HEALTH RESEARCH REGULATIONS SEMINAR

CONSISTENCY | CLARITY | CERTAINTY

GIBSON HOTEL, DUBLIN 1
19 OCTOBER 2018

Overview

At the Health Research Regulations Seminar on the 19th of October 2018, participants submitted questions via a Sli.do app. 225 questions were submitted in total via the app. As many of the questions were left unanswered at the seminar due to time constraints, the HRB has undertaken an analysis of the questions and removed duplicate questions, questions answered at the seminar itself and questions that could / should be answered by institutional DPOs. Out of the remaining questions proposed, the HRB has tackled those questions that they were in a position to answer. See below for full list of questions and corresponding answers.

Questions and answers:

1. **Is there a risk that asking for re-consent to ongoing research will cause distress by suggesting initial consent was in some way unprofessional? Ethical issues?**
   The right to privacy is a constitutional right of all Irish citizens and it is essential that participants in research studies are fully aware of, and agree to, how their personal information will be used. For this reason reconsent is an important step in being fully compliant with GDPR, and participants are fully aware of how their data will be used and how they can withdraw their consent at any point in time if they choose to.

2. **Is re-consent required for archived identifiable information?**
   This will depend on whether the consent obtained previously is compliant with GDPR. If the consent previously obtained is not compliant with GDPR, then reconsent will be required. Even if it is archived there is potential that the data could be used in the future, therefore reconsent will be necessary. If there is no reason to keep the information, the data controller should consider deleting the information for which no consent is necessary.

3. **Have you considered that attempts to re-consent when original consent was given in good faith may in itself be unethical?**
   See answer to Q1.

4. **How can we get consent for analysis of databases kept by clinical staff when the patients have died or left the hospital?**
   Data of the deceased do not come under GDPR unless there is a data privacy risk to living relatives. Consent will be required from all other living participants within a study unless a consent declaration is obtained. Consent should be part of a clinical process during the treatment of a patient – these processes should be implemented if not already in place.

5. **Pre-screening question and support staff access to information**
   Currently, only staff involved in the direct care of an individual can access information for purposes of pre-screening. However, the Department of Health are aware that this can be problematic when the numbers to pre-screen can be large and are currently in the process

of finding a solution to both protect the privacy of the individual and support the health research community to undertake high quality research.

6. **Will the HRB be able to analyse and report to the minister on the efficiency of the committee and its impact on the health research ecosystem in Ireland?**
   The HRB is not responsible for reporting on the committee. The committee will answer directly to the Department of Health and the Minister. A dedicated HRCDC Secretariat will sit within the HRB who will be responsible for managing the *process* behind the Health Research Consent Declaration Committee. It will be the responsibility of this Secretariat to ensure that the process runs effectively and efficiently and determine the impact of the committee. This Secretariat will be almost fully in place by January 2019.

7. **Could the remit of the Health Declaration Committee be extended to include providing advice to DPOs? No single individual will be able to answer the range of questions that arise during Health research, especially in the area of genomics.**
   It will not be within the remit of the HRCDC to support institutional DPOs. The Office of the Data Protection Commissioner advises that DPOs working in specific areas should work together as a collective to answer the various questions that may arise within the area of health research. This should be managed by the DPOs themselves.

8. **To demonstrate to the Declaration Committee that reconsent has been attempted, will it be acceptable to reconsent a sample of subjects to assess the practicality and acceptability of reconsenting to patients and surviving family members?**
   The HRB cannot make decisions or provide advice on behalf of the HRCDC. However you may wish to refer to some applications from the Confidentiality Advisory Group in the UK that used patient focus groups to assess similar issues when re-consent for all patients within the study was not possible.

9. **Can students continue to undertake clinical chart reviews under these new regulations?**
   The Department of Health has recently made this statement on clinical chart reviews:

   'As regards Retrospective Chart Reviews carried out for research purposes, and having consulted with the Data Protection Commission, it has been determined that the requirement for explicit consent will commence on 1 May 2019. This is to allow hospitals and other data controllers who carry out such reviews to adapt their procedures to capture the relevant explicit consent from patients. All other suitable and specified safeguards set out in the Health Research Regulations will continue to apply in the interim period as will other requirements arising under the General Data Protection Regulation. Where a hospital or other data controller does not use this time to put a mechanism in place to capture explicit consent for retrospective chart reviews for research purposes then applications to the Consent Declaration Committee for a consent declaration for such reviews will be unlikely to succeed. '

10. **How will this affect hospital staff conducting locally approved quality improvement projects which may or may not lead to a peer reviewed publication?**

It is not up to the HRB or the Department of Health to determine what is classified as 'research' and therefore what comes under the Health Research Regulations. This should be a discussion for you and your institutional DPO.

11. **Clinical audit now subject to GDPR. Over 20k doctors in Ireland, all must perform annual audit to maintain registration- how will REC be able to process applications and doctors consent pts before they even start audit (due every May)**
    Audits are currently not classified as research and therefore do not come under the Health Research Regulations. The HRB and the Department of Health are not in a position to comment on the structure and processes of any of the Research Ethics Committees.

12. **Usually draconian legislation & regulations follow on as a reaction to some major harm. What harm has arisen to patients in Ireland from the longstanding practice of simple retrospective chart reviews?**
    GDPR is a European Union-wide piece of legislation that builds on previous Data Protection directives. The Health Research Regulations pull out the necessary information for health research from the GDPR and places them within a single document. The Health Research Regulations also offer, for the first time in Ireland, a legal alternative to consent – a consent declaration. These regulations are not draconian, but are there to protect the privacy and confidence of European/Irish citizens.

13. **Will chart review to identify patients for studies be justified providing process has been defined and approved by REC and only delegated persons complete chart or database review?**
    See Q5 on Pre-screening.

14. **If research involves whole hospital retrospective data sets eg HiPE data over many years, is there a requirement to get consent from tens of thousands of patients?**
    To protect the privacy of patient's data and maintain confidence in the process, it is important that patients know and understand how their personal information will be used. Therefore obtaining consent from patients involved in any study is an essential step in the process of health research. If it is felt that the public importance of the study significantly outweighs the public interest in obtaining explicit consent from the patients, then it may be possible to apply for a consent declaration through the HRCDC.

15. **Does the HRB intend to provide guidelines on the re-consenting of vulnerable patients ie those in palliative care, those experiencing relapse?**
    The HRB is not in a position to develop and distribute guidelines in relation to the Health Research Regulations. It is known that consenting and re-consenting of vulnerable patients and patients with impaired capacity is an area that needs more clarity within health research. The Department of Health is currently working closely with representatives working in this field and the Data Protection Commissioner's office to find an adequate solution.

16. **Do guidelines exist for genome studies on biobanked archival issue?**

There are currently no guidelines in relation to genome studies on biobanked archival issue and the Health Research Regulations. The Department of Health are aware that clarity needs to be provided on the processing of, and access to, biobanks in relation to the Health Research Regulations and are currently investigating an adequate solution.

17. **Should genome sequence data, transcriptome data and proteomic data be always treated as personal data and/or whether additional information associated with the data subject is required to consider them as personal data?**
    This is a broader issue than the Health Research Regulations and discussions are on-going within Europe on this topic. There is currently no clear answer as to whether genomic information should always be treated as personal data even if it is 'anonymised'.

18. **Where consent is not possible, but anonymisation is possible, does this mean that a consent declaration is not required in this setting?**
    Although anonymised data does not come under GDPR, the process of anonymising identifiable data does and consent is required for this.

19. **Can the data controller search and render the data fully anonymous before giving it to the researcher; and then the researcher use/analyse this data without consent?**
    Anonymised data does not come under GDPR so researchers may use and analyse anonymised data without consent. However, the process of anonymising identifiable data does come under GDPR and consent is required for this process.

20. **Is there or will there be a GDPR guidelines document for students who are undertaking research?**
    The Health Research Board and the Department of Health have no plans to provide GDPR Guidelines for students. If this is a document that is required, then we encourage students to work with their institutions and institutional DPOs to develop such a document.

21. **Can we exchange existing longstanding biomaterials with international collaborators without reconsenting?**
    If there is the potential that patients may be identified based on the biological sample shared, then it is essential that the participants involved provide explicit consent / reconsent.

22. **Would the hrb support the development of a set of shared guidelines for researchers and for ethics committees to outline the requirements for projects, information leaflets, and consent forms to meet GDPR and the health regulations?**
    The HRB is not in a position to develop such guidelines. If these are required documents, then we encourage researchers to work with their and other institutions, and institutional DPOs to develop such guidelines.

23. **Will the HRB provide a guidance document for researchers to ascertain themselves where and what role they fall under GDPR? I.e. whether their role falls under controller or processor?**

See answer to Q22

24. **What are the implications for providing open access to data with publications? Does this need to be specified in advance when obtaining informed consent? What about publishing such (anonymous) data from existing studies?**
    Most journals that require open access to data have exceptions to policy and restrictions on data availability for reasons associated with the protection of human privacy. GDPR and the Health Research Regulations should not affect this. Anonymised data does not come under GDPR so it can be safely made available without risk to public privacy.

25. **What happens if proper consent requested and given, data is collected and anonymised and person subsequently withdraws consent?**
    Anonymised data does not come under GDPR and it should not be possible to identify the individual who withdrew their consent from this dataset. Therefore it will not be a requirement to remove their information from the anonymised dataset. It will be a requirement to remove any identifiable information on this person from your systems to adhere to the person's wishes of withdrawal.

26. **Data Flows. Is there a decision tree/ tool to help researchers?**
    Neither the HRB nor the Department of Health plan to develop a decision tree / tool for Data Flows.

27. **Do the Health Regulations apply to research conducted by Irish researchers in a different EU country? Or is it only relevant to Data Subjects based in Ireland?**
    The Health Research Regulations only apply to Ireland. Irish Researchers based at institutions in other EU countries must adhere to the data protections laws of that country.

28. **Ruth's comments that the Regs would apply to data coming in from abroad contradicts other guidance from the DOH - could she clarify**
    The Health Research Regulations only apply to Ireland. It will be assumed that data that comes into Ireland from other EU countries will have the necessary levels of consent as required under GDPR and any other privacy legislation within the country of origin.

29. **It seems that an Institution's Data Protection Officer will play a central role in permitting access to personal data. What is being done to ensure that DPOs across multiple hospitals have a consistent approach?**
    The HRB and the Department of Health do not have any remit over institutional Data Protection Officers. It has been previously suggested by the Data Protection Commissioner's Office that DPOs working in specific areas should work together as a collective to answer the various questions that may arise within the area of health research. This should be managed by the DPOs themselves.

30. **Whether an activity is research or not cannot be defined by an individual's intention to publish or whether it is part of a degree. Results of evaluations can be publishable- that does not make it research.**

Neither the HRB nor the Department of Health can tell you if your work is classified as research or not – this needs to be a discussion between you and your institutional Data Protection Officer.

31. **The Health Research Regulations' appear to go further than GDPR in that record keeping is also required for all transfers of anonymised data – please confirm this is the case?**
    Anonymised data does not come under GDPR or the Health Research Regulations. However, the process of anonymising identifiable data does come within under the remit of GDPR as it constitutes as data processing and consent will be a requirement to undertake anonymisation.

32. **Re-consent is not a practical option for the majority of studies and shouldn't be considered as the default position. What alternatives are you offering apart from the declaration committee?**
    Prior to the Health Research Regulations and under the Data Protection Acts 1988 and 2003, consent was the only option for the use of identifiable data in research. The consent declaration is the first time in Ireland there is a legal alternative to consent. Ireland is currently not offering other alternatives to consent in health research to protect public confidence.

33. **Exploratory research is the basis for scientific discovery and requires as much data as possible. The minimisation of necessary data in GDPR seems to be in the exactly different direction. How these can work together? Only by anonymisation?**
    Such future exploratory research should be included within consent processes when the data is initially collected. GDPR requires that you should identify the general areas of research, and where possible give people granular options to consent only to certain areas of research or parts of research projects – exploratory research could be included as an option for consent under this granular approach. Broad consent is about giving people consent choices to limit their consent at any stage of the research process.