HRCDC
Health Research Consent Declaration Committee

Time: 09:30am - 13.30pm
Date: 5th November 2019
Location: Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kevin Clarke
Sheelah Connolly
John Ferguson
Dan Rea
Aideen Hartney
Kathy Brickell
Claire Collins
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

External Invited Speakers

Name	Organisation	Topic
Patricia Rickard-Clarke	Sage Advocacy	Capacity to Consent
Peter Lennon (PL) Dr. Teresa Maguire (TM)	Department of Health, Research Services & Policy Unit	Health Research Regulations – reflections, amendments, appeals

Meeting Items

1. Opening
The Chair opened the meeting and welcomed the members.

2. Apologies
Zubair Kabir, Malcom Kell, Simon Furney, Barry O'Sullivan

3. Meeting introduction
The Chair provided an overview of the meeting, structure and rationale. The meeting was convened to provide an opportunity to discuss the appeal process and any items that the HRCDC need to consider going forward regarding HRCDC business as well as briefing on issues of interest. The Department of Health (D/Health) will join the meeting later to discuss the Health Research Regulations (HRRs), amendments and the appeal process. There will also be a briefing session on capacity to consent, which is the subject matter in many HRCDC applications. The meeting was intended to be an open and engaging session.

4. Appeals Process

The Chair noted that it was a useful opportunity to consider the appeal process following the first appeal. It was noted that the appeal process is independent of and separate to the HRCDC and was the operational responsibility of D/Health. It was understood that D/Health would be considering the operation of the appeal process in the light of experience with the practical operation of the first appeal and would be happy to receive any HRCDC views on the process. It was intended that this could be discussed in the later session with D/Health.

The HRCDC discussion was a wide ranging one discussing pros and cons of different aspects of possible appeal processes. It was noted that some of the options discussed would require changes to the HRRs.

On the appeal process, issues discussed included:

The possibility of an initial appeal to HRCDC before triggering an appeal process:
Consideration could be given to allowing an Applicant an initial appeal/review of decision to HRCDC and an opportunity to present additional information in the light of the HRCDC decision.

It was noted that conditions attached to a declaration could be appealed. The HRCDC would encourage any Applicant to discuss any condition or recommendation that may be problematic to meet, as the HRCDC will consider flexibility on the practical implementation of conditions before any appeal is required.

The nature of Appeal Panel process:
The HRCDC recognised the importance of an independent appeal process for Applicants who were not happy with HRCDC decision. While recognising the need for fair procedures the importance of not having an overtly legalistic appeal was noted, as this would detract from the nature and spirit of the Health Research Regulations (HRRs) and could be disproportionately resource heavy for the Applicant and for the system. Applicants always had the ultimate option of judicial review through courts and the appeal process was not to substitute for this.

It was noted that when weighing up the public interest case, it is important to ensure the process was reasonable in this regard. The difference between this process and the type of process for determining issues around eligibility under Government schemes was noted.

The HRCDC queried if the process was intended to be a *de novo* review of the Appellant's application. The Appeal Panel had reviewed additional submitted documentation and also the original application that was submitted to the HRCDC.

The nature of the Appeal Panel process was discussed, as to whether it should take the form of a written procedure or an oral hearing, possibly including legal representation. The value of oral presentations and the importance of additional information may further substantiate the application and address issues of concern was discussed. It was considered that a written procedure as a general rule, as in many other appeal processes, may be more appropriate.

It may be worth considering a larger appeal panel than 3 and/or appointment of specialist advisers to panel.

Role of HRCDC
The possibility that the HRCDC might be asked to provide observations on the Applicant's appeal documentation was discussed and the implications of this for HRCDC role and way of operating and resources. It was noted that if the HRCDC reviewed additional submissions for an Appeal Panel this would have implications for resourcing and time of the HRCDC. It would also be more complex if participation in oral hearings was required.

General
The HRCDC considered that the Appeal Panel decision aligned with the areas of concern that were noted in the original decision of the HRCDC.

The HRCDC discussed the precedence of the Appeal Panel decision and considered that the first case of the appeal should not take precedent.

5. Health Research Regulations - Department of Health

The Chair welcomed and introduced the D/Health and set out the intention of the meeting to ensure the processes and HRRs are working for the benefit of all stakeholders. TM said she welcomed the opportunity to reflect on the HRRs and processes and discuss the current research environment and learnings from the appeal process.

Reflection on HRRs: PL provided a brief presentation to the HRCDC reflecting on the HRRs and proposed amendments. It was reiterated that consistency, clarity and certainly regarding health research are the objective of the HRRs. It was stated that data protection, long established legal and ethical duties of confidentiality and the European Convention on Human Rights all give rise to consent considerations in processing personal data for health research. The HRCDC was set up to provide a consent declaration under certain limited and specified circumstances. There was now considerable information and educational guidance publicly available to assist researchers in navigating the HRRs. Corporate governance by controllers regarding information management for health research has improved as a result of GDPR and the HRRs. Other matters were referenced such as Biobanks, which currently have no legislative framework and such a framework would require primary legislation. Accordingly, the extent to which the HRRs (as secondary legislation) can provide a regulatory structure for biobanks (and similarly with adult capacity to consent) is limited to matters of personal data processing for health research. y. It was also clarified that all consent to be valid must be informed and that explicit consent is informed consent that has been properly recorded.

A Wider Agenda: TM referenced the necessary wider agenda the Department was examining or already engaged in to reform and strengthen the regulatory framework underpinning the health research sector. Current initiatives such as the National Research Ethics Committee (REC) Bill, and planned developments such as a Biobank governance strategy and a National Genetic and Genomic Policy aim to facilitate these reforms. Furthermore, the Department of Health is working with the HSE to strengthen and embed research, underpinned by actions set out in the National Service Plan 2019 and 2020.
The HRCDC noted that HRCDC decisions and deliberations should remain within the remit of the HRRs. It would be important to align conditions attached to a declaration with possible future policy guidelines. In that regard it would be useful for the HRCDC to understand best practices to ensure these conditions are reasonable, and in the context of the public interest test and data subject rights. TM said the Department would be happy to discuss what possible practices could be considered and would share early draft papers or working proposals where appropriate. The Chair offered that the HRCDC could send feedback to the D/Health on any matters that may arise during the course of its business that the D/Health could benefit from hearing.

Amendments: PL provided an overview of the proposed amendments under review. He pointed out that the D/Health had made clear publicly when the HRRs were made by the Minister (August 2018) that consideration was ongoing on certain matters (for example, retrospective chart reviews) and the amendments now being made represented the outcome of that process and meaningful engagement with the health research sector on genuine challenges. The D/Health was committed to continuing its constructive engagement with the health research sector and to promoting public confidence in health research. TM then discussed individually the proposed amendments to the HRRs which were being finalised;

Pre-screening: Pre-screening is where patient charts are reviewed for suitability and eligibility for possible inclusion in a research study. Pre-screening is considered worldwide as human subject research requiring informed consent, but many countries have national processes and frameworks in place which allow pre-screening to progress in certain circumstances in the absence of consent. Arising from a lack of clarity as to who can conduct pre-screening without consent in Ireland, and in particularly over different interpretations of who is considered part of the "direct care team", this amendment seeks to provide clarity for all concerned on this issue This amendment will clarify who can carry out pre-screening in the data controller's organisation without consent (but only where the research study has been REC approved). Such pre-screening can be carried out by health practitioners (including students who are under the supervision of the health practitioners) and employees of the controller (with access to medical records in the normal course of their employment) and it also allows for "an authorised person" who is not an employee of the controller (for example a research nurse employed by a clinical research facility) to be authorised to do so subject to specified corporate governance rules, strict access to data rules and suitable transparency arrangements. Importantly, once participants have been identified as being suitable for a study, and a decision is made that the study will proceed, the amendment does not change the requirement for the data subject's informed consent to participate in the research study. The process is aligned with international best practice.

- **Retrospective chart review:** This amendment provides that informed consent will not be required for certain retrospective chart reviews, as is the case internationally. The amendment will apply only to retrospective chart review studies which have secured REC approval and have been deemed to be low-risk, and which are carried out in the controller's organisation by health practitioners (including students who are under the supervision of the health practitioners) and employees of that organisation (with access to medical records in the normal course of their employment). The amendment provides that transparency notices are the key consideration here (as per the recent Health Research Authority guidance in the UK) along with other appropriate safeguards, including assessment of risk. The amendment will be available only where the required assessment of risk indicates a low data protection risk to data subjects.

-Deferred consent for emergency care intervention studies: Where an individual arrives in a hospital (or indeed anywhere that provides healthcare) in an unconscious state, the focus must be on care and treatment. It may be that in the hospital concerned they are engaged in a research project (approved by a REC) on a new treatment and the healthcare professionals involved in the treatment of the individual make a clinical call that the new treatment represents the best option in terms of care. In such a situation, the provision of this new treatment has the effect of automatically enrolling the individual in the research programme. It is in the best medical

interest of the individual to permit this situation. That is what this amendment does. When the individual recovers sufficiently to make a consent decision, then a decision to continue or withdraw participation in the research can be made by him or her.

Amendment in relation to personal data obtained before the Regulations came into effect: While the HRRs are concerned primarily with health research that commenced on or after the date they came into effect (8 August 2018), they also applied to personal data obtained before that date which was continuing to be used, stored or disclosed for health research. That "ongoing" research was addressed by a transitional provision (Regulation 6) of the HRRs which expired on 7 August of this year. In its ongoing engagement with stakeholders (and in consultations with the Data Protection Commission), it was recognised that the matter was continuing to raise certain practical challenges for health researchers who had valid consent under the previous EU Directive in terms of (a) whether they needed to re-consent at all (which most didn't), and (b) if they concluded that they did need to re-consent, what would be regarded as reasonable efforts in that regard. The need to find a pragmatic but also appropriate solution to the above led to the following amendment: namely, where informed consent was obtained in accordance with the EU Data Protection Directive (and the 1988 & 2003 Data Protection Acts) for personal data obtained for health research prior to the commencement of the HRRs that such informed consent remains valid unless it has been withdrawn by the data subject. It was discussed generally that any existing declarations made to researchers for current studies should be reviewed to see if they are still required once the amendments are approved. The HRCDC Secretariat proposed to write to applicants to invite them to review and consider if they still require the Declaration based on the new Amendment.

In addition, the Department will take the opportunity to make some minor but important changes to the HRRs having reflected on the interim period and the operationalization of the the first appeal. These include:

- An amendment to broaden the Appeal Panel from 3 members to 'up to 7 members'.
- An amendment to specifically reference the requirement for researchers to have 'patient and public' consultations with respect to a research study.
- A technical amendment to bring Regulation 10(1) into line with Regulation 13.

The Appeal Process: PL discussed that one of the key objectives of HRRs was to avoid legalism in the HRCDC and the appeal process. He added that the D/Health would be examining the appeal process to ensure that it was as efficient and effective as possible. In that regard, the examination would have particular regard to any insights that might be derived from the operation of the first appeal. The D/Health would welcome any observations from the HRCDC.

The HRCDC suggested that the Appeal Panel should always have a PPI representative and the Department should consider how the appeal should be reviewed. The HRCDC discussed that any future involvement of the HRCDC would need to consider the availability and resources of the HRCDC and the timelines for any input to the Appeal Panel to allow for the HRCDC consideration.

The session closed with positive feedback from the D/Health regarding the work of the HRCDC and the overall advancement of the HRRs.

6. Information Session: Capacity to Consent: Patricia Richard-Clarke

The Chair introduced the session and welcomed Patricia Richard-Clarke to the meeting and highlighted the importance of the topic in the context of the HRRs.

PRC discussed the current legislation and UN Convention on the Rights of Persons with Disabilities ("Convention"). The current practice of using 'next-of-kin' to make decisions on behalf of individuals who lack decision-making capacity is not lawful.

PRC provided overview of the Assisted Decision-Making Act ("ADMA"), 2015 and highlighted a number of sections. The commencement orders have been made for the Office of the Director of the Decision Support Service to be established. Codes of practice have been drafted by National Disability Authority and HSE. Commencement of the ADMA in fully is anticipated in 2020 when codes and regulations are in place.

The Convention was ratified in Ireland in 2018 and sets out that there should be no discrimination on the basis of disability and individuals with disabilities have rights equal to all others. Individuals should enjoy equal capacity and equal legal and constitutional rights. The Hague convention on International Protection of Adults is also important to note and has yet to be ratified by Ireland.

PRC highlighted key areas and definitions regarding capacity. The common law principle of presumption of capacity (which is given statutory effect in the ADMA) should be applied at all stages, unless it's clear and evident that the person lacks decision-making capacity.

- There is a burden of proof on the person claiming that a person lacks capacity to prove this is so.
- The legislation is for everyone, including those with mental and physical disabilities.
- 'Decision-making' capacity is the preferred terminology to ensure to ensure no 'disability' tag is applied or anything specific, to avoid discrimination.
- An individual may have capacity to make decision/s in different matters e.g. health, finance etc. Capacity is defined as decision, time and issue specific.
- Capacity is a legal test, not a medical test.

PRC discussed when individuals lack capacity; This is when a person is unable to; understand, or retain information or, use and weigh up the information, or communicate the decision by any means. There is a requirement to support individuals to enable them to make a decision.

The Guiding Principles regarding capacity are taken from the Convention;

- The least level of intrusion should be implemented.
- All steps should be made to assist the individual.
- Voice of the individual is paramount, and support must be provided.
- The will and preference of the individual must be considered.
- Decision making mechanisms are important; decision making assistants, co-decision makers, decision making representatives (agent).

PRC referenced *A.C. v HSE [2018] IECA 217* to highlight issues that can arise when the will and preference of an individual is not taken into account.

PRC discussed decision-making mechanisms such as an Enduring Power of Attorney (EPA) which can be put in place in advance when a person has capacity; to come into effect when the individual

lacks capacity, and the EPA is registered with the Director. The stage for appointment of an EPA and the scope of authority of an EPA was discussed.

Existing EPAs will still be valid and can be registered post the ADMA 2015. EPAs can be made subject to conditions and restrictions. Under the ADMA, complaints can be made to the Director, to investigate.

PRC provided an overview of the specific function of the 'Decision-Making Assistant' which is to assist the appointor with information and making and implementing the decision. The function of Co-decision Maker is to advise the appointor regarding the information - input and interpretation.

Under the ADMA a court may make a determination that an individual lacks capacity and not that they have capacity. There will be a review of current Wards of Court who will be assessed to see if they have capacity or to transition to avail of supports under ADMA.

The presentation ended and the HRCDC had an opportunity to ask questions regarding the ADMA and capacity to consent in the context of any consent declaration made by the HRCDC. The HRCDC asked PRC to provide specific advice when reviewing applications where consent could not to be obtained as participants lacked capacity.

PRC advised the HRCDC to consider whether appropriate support was provided to individuals when decisions were made regarding the enrolment in a research study. Decisions should be made with the individual's voice, will and preference where possible. There should be a clear benefit to the individual, supporting a public interest case. Where the burden of proof lies with person alleging lack of capacity, the HRCDC queried the role of the HRCDC in ensuring capacity has been determined appropriately. PRC stated the obligation is on the researcher to confirm this. There is a reasonable obligation on HRCDC to ensure compliance with law has carried out in making the decision that the individual lacks capacity. It should be assumed that those carrying out the capacity assessment are complying with the current common law functional test for capacity and in compliance with the ADMA when fully commenced. It was reiterated that a functional test is appropriate to determine capacity, not a medical diagnostic test such as MMSE.

The meeting closed and the Chair thanked the invited speakers for their time to discuss the various topics. The Chair noted the next HRCDC meeting would convene on November 25th, 2019.

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