No Laughing Matter: Comic Assent for Biobanking
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Problem Statement: Sections of the US Code of Federal Regulations pertaining to protection of human research subjects state that "the IRB shall determine that adequate provisions are made for soliciting the assent of the children." 45 CFR §46.408(a) (2010). Assent is defined as "a child’s affirmative agreement to participate in research." 45 CFR §46.402(b) (2010). The phrase “adequate provisions” has not been clarified by any regulating body, although the age, maturity, and psychological state of the children involved should be considered. Assent does not carry the same requirements as the informed consent given by adults; it is meant to give the child a voice about participating in research, particularly since research is not a clinical need. Although there is not a lot of data about children’s understanding of assent, the studies that have looked at comprehension suggest that children do not fully understand the information presented to them.

Description of Research: In order for the concept of assent to be meaningful, it is critical that minors are given enough information to understand the consequences of participating in research. The last several years have seen a rise in graphic novels depicting medical experiences and graphic stories used for patient education purposes, both of which have proven successful. Graphics have not been utilized in the context of assent, though. Will the engaging nature of an illustrated document improve minors’ interest in and comprehension of a research assent document? An interdisciplinary team comprised of individuals with expertise in design, illustration, ethics, research, genetics, and law developed a comic assent for children ages 12-18 enrolling in a research biobank. The comic assent was compared to a text-based assent in a study that assessed preference and comprehension among 267 adolescents. While there were no significant differences in comprehension scores based on participant age, sex, or number of doctor’s visits in the last year, non-native English speakers did show a higher comprehension score when the comic assent was used. Also, overall, the comic assent was preferred, and rated as more interesting to read.

Additional Information: Rather than just adding illustrations to existing text, we developed a narrative flow which shows a group of peers discussing biobank participation. This assent is also novel because it focuses on biobank participation rather than engagement in a typical clinical trial. Consent for biobanking is a complex issue because participants are typically asked to give broad consent for unspecified future research.