NATIONAL ACADEMY OF MEDICINE *AND*
NATIONAL ACADEMY OF SCIENCES

THE ROYAL SOCIETY

International Commission on the Clinical Use of Human Germline Genome Editing

Statement of Task

Clinical applications of germline genome editing are now possible and there is an urgent need to examine the potential of this new technology. Many scientific and medical questions about the procedures remain to be answered, and determining the safety and efficacy of germline genome editing will be necessary but not sufficient conditions for future clinical usage. There is a need for a framework to inform the development of a potential pathway from research to clinical use, recognizing that components of this framework may need to be periodically revised in response to our rapidly evolving knowledge. In addition, other important discussions are ongoing internationally about the implications for society of human germline genome editing and include issues such as access, equity, and consistency with religious views.

An international commission will be convened with the participation of National Academies of Sciences and Medicine throughout the world to develop a framework for considering technical, scientific, medical, regulatory, and ethical requirements for germline genome editing, should society conclude such applications are acceptable.

The U.S. National Academies of Sciences and Medicine and the U.K. Royal Society will serve as the commission's secretariat.

Specifically, the commission will:

1) identify the scientific issues (as well as societal and ethical issues, where inextricably linked to research and clinical practice) that must be evaluated for various classes of possible applications. Potential applications considered should range from genetic correction of severe, highly penetrant monogenic diseases to various forms of genetic enhancement;

2) identify appropriate protocols and pre-clinical validation for assessing and evaluating on-target and off-target events and any potential developmental and long-term side effects;

3) identify appropriate protocols for assessing and evaluating potential mosaicism and long-term implications;

4) identify ways to assess the balance between potential benefits and harms to a child produced by genome editing and to subsequent generations.

5) design appropriate protocols for obtaining consent from patients, for obtaining ethical approval from knowledgeable review committees, and for satisfying regulatory authorities;

6) identify and assess possible mechanisms for the long term monitoring of children born with edited genomes; and

7) outline the research and clinical characteristics developed in tasks 1-6 that would form part of an oversight structure, including defining scientific criteria for establishing where heritable genome editing might be appropriate, overseeing any human clinical use, and bringing forward concerns about human experiments.

The commission will hold three meetings and an international workshop. After the first meeting a call for public input will be issued. The results of this call will inform the second meeting and the international workshop. The third meeting will be used to develop the commission's findings and recommendations.

A final report providing the commission's findings and recommendations will be issued at the conclusion of the project.