

An Update on Forthcoming Legislation

Health Information Bill and Human Tissue Bill

MEETING SUMMARY



BACKGROUND

On Wednesday 12th of December IPPOSI and MRCG held An Update on Forthcoming Legislation, a member's information meeting which dealt with the research aspects of the Health Information Bill and the Human Tissue Bill, key pieces of legislation which are due for publication in 2013. The measures contained in these bills will impact the health research environment in Ireland and will contain new policy initiatives in the areas of population health registers, the structure and regulation of research ethics approval and regulations for the removal, retention, storage, use and disposal of human tissue.

Bernie Ryan of the Corporate Legislation Unit of the Department of Health who briefed members on the research aspects of these bills and also provided an opportunity to discuss the implications of these legislative changes.



Philip Watt, Chairperson MRCG, Eibhlin Mulroe CEO IPPOSI and Bernie Ryan Department of Health

HEALTH INFORMATION BILL

The Health Information Bill is currently being drafted. It will be consistent with EU Data Protection Directive and build on data protection legislation while also keeping in mind the Draft EU Clinical Trials Regulation. All provisions of the bill are still subject to legal advice and drafting changes.

The main initiatives from the Bill are;

- Data matching, population health resources and unique patient identifiers for use in the health service.
- New Research Ethics Approval Structures for some health research. Approved Research Ethics Committees (ARECs) will be established with HIQA as the supervisory authority. HIQA will also set the standards on quality and procedures for Approved RECs.

Research Ethics Committees

There will be two types of Research Ethics committees;

- Research Ethics Committee (REC) approved by HIQA on application by Appointing Authority of REC (main basis).
- Research Ethics Committee (REC) established by HIQA.

Note: There is no statutory requirement to obtain ethical approval for health research covered by the Health Information Bill but approval by an Approved REC under the Bill brings benefits to the researcher.

Ethics Approval Process

- HIQA will refer application to Approved REC.
- Research may be national, regional or local.
- Approved REC considers application for ethical approval referred by HIQA.
- Applications will be considered against defined criteria for ethical approval. (See Appendix 1)
- Approved REC monitors the ethical dimension of the applications approved by it when the research is being carried out.

If approved, issues will not re-examined by other research ethics committees established by agencies receiving State funding.

Consent exemption will be allowed in strict circumstances and the decision will be made by Data Protection Commissioner.

DISCUSSION AND QUESTIONS RAISED BY MEMBERS

How will the committee monitor ethical issues as the research progresses?

The onus to ensure continued compliance will be on the researcher. Researchers must go back to the committee if there is any change in the proposal. The Research Ethics Committee would also have an on-going interest in how research is going.

The Logistics of this proposal was queried i.e. how will it be feasible for large volumes of proposals to quickly be processed by HIQA.

This bill is offering opportunity for research – particularly multicentered research to have a more streamlined journey i.e. by getting central approval. Researchers will know how long it will take to get a decision and no other REC can make them revisit the research. This bill addresses the concern that researchers may only approach committees where they believe they will get a more favourable outcome.

Problems occur currently where a single ethics committee approve but blockages occurs when local hospital or institution have an opportunity to review. Can this occur with this new bill?

If approved, issues will not re-examined by other research ethics committees established by agencies receiving State funding.

There is a concern amongst patient organisations in relation to consent and data that researchers currently hold. Will this need a change in legislation?

The bill will give data protection commissioner a role. The commissioner is the regulator for data in this country and researchers must prove to commissioner's

satisfaction that the researcher needs the data or in some cases that getting consent from each individual is impractical and that research is of significant importance. The commissioner will have special regard to ensuring data cannot distress or damage individuals and is interested in security arrangements for data. The bill specifically provides for identifying how often this is being used and provides for HIQA knowing how many go to commissioner. There will be public transparency on this.

It appears that legislation mainly relates to multisite research. For small projects, we don't want to have additional barriers. A number of small projects also look for waiver of consent. Will legislation provide for this? Will it need to go to data commissioner?

Local committees will continue to operate in local sites and you don't have to go to HIQA approved committee for local studies. However local committees must meet the standards set by HIQA

Who is data controller for data collected?

There were mixed views at the meeting regarding whether the research institutions are data controllers or data agents. The Data Protection Commissioner has informed research institutions that they are data agents. This is still unclear and we are currently still waiting for clarification.

How will this affect registries? Will it be faster process than before to get ethical approval for new registries?

There is a proposal to make provision for registries (Health Information Resource) in a separate part of the bill. Currently there is no impediment to give information for registries but there is also no obligation to give information.

HUMAN TISSUE BILL

The proposed Human Tissue Bill will regulate the removal, retention, storage, use and disposal of human tissue from deceased persons, and the use of donated tissue from living persons for the purposes of transplantation and research. The main initiatives from the bill are;

- Research on human tissue will need approval from Approved Research Ethics Committees (ARECs).
- Consent of donor will be needed for the collection, use and storage of human tissue for research purposes.
- Consent must be given freely and without coercion.
- Appropriate information must be given on the nature and purpose of the research.
- Consent may be specific, limited or qualified or may be general, to include future unspecified uses.
- Consent and any conditions attached to that consent must be given in writing.

- Consent may be withdrawn at any time, unless the tissue is to be irreversibly anonymised during the proposed research, in which case this must be explained to the donor at the time consent is sought.
- Other approach for adults who lack capacity and children.

DISCUSSION AND QUESTIONS RAISED BY MEMBERS

How will consents be implemented?

If tissue is taken as part of medical procedure, consent for research must be gained separately. Donors may be asked to give consent for purposes as yet unspecified.

Is a different form needed for consent for procedure & research?

Ideally consent should be given at different time to giving consent for treatment. A Research form must be separate, be to a high standard and contain very clear information.

What about historical tissue? Material will continue to be stored – is it no longer available for research

If you know identity of historic tissue, you should ask for consent. Exemption would exist if there were practical reasons for not requesting consent.

The issue of Guthrie Cards retention was discussed:

Tissue retention is also done for diagnostic purposes – as opposed to research. For people who have died suddenly and cannot give consent, Guthrie blood cards hold tissue.

This bill does not interfere with coroner post-mortem. Bernie Ryan agreed to take this point further.



APPENDIX 1

Potential issues to be considered by Approved Research Ethics Committee when considering research ethics proposal:

- (1) Is the health research likely to substantially assist in—
 - (a) the advancement or protection of human health, whether of the population as a whole or of any part of the population,
 - (b) the scientific understanding of human health,
 - (c) the understanding of social factors affecting human health,
 - (d) the identification, prevention or treatment of illness, disease or other medical impairment, or
 - (e) the effective management of health services, including improvements in the delivery of those services?
- (2) Has the person making the proposal identified and assessed the potential benefits and risks associated with the health research?
- (3) Will the person making the proposal make every effort to ensure that the participation of individuals in the health research will be informed and voluntary?
- (4) Is the person making the proposal qualified to carry out the health research concerned?
- (5) Are there adequate safeguards in place to protect the privacy of individuals participating in the health research and the confidentiality of their personal data?
- (6) Will anything in the health research concerned undermine or decrease public confidence in health research generally?
- (7) Is the proposed research methodology appropriate?
- (8) Is the person making the proposal and all other persons who will be carrying out the health research concerned independent of any person who provides funding or otherwise supports the project?
- (9) Any other matter set out in standards made by HIQA for approved research ethics committees in relation to quality and procedures.

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