

## ACTIVITY 6: Clinical Trials from a Patient's Perspective

### Teacher Instructions

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**Research literacy** relates to the understanding of research and the research process, use of research evidence in practice, and/or ability to critically appraise research. It also refers to one's ability to make informed decisions about participating in research studies.

Children may be asked to take part in a clinical trial. A clinical trial is a research study designed to test a medication, program or other intervention to see if it has an effect. The National Institutes of Health (NIH) has been making efforts to raise awareness of clinical trial participation for children. This activity provides students with an opportunity to learn about clinical trials from a patient's perspective. It also helps students learn about the role of informed consent, so that they are better able to determine whether they want to participate in a research study.

In this activity, students will create a research study child assent form for a clinical trial. They will first review information about this clinical trial:

#### **A Nutrition Intervention to Lower Blood Pressure in Adolescents**

<https://clinicaltrials.gov/ct2/show/NCT00431288?term=adolescents+and+nutrition&rank=2>

Students will then use the Research Study Assent Form Template to create an assent form for the clinical trial. It is important to use the existing template as there are legal requirements about what needs to be included in an assent form. The information in the assent form should be written in an easy to understand way.

This series of websites provide information on the importance and role of children in clinical trials. You may want to share one or more of these with the class:

- **Why do Research in Children?** <http://www.childrenandclinicalstudies.org/Why-Its-Important/Why-Do-Research-In-Children>
- **Why Clinical Studies are Important** <http://www.childrenandclinicalstudies.org/Why-Its-Important/Why-Clinical-Studies-Are-Important>
- **Research Versus Care** <http://www.childrenandclinicalstudies.org/Why-Its-Important/Research-Versus-Care>
- **How Children Benefit** <http://www.childrenandclinicalstudies.org/Why-Its-Important/How-Children-Benefit>

You also might want to show this video that was created by the NIH National Heart, Lung, and Blood Institute:

**Children and Clinical Studies: For parents and caregivers**

<https://www.youtube.com/watch?v=JXoSLynCwgE&feature=c4-overview&list=UUsvTFTNyvxcartbMrVwoXw>