

Including Pediatric Populations in Research:

Challenges and Strategies for Recruitment



Outline

- Who is the pediatric population?
- Barriers to inclusion in research
- Inclusion in research: Addressing the barriers
 - Thinking about study planning and design
 - Recruitment materials
 - Identifying and communicating with children and parents/caregivers
- IRB and regulatory requirements
- Resources

Who is the pediatric population?

- The pediatric population includes infants, children and adolescents
 - Per the NIH, individuals under 18 years old are considered “children”
- Working with pediatric populations involves working with both the child and their parent/caregiver (or legally authorized representative (LAR))
- Children are considered a vulnerable population in research
 - Special [regulatory requirements and additional protections](#) govern their inclusion as research participants
- Additionally, children’s inclusion in research is ensured through the [NIH Inclusion of Children Policy](#)*, which aims to increase the participation of children in research so that adequate data will be developed on diseases and their treatments

*Policy renamed “Inclusion Across the Lifespan” in January 2019, now including children through older adults

**NIH (2015). [“Inclusion of Children: Change in NIH Definition.”](#)

Known barriers to including pediatric populations in research:



- Research risk level
- Time
 - Length of study and/or timing and frequency of study visits
- Distance/Travel to study site
- Transportation
 - Parking (location, ease, cost, etc.)
 - Public transit (availability, accessibility, cost, etc.)
- School schedule
 - For child participant and any siblings
- Extracurricular activities schedule
 - For child participant and any siblings
- Work schedule for parent/caregiver

Known barriers continued:

- Parent/caregiver has other children or family they care for
- Ability or mobility level of child participant
- Developmental or cognitive status of child participant
- Accessibility of study site
 - Location, ramps, elevators, etc.
- Language/Non-English speaker
 - For child participant or their parent/caregiver
- Immigration status
 - For child participant or their parent/caregiver
- Other
 - Other barriers that apply to the specific disease/condition or population being studied

Inclusion in research: Addressing the barriers

There are known barriers that exist to pediatric populations inclusion in research. However, there are also measures or practices study teams can put into place to address these barriers and work with this population.

First, start by asking what are the lowest barriers to their inclusion in research? When thinking about study design and recruitment strategies, what measures can be taken to ensure children's inclusion? Additionally, what extra steps can be taken to ensure this vulnerable population is protected? For example:

- In the protocol, can certain study procedures be adapted to match the child's diverse ability levels? Are there other parts of the protocol that can be evaluated or adapted?
- Does the study staff have experience working with children? Does the staff have appropriate training, are they bi-lingual (if needed), etc.? And if not, is there the time and resources for them to become so or for additional staff or collaborators to be added to meet this need?
- Is the study site accessible and appropriate for this population? Is the location convenient to get to? Are there ramps and elevators to accommodate strollers, wheelchairs, walkers, etc.? Is the waiting room child friendly – are there toys, books and other activities to occupy the child participant and/or their siblings? Is the study room child friendly? And if not, what measures can be taken to address these needs?

Addressing the barriers continued:

- Can study visits be aligned with standard of care (SOC) visits to minimize trips to and time at the study site?
- Can SOC medical procedures be combined with study procedures to minimize procedures and impact to the child? For example, if a blood draw is needed for both SOC and study procedures, can it be done at the same time, with the combined amount of blood drawn, so that the child only has to be stuck with a needle once.
- Can there be flexibility in the window of time around study visits to accommodate for school, extracurricular activities, work, family obligations, etc.?
- What measures will be taken to avoid assumptions, and identify and address any special or additional needs of children with varying ability and mobility levels, cognitive or developmental status, and sensitivities?
- What is the primary or preferred language of your child participant and/or their parent/caregiver? Are all recruitment and study materials translated? Is there a bi-lingual study team member or interpreter available?
- Are your recruitment materials sensitive to and inclusive of the pediatric population and their parent/caregiver? What images and words are being used and how is the material being presented?

Recruitment Materials

Images

When choosing images for recruitment materials, it is important to represent the full spectrum of children, genders, age, race, ethnicity, body shape, ability, mobility, etc.





Make sure your images are inclusive and representative of the children and populations you are trying to recruit.

It is also recommended to have different versions of your materials to reach the different age groups you are trying to recruit. Different age levels need and respond to different image types.



Version A



Version B

For example, Version A might be more attractive and better received by an adolescent cohort, where Version B might be best for younger children.

Just like different images for different children's ages, it's also important to have different images to reach the parent/caregiver.



When recruiting from the pediatric population, it's important to have different versions of materials, in both images and wording, to broaden your recruitment reach by speaking to the different individuals and groups involved.

Words

Word choice and writing style is important. It impacts a child participant and their parent/caregiver's ability to be drawn to and understand the recruitment materials, the study, and the decision to enroll in the study.

When creating recruitment and other study materials, it is important to adapt the materials to the different age groups of the children you are recruiting and to the parent/caregiver. It is recommended to create a couple different versions of the materials to effectively reach the different individuals and groups involved.

When writing materials, it is important to consider:

- Are the words understandable to the reading level for the child's age? If an adolescent and/or parent/caregiver, are the words no more than a 6th grade reading level?
- Has all medical terminology been turned to lay language? Was it simplified even further to match the comprehension level of the child's age?
- Are you using people first language?
- Are your words sensitive to the child's state of being, disease or condition?
- Are your words culturally, spiritually, or otherwise competent?
- Is your material health literate?

Other Considerations

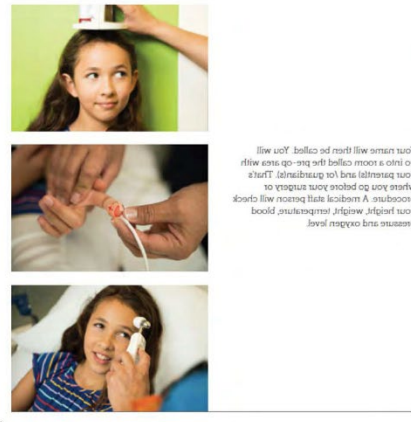
- The amount of words
 - It is recommended to have less words, with only the pertinent information. Less writing on the page makes the recruitment material more attractive, readable, and people are able to draw out the main information.
 - Additionally, consider the average attention span of a child or adolescent. By limiting the amount of words to what is necessary, you are further ensuring they have the ability to fully read and understand your materials.
- The size of your words
 - Make sure your chosen font size is readable, not just overall, but to all vision and age levels.
- The language of your materials
 - What is your pediatric population or their parent/caregiver's primary or preferred language?
 - Are your materials [translated](#) to meet this need?
- Layout and formatting
 - Are your materials laid out in a way that is appealing, readable, and understandable to your intended audience?

When words alone aren't enough

Based on the child participant's age, cognitive status, sensitivities, and other factors, words alone might not be enough to communicate.

Recommendations include:

- On materials, use images, along with the words, to visually represent the words.
- When discussing the study with the child, show them the different instruments, machines and other items that will be used, either in person or through pictures.
- When discussing the study, describe the procedures to them, using both words and images, allowing the child to know what to expect and be prepared for it.
 - For example, study teams have created subject materials for the child with pictures and words to inform and prepare them for what a study visit will look like.



Where can I find some examples of this?

There are many great books and resources available for children explaining healthcare related topics. These provide great examples of how to communicate with children, combining words and images in a child friendly way. Below are a few examples:

Gaydos, N. (2011). *A visit to the doctor*. Norwalk, CT: innovativeKids.

Parker, V. (2011). *Having a hearing test*. Chicago, IL: Heinemann Library.

Radabaugh, M.B. (2004). *Going to the doctor*. Chicago, IL: Heinemann Library.

Singer, M. (2009). *Getting a checkup*. Boston, MA: Clarion Books.

Ziefert, H. (2012). *ABC doctor*. Maplewood, NJ: Blue Apple Books.

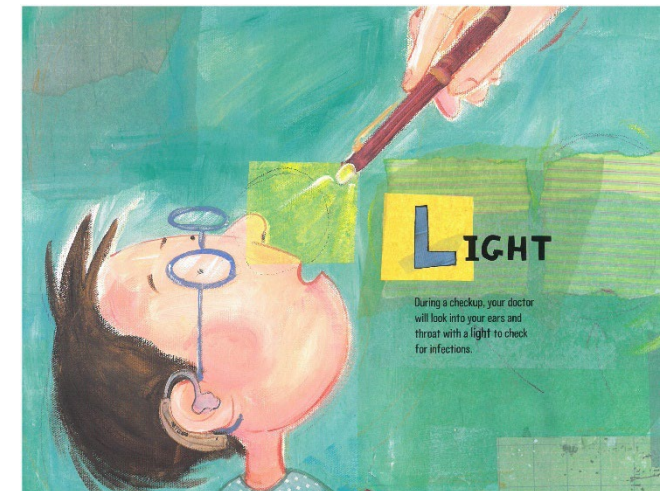
What Type of Equipment Will I See?



You may see a machine that makes different sorts of sounds.

You listen to the sounds through headphones.

12



Identifying and communicating with the pediatric population

Identifying potential participants – Healthcare setting:

- It is advised to build relationships and collaborate with healthcare providers who interact with pediatric populations
 - Getting their buy in and support is important for identifying and approaching potential participants and their families
 - They are the expert on this population - who might be eligible, when the best time to approach them is, and other important information
- The best time to approach a potential pediatric participant is often when they are in clinic for a SOC visit
 - Coordinate in clinic with the healthcare provider and their team for when and how to approach potential participants, including the possibility of them making an introduction between the study team and participant
 - By coordinating with healthcare staff, the study team is able to better align with staff, services, and what is happening and approach at the right time
 - Even if clinic time is agreed to and coordinated, always check in with the healthcare staff before approaching

Identifying potential participants – Community setting:

- In the community, pediatric research can take place at schools, daycares, community centers, parenting groups, or other organizations or individuals that interact with this population
 - It is advised to build relationships early with them to have the time to build visibility, trust and the potential to collaborate with these community partners
 - These community partners are the expert on the population they serve and the bridge between study teams and the children and their parents/caregivers
- Be aware of the policies and procedures surrounding research at your chosen community setting. Many settings have application processes to perform research at their site, in addition to policies around how children can be identified and interacted with
 - Remember doing research in a community setting requires the buy in and support of not only the chosen community partner, but oftentimes their stakeholders as well. For example, a study taking place within the school system may not only need the approval of the School District, but also the Parent Teacher Association (PTA)
- To ensure a more inclusive sample of children, choose community settings in different parts of the city. Many community settings serve only those in the neighboring vicinity, thereby limiting the potential participants to that neighborhood. To ensure diversity and inclusion, and expand the recruitment reach, choose multiple settings to partner with

Communication Style:

How you approach and communicate with children and their parent/caregiver is important. Make sure to pay attention to verbal and non-verbal behavior in your communication style. Best practices include*:

- When the study team enters the room, make eye contact with the child first, introduce yourself to the child and then the parent/caregiver. It is important to fully acknowledge both parties
- Communicate with the child and parent/caregiver both, ensuring both are fully informed and understand
 - Make sure to meet them at their level, explaining in a manner they understand
 - Use a combination of words (verbal and written) and images to communicate the information
 - Provide materials for them to keep and review later as needed
- Be mindful of body language. Bring yourself to the child's level to talk with them, don't tower over them, this helps to set them at ease and eliminate any possible feelings of fear or anxiety
- Connect with the child and their parent/caregiver and build trust
 - Find out what things the child likes and talk with them about it
 - Have toys available for the child, it helps to set them at ease and gives the team an ability to connect with them
 - If possible, stay consistent in the staff they interact with, helping to build a relationship and their comfortability with staff
- Be mindful of actions and words that can help to alleviate any fear or anxiety and help the child and parent/caregiver retain a sense of control over the situation

IRB & Regulatory Requirements

IRB review and approval is required prior to beginning any recruitment or inclusion of children in research. Your IRB approved protocol should describe your recruitment methods.

For pediatric populations, the consent process involves the authorization of the parent/caregiver or other legally authorized representative (LAR) and the child (dependent on age). Additionally, as children are considered vulnerable populations, there are special regulatory protections that govern their inclusion.

To learn more about IRB requirements for involving children in research:

- [Vulnerable Populations - Children \(Quick Guide\)](#)
- [HRP-310 Checklist - Children](#)
- [HRP-021 Policy – Legally Authorized Representatives Children and Guardians](#)

For a full listing of OHSU IRB requirements, please visit the [OHSU IRB website](#). For additional information and questions, please email irb@ohsu.edu.

***Please note, these IRB guidelines are only for studies where OHSU IRB is the IRB of record.
If another IRB is the IRB of record (e.g., the VA, a central IRB), please email irb@ohsu.edu for specific policies and procedures.***

Resources

NIH - Clinical Research Trials For Parents & Children

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/parents-children>

OHSU - Oregon Center for Children & Youth with Special Health Needs (OCCYSHN)

<https://www.ohsu.edu/occyshn>

OHSU Communications - Image Sources

<https://o2.ohsu.edu/communications/photography>

CDC – Health Literacy

<https://www.cdc.gov/health-literacy/php/about/index.html>

For more information, additional resources, and to request a recruitment consultation, please visit the OCTRI Recruitment [webpage](#) or email us at octrirecruitment@ohsu.edu.



This document was created in support of CTSA grant UL1TR002369.

Document Version: 09 Feb. 2026