

# Ethics of AI in global health research

Cape Town, 29&30 November 2022



## Governance paper Recommendations for the development of ethical guidelines for AI-related health research in Egypt

Ahmed Samir Abdelhafiz, National Cancer Institute, Cairo University, Egypt

### Introduction

In November 2019, the National Council for Artificial Intelligence (AI) was founded by the Egyptian government as a partnership between the government, academic institutions, and leading companies in the field of AI. The AI strategy enablers included, among others, the development of governance to monitor the execution of the strategy, laws, and regulations, ethical principles, and guidelines. Healthcare was among the priority sectors where the government was looking for partners to develop AI solutions for triage and diagnosis of diseases, smart management of healthcare data, mental health, and bioinformatics<sup>1</sup>.

A personal data protection law was issued by the Egyptian parliament in 2020<sup>2</sup>. Another law for clinical research was approved in the same year<sup>3</sup>. However, both laws are specific for certain aspects and don't cover several ethical, legal, and social (ELSI) issues related to AI, especially in the field of healthcare research. While the data protection law is not related to medical research, the clinical research law is mainly related to clinical research, including clinical trials, and doesn't cover many aspects of pre-clinical research<sup>4</sup>.

Some ELSI issues are common in different types of medical research, including AI research. However, some challenges are more related to the nature of AI research. These challenges could arise before, during and after conducting this research. First: Knowledge about the nature of AI research is not known among Institutional Review Board members. While these members are familiar with traditional types of research, this could not be the case with AI research, which could affect their decision. The informed consent model to be used with participants in AI research represents another challenge. Third: During and after the research process, questions about data protection, confidentiality, and privacy also arise. While these issues represent a concern in all types of medical research, the risks associated with privacy could be different or greater in AI related research for different reasons. Since AI research usually involves the partnership of many new private bodies, they may not stick to the privacy roles followed in academia or pharmaceutical companies. Moreover, AI research itself is associated with high risk of privacy breaches through AI-driven methods, where the process of anonymization could be compromised or fail using AI algorithms<sup>5</sup>. Fourth: When research is done, issues related to fairness and equitable benefit sharing could arise, both at the macro-level (sharing benefits between governments, companies and research institutions), and at the individual level (return of results). This governance paper aims at identifying some ethical issues that may arise during AI related health research on humans, and to provide recommendations to deal with these issues. Three issues/themes represent the concern of this paper, namely; informed consent, commercialization and benefit-sharing and institutional review boards. Each issue will be discussed in brief, followed by providing some recommendations based on the knowledge of the author about the local laws and regulations. These recommendations could guide researchers, ethicists, and policymakers to develop guidelines or laws to govern this research in the future in Egypt.

### The informed consent

The traditional concept of informed consent is challenged in AI-related research for many reasons. First: it is difficult to predict who will have access to the data in the future, and in what type of research this data will be used. Second: the nature of research and expected outputs could be too

difficult for patients/participants and doctors to understand and sometimes for researchers to explain<sup>6-8</sup>. Third: Growth of the use of AI based health applications, including those used for assessment of symptoms, to improve compliance to treatment, or to guide healthy decisions such as diet, raises new ethical concerns. Before using these apps, users agree to terms of participation, and in many cases may not read them at all. This agreement is different from the traditional informed consent used before data collection for treatment or research. What kind of informed consent should be used if research is conducted using data collected through these applications?<sup>8</sup> Fourth: How will secondary use or analysis of data collected for another purpose be explained in the informed consent, especially if data is stored in large accessible databases? Finally: The risks related to privacy, including potential re-identification risk could be greater in this type of research. This risk should be explained in detail to potential participants during discussion of informed consent. In Egypt, a previous study showed that among Egyptians who were willing to participate in medical research, many preferred a consent that gives them control over the selection of diseases in which their samples will be used for research<sup>9</sup>. These preferences should be taken into consideration during the discussion of the consent models to be used in AI research.

*Recommendations:* Research should be carried out to understand participants' attitude and preferences regarding AI research, including the type of informed consent that can be used in this type of research. Experts in the field should also discuss this issue with Institutional Review Board members and other concerned parties to select appropriate consent models. Although it is premature to recommend a mode for consent since little is known about which model best aligns with public preference and scientific practicability, we have some primary suggestions for selection among the available consent models. Specific consent that explains all details about proposed research is a suitable option. If research will include multiple future studies, other options should be considered. Among these options, we think that the use of broad consent, which is implemented in biobanks in Egypt and other countries for future use of samples and data, is difficult for use in AI related research due to the unknown nature of future research in this research<sup>6</sup>. Tiered or dynamic consent models, or a mix of both, could be preferred options for use in this AI research. However, the use of dynamic consent is restricted by the limited access to the internet in some regions of Egypt. Interestingly, there is a significant growth in the number of internet users in Egypt<sup>10</sup>, which could support the use of this type of consent in the future.

### **Commercialization and benefit-sharing**

AI research requires the use of advanced technology and sometimes "supercomputers". This necessitates collaboration with technology partners and private sector companies which can support this research<sup>1</sup>. Such collaboration raises issues about the commercialization of data and benefit-sharing. While commercial entities usually look for profits, governments and academic institutions look for other types of benefits as well. These include, among others, capacity building, authorship over scientific publications, sharing in patents and intellectual property rights, and getting final research products (such as new technologies) at affordable prices. These issues could be even more complicated if collaboration is done between researchers from high income countries or international companies or on one side and researchers from low or low middle income countries on the other side<sup>11</sup>.

*Recommendations:* Material and data transfer agreements used in biobanks for sample and data sharing are interesting examples for documents that explain the rights of each involved party in this scientific collaboration. This model can be adopted in other types of research that includes benefit sharing. In Egypt, we think that guidelines, regulations, and policies regarding commercialization and benefit sharing should be developed and implemented. Since the government proposes binding law and regulations, usually look for the interests of the local community, and has better negotiation power than individual researchers or institutions when it comes to the discussion about benefits, we think that the government and its representatives can negotiate benefit sharing with technology partners to reach the best deals with them in this aspect. Alternatively, the government may set the boundaries of acceptable practice, and specific terms can be negotiated by the involved parties.

## Institutional Review Boards (IRBs)

There is no available data about the knowledge of Institutional Review Board members in Egypt about AI and ethics related to its implementation in health research. This novel type of research could represent a specific challenge for IRB members. It has been reported that the lack of national research ethics guidelines and the need for training of IRB members in research ethics were among the challenges faced by members of ethics committees in Egypt<sup>11</sup>.

*Recommendation:* Evaluation of the knowledge, perceptions and attitude of IRB members about this type of research is necessary. Based on the results of this assessment, proper education and training about issues and challenges associated with this novel type of research are needed. The Supreme Council for the Review of Clinical Research Ethics established based on the clinical research law<sup>3</sup> and The Egyptian Network of Research Ethics Committees<sup>12</sup> can play a major role in coordinating these activities. Additionally, experts in the field should be available to explain some technical aspects of this research to IRB members upon request, which could help them to make an informed decision about research proposals submitted to them.

## Conclusions and recommendations

Egypt is trying to improve its capacity building capabilities in the field of AI. As science leaps forward, ethics should not lag behind! Many ethical committees have been working in different academic institutions for years. However, many of them have not been updated with new types of research that go beyond traditional medical research. In general, Egyptians are a bit skeptical about certain types of research and collaborations (e.g. genetic research and collaboration with western countries and commercial entities). Moreover, many of them think that medical research be conducted under some level of government oversight<sup>9,13</sup>. The development of laws, guidelines and recommendations to support AI health research is necessary to equip IRB members with tools to monitor this type of research, and to preserve the rights of the involved parties. Training of IRB members on how to use these tools is essential to allow them to create a balance between advancing medical research and the protection of the community. Encouraging and supporting AI research in the medical field will allow real-time detection of problems and discussions to find solutions for them.

## References

1. The Egyptian Ministry of Communications and Information Technology. Artificial Intelligence page. Available at: [https://mcit.gov.eg/en/Artificial\\_Intelligence](https://mcit.gov.eg/en/Artificial_Intelligence). Accessed 29th of October 2022
2. Egyptian Court of Cassation. Data Protection law. Available at: [https://www.cc.gov.eg/legislation\\_single?id=404869](https://www.cc.gov.eg/legislation_single?id=404869). Accessed 29<sup>th</sup> of October 2022
3. Egyptian Court of Cassation. Clinical research law. Available at: <https://www.cc.gov.eg/i/407276.pdf>. Accessed 29th of October 2022
4. Matar A, Silverman HJ. Ethical Analysis of Egypt's Law Regulating Clinical Research. *Journal of Empirical Research on Human Research Ethics*. 2022;17(4):494-503. Doi:10.1177/15562646221096188
5. Murdoch, B. Privacy and artificial intelligence: challenges for protecting health information in a new era. *BMC Med Ethics* 22, 122 (2021). <https://doi.org/10.1186/s12910-021-00687-3>
6. Blasimme, Alessandro and Vayena, Effy, The Ethics of AI in Biomedical Research, Patient Care and Public Health (April 9, 2019). Oxford Handbook of Ethics of Artificial Intelligence, Forthcoming, Available at SSRN: <https://ssrn.com/abstract=3368756> or <http://dx.doi.org/10.2139/ssrn.3368756>
7. Naik N, Hameed BMZ, Shetty DK, et al. Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? *Front Surg*. 2022;9:862322. Published 2022 Mar 14. Doi:10.3389/fsurg.2022.862322
8. Gerke, S., Minssen, T., & Cohen, G. (2020). Ethical and legal challenges of artificial intelligence-driven healthcare. *Artificial Intelligence in Healthcare*, 295–336. <https://doi.org/10.1016/B978-0-12-818438-7.00012-5>

9. Abou-Zeid A, Silverman H, Shehata M, et al.: Collection, storage and use of blood samples for future research: views of Egyptian patients expressed in a cross- sectional survey. *J Med Ethics*. 2010;36(9):539–47. 10.1136/jme.2009.033100
10. Dataportal. DIGITAL 2021: EGYPT. Available at: [shorturl.at/inAQ3](http://shorturl.at/inAQ3). Accessed 29<sup>th</sup> of October 2022
11. Sleem H, El-Kamary SS, Silverman HJ: Identifying structures, processes, resources and needs of research ethics committees in Egypt. *BMC Med Ethics*. 2010;11:12. 10.1186/1472-6939-11-12
12. The Egyptian Network of Research Ethics Committees website. Available at: <http://www.enrec.org/>. Accessed 29<sup>th</sup> of October 2022
13. Abdelhafiz AS, Sultan EA, Ziady HH, et al.: What Egyptians think. Knowledge, attitude, and opinions of Egyptian patients towards biobanking issues. *BMC Med Ethics*. 2019;20(1):57. 10.1186/s12910-019-0394

**This paper was prepared for GFBR 2022. Further details on the meeting are available at [www.gfbr.global](http://www.gfbr.global).**