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

  - 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

**PARTICIPANTS**
This research is being overseen by an institutional review board (IRB). You may call to the IRB at (202) 444-7607 or visit [webpage](https://example.com).

- Your questions, concerns or complaints are not being monitored by the research team.
- You have the right to someone besides the research team.
- You have the right to withdraw from the study at any time.
- You are entitled to ask questions or get more information about the research.

No. If you are interested in participating in any research study, you should talk to your doctor or a representative of the research team.

You will receive copies of your information. If you have any questions or concerns, please contact the research team at [contact information].

**Primary contact information**

- First Name
- Last Name
- Baby's First Name
- Phone Number
- Email Address

- Can this number receive text messages?
  - Yes
  - No

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

Are you a parent or guardian with custody of a baby that is less than 2 months old (about 9 weeks)? *
- Yes
- No

Are you 18 years or older? *
- Yes
- No

Do you have convenient access to the internet? *
- Yes
- No

Did your baby weigh MORE than 2.2 pounds (1 kilogram, 500 grams) at birth? *
- Yes
- No

Has your baby been diagnosed with atopic dermatitis by a medical provider? *
- Yes
- No

Has your baby been diagnosed with an immunodeficiency genetic syndrome, such as Wiskott-Aldrich Syndrome or Severe Combined Immunodeficiency Syndrome? *
- Yes
- No

Ineligible for Screen Calculation

View equation

FAILURE TO CAUSE:
1. Ineligible at screening (based on the 63 day rule)

PBO for DAS

Informed consent...do you have questions?

Click on the file attachment below to download a copy of the Consent Form to your device.

Attachment: CASCADE Consent English v2.0 15jan20.pdf (0.17 MB)

Do you have any questions about the study or consent form that you would like to discuss with a study staff member? *
- I do not have questions and AM READY TO participate
- I have questions about the study
- I DO NOT want to participate

Ineligible for Consent Review Calculation

View equation

FAILURE TO CAUSE:
1. Ineligible at consent review (based on the 63 day rule)
Study staff calls any participant who clicks “I have questions about the study”
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