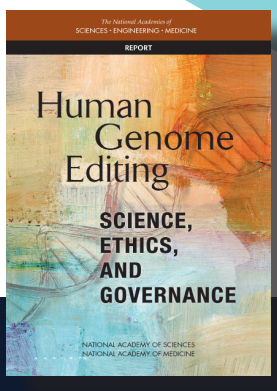
Human Genome Editing:
Science, Ethics, and Governance

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**



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