

Guideline:

Research using Mental Health Apps & Therapeutic Interventions

Given the expansion in the production and availability of apps for mental health support, UCD researchers should note that there are a range of ethical issues involved in the production and use of these apps (see references below). A core distinction for these apps is between those developed to support general wellbeing, and those developed as some form of intervention or diagnostic tool.

In the Irish context, HPRA notes on medical devices and apps give some background (see [HPRA-software-and-applications-overviews](#) and [HPRAguide-to-placing-medical-device-standalone-software-on-the-market](#)). From the HPRA “guide to placing medical device software on the market”, we have the following definition:

A ‘medical device’ is defined in S.I. No. 252 of 1994 as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease [...]

In terms of mental health apps and software, this definition, that an app intended to be used as therapy, treatment or alleviation of ‘disease’ (in this context, diagnosed or undiagnosed mental illness), is potentially a medical device. The same HPRA document further notes:

Not all standalone software used in the healthcare sector are medical devices. For example, apps for general health and wellbeing that record lifestyle habits such as smoking and exercise are generally not considered as medical devices. It is essential that manufacturers of standalone software understand whether their product is a medical device or not.

Ethics Approval Criteria:

For research studies involving mental health apps and therapeutic interventions, please note the following criteria:

- 1) Given that medical devices require approval and that consumers will place significant weight on that approval being present, it is important to be clear that, even for apps for general health and wellbeing produced as part of research projects in UCD, **any ethics approval provided by UCD HREC does not in any way support or approve the app as a**

form of treatment or therapy for mental health. Given the potential of confusion among consumers over the difference between “ethics approval” and “approval” (as an intervention or therapy), **the HREC require that no indication of “ethics approval by UCD” be associated with the app or intervention or used anywhere in marketing.**

- 2) **Approval for therapeutic medical devices is not within UCD’s gift.** If a researcher is making an application for ethics approval involving an app or software intended to provide therapy or treatment, **the researcher needs to understand whether this software meets the requirements for a medical device;** if it does, the researcher should consult with HPRA.
- 3) For an ethics approval to be granted in UCD by the HREC, such apps should have HPRA approval.
- 4) There are insurance implications for researchers using apps that fall into the interventional or diagnostic description, especially if these have not been approved by the HPRA. Further information can be obtained from insurance@ucd.ie

References

Martinez-Martin, N., & Kreitmair, K. (2018). Ethical issues for direct-to-consumer digital psychotherapy apps: addressing accountability, data protection, and consent. *JMIR mental health*, 5(2), e32.

Jones, Nick, and Matthew Moffitt. "Ethical guidelines for mobile app development within health and mental health fields." *Professional Psychology: Research and Practice* 47.2 (2016): 155.

Palmer, Kathleen M., and Vanessa Burrows. "Ethical and Safety Concerns Regarding the Use of Mental Health–Related Apps in Counseling: Considerations for Counselors." *Journal of Technology in Behavioral Science* 6.1 (2021): 137-150.