World Health Organization (WHO)

TOPIC B:

Addressing the ethical issues arising from emerging genetic health technologies.

I. Introduction of Topic

Emerging genetic health technologies, including genome editing (e.g., CRISPR), gene therapies, genetic testing, and large-scale human genome data sharing, are rapidly changing how countries prevent, diagnose, and treat disease. While these technologies offer major public-health benefits (such as targeted therapies and improved screening), they also raise difficult ethical questions about safety, consent, privacy, fairness, discrimination, and governance.

The WHO has highlighted that global governance and oversight are essential, especially for human genome editing, where irresponsible or unregulated use could cause harm to individuals and undermine public trust. WHO's recommendations emphasize building strong national and international mechanisms to ensure genome editing is used safely, ethically, and for public benefit.

At the same time, human genome data is increasingly collected and shared across borders for research and health systems. WHO has also issued global principles for ethical collection, access, use, and sharing of human genome data, centering transparency, equity, and protection of rights.

II. Definition of Key Terms

Genome editing (human): Technologies that change DNA sequences in human cells (commonly using tools like CRISPR). Can be somatic (not inherited) or germline/heritable (potentially passed to future generations).

Somatic gene therapy/editing: Genetic changes made in non-reproductive cells to treat disease in one patient; not passed to children.

Heritable (germline) genome editing: Changes to embryos, eggs, sperm, or early-stage reproductive cells that may be inherited; ethically controversial due to long-term and intergenerational impacts.

Genetic testing: Medical or commercial tests that analyze DNA to identify variants linked to disease risk, diagnosis, drug response, or ancestry.

Human genome data: Information derived from sequencing or analyzing human DNA (often stored in databases/biobanks). WHO has issued principles for responsible collection and sharing of this data.

Informed consent: A person's voluntary agreement to a medical intervention or research participation, based on understandable information about risks/benefits/alternatives. Core to international research ethics.

Genetic discrimination: Unfair treatment based on genetic information (for example, in employment or insurance). Some countries have laws restricting this (e.g., the US GINA).

III. Background Information

Why ethical issues are rising now

1. **Faster innovation, slower governance:** Technologies like CRISPR advanced rapidly, sometimes outpacing national regulations and international consensus. WHO responded by publishing global recommendations and encouraging stronger oversight structures.
2. **Cross-border impacts:** Genetic research and data sharing often involve international trials, multinational datasets, and commercial companies. This makes consistent standards and accountability harder. WHO created a **Human Genome Editing Registry** using clinical trial data linked to its trial registry infrastructure to increase transparency.
3. **Ethical tensions in public health:** Governments must balance innovation (new cures, improved screening) with harms like inequity (who gets access), privacy risks,

discrimination, and misuse.

Major ethical issue areas (useful to organize debate in committee)

- **Safety & long-term uncertainty:** Off-target edits, unknown intergenerational effects (especially for germline interventions).
- **Consent & autonomy:** Hard questions for embryo-related interventions, children, and communities whose data is collected; also the "right not to know" genetic results.
- **Equity & access:** Risk of widening global health gaps if advanced therapies are only available in wealthy health systems; UNESCO's genome/human rights framework also stresses equitable benefit-sharing.
- **Privacy & data governance:** Genetic data can be uniquely identifying and implicates family members; WHO published global principles to guide ethical genome-data use and sharing.
- **Discrimination & stigma:** Genetic risk information may be used to deny jobs/insurance or stigmatize groups; some regional instruments explicitly warn against misuse and discrimination.
- **Dual-use and misuse:** Tools could be used beyond healthcare goals (unethical enhancement, coercive programs, or unsafe experimentation), requiring governance and accountability.

IV. Relevant Treaties, Declarations, and Global Events

Key international instruments (ethics & human rights)

- **UNESCO Universal Declaration on the Human Genome and Human Rights (1997):** Frames the human genome in terms of dignity, human rights, non-discrimination, and equitable access to benefits of genetic advances.

- **UNESCO International Declaration on Human Genetic Data (2003):** Addresses consent, confidentiality, governance of genetic data, and risks to rights and dignity from

collection/processing/storage of genetic information.

- **Council of Europe Oviedo Convention (1997):** A binding regional treaty focused on protecting human rights and dignity in biomedicine.

- **Additional Protocol (Council of Europe) on Genetic Testing for Health Purposes (2008):** Sets safeguards for genetic testing and aims to prevent improper use of genetic testing and genetic information.

- **Declaration of Helsinki (WMA):** Core ethical principles for medical research involving humans, including identifiable human material and data, emphasizing informed consent and protection of vulnerable groups.

- **CIOMS International Ethical Guidelines (2016, with WHO collaboration):** Provides widely used guidance for ethical health-related research, including protections relevant to data, consent, and equity in lower-resource settings.

WHO-specific governance milestones

- **2019:** WHO announced plans for a global registry on human genome editing, using its clinical trials registry infrastructure to improve transparency.

- **2021:** WHO published *Human genome editing: recommendations* to guide institutional, national, regional, and global governance mechanisms.

- **2024:** WHO released principles for ethical human genomic data collection, access, use, and sharing to protect rights and promote equity internationally.

V. Major Countries, Agencies, and Groups Involved

World Health Organization (WHO): Central actor for global governance guidance, standards-setting, and transparency mechanisms (recommendations + genome editing registry).

UNESCO (International Bioethics Committee and Member States): Key normative role through declarations on the genome, genetic data, human rights, dignity, and non-discrimination.

Council of Europe: Regional legal framework on human rights and biomedicine (Oviedo Convention + protocols on genetic testing).

Governments & national regulators: Health ministries, medicines agencies, and data protection authorities that approve therapies, regulate trials, govern biobanks, and enforce privacy/anti-discrimination rules.

Researchers, universities, and hospitals: Develop and test gene therapies, run sequencing projects, and manage biobanks, responsible for consent, ethics review, and safe research conduct.

Private sector (biotech, pharma, DTC testing companies, data platforms): Drive innovation and scale, but also raise concerns about commercialization, unequal access, and data use beyond health purposes.

Patients, communities, and civil society: Essential for trust, legitimacy, and fair policy, especially when groups have historically been exploited or underrepresented in research.

VI. Possible Solutions (Policy Options for WHO Debate)

1. **Strengthen national governance aligned with WHO recommendations**
    - Create/upgrade national laws and regulatory pathways for gene therapy and genome editing.
    - Require independent ethics review, safety monitoring, and clear accountability mechanisms.
2. **Global transparency and registry participation**
    - Encourage Member States to register genome editing trials and share oversight information through WHO-linked systems to reduce “ethics shopping” across borders.
3. **Guardrails for heritable (germline) interventions**

- Maintain strict limits or moratoria unless internationally agreed conditions are met (broad societal consensus, compelling medical justification, high safety threshold, and enforceable oversight).

4. **Equitable access strategies**
    - Promote technology transfer, pooled procurement, tiered pricing, and capacity-building so gene therapies don't become "boutique medicine" for wealthy systems only.
    - Build benefit-sharing principles into research partnerships.

5. **Human genome data governance (privacy + fairness)**
    - Implement WHO genome-data principles: transparency, safeguards, clear access rules, and protection of individual and collective rights (including communities).

6. **Anti-discrimination protections**
    - Encourage Member States to adopt legal protections against misuse of genetic information (employment/insurance), taking inspiration from existing models and regional guidance.

7. **Consent modernization**

    - Improve consent models for genomics (plain language, meaningful choices about future data use, options to withdraw where feasible, respect for the right not to know).
    - Align research practices with international ethics standards (Helsinki/CIOMS).

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