Pediatric PittNet

Here at **Pediatric PittNet** we are dedicated to helping researchers connect with families and children in the community. One of our goals is to enhance *informed* consent of potential research participants. We are always seeking to improve our consent process to better serve the interests of the families in our practices. Below we have provided various pediatric friendly tips and examples for developing comprehensive and practical consent forms. Incorporating some of these techniques will help to enhance both parent interest in and understanding of what their child's participation in your study will involve.

Tips for making Pediatric Consent Forms

- Strive for **SIMPLICITY and CLARITY!** "If you can't explain it simply, you don't understand it well enough." –Albert Einstein. You should try to make your consent as simple and short as possible to enhance attention and understanding.
  - ✓ **DO** try to keep it within 4 pages, including parental consent and child assent, when possible, while also still meeting IRB requirements.
  - ✓ **DO** use easy to read front and sizes (Examples in pt. 14: Ariel, Calibri, Times New Roman, Helvetica)
  - ✓ **DO** use bullet points when appropriate.
  - ✓ **DO** keep it at the 6th – 8th grade reading level. (You can check this on Microsoft Word! Note: Can you add that the Word program for calculating reading level (Flesch Kincaid) tends to underestimate by approximately 2 grade levels. So investigators should aim for a 6th grade reading level or below.
    - ✓ Find this under: FILE → Options→ Proofing→ UNDER 'When correcting spelling and grammar in Word SELECT 'show readability statistics' →Hit OKAY→ then run a spelling check in REVIEW (This document is in the 8th grade level.)

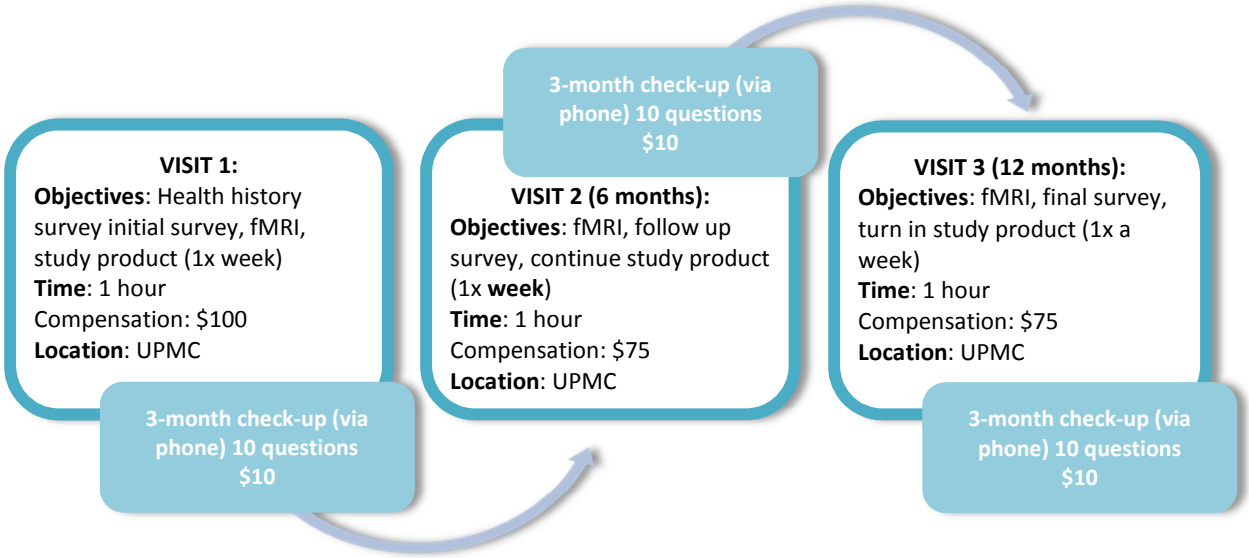
- ✓ **DO** keep your explanations short and concise; avoid use of complex descriptions unless necessary.
- ✓ **DO** make your consent clean looking and less cluttered. Make sure to have white space throughout your document.

- Get **COMFORTABLE!** Along with using simple and lay terms, allow your consent to have a comfortable and conversational tone. This can help make your participants be more engaged in the informed consent process.
  - ✓ **DO** use a positive spin to show you are passionate about your research topic!
- **EMPHASIZE!** Emphasizing the important information can help tune your subjects into what they need to know most.
  - ✓ **DO** **BOLD or <u>UNDERLINE</u>** headlines and important information.
  - ✓ **DO** use visual aids and charts to describe your study. These can help highlight the important components of your study and are very **SIMPLE**! This can be especially helpful for studies that have multiple time points for subject participation.

Example of a chart 1:

<u>TIME 1 (Start)</u>	**<u>TIME 2 (6 months)</u>**
Objectives: • Initial survey (40 questions) • Study product and diary entry (1x every 2 weeks until 6 months) **Time**: 30 minutes **Location**: UPMC Compensation: $25	**Objectives**: • Initial survey (40 questions) • Study product and diary entry (1x every 2 weeks until 6 months) **Time**: 30 minutes **Location**: UPMC Compensation: $25

Example of Chart 2:



- Can they **PICTURE** it? When appropriate, using pictures about your study can help your participants understand what they are actually going to be doing in your study.
  - ✓ **DO** use pictures if you are doing any complicated or technical medical procedures for your study (e.g., fMRI or EEG). Using pictures can help decrease worry and stress about the procedure.
  - ✓ **DO** use maps or pictures of your study's building to show your study's physical location! This is great for participants unfamiliar with the area.

- Show your true **COLORS!** Using colors is a great way to make your consent form stand O U T. This can help encourage your subjects to read the consent form more thoroughly.

  Tips for using color:
  - ✓ **DO** choose bold and basic colors.
    - ✓ **RED**, **GREEN**, and **BLUE** are great choices for **EMPHASIZING** important sections on your consent such as headlines.
  - ✓ **DO** use lighter colors for accents and borders. This will allow you to use more colors without making it seem too distracting.

- ✓ **One Caution:** Avoid certain color combinations when differentiating important points (such as comparing items in a chart) Common combination to avoid include: red and green; blue and yellow; green and brown; blue and purple, green and blue). About 10% of us have color blindness and may see no difference in between colors in these pairs.

- Don't forget to **ASSENT**! The Human Rights Protection Office (formerly the IRB) requires that consent forms include an assent section which is: "An affirmative agreement by the child to participate in research. Mere failure to object should not be construed as assent without an affirmative agreement." (University of Pittsburgh IRB)

Tips for Assent!

- ✓ **DO** consider the age and maturity of a child with the study protocol when obtaining assent
  - ✓ Always explain assent in age appropriate language.
- ✓ **DO** include an assent section according to IRB requirements
- ✓ **DO** have the parent and child (if appropriate) explain in their own words what their participation in the study would be
- ✓ **DO** include child signature line (for children developmentally able to sign their name) or check box to document assent.
- ✓ **Do** use the emphasized information throughout the consent form (i.e. bolded sections, charts, etc.) to help your child/adolescent understand their research participation.