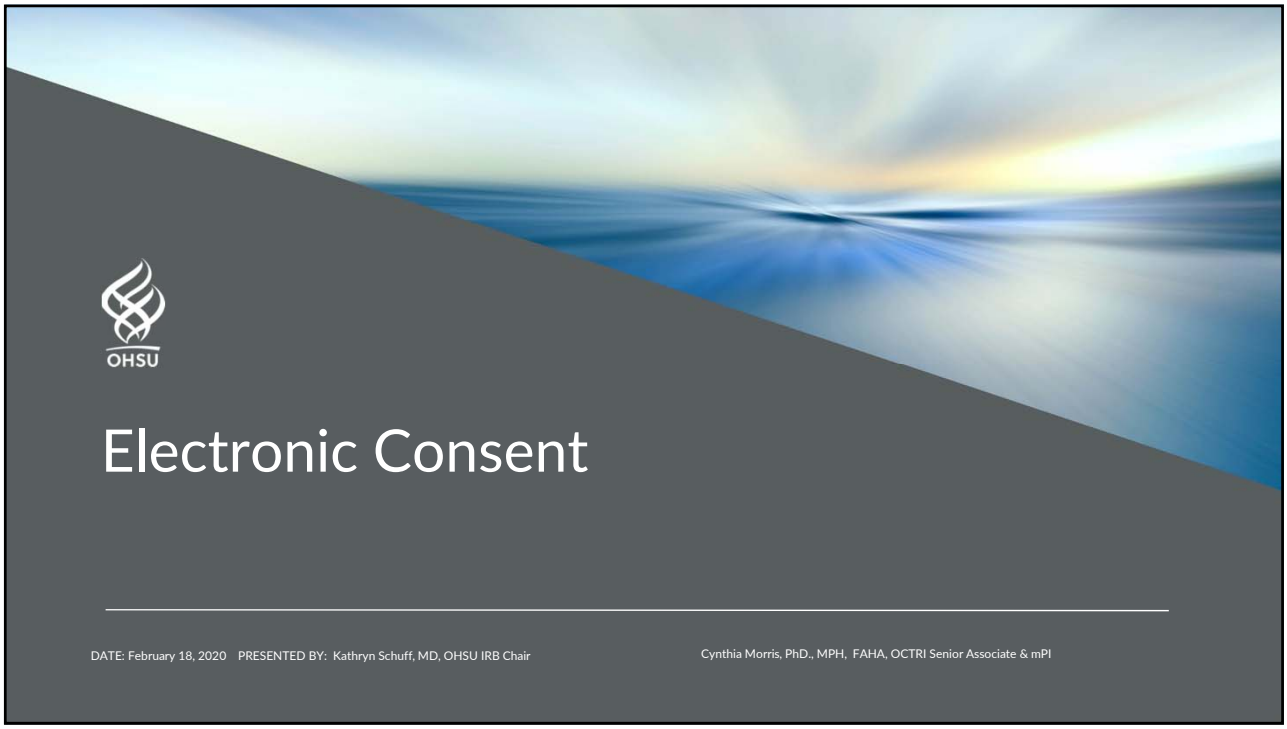


IRB Requirements

- Same requirements for paper and electronic consent:
  - IRB approved language and format
    - Must contain all elements of informed consent required by HHS and/or FDA
  - Signature(s) unless waived by IRB
  - Study staff involvement
  - Copy provided to participant

Is e-Consent right for my study?

- Pros
  - Accessible to participants anytime
  - Can add audio tracks, videos, decision tools, quizzes to assess understanding, screening questionnaires, etc.
  - Expense (can save staff time)
  - Better access for some populations
- Cons
  - Requires training on system (study staff)
  - Expense
  - Time for set up
  - Access for some populations (wifi required, device compatibility, not computer literate participant population)

What to submit to the IRB

- Paper version if transferred almost identically to electronic format or editable electronic page mock-ups
  - Along with email invitations, text messages, and directions for use, etc.
- Consent plan should describe
  - How subjects can ask questions and how questions will be answered
  - When/where the electronic consent process will occur
  - Documentation
  - Backup plan if internet or system is down

What to submit to the IRB, cont.

- Audio/images/quizzes
- System security
  - What system are you using?
  - System security specifications
  - User access
- Verification/validation
  - How do we know it was the participant?
  - Record retention
  - Must be auditable and available in the event of an audit

Legally Valid e-Signatures

- Federal Requirements – US Electronic Signatures in Global and National Commerce Act (2000 – ESIGN)
  - Grants electronic signatures the same legal status as handwritten signatures
- Oregon Uniform Electronic Transactions ACT (2001 - UETA)
- Systems must:
  - Validate signatures (intended signee, time/date, un-editable)
  - Demonstrate intent to sign
  - Provide clear "opt out"
  - Provide signed copies
  - Retain records for duration required by applicable regulations
- If done remotely and not personally witnessed by study personnel, the system/process must include a method to ensure the person signing is the subject/LAR

FDA Regulated Studies

- Electronic Consents 21 CFR Part 11 requirements
  - Must verify the identity of an individual before "it establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature"
    - Can use official IDs, security questions, biometric methods with appropriate controls
  - Audit trails
  - Auditable and Accessible by monitor/auditor
  - Retention and Storage
  - Validation
  - Backup/disaster recovery plan
  - And more… see regulations and guidance
  - Sponsor-Investigators should submit copies of all forms and materials (videos, hyperlink materials, etc.) that are used to convey information to participants to FDA

Study Staff

- Study staff must be trained and available to
  - Answer participant questions
  - Address technical issues
  - Provide alternative consent methods for participants who can't or don't feel comfortable with electronic consent
    - Telephone consent
    - Paper in person consent
    - Electronic in person

Copies of Consent

- A copy of the consent must be made available to participants (paper or electronic)
  - Signed copy must be made available for consents that include the HIPAA authorization
  - Information included in hyperlinks should be accessible through study completion
  - Hyperlink information should be provided with a printed paper copy
- Copy of consent must be placed in the OHSU medical records if the study involves clinical services at OHSU (PDF or Print and scan the e-consent)
  - HC-RC-100-RR Content of the Integrated Health Record

e-Consent Considerations

- E-Consent should be easy to navigate
  - Allow participant to go forward and back
  - Allow participant to stop and continue later
- Must be monitorable/auditable
  - Must be able to grant access to all versions of the e-consent and additional materials approved by the IRB
  - System documentation (specifications, validation, testing)
  - In paper or electronic form

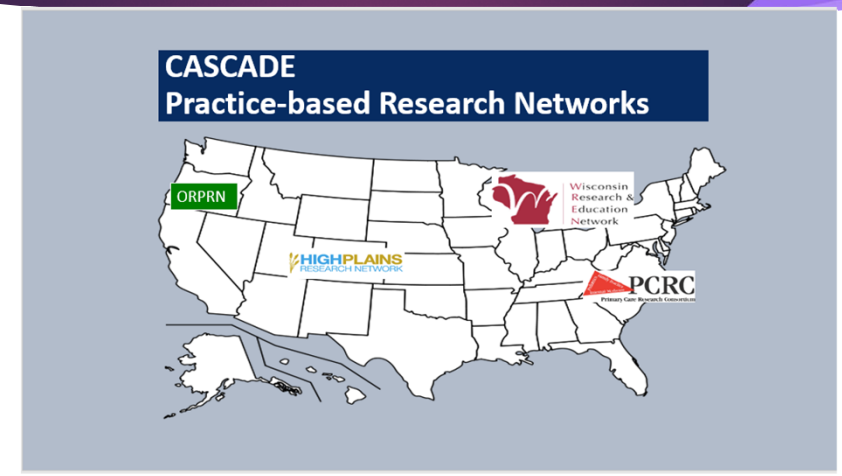
When should I not use e-Consent

- When you are not able to fulfill the obligations we discussed
  - "The investigator cannot delegate authority to obtain informed consent to the electronic system." OHRP 12/2016
- When you don't have a system that can comply with the applicable state and federal electronic signature requirements

CASCADE Objectives/Study Design

- **Does once daily full-body emollient use for infants reduce the cumulative incidence of atopic dermatitis at 2 years of age in a community setting?**
- **Randomized, pragmatic single–blind multicenter trial**
- **Newborns aged 0–8 weeks of age presenting to their primary care office for well–child checks**
- **Primary outcome: ever having a diagnosis of atopic dermatitis by their provider as recorded in the EHR by 2 years of age using standard criteria**

4 PBRNs and 25 participating primary care clinics in 4 different regions



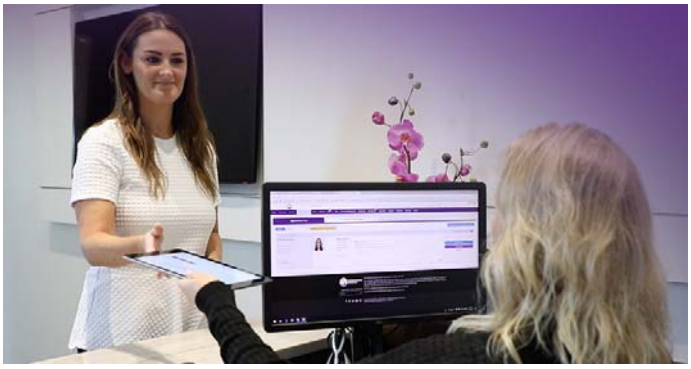
Why did we need e-consent?

- **Limited budget**
- **With 25 clinical sites, minimize the involvement of clinical site personnel to the absolute minimum**
- **Clinic personnel should not be "engaged in research"**
- **Standardize consent process**
- **Uncomplicated inclusion/exclusion criteria**
- **Locus of control is central, not within each clinical site**

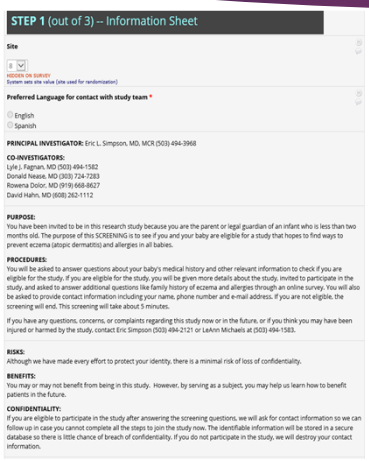
Multi-step process to obtain consent

1. Info Sheet and Limited Consent
2. Primary Contact Information
3. Screening Questionnaire
4. Informed Consent, Questions?
5. Informed Consent
6. Baseline Questionnaire
7. Randomization

Clinic staff provide an Ipad to potential study participants at child's appointment



Info sheet & limited consent



STEP 1 (out of 3) -- Information Sheet

Site

HIDDEN ON SURVEY
System sets site value (site used for randomization)

Preferred Language for contact with study team *

English
Spanish

PRINCIPAL INVESTIGATOR: Eric L. Simpson, MD, MCR (503) 494-3968

CO-INVESTIGATORS:
Lyle J. Fagnan, MD (503) 494-1582
Donald Nease, MD (303) 724-7283
Rowena Dolor, MD (919) 668-8627
David Hahn, MD (608) 262-1112

PURPOSE:
You have been invited to be in this research study because you are the parent or legal guardian of an infant who is less than two months old. The purpose of this SCREENING is to see if you and your baby are eligible for a study that hopes to find ways to prevent eczema (atopic dermatitis) and allergies in all babies.

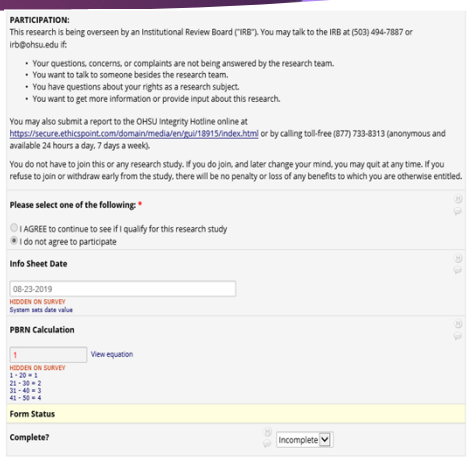
PROCEDURES:
You will be asked to answer questions about your baby's medical history and other relevant information to check if you are eligible for the study. If you are eligible for the study, you will be given more details about the study, invited to participate in the study, and asked to answer additional questions like family history of eczema and allergies through an online survey. You will also be asked to provide contact information including your name, phone number and e-mail address. If you are not eligible, the screening will end. This screening will take about 5 minutes.

If you have any questions, concerns, or complaints regarding this study now or in the future, or if you think you may have been injured or harmed by the study, contact Eric Simpson (503) 494-2121 or LeAnn Michaels at (503) 494-1583.

RISKS:
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

BENEFITS:
You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

CONFIDENTIALITY:
If you are eligible to participate in the study after answering the screening questions, we will ask for contact information so we can follow up in case you cannot complete all the steps to join the study now. The identifiable information will be stored in a secure database so there is little chance of breach of confidentiality. If you do not participate in the study, we will destroy your contact information.



PARTICIPATION:
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

Please select one of the following: *

I AGREE to continue to see if I qualify for this research study
I do not agree to participate

Info Sheet Date

08-23-2019
HIDDEN ON SURVEY
System sets date value

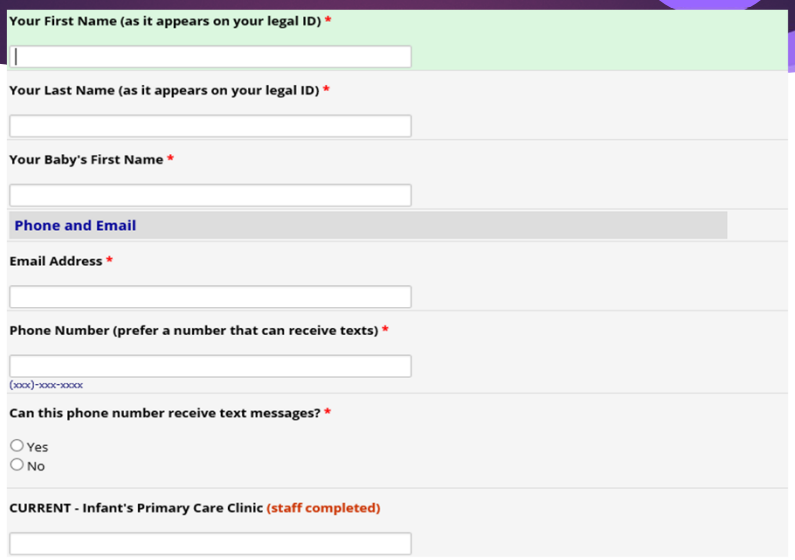
PBRN Calculation

1 View equation
HIDDEN ON SURVEY
1 - 20 = 1
21 - 30 = 2
31 - 40 = 3
41 - 50 = 4

Form Status

Complete? Incomplete

Primary contact information



Your First Name (as it appears on your legal ID) *

Your Last Name (as it appears on your legal ID) *

Your Baby's First Name *

Phone and Email

Email Address *

Phone Number (prefer a number that can receive texts) *

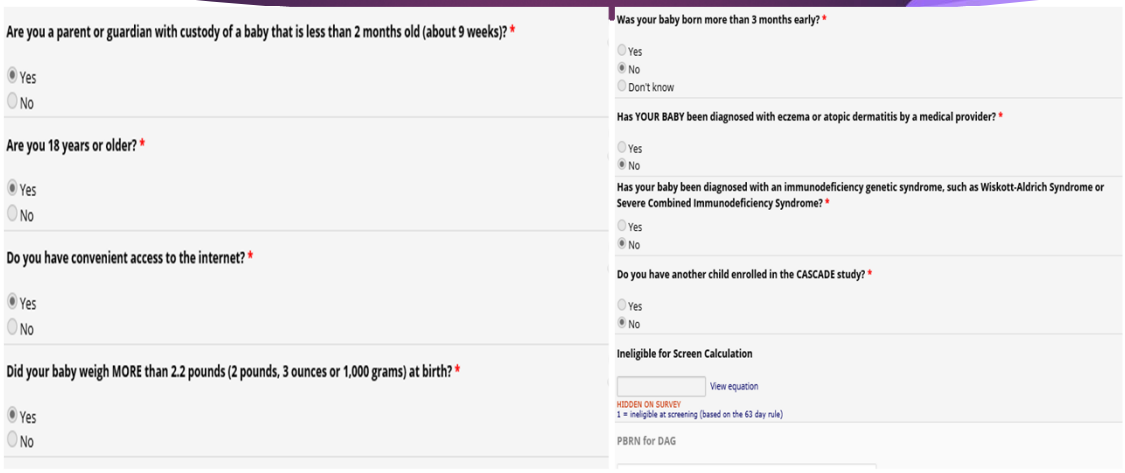
(xxx)-xxx-xxxx

Can this phone number receive text messages? *

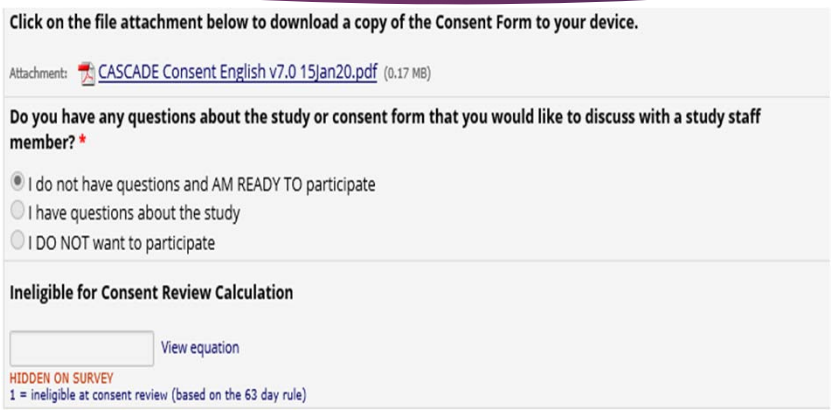
Yes
No

CURRENT - Infant's Primary Care Clinic (staff completed)

Screening questionnaire



Informed consent…do you have questions?



Study staff calls any participant who clicks "I have questions about the study"

Informed consent

Informed Consent Date (please update with the date you are completing this form) *

02-13-2020 Today M-D-Y

Enter month-day-year (format mm/dd/yyyy) || Introduzca mes-día-año (formato mm/dd/aaaaa)

If you need to review consent again - click on the file attachment below to download a copy of the Consent Form to your device

Attachment: CASCADE Consent English v7.0 15Jan20.pdf (0.17 MB)

I have READ the Informed Consent and I AGREE to participate in this study. *

- Yes
- No

reset

Signature of Study Staff

Add signature

HIDDEN ON SURVEY

Study Staff Name

First and Last name

HIDDEN ON SURVEY

Form Status

Baseline questionnaire & randomization

- Cannot randomize the child without completing the baseline questionnaire
- Ensures that we have the necessary data prior to continuing
- Then allocated to intervention or usual care
- Parents sent packet

What to be aware of

- What happens when parent is interrupted in reviewing the material in the waiting room?
- Save and return? No
- Very important to check signature on consent form. Does it agree with the patient's name?
- What about duplicates?
- Language – dual English and Spanish
- What proportion have access to internet? Smart phone?

Is it effective? Yes

- Screened N=1245, 7% have refused to consider study or sign pre-consent
- In those who progress towards consent:
  - Old process – 6% signed consent but did not provide contact info or complete screening
  - 6% did not meet inclusion/exclusion criteria
  - 5% did not agree to sign consent form
  - 1% had questions about study prior to consent
  - 4% stopped at some point in process prior to randomization and did not continue

The Cadillac model.....

- Uses digital story telling with multimedia such as videos, animation
- Patients can drill down for more info
- Findings
  - Higher satisfaction
  - Higher ease of use
  - Shorter time to complete
- Teach-back procedures using multiple choice questions to restate key elements and confirm comprehension
  - If incorrect, provide correct info

e-Consent System Options available

- REDCap - not 21 CFR Part 11 Compliant
  - Must be OHSU investigator initiated trials
- Part 11 options available for a fee
  - Consultation required
- Submit OCTRI Resource Request form or contact OCTRI Navigator (octri@ohsu.edu)

References/Resources

- 21 CFR Part 11
- Use of Electronic Informed Consent Questions and Answers – Guidance for Institutional Review Boards, Investigators, and Sponsors (2016) https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html