

Statement of Guiding Principles for Ethics in Digital Health

Arising from the Seminar of 10 July 2018 and its continuation on 5 November 2018, the initial topic of the Stanford Libraries' program of cross-sector seminars on Ethics in the Digital Age

DEFINITIONS

- These principles address the ethical use of digital health products and information.
- A “digital health product” is a commercially marketed device, app, medicine or other offering that is promoted based on claims to improve human health outcomes, and which collects and generates digital health information.
- “Digital health information” is all information collected and generated by a digital health product that is connected to the Internet.

PURPOSE

- This Statement begins to define principles for digital health companies to ensure the ethical use of their products and the information they collect and generate.
- These principles should neither replace nor be replaced by:
 - the obligations of digital health companies to regulatory agencies and other government bodies that may control health standards
 - all applicable laws and regulations where digital health companies choose to operate
- These principles should help digital health companies navigate potential conflicts between individuals' need for privacy and society's need for protecting public health:
 - sharing anonymized health information can be beneficial to individuals and populations, such as in cases of controlling disease outbreaks and discovering cures to conditions without adequate treatments.
 - but sharing health information can also lead to risks for individuals and populations, requiring patients, health care providers, regulators, policy makers and bioethicists to work together to create trusted solutions.

LIMITATIONS

- Investigational products or those being used in clinical trials may be covered by this Statement, but the protocols and rules governing them take precedence.
- There will always be situations when the principles in this Statement are insufficient to navigate particular conflicts. For these situations, digital health companies should take advice from qualified bioethicists.

FURTHER DEVELOPMENT

- Digital health companies commit to updating and improving the Stanford Statement of Guiding Principles for Ethics in Digital Health based on feedback and issues raised by the communities they serve; these changes should be shared widely.
- As part of these ongoing efforts to improve transparency and establish clear norms for ethics in digital health, companies will collaborate to create a voluntary certification program based on auditable standards and administered by a notified body such as the Industrial Engineering Council (IEC) or British Standards Institution (BSI).
- Digital health companies will pro-actively work with regulators, State and Federal authorities to develop appropriate new guidelines and laws designed to promote improved health outcomes for both individuals and society at large; these too should be shared widely.

Statement of Guiding Principles for Ethics in Digital Health

- 1. The products of digital health companies should always work in patients' interests.**

Digital health companies should work with care providers, insurance companies, regulators, and governments to ensure their products are:

 - part of an eco-system that enables effective, affordable access to high quality health services
 - never used to discriminate, persecute or deny necessary care
- 2. Sharing digital health information should always be to improve a patient's outcomes and those of others.**

Digital health companies receive consent from patients for information to be shared. They recognize that consent represents only a broad statement of trust by the patient. They acknowledge their absolute duty of care with respect to the use of patient information.
- 3. "Do no harm" should apply to the use and sharing of all digital health information.**

Digital health companies are alert to the risks of malicious use of health information and unintended consequences of well-intentioned uses. They adopt safeguards to anticipate and mitigate these risks.
- 4. Patients should never be forced to use digital health products against their wishes.**

Patients' use of digital health products should be voluntary and with a positive mindset.
- 5. Patients should be able to decide whether their information is shared, and to know how a digital health company uses information to generate revenues.**

Patients should be aware that their shared information will be used for many purposes. They should know who has the duty to care for their digital health information and how that organizations gets paid when they use it.
- 6. Digital health information should be accurate.**

Digital health products should maintain high standards of data quality, reproducibility, and integrity. Validation methods should be auditable and transparent to ensure that high standards are being reliably met.
- 7. Digital health information should be protected with strong security tools.**

Digital health products should meet state-of-the-art security standards. Patients should be able to know how well companies are performing against those standards.
- 8. Security violations should be reported promptly along with what is being done to fix them.**

Within ten (10) business days of detection (or sooner if required by law), digital health companies should inform affected patients of any breach, potential consequences and steps taken to mitigate risk.
- 9. Digital health products should allow patients to be more connected to their care givers.**

The information created by digital health products should strengthen the voice of patients and their families in care decisions. That information should help educate and inform patients, improving communication, and trust with health care professionals.
- 10. Patients should be actively engaged in the community that is shaping digital health products.**

Digital health companies should provide patients with tools to easily express their opinions, provide their feedback, and communicate their needs in timely, professional ways.