

Assent Best Practices

Jennifer Mullett, BSN RN-BC CCRP

Sr. Clinical Research Project Manager

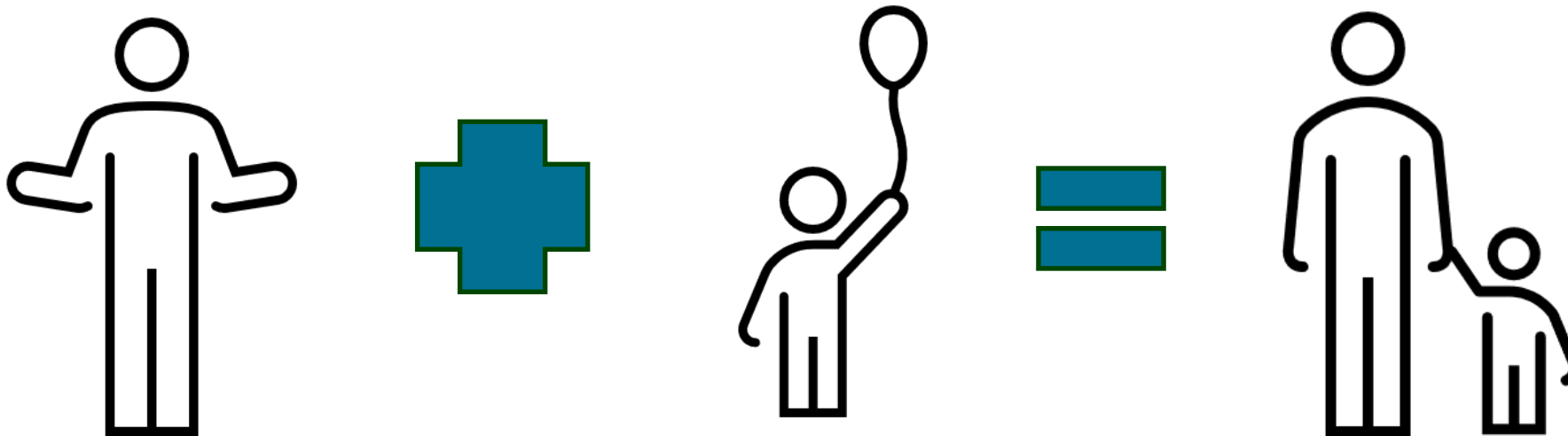
MAD99 - Lurie Center for Autism - Massachusetts General Hospital



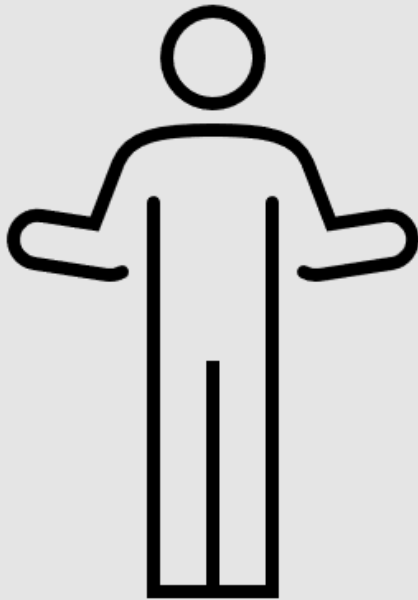
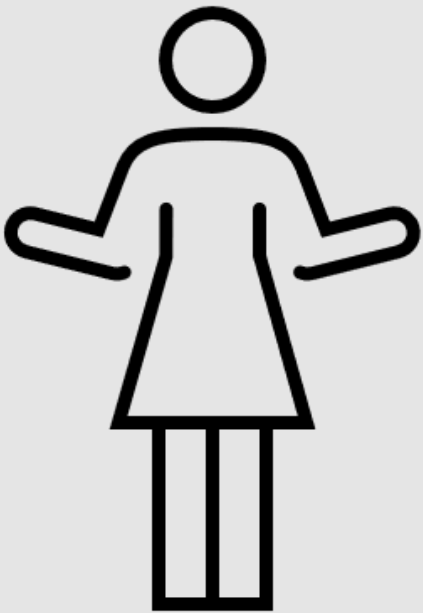
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- Know the local and state laws for research at your site
- Be aware of local institution's practices for obtaining assent
- Consult any local relevant policies
 - Who is authorized under local laws to make medical decisions
 - Parent, guardian, relative with temporary custody

- The combination of parental permission and assent is equivalent to informed consent.



What is Assent?



- A parent of a minor or a legally authorized representative (LAR) gives **permission** for their child to participate in research
- A child gives **assent** to participate

Who can give parental permission?

- a) Child's mother
- b) Child's father
- c) Child's non-biological parent
- d) Court appointed guardian
- e) Visiting grandparent

Who can give parental permission?

- e) Any of these are possible if there is legal documentation stating person has the authority to provide parental permission
 - i.e., court documents, Hospital generated demographic (face sheet)

- IRB determines how many parents must give parental permission
 - POP02 – requires permission of at least one at most sites
- Even if IRB determines both parents are required, certain circumstances allow this to be waived:
 - Deceased
 - Unknown
 - Incompetent
 - Not reasonably available
 - Does not have legal custody of the child
- Make NTF to why both parents did not consent

- Trained study staff delegated to this task by the PI
- Parent and child in same room during discussion and assenting process.
- Use plain language with both parent and child.
- Use of aids to help explain the trial
 - Written form
 - Graphics or other visual aids
- Encourage questions

How do I know if the child is capable of providing assent?



- Things to consider:
 - Maturity of child
 - Communication skills
 - Is the child listening to what you are saying?
 - Does the child have any developmental or cognitive delays?

Red Flags

- Not paying attention
- Unable to answer questions
- Poor language skills for his/her age
- Health condition that may interfere with ability to communicate (autism, traumatic brain injury, severe ID)
- Consult with PI



2 pm Wednesday - Screen visit for POP02-DS

- 8 yo boy Down syndrome
- Mother and step-father present
- Significant hyperactivity and inattention during visit, not able to remain seated and required several breaks over 45 minutes
- “No needles, no pinch.” “Time to go.”
- Parent concerned about duration of visit.
- Step-father has to get to work by 4pm

Best strategy to assent Billy?

- a) Tell them it sounds like they are not ready for the visit and to come back another day.
- b) Review the consent with step-father and have mother take the child for a walk then return to sign the forms
- c) Find a hallway or room for you and the child to move/play and talk.
- d) Tell mother and child not to worry about all the legal jargon and to sign the forms so the child can get a prize for him at the end.

C) Find a hallway or room for you and the child to move/play and talk.

Ask simple questions to assess his communication level.

What he came the clinic to do today?

Do you have to do the study?

Study specific

How many people will be in the study?

What will you be asked to do?

What happened to Billy?

- Study staff engaged with activities to build rapport with Billy
- Allowed movement about room
- Billy responded to questions
 - “Billy does good. Go to doctor. No pinch. “
 - “All done.” “Go to McDonald’s.”
- Did not assent Billy
- Documented he was not developmentally able to assent

- Female turning 18 yo at midpoint visit
- Father present, health care proxy as noted in medical record
- Cheerful, cooperative, requesting stickers
- “I love Dr. T.” “She makes me feel better.” “I’m brave and I’m going to sit still.”
- Impaired fine motor skills with upper extremities
- Learning to read

Should Susie sign an assent if her father is her health care proxy or LAR?



- a) No. Her father said not to bother asking her about the study because she wouldn't understand.
- b) Yes. Because she is cooperative and says she is getting her blood drawn.
- c) Yes. Susie can sign the assent with the LAR as person giving permission to participate if study staff assess her ability to comprehend the assent form.
- d) No. Susie can only participate in the discussion and is not allowed to sign any documents

c) Yes. Susie can sign the assent with the LAR as person giving permission to participate if study staff assess her ability to comprehend the assent form.

- For adult participants consider asking:
 - Do your parents help you make medical decisions?
 - What will we ask you to do in this study?
 - Do you have to be in the study?
 - Will you get anything for being in the study?
 - What are the risks of the study?
 - What are some bad things that could happen?
 - Engaging them in the conversation in the beginning
 - Ask parent/LAR about preferred terminology (i.e., green mosquito for butterfly needle)

What happened to Susie?

- Assent obtained
- Susie able to reply to study staff questions
- Signed form by printing first name as her signature
- Dated form on signature line across to date line

Questions/Comments?

Feel free to contact me:

jmullett@mgh.harvard.edu

Thank you!