

Genome Editing for Human Benefit: Ethics, Engagement and Governance

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Pecha Kucha: “Mirror, mirror on the wall...who is the most ethical of us all?” Decoding genetic studies from Pakistan - A review of international, regional and local guidelines and compliance

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Background: “Reflecting” on behaviour and practise is vital and provides important information regarding effective implementation and dissemination of guidelines and standards. The following research was carried out to explore, identify and examine ethical guidelines available for genetic studies and to then analyse and describe the extent to which researchers in Pakistan, comply with existing ethical standards specified for genetic research.

Methods: The International Compilation of Human Research Standards 2019 edition compiled by the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services was used to identify local, regional and international standards for genetic research. Studies published between Jan 2017 and Dec 2018 were reviewed for the following analytic categories derived from the established ethical standards specified by guidelines for genetic research: informed consent, conflict of interest, and IRB review. These categories were complemented by author, institution, the disease studied, study type, and National Bioethics Committee review.

Results: Of the 131 countries that submitted data to the OHRP, only 36% have developed and published specific guidelines for genetic research. No regional guidelines for Asia Pacific have been formulated, and only 12 countries of a total of 32 countries listed under the Asia/Pacific region have guidelines for genetic research. Regional partners India and China both have specific guidelines for the use of new technologies such as gene editing and gene therapy. Pakistan has a National Bioethics Committee (NBC) which has published several clinical ethics guidelines and listed the review of genetic research studies. However, there are no guidelines for genetic research, gene therapy or gene editing studies. A total of 52 studies, published between 2017 and 2018 were included in a further content analysis of ethical standards. Over 90% of the research was conducted through international collaborations. 19/52 publications were first author studies by a Pakistani researcher based at a Pakistani institution. And most (39/52) were collaborations with either a UK or US based institution. Funding for 57% of the studies was solely from an international funding agency. The highest number of publications were related to blindness, deafness, neurological and development disorders (24/52), with 45% conducting whole exome sequencing, no gene editing or gene therapy studies were identified. Many of the genome wide association and consortium studies using biological material or genetic data from Pakistan had not been submitted for IRB review, and no study mentioned a review by the NBC or a material transfer agreement. There was no genetic counselling offered to support participants in any of the studies. There is no clear reference to any community engagement activities or awareness sessions. Although informed consent was mentioned in most of the studies, a blanket statement that “consent was taken” does not indicate the quality or understanding of the process.

Conclusion/discussion: International guidelines suppose an established system of accountability and oversight, in which the researcher is working. However, Pakistan like many other LMICs does not have strong internal or national oversight and accountability. There is also an overwhelming expectation about the integrity of the researcher and his/her familiarity with ethics. Many of the

guidelines reviewed trend toward a focus on individual obligations. Discussions of institutional imperatives, broad social goals or collective responsibility are rarely concrete.

Although no human gene therapy or gene editing studies were identified, gene editing technology is being explored in agricultural research in Pakistan. Applications of this tool will transition to microbial and human genetics. It is vital that we begin to establish systematic changes to ensure compliance, appropriate oversight and accountability. The findings from this content analysis of genetic research studies in Pakistan, provide a foundation of behavioural practises of researchers. It is a starting point to develop systematic changes. The role of funding agencies and research institutions is pivotal. Within institutions we need to expand our capacity for biomedical ethics, so that researchers have ethical input from inception and design of the study, all the way to publication of their work. Institutions and their IRBs must be held accountable for the research being conducted by their staff and students. Guidelines should be developed together with all stakeholders in the country so that they are incorporated effectively into practise. Effective training, implementation and monitoring will ensure better ethical conduct.