- Families will receive an additional $50 upon receipt of the stool sample (from in-home collection).

- Families that live >25 miles from the site of the exam will receive an additional $25 for each additional 25 miles in appreciation of the additional travel time and costs incurred.

- The EMNet (Emergency Medicine Network) Coordinating Center at MGH will process all remuneration check requests.
Exam Overview

- Exam Scheduling
- Informed Consent
- Contact, PCP, Asthma Specialist Information
- Vital Signs & Lung Exam
  - Temperature, blood pressure, heart rate, height, weight
  - Auscultation
- Flexural Dermatitis Exam
  - Questions on skin health and medications
  - Checking for atopic dermatitis/eczema
- Infants’ Dermatitis Quality of Life Index (IDQOL)
- Nasal Exam
  - Checking for polyps
- Nasal Swab Questionnaire
- Nasal Swab Specimen
- Saliva Swab Specimen
- Stool Collection Kit Distribution
- FeNO
- Spirometry
- Blood Collection
  - Lavender top for CBC/diff
  - Red top research blood

New to age 6-year exam
Exam Scheduling

- **EMNet responsibilities:**
  - Recording parent/legal guardian willingness to participate (yes or no)
  - Collecting information on parent/legal guardian’s scheduling availability (good & bad days/times)
  - Collecting child’s pre-existing medical conditions, including allergies and contraindications to spirometry and albuterol

- **Your site’s responsibilities:**
  - Scheduling the exam locally
  - Following-up on missed visits and/or re-scheduling as needed
Informed Consent: General Principles

- Conduct informed consent prior to initiation of any study procedures, including collection of contact and provider info.
- Include a thorough review of study procedures.
- Allow parent time to think over and please address any questions or concerns.
- Consent to genetic testing is optional but strongly encouraged.
  - 85% of parents agreed to genetic testing at baseline.
  - 87% agreed at the age 3-year exam.

Genetic testing is an optional part of the study. You do not have to provide your child’s samples for genetic research to participate.

- YES, interested in participating in the genetic part of this study
- NO, not interested in participating in the genetic part of this study. Please note, that we will store the pellet created from the blood draw for possible future testing associated with severe bronchiolitis, recurrent wheezing, asthma and related concepts, but not genetic testing.
Informed Consent: Off-Site

- For participants who live outside of a reasonable proximity to an enrolling site, the EMNet Coordinating Center will consent parents/legal guardians.
- Discussion and question-answer session will occur over the telephone.
- Physicians will be available to answer clinical questions, as needed.
- Parents *with* an internet-ready device will review, sign and return consent forms electronically.
- Parents *without* internet-ready device will review, sign and return hard-copy of consent form via snail mail.
Note: Collect contact, primary care provider and asthma specialist information after completion of informed consent.
Give parent/legal guardian ‘Authorization for Release of Protected or Privileged Health Information’ to complete.

Reminder: Refusal to complete is an exclusion criteria.
Vital Signs & Lung Exam

- Measure and record temperature, blood pressure, heart rate, height and weight.

- Listen to the lungs, with a focus on:
  
  **Wheezing:** A continuous whistling sound heard predominantly during expiration that is caused by narrowing of the lumen of a respiratory passageway.

  **Crackles:** A discontinuous, inspiratory or expiratory lung sound, as opposed to a wheeze, which is continuous. Crackles are produced by air passing over retained airway secretions or the sudden opening of collapsed airways.

Vital Signs & Lung Exam (continued)

Record vital signs, height, weight.

Auscultation: yes or no to clear, wheezing, crackles, other sounds.
### Flexural Dermatitis Exam

#### Frequency of dry itchy skin (past week, past year)?
- In the past week, has your child had itchy skin, and by itchy we mean scratching or rubbing of the skin? [ ] Yes [ ] No
- In the past year, has your child had itchy skin, and by itchy we mean scratching or rubbing of the skin? [ ] Yes [ ] No
- In the past week, has your child suffered from dry skin in general? [ ] Yes [ ] No
- In the past year, has your child suffered from dry skin in general? [ ] Yes [ ] No

#### Seasonality of dry itchy skin?
- Think about your child’s itchy and dry skin and when it generally gets worse. Does it generally get worse when the weather is cold? [ ] Yes [ ] No

#### Areas affected?
- Is your child’s itchy and dry skin generally worse during a specific season (mark all that apply)?
  - [ ] Fall
  - [ ] Winter
  - [ ] Spring
  - [ ] Summer
  - [ ] No, all seasons

#### Past diagnosis of atopic dermatitis/eczema, date?
- Has this skin condition ever affected the skin creases, and by skin creases we mean around the eyes, around the neck, fronts of elbows, behind the knees, or fronts of ankles? [ ] Yes [ ] No
- Has your child ever been diagnosed by a medical professional with atopic dermatitis/eczema? [ ] Yes [ ] No [ ] Unsure
- What was the approximate date of this diagnosis?
- Date (MM/DD/YYYY): __/__/______
- Please enter ‘01’ for ‘DD’ (day), and record month and year based on the response.
Flexural Dermatitis Exam (continued)

Clinical examination

Upon evidence, recall date noticed?

Reminder: remind parent/legal guardian to dress child in loose comfortable clothing when scheduling visit or providing visit reminders.

Past and current use of medications?
Infants’ Dermatitis Quality of Life Index (IDQOL): 10-question survey for parent/legal guardian on quality of life of child with atopic dermatitis (Finlay et al., University of Cardiff, UK).

Clinician’s choice: option to hand IDQOL questions to parent (legal guardian) to complete on their own. Remember to collect the form before end of exam!
DO administer IDQOL to parent/legal guardian: if child displays any signs of atopic dermatitis/eczema on clinical examination OR has reported atopic dermatitis/eczema within the past week or year. Collect during the exam.

DO NOT administer IDQOL to parent/legal guardian: if child does not display any signs of atopic dermatitis/eczema on clinical examination AND parent reports no symptoms of atopic dermatitis/eczema within the past week or year.
Visible Flexural Dermatitis

- Please record the presence or absence of physical signs consistent with "visible flexural dermatitis" (VFD)

- To decide whether VFD is present or not, there are two components to consider:
  - Step 1. What dermatitis looks like
  - Step 2. Where to look

*Adapted from the work of Hywel Williams, MD*
Visible Flexural Dermatitis Summary

- **Step 1. What dermatitis looks like**
  Poorly demarcated “erythema” with surface changes

- **Step 2. Where to look**
  - Around the eyes
  - Around the sides or front of neck
  - Front of elbows
  - Behind the knees
  - Front of ankles
**Step 1. What dermatitis looks like**

**Definition of dermatitis**: poorly demarcated erythema (redness) with surface change.

- Surface change can mean fine scaling, vesicles, oozing, crusting, or lichenification.

- In children with dark skin, redness may be difficult to see. Therefore, redness is not an essential feature. You must, however, see surface change (e.g. scaling, oozing, etc.)
Erythema & Scaling
Oozing & Crusting
Vesicles
Lichenification (white skin)
Lichenification (black skin)
Follicular Lichenification
"Flexural" in this study means only the following five areas:

1. Around the eyes
2. Around the sides or front of neck
3. Front of elbows
4. Behind the knees
5. Front of ankles

Get into the habit of working from top to bottom when examining subjects.
1. Around the eyes
2. Around sides/front of neck
Size of lesion

Any patch of dermatitis…

- **larger than 1 cm** in diameter, and

- within an area marked out by the **subject's palm**
Around sides/front of neck
3. Front of elbows
4. Behind the knees
5. Front of ankles
Front of ankles (continued)
Some additional practical points

Most of the time it will be straightforward where the skin creases are, but if you need to check where a skin crease begins and ends by using the subject's palm, then the middle of the palm (held horizontally) should correspond to the axis of where the joint bends, as shown here.
Practical points (continued)

- Remember it is not necessary to fully undress the subject.

- Try to avoid the trap of deciding whether the visible skin changes are due to a specific disease such as psoriasis. If it fits the definition, then you must mark it down as "dermatitis."

- Now let’s review some common questions…
Dermatitis is only on the side of the limb?

If you can see the dermatitis with arm facing directly forward (or leg facing backwards), then you may consider it as “flexural dermatitis present.”
All of the limb is affected?

This does not matter. As long as the skin crease is involved, you should record as “flexural dermatitis present.”
If it is a tiny pimple, then ignore it. Any patch of dermatitis larger than 1 cm at its minimum diameter counts, however, so this child's arm should be recorded as "flexural dermatitis present."
Small group of spots in skin crease?
Small group of spots (continued)

When there is a small group of spots behind the knees or in front of the elbow (as shown below), you may count it as VFD only if:

- the spots are confined to skin crease as opposed to all over the limb
- they cover an area greater than 1 cm in diameter
You cannot see any redness?

In dark skin, redness is not an essential feature, but you must see surface change.
Cannot see any redness (continued)
VDF Test Photographs (n=48)

Available at: http://emnet-usa.org/Marc_35.7/M35.7_train.htm

A few examples follow …

Do the series of photographs on the following slides show visible flexural dermatitis?
Test Photograph 1
Test Photograph 2
Test Photograph 3
For Further Training

- Please review this training slide set

- Review the test photographs, which are designed to test your ability to determine the physical sign of “visible flexural dermatitis”

- Both slide sets are available online within age 6-year exam training materials: http://emnet-usa.org/Marc_35.7/M35.7_train.htm

- During the actual study, please discuss difficult cases with your colleagues
Nasal Exam: checking for polyps

- Checking for polyps:
  - Position yourself in front of the patient
  - Gently insert the wide-tipped speculum into the patient’s nostril
  - Examine the nostril
  - Repeat on the opposite side

- Confirming a polyp:
  - Ask child to blow his/her nose to clear any mucus (as needed)
  - Re-examine the nose
Nasal Anatomy: turbinates

Turbinates

- inferior and middle turbinate are normally visible
- normally pink and shiny
- may be pale/bluish or red
- may be enlarged
Nasal Anatomy: normal vs. enlarged turbinates
Nasal Anatomy: polyps

Nasal polyps appear as fixed, glistening, gray or white, mucoid masses in the nasal cavities.
Nasal Exam: polyps
Nasal Exam:
enlarged turbinates vs. polyps

- enlarged turbinate

- nasal polyp
Concerning Findings

If potentially concerning findings are made upon examination (e.g., unexpected atopic dermatitis, unexpected nasal polyps, and/or unexpected wheezing or crackles), the clinician should advise the parent/legal guardian to contact the child’s primary care clinician for further evaluation.
Clinician choice: option to collect nasal swab specimen first (before doing nasal exam). This sequence ensures sufficient mucus in both nares, if nose needs to be cleared prior to nasal exam.
Nasal Specimen

- Note we will be using saline as the viral transport media, which can be stored at room temperature until sample collection.

- Sticker with ‘Nasal Swab Specimen’ label, and complete with 6-digit study ID, date, time.

- Store specimen on-site at -80°C.


- Watch instructional video: http://emnet-usa.org/Marc_35.7/M35.7_train.htm

**Note:** this video was filmed at baseline. Watch minutes **11:50 to 15:00** and ignore mention of pink VTM (we’re using saline).
**Nasal Swab Questionnaire (NSQ)**

**Clinician choice:** option to hand the NSQ to parent (legal guardian) to complete on their own. Remember to collect the form before end of exam!

<table>
<thead>
<tr>
<th>MARC-35/WIND Study</th>
<th>Research Exam Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam Date: <em>/<strong>/</strong></em>______</td>
<td>Study ID: __________</td>
</tr>
<tr>
<td></td>
<td>Staff Initials: ___</td>
</tr>
</tbody>
</table>

### NASAL SWAB QUESTIONNAIRE

Please ask parent/legal guardian:

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does [child] have a cough? (Y/N)</td>
<td>Yes, No</td>
</tr>
<tr>
<td>[If ‘Yes’ to ‘Does [child] have a cough?’] Is this cough</td>
<td>Mild (mostly gaging), Moderate (cough is significant, but not waking child at night), Severe (cough that causes vomiting and/or wakes your child at night)</td>
</tr>
<tr>
<td>Does [child] have a runny nose?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>[If ‘Yes’ to ‘Does [child] have a runny nose?’] Is this runny nose:</td>
<td>Mild (have to suction 0-4 times/day, or wipe every 2 hours or less), Severe (have to suction 5 or more times/day, or wipe every 1 or more times/hour)</td>
</tr>
<tr>
<td>Do you think your child has a fever (temp of 100 F or higher)?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is your child hoarse (muffled, scratchy voice)?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is your child breathing faster than normal?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Do you think your child is “wheezing”?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>(By wheezing, we mean high-pitched whistling sounds when your child is breathing out.)</td>
<td></td>
</tr>
<tr>
<td>When was the last time your child had a snack or meal? Enter the date and time of the last snack/meal:</td>
<td>Date (MM/DD/YYYY): <em>/<strong>/</strong>/</em>/___ Time (24-hour clock): <strong>:</strong></td>
</tr>
</tbody>
</table>

MARC-35 Age 6-Year Exam 67
Saliva Specimen

- Sticker with ‘Saliva Swab Specimen’ label, and complete with 6-digit study ID, date, time covering original label.

- Store specimen on-site at -80°C.


- Watch instructional video: http://emnet-usa.org/Marc_35.7/M35.7_train.htm

**Note:** this video was filmed for our sister CHIME Study. Saliva swab documentation is embedded in Research Exam Form (and not separate as discussed in video).
Stool Specimen

- Open package of OMNIGENE-gut stool collection tube (avoid touching spatula), and apply ‘Stool Specimen’ label to tube. Complete with 6-digit study ID, covering original label. Leave date and time for parent to complete at home.

- Complete study ID on sticker attached to inside of box lid.

- Familiarize yourself with instructions in protocol ‘Appendix E2. Stool Specimen Procedures’.

- Watch instructional video: http://emnet-usa.org/Marc_35.7/M35.7_train.htm
Complete 6-digit study ID on Stool Specimen Form.

Even though collection will occur at home, it is very important to review collection instructions with parent, including stool preparation, form completion, and shipping.

If child would like to produce a bowel movement during visit, offer the parent the opportunity to complete the stool collection in clinic.
FeNO

- NIOX VERO measures fractional exhaled nitric oxide (FeNO) concentration (ppb).
- Used as a biomarker for $T_H^2$-associated airway inflammation.
- Levels >35 ppb in children are correlated with eosinophilic airway inflammation.
- 6-second expiratory mode was FDA approved in late 2017 for clinical use in ages 7 to 10 years. We will be using 6-second mode for research purposes.
- Use clinical judgement to preclude testing for participants with contraindicated medical conditions from performing FeNO.
FeNO (continued)

- Watch instructional video:
  [Watch instructional video](https://www.youtube-nocookie.com/embed/KPp_Zb-74jA?rel=0&showinfo=0&autoplay=1)

- Read user manual:

- Follow Quality Control procedures in manual to ensure operation within product specifications.

- Ensure 6-second mode is enabled prior to WIND Study visit.
FeNO (continued)

- Perform FeNO prior to spirometry.
- Coaching and encouraging the child along with the pictorial incentives will be instrumental.
- Participants empty the lungs by breathing out thoroughly, close their lips around the mouthpiece and inhale deeply to total lung capacity. Exhale slowly and continuously through the filter.
- Make at least 2 reproducible maneuvers. Record higher (best) value of these similar values.
- If initial ‘failure’, we recommend re-trying maneuver 3 or 4 times.

FeNO

| Collection date and time of FeNO: | (MM/DD/YYYY): ___/___/______  
(24-hour clock): ___:___ |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please obtain two valid FENO measurements that are reproducible. Record the best FeNO. The value below is required.</td>
<td></td>
</tr>
<tr>
<td><strong>FeNO</strong></td>
<td>Value</td>
</tr>
<tr>
<td>How many measurements were performed to obtain the FeNO value?</td>
<td></td>
</tr>
</tbody>
</table>
Spirometry with bronchodilator reversibility (BDR)

In general, some questions are just informational (e.g., have cold? caffeine?) others are potential exclusions.

Exclusions will be RARE, but important to review all screening questions with parent/legal guardian:

- Hypersensitivity to albuterol or other bronchodilators (do **not** administer albuterol, but **do proceed** with other spirometry).

- “Surgery” in the past 4 weeks (do **not** proceed with spirometry; we can defer to later date)
Examples of potential exclusion criteria include:

- Thyrotoxicosis
- Heart failure, tachydysrhythmias, or any other heart condition
- Hypertension
- Decreased glucose tolerance
- Unstable diabetes mellitus
- Taking cardiac glycosides

... review with on-site clinician!
Spirometry (continued)

We developed standardized protocol based on published recommendations:

- 2 inhalations of albuterol sulfate (90 mcg per inhalation) using metered dose inhaler with a valve-holding chamber (spacer).

- Wait 10 to 15 minutes after medication administration to do post-bronchodilator maneuver.

- Conduct minimum of 3 acceptable maneuvers, with maximum of 8 maneuvers, both pre and post-bronchodilation.
We recommend the use of an age-appropriate face mask.

Children who have previously used an inhaler with mouth spacer – with success! – are welcome to forgo the mask.

Please do not use inhalers brought by parents from home in lieu of study-ordered medication (even if identical).
Spirometry (continued)

Record height and weight.

Date and time of spirometry.

Record Largest FVC, largest FEV₁, FEF₂₅₋₇₅% from maneuver with largest sum of FVC + FEV₁.

Upload all maneuvers files.

Date and time of bronchodilator administration.

Pre-bronchodilator

Post-bronchodilator
Blood Specimen: CBC/diff

**Reminder:**
Ensure all required test values (differentials, etc.) are included in your lab order for CBC/diff.

Enter all test values.

Time, date of collection.
Blood Specimen: Red-Top

Time, date of blood collection.

**Reminder:** Document blood collection date and time on white-top serum tube and blue-top pellet tube (and NOT spinning/processing times).

Document volume of collection.
Blood Specimen (continued)

- Follow instructions in protocol ‘Appendix E3: Blood Specimen Procedures’.

- If topical anesthetic option is chosen, plan to apply to phlebotomy site prior to the procedure, as directed.

- For incomplete or unsuccessful blood draws, schedule agreeable parents for return visits.

| Kit | MARC-38A Research Exam Blood Kit contains supplies for the blood draw |
| Collection | Various Assays (e.g., IgE) for centralized analysis by WIND Study Team |
| | Collect blood in a lavender-top tube |
| | Label according to institutional procedures for send-out to your local hematology laboratory |

| Processing | | |
| | Invert tube 5 times immediately after collection |
| | Centrifuge blood at 3000 RPM for 10 min at room temperature |
| | Aliquot serum into white cap tube |
| | Aliquot pellet into blue cap cryogenic vial |
| | Label each cryogenic vial with WIND Study sample type (serum or pellet) participant study ID collection date collection time |

| Storage | Not applicable |
| | Store both the serum (white cap) and the pellet (blue cap) in -80°C freezer. Do not ship samples until instructed to do so by the EMINet Coordinating Center |
The Research Exam Form is being translated into Spanish by EMNet and will be forwarded along to your site once available.

**Note:** Given IRB differences, your site will independently decide on the need for further translation of the Consent Form.
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Adverse Events

Blood Draw
- Bruising at puncture site >2 cm diameter
- Bleeding from puncture site lasting >5 minutes
- Swelling at puncture site >2 cm
- Infection at puncture site (rare)

Nasal Swab
- Epistaxis within 24 hours from the procedure in which bleeding does not subside spontaneously within 5 minutes

Saliva Swab
- Oral mucosal bleeding within 24 hours of swab collection

Spirometry with Bronchodilator Reversibility
- Bronchospasm (wheezing, chest tightness, trouble breathing)
- Chest pain, angina
- Allergic reaction (hives, throat swelling, anaphylaxis)
Serious Adverse Events

- Death
- A life-threatening event
- An inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE
Protocol Deviations

- **Major Deviation:** Any change, divergence, or departure from the study design or procedures of a research protocol that affects the study participant's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data constitutes a major protocol deviation (protocol violation).

- **Minor Deviation:** Changes or alterations in the conduct of the study which do not have a major impact on the study participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data are considered non-major protocol deviations.

Overall PI (Carlos Camargo) makes final determination of major vs. minor deviation so please report all deviations within 48 hours.
Reporting Serious Adverse Events & Deviations

- Major protocol deviations need to be reported by email to Ashley Sullivan (EMNet) within 48 hours. EMNet will report to NIAID/NIH.

- Serious adverse events need to be reported by email to Ashley Sullivan within 24 hours. EMNet will report to NIAID/NIH.

Ashley Sullivan
E-mail: afsullivan@partners.org
Phone: 617-724-9712
Outline of Presentation

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REDCap: Overview of Database

- **REDCap (Research Electronic Data Capture)** is a secure, web-based, HIPAA compliant application designed exclusively to support data capture for research studies.

- Initiated at Vanderbilt University and includes 1,515 active institutional partners in 92 countries. [http://project-redcap.org/](http://project-redcap.org/)

- Access granted by Partners (MGH) via completion of the Electronic Data Capture Use Agreement.
**REDCap: Tips**

- Firefox or Chrome strongly recommended as browser. 🌟

- Hit ‘Save’ frequently and avoid inactivity (10 minutes or more) to prevent losing data via auto-logout.

- **Do not** hit ‘Enter’ after entering values in fields, to avoid automatic pop-up error messages.

- **Do** use cursor to move between fields.
Log into REDCap with username and password.
https://redcap.partners.org

Select ‘MARC-35 Age 6-Year Exam’ under ‘My Projects’.

Select individual forms under the ‘Data Collection Instruments’ in the left-hand toolbar.
Access to new users granted by Partners.

New procedure to get access includes completing electronic form.

Daphne will reach out to get a list of study staff who need REDCap access.
REDCap: Overview of Forms

- Scheduling Form
- Research Exam Form (brief mention)
- Protocol Deviation Form
- AE & SAE Case Report Form
The **Scheduling Form** is a shared form completed by **both EMNet and the exam site**: 

- Parent/guardian’s willingness to participate (yes or no)
- Parent/guardian’s scheduling availability (good/bad date/times)
- Child’s medication, latex and food allergies
- Screening questions (reviewed earlier)
Your site documents:

- Communication attempts with parent/legal guardian via phone or e-mail.
- Date and time of scheduled and re-scheduled visits.
- Missed or unsuccessfully scheduled visits.
- Incomplete visits, including missing elements and scheduling of additional visits.
- Please complete in real-time: EMNet uses documentation to assess trends in communication for hard-to-reach/schedule to help your site.
EMNet strongly encourages completing study documentation using REDCap in real-time – but please remember to save after each section to avoid getting logged out and losing data for (only a few minutes) of inactivity.

Participant payment hinges on form completion, so please aim to complete forms in real-time.
Document details of a protocol deviation within 48 hours of deviation.

Complete separate protocol deviation forms for each independent deviation.

Overall PI (Carlos Camargo) makes final determination major vs. minor deviation.

For major deviations only, site PI should provide wet signature and forward to Ashley Sullivan (afsullivan@partners.org)
Document details of adverse event as soon as study team becomes aware, including: attribution, description, action taken, severity, relationship to study procedures, expectedness and resolution.

If adverse event qualifies as a serious adverse event, site PI should provide wet signature and study team should e-mail PDF to Ashley Sullivan (afsullivan@partners.org) within 24 hours.
Additional Training

Daphne to reach out to your site coordinators to arrange more targeted ‘micro-trainings’ focusing on data entry, specimen collection, scheduling logistics, and other topics as needed.
## Training Elements:

- General Training
- VFD test photos
- Nasal Swab Specimen
- Saliva Swab Specimen
- Stool Specimen
- Blood Specimen
- FeNO
- Spirometry
- REDCap
- Manual of Procedures

### Delegation & Training Log

<table>
<thead>
<tr>
<th>First and Last Name</th>
<th>Role</th>
<th>Training Elements: indicate date of training for all applicable and indicate 'NA' if not applicable</th>
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</table>

1. Direct and live presentation or slideshow
2. Online BITE photographs
3. Protocol procedures, instructional video
4. Protocol procedures
5. Protocol procedures, interactive review, user manual
6. Protocol procedures
7. Protocol procedures, practice database

Site Principal Investigator:

Study Title:  

MARC-35 (WIND Study) Age 6-Year Exam: Study Delegation & Training Log

Please use this log to document the completion of training for MARC-35 Age 6-Year Exam. Indicate the date of all trainings completed for each staff member, including the Site Principal Investigator (PI). The PI should initial and date (last two columns) to confirm that the staff member has received appropriate training related to his/her respective tasks. Please return the completed log to study@windspharmacology.com.
Outline of Presentation

1. Overview
2. Exam Procedures
3. Deviations & Adverse Events
4. REDCap
5. Questions
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Thank you for participating in the MARC-35 Age 6-Year Exam!