

# Human Genome Editing: Science, Ethics, and Governance

## Criteria for heritable germline editing

The committee recommends that clinical trials using heritable genome editing should be permitted only within a robust and effective regulatory framework that encompasses:

- Absence of reasonable alternatives**
- Restriction to preventing a serious disease or condition**
- Restriction to editing genes that have been convincingly demonstrated to cause or to strongly predispose to the disease or condition**
- Restriction to converting such genes to versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects**
- Availability of credible pre-clinical and/or clinical data on risks and potential health benefits of the procedures**
- Ongoing, rigorous oversight during clinical trials of the effects of the procedure on the health and safety of the research participants**
- Comprehensive plans for long-term, multigenerational follow-up while still respecting personal autonomy**
- Maximum transparency consistent with patient privacy**
- Continued reassessment of both health and societal benefits and risks, with broad on-going participation and input by the public**
- Reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition**

