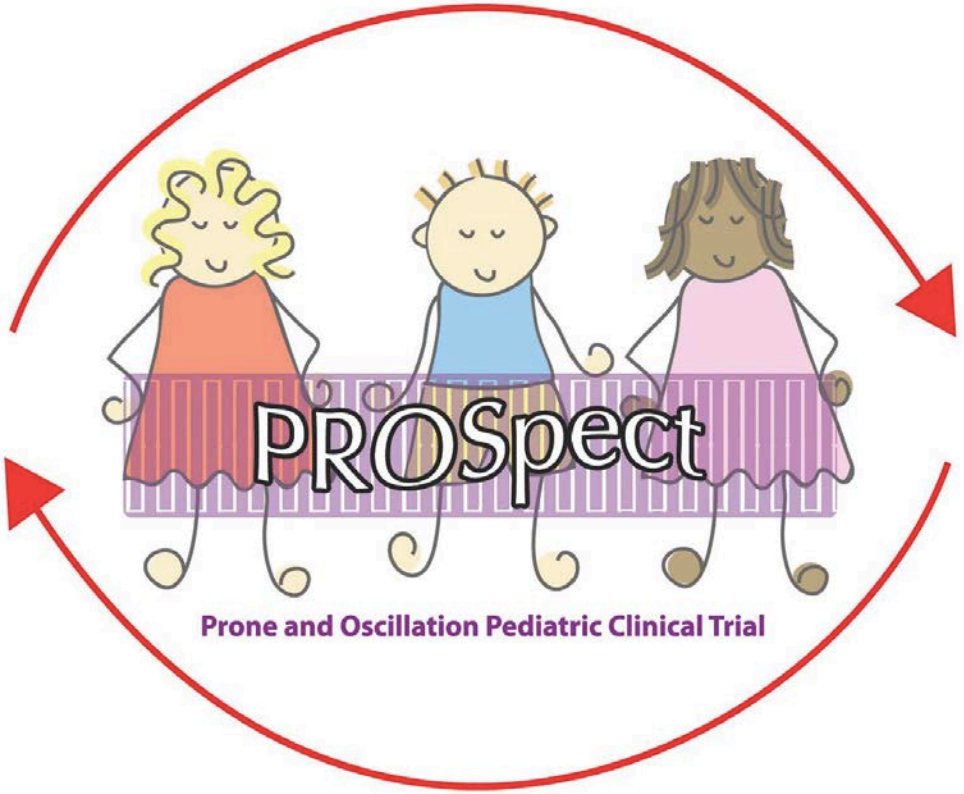
*PROSpect*: PRone and OScillation PEdiatric Clinical Trial

Phase III Clinical Trial

UG3 HL141736-01

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# Overview

- Study Terms
- Reliance Agreements
- SMART IRB
- IRB Approval Process in the US
- International Ethics Approval

# Study Terms

A few terms to remember:

- *IRB of Record* = University of Pennsylvania
- *Reliance Site* = a US study site collecting data for the PROSpect study
- sIRB = single IRB, the preferred mechanism for all NIH funded multi-site studies
- SMART IRB = a Master Reliance Agreement and reciprocal IRB reliance model enabling sIRB review in accordance with NIH policies
  - Penn IRB has signed onto SMART IRB
  - Multiple academic centers throughout the country signed on – to check your institution's status:

    https://smartirb.org/participating-institutions

✓ CCC = Clinical Coordinating Center

- Dr. Curley and her team at Penn serve as the CCC for this study

# Reliance Agreements

- Only apply to US study sites
- Each US site will enter into an agreement with Penn
- Each US site's IRB accepts the ethical review and approval of the IRB of Record (i.e. Penn)
  - Rather than performing their own separate IRB review and approval
- Each US site maintains IRB responsibility to ensure adherence to Institutional policies and practices established by their research protections programs
  - e.g. HIPAA; conflict of interest, injury compensation

# Responsibility of Relying IRBs

1. Sign the IRB Authorization Agreement **or** provide SMART IRB acknowledgement letter
2. Complete local regulatory review:
   - Confirms the study team completed institutional human subjects training requirements
   - Determines additional requirements the site must adhere to for compliance with local institutional policies and best practices
   - Reviews site specific language required within the informed consent / assent forms per institutional policy
   - Reviews potential financial conflicts of interest according to the institutions conflict of interest policies
   - Ensures any applicable Ancillary Review Committees (e.g. laboratory) reviews the study

# SMART IRB member or not?

- Whether or not your site is a member of the SMART IRB the result is the same:
  - Penn is relying IRB
  - Study site IRB cedes review to Penn

- For SMART IRB members:
  - the process to approval is quicker
  - being a member reduces the back and forth communication of an IRB Authorization Agreement

# US Sites – Overview

- Sites a part of SMART IRB
  1. Site PI will request local IRB to cede review and provide acknowledgement letter to Penn
  2. Submit Penn CCC supplied protocol, consents and sIRB approval to local IRB (Consents must be edited prior to submission)

- Sites not a part of SMART IRB
  1. Site PI will execute an IRB Authorization Agreement with Penn
  2. Site is still ceding reviewing to Penn IRB
  3. Submit Penn CCC supplied protocol, consents and sIRB approval to local IRB (Consents must be edited prior to submission)

# Penn's IRB Role

- The Penn IRB will be responsible for:
  - Initial full board review of the protocol
    - Ethical review; Common Rule; Belmont principals
  - Acceptance of reportable events and deviations
  - Track key personnel
  - Conduct annual continuing reviews
  - Approve modifications

# Your site's IRB role

- Reliance Site IRB's will only be responsible for:
  - Confirm institutional policies adhered to
    - e.g. training, licenses
  - Complete a Conflict of Interest analysis
  - Review site specific language in the ICFs
    - Injury/compensation language
    - Local contact information
    - EMR usage (if applicable)
    - State and local laws/regulations
  - Ancillary Reviews (if applicable)


# Let’s review the process

# Approval Process

**Penn review is first**

Step #1

- Initial review
- Full IRB board approval of protocol from Penn IRB

**Site review is second**

Step #2

- SMART IRB authorization
- Local IRB review at your site

**Penn conducts a final review**

Step #3

- Modification submitted
- Approval from Penn IRB adding your site and stamping consent forms

# Step #1: Penn Review

**Penn CCC Submits sIRB and Reliance Agreement Acknowledgement for Review**

**Penn CCC Submit:**

- ✓ Study Protocol
- ✓ ICF template
- ✓ Study Site Contact Information

**Penn IRB Review:**

- ✓ Approves use of a sIRB & Penn as IRB of record
- ✓ Approves ICF template(s)
- ✓ Approves study protocol

# Step #2: Site Review

**Your site will receive documents from Penn CCC**

**Prepare these documents for Local Submission:**

1. Revise ICF template to include local requirements and site specific language
2. Complete Penn IRB Authorization Agreement Form
3. Complete sIRB Site Addition Form^

**Submit documents for Approval:**

1. Study Protocol
2. Penn sIRB Approval Letter
3. Penn IRB Authorization Agreement Form
4. Site Specific ICFs

*^ this form does not need to be approved by your IRB. It is completed and returned to the Penn CCC with your approval documents*

# Step #2 Complete

**Your site receives local IRB approval**

**Site Returns the following documents to Penn:**

1. Acknowledgement to rely on Penn IRB*
2. Local IRB approval letter*
3. Approved ICFs *(your IRB does not stamp the ICF)*
4. Completed sIRB Participation Site Addition Form

* Review boards may provide both of these within one letter

# Step #3: Penn Final Review

1. **Penn CCC submits a Modification to Penn IRB**
   - **This modification requests approval to add your site and begin data collection**
2. **After approval received, the CCC will send <u>to your site</u>:**
   - Approved and Stamped Site-Specific ICFs
   - IRB Approval Letter
   - Signed Site Addition Form

Site may now begin screening and enrollment

# Ethics Review
# International Sites

- Confirm your local independent ethics committee (IEC) is registered with DHHS/OHRP

  https://www.hhs.gov/ohrp/international/index.html
- Identify a local Point of Contact for communication with Penn CCC
- Will you utilize a reliance review approach in your geographical area

# Ethics Review
# International Sites

- Execute regulatory review and approval to conduct human subject research according to national and institutional guidelines with IEC
- Provide Penn CCC with IEC approval letter
  - including informed consent forms
- Submit annual review for continued approval with IEC
  - Provide Penn CCC with yearly approval letters

You will receive an email update from the Penn CCC when this process begins.

Please contact Amy Cassidy at 215-898-4151 or by email acassidy@nursing.upenn.edu if you have any questions.

Thank you!

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