As genome-editing trials become more common, informed consent is changing

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As genome-editing trials become more common, the process of informed consent is changing. Credit: Ernesto del Aguila III (NHGRI)

As public interest and expanded research in human genome editing grows, many questions remain about ethical, legal and social implications of the technology. People who are seriously ill may overestimate the benefits of early clinical trials while underestimating the risks. This

makes properly understanding informed consent, the full knowledge of risks and benefits of treatments, especially important.

In response to this emerging need, researchers at the National Human Genome Research Institute (NHGRI), part of the National Institutes of Health, asked patients, parents and physicians in the sickle cell disease community what they wanted and needed to know about genome editing to make informed decisions about participating in genome-editing clinical trials. Gene-editing treatments, which appear to provide a potential for sickle cell, are among the most widely publicized medical advances in recent years. The results were published this week in the journal *AJOB Empirical Bioethics*.

"An important goal of informed consent is to facilitate decisions that are consistent with a person's values," said Sara Hull, Ph.D., director of the Bioethics Core at NHGRI. "By talking to sickle cell disease stakeholders ahead of time, we can learn more about their values and hopefully do a better job of pinpointing what kinds of information will be most useful to potential research participants as they make very a difficult decision."

Researchers contacted adults with sickle cell disease and parents and physicians of adults and children with the disease. These participants completed a genetic literacy survey, watched an educational video about genome editing, completed a two-part survey, and took part in focus group discussions about CRISPR somatic genome editing, an experimental treatment option for sickle cell disease.

The researchers found that all participants wanted informed consent to include the treatment side effects of CRISPR somatic genome editing. Many people also wanted to know how such editing works and its impact on their quality of life. The groups reflected on the need to have flexibility in the kind of information provided since people have differing levels of knowledge of biology and genomics.

Interestingly, while some physicians were concerned about how well patients would understand concepts related to somatic genome editing, study participants demonstrated higher genetic literacy levels than estimated.

The NHGRI study suggests that the sickle cell disease community is optimistic about the promises of somatic genome editing. Responses highlight the need to begin discussing what informed consent looks like, especially when lack of information and misconceptions about the risks and benefits can influence a person's decision to participate in a clinical trial.

"Designing clinical trials for curative genetic therapies requires addressing the patient communities and their families need for accessible information about the risks and benefits," said Vence Bonham, J.D., an associate investigator in the Social and Behavioral Research Branch at NHGRI and senior author on the paper. "These first-in-human curative genome editing therapies are an opportunity to develop new consent approaches to meet the information needs of potential research study participants and their families."

By creating a standard for informed consent with respect to genome editing clinical trials, such engagement with patient communities may be replicated across biotechnology companies and research institutions.

"Participating in any clinical trial is both a matter of faith and good judgment for individuals, and the research community must build models of consent, understanding and trust as crucial pillars that promote safety and success for the patients," Bonham said.

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