ihrf Recommendations on **data protection** and **health research**

These recommendations have been arrived at through discussions at the IHRF event; *GDPR and Health Research: Stakeholder Voices*, through deliberations of the IHRF Steering Group and through MRCG consultations with relevant stakeholders.

1. **Putting patients first:** all efforts to implement data protection legislation should ensure that patient needs are placed above all else. An increased polarisation of views, measures to penalise the research community based on a small number of research groups not making efforts to comply with the legislation, or not using patient data due to being overly risk adverse, are not in the interests of patients. Where appropriate, patients should be consulted on major decisions.
2. **Reducing confusion:** Improved communication is required between all individuals and organisations responsible for implementing, interpreting and complying with the Health Research Regulations and other data protection legislation. Researchers need to understand the rationale and good intention behind the regulations and the fact that most of the requirements of the new legislation already existed in law. The Department of Health should work to ensure that researchers are given more clarity and support in interpreting and implementing the legislation.
3. **Support for health research professionals:** Establishing networks of key professionals, involved in the regulation and support of health research, such as data protection officers, data controllers and ethics committee representatives, would be valuable, in order to support each other in the implementation of the legislation. Greater institutional support, training and better structures, to facilitate increased legal awareness, would give researchers more confidence to process research data in compliance with the law.
4. **Sensible approaches to re-consent:** In considering whether patients need to be re-consented for their data to be used in future studies, several things need to be considered, including the spirit in which the patient originally consented to their data being used in research and whether re-consent is likely to cause any harm. As a rule of thumb, if a patient is likely to be surprised or shocked as to how their data is being used, then re-consent is necessary. If re-consent is required, considerable effort should be made to ensure that it is done sensitively.
5. **Future proofing through explicit consent:** Explicit consent is informed consent that is recorded. Informed consent processes and documentation have been improving in recent years and the health research community should continue to share best practices through their networks. In cases where it is not feasible to know exactly how a patient's data will be used for research in the future, a tiered approach to consent should be considered, together with measures to update patients over time and to ensure that they can easily opt-out. Investment in technology to enable these approaches will be required to aid implementation. Patients should also be informed that any future studies will be approved by a research ethics committee.
6. **Facilitating pre-screening:** The process of pre-screening health records by research staff for potential research participants plays an essential role in Irish clinical research. Sensible approaches, likely to include hospital-wide transparency notices and formal agreements between clinical research centres and hospitals, should be taken, to ensure that appropriately trained, supervised and indemnified health research professionals can undertake pre-screening.
7. **Managing consent exemptions:** The April 30th deadline for consent exemptions to be granted by the Consent Declaration Committee (in cases where consent in line with GDPR standards is not possible) should be extended, if the Committee is not able or equipped to consider all valid applications in the necessary timeframe. In the longer term, mechanisms to increase the efficiency of the Committee, such as fast track routes to consent exemptions based on precedence and advance notification by researchers of intent to submit an application, should also be considered.
8. **Including patient perspectives:** The Consent Declaration Committee needs to include meaningful patient and public involvement. The inclusion of patients on this committee is particularly important as their perspectives can be different from those of the general public. Researchers applying to the Consent Declaration Committee should make efforts to capture the views of the relevant patient population, for inclusion in their applications. Medical research charities and patient organisations should work to support patient involvement in the Committee.
9. **Increasing public awareness:** A national campaign should be funded by the Department of Health to increase public and patient awareness around health data, consent and the value of research. This campaign should be co-designed with patients, the public and researchers.
10. **Improving together over time:** On-going discussion and further clarity is needed on the interpretation and implementation of data protection legislation in the context of health research. It is the intention of the Medical Research Charities Group, with the guidance of the Irish Health Research Forum Steering Group, to re-visit the topic at the next Forum event in May 2019.

ihrf Irish Health Research Forum

SUPPORTED BY

medical research charities group
Unity is our Strength

pobal
government supporting communities

An Roinn Tithíochta, Pleanála, Pobail agus Rialtais Áitiúil
Department of Housing, Planning, Community and Local Government

CONTACT US: Irish Health Research Forum, c/o MRCG, Digital Office Centre, 12 Camden Row, Dublin 8, Ireland. Tel: + 353 1 4793234 **www.ihrf.ie**