

Date: 13th December 2022

Location: The Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Zubair Kabir
Dan Rea
Cornelius Cooney
Mary Tumelty
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)
Caroline Byrne (Secretariat)
Marta Pisarska (Secretariat)

Quorum for Decisions

YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Bairbre McNicholas	20-039- AF1/AMD1	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock
Patricia Fitzpatrick	22-001- AF1/CSO/AMD1	Study of the impact of lifestyle factors on COVID-19 outcomes
Norman Delanty	22-005- AF1/AMD1	Longitudinal Analysis of Clinical Markers of Response to Treatment in People with Epilepsy (EPIDIVE Phase 2)

New Applications – For consideration

Applicant	Ref No.	Title
Iracema Leroi	22-011-AF1	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

Kathy Brickell, Claire Collins, Simon Furney, Aideen Hartney, Barry O' Sullivan, John Woods, Barry Lyons

3. Disclosure of Interest

- Alyson Bailey (AB) declared her interest in application 22-011-AF1 (SENSE-Cog). AB was absent during the meeting when this application was considered.
- Sheelah Connolly (SC) informed the HRCDC that she has previously worked with some of the researchers noted in application 22-011-AF1 but is not involved in this study. The HRCDC was of the view that there was no conflict of interest that would require SC to be excluded from the discussion of this application.
- Zubair Kabir (ZK) informed the HRCDC that he professionally knows researchers named in amendment request 22-001-AF1/CSO/AMD1, however ZK is not involved the study. This was previously disclosed by ZK when the original application was considered. The HRCDC was of the view that there was no conflict of interest that would require ZK to be excluded from the discussion of this amendment application.

4. Minutes of the last meeting

Draft minutes of 8th November 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

- **19-019-AF2/AMD1 (IMPROVED study):** The Secretariat provided an update on the Applicant’s response to Condition 1 (seeking consent for data processing at 18-years-old), that was attached to this approved amendment. The Applicant informed the Secretariat that it does not intend to process child data from the IMPROVED study for the purpose of the IDEA study under this amendment; only personal data on the mothers recruited to the IMPROVED study will be processed. The Secretariat informed the Applicant that Condition 1 remains in place and must be progressed where personal data of children from the IMPROVED study is processed for the IDEA study. The Applicant was also informed that a response to this condition must be provided as part of the Annual Review process.
- **22-010-AF1 (BEST pilot study):** Following the decision of the HRCDC to not make a consent declaration, the Applicant provided an update that the study will proceed and process the personal data of participants who have decision-making capacity to consent.
- **Remaining AF2s:** The Secretariat provided an update on the most recent correspondence it has received from the data controller regarding the AF2 applications that have been deemed withdrawn.
- **Amendment request form:** Following the discussion and approval of the HRCDC’s amendment request procedure, the Secretariat circulated the latest version of the HRCDC amendment request form and accompanying guidance to the HRCDC for its information.
- **2023 Meeting dates:** The Secretariat reminded the HRCDC that the meeting dates for 2023 have been circulated and calendar invites sent. In addition to holding an in-person meeting in May 2023, it was discussed whether it would be beneficial to move the other in-person meeting in 2023 from December to November to facilitate attendance. The HRCDC discussed and agreed upon moving the second in-person meeting to November and to hold the December meeting by videoconference.

6. Amendments:

Reference ID:	20-039-AF1/AMD1
Lead Applicant:	Bairbre McNicholas
Lead Data Controller:	Galway University Hospital - Saolta Hospital group

Title:	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock
Research Objective:	Please see HRCDC meeting minutes of 2 nd March 2021.
Purpose of Amendment:	The purpose of the amendment is for (i) the inclusion of telephone proxy assent and (ii) the addition of Tallaght University Hospital as an additional hospital site/data processor.
HRCDC Comments:	<p>The Secretariat introduced the amendment. The Chairperson noted that the amendment was relatively technical in nature and requested the HRCDC to indicate whether the amendment to the consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment should be approved.</p> <p>REC approval & scope of amendment</p> <ul style="list-style-type: none"> • It was noted that approval from the Chairperson of the REC had been obtained for the use of telephone proxy assent at the Galway Hospital site only. It was discussed that approval from the Chairperson of the REC is acceptable for consent declaration amendment requests such as the inclusion of telephone assent. • The Secretariat highlighted that confirmation that full REC approval, including approval for the use of telephone proxy assent, from the other two sites noted in the original application (Beaumont Hospital and St Vincent’s University Hospital) remain pending. Correspondingly it was noted that Condition 2 attached to the original declaration remained in progress. • It was further noted that REC approval for the inclusion of Tallaght University Hospital as a new site/data processor remained pending. • It was discussed and agreed that the amendment can be made to cover the addition of telephone proxy assent at the Galway Hospital site, and that it would also cover telephone proxy assent at Beaumont Hospital and St Vincent’s Hospital, subject to confirmation that the REC approval for these sites, when obtained, covers telephone proxy assent. • For the inclusion of Tallaght University Hospital as a new site and data processor, it was agreed that this would be considered by the HRCDC at a later date, when REC approval or provisional approval for Tallaght University Hospital has been obtained. <p>Study Information Leaflets</p> <ul style="list-style-type: none"> • Condition 6 attached to the original consent declaration requested the Applicant to amend the study information leaflets and assent/consent forms to be used in this study. • The HRCDC noted that while progress has been made to address the points outlined in Condition 6, it was highlighted that not all the requested changes have been fully addressed throughout the study documentation. For example, there were still

	<p>inconsistencies on the number of participants to be recruited as well as the incorrect use of the term consent in some sections.</p> <ul style="list-style-type: none"> • It was the view of the HRCDC that the Applicant should revisit the study documentation and ensure Condition 6 is fully addressed. Other comments were made regarding the study documentation for addressing by the Applicant. <p>Other</p> <ul style="list-style-type: none"> • It was discussed and confirmed that the specific and standard conditions attached to the original consent declaration remain valid.
<p>HRCDC Decision:</p>	<p>The consensus of the HRCDC was that the conditional declaration could be amended.</p>
<p>Conditions Attached:</p>	<p>Condition 1. Further to Condition 2 attached to the original consent declaration, the Applicant must provide confirmation that full REC approval for Beaumont Hospital and St Vincent’s University Hospital, when obtained, covers the use of telephone proxy assent at these sites. The consent declaration will not cover the Beaumont Hospital or SVUH sites, or the use of telephone proxy assent at these sites, until the requisite REC approval is in place and that such confirmation is provided to the HRCDC.</p> <p>Condition 2. Based on the updated study information leaflets and assent/consent forms submitted with the HRCDC amendment request form, it is noted that the observations outlined in Condition 6 attached to the original consent declaration have not been fully addressed throughout the latest version of the study information and assent/consent forms. The Applicant must therefore revisit the study information leaflets and assent/consent forms and ensure that Condition 6 is fully addressed. In this context the following observations are provided, which include some additional observations from that already outlined previously in Condition 6:</p> <ul style="list-style-type: none"> • Pg 1 of the Participant Information Leaflet/Consent to continue document references that the patient has been enrolled in the study based on the “consent” of the next-of-kin - this should be changed to ‘assent’. As per point (i) of Condition 6, for correctness, relative or next-of-kin ‘consent’ for data processing should be replaced with ‘assent’, when referring to a proxy individual providing assent on behalf of the research participant throughout the study documentation. • Pg 2 of the Participant Information Leaflet/Consent to continue form and the relative/next-of-kin information sheet still refers to 30/thirty participants being recruited, not 50/fifty as was confirmed by the Applicant. • Pg 4 of the Participant Information Leaflet/Consent to continue form incorrectly uses the term ‘they’, rather than ‘your’, in several places e.g., when referring to the participant’s data rights.

	<ul style="list-style-type: none"> Review and amend both the proxy assent/participant consent form provided on pages 6-7 of the Participant Information Leaflet/Consent to continue form and the relative/next-of-kin information sheet, to ensure that the correct wording and terms are used. For example, the consent to continue form for the participant is incorrectly entitled '<i>Person Responsible Consent Form</i>' and states '<i>I have been asked to give permission for the following person to participate....</i>'. Correspondingly the proxy assent form for the next-of-kin provides a space for 'Participant Signature' and not 'Proxy signature' <p>Note: The Applicant should ensure that Condition 6 attached to the original consent declaration, and condition 2 above, are applied to the information leaflets and proxy assent/participant consent forms used at each of the hospital sites in Ireland involved in this study.</p>
<p>HRCDC Recommendations:</p>	<p>Recommendation. While not part of Condition 6 attached to the original consent declaration, the Applicant may wish to seek more explicit proxy assent/participant consent with regards contacting the participant's GP at 3 months to request serum creatinine results (e.g., an yes/no tick option in the assent/consent form).</p>

Reference ID:	22-001-AF1/CSO/AMD1
Lead Applicant:	Patricia Fitzpatrick
Lead Data Controller:	University College Dublin
Title:	Study of the impact of lifestyle factors on COVID-19 outcomes
Research Objective:	Please see HRCDC minutes of 12 th April 2022.
Purpose of Amendment:	To extend the duration of the consent declaration by 1 year.
HRCDC Comments:	<p>The Chairperson introduced the amendment request and noted that the amendment was a technical extension of the consent declaration. The Chairperson requested the HRCDC to indicate whether the amendment to the consent declaration should be made.</p> <p>Based on the information provided by the Applicant, the Secretariat informed the HRCDC that the study had not yet commenced or gained access to the CSO COVID-19 Data Research Hub and that Condition 4 (enhanced transparency measures) had yet to be implemented due to study delays. It was noted that the Applicant has outlined that they will enhance transparency measures via the website after the relevant study approvals have been obtained. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment should be approved.</p> <p>REC Approval</p> <ul style="list-style-type: none"> It was noted that the current REC approval for this study is due to expire in December 2022. It was discussed that the Applicant must seek an extension of the REC approval to cover the duration of the extended consent

	declaration. It was further discussed that a consent declaration does not cover research where the requisite REC approval is not in place and that it is the responsibility of the Applicant/Data Controller to ensure that the necessary approvals are in place and remain valid.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Conditions Attached:	Condition 1. Extended research ethics approval for this study must be obtained as soon as practicable and confirmation of the extended REC approval submitted to the HRCDC.

Reference ID:	22-005-AF1/AMD1
Lead Applicant:	Norman Delanty
Lead Data Controller:	Royal College of Surgeons in Ireland <i>New Data Controllers: Beaumont Hospital and St James's Hospital</i>
Title:	Longitudinal Analysis of Clinical Markers of Response to Treatment in People with Epilepsy (EPIDIVE Phase 2)
Research Objective:	Please see HRCDC minutes of 14 th June 2022.
Purpose of Amendment:	This amendment request is to (i) add Beaumont and St James's Hospitals as joint data controllers with RCSI and (ii) extend the duration of the consent declaration by 6-months.
HRCDC Comments:	<p>The Chair introduced the amendment and requested each HRCDC member to indicate whether the amendment to the consent declaration should be made. The Secretariat highlighted that the responses from the Applicant on the original application confirmed RCSI as the sole data controller of the study. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment should be approved.</p> <p>Outstanding signatures</p> <ul style="list-style-type: none"> It was noted that authorised signatures on the HRCDC amendment request form were outstanding from Beaumont Hospital and St James's Hospital and that they should be requested from the Applicant. <p>Data Agreements</p> <ul style="list-style-type: none"> It was discussed that appropriate joint data controller arrangements should be in place between RCSI, Beaumont Hospital and St James's Hospital. <p>Previous Conditions</p> <ul style="list-style-type: none"> The HRCDC discussed that the previous conditions attached to the consent declaration remain valid and must be progressed by the Applicant, including Condition 1 on enhanced transparency measures.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Conditions Attached:	Condition 1. Authorised signatures on behalf of Beaumont Hospital and St James's Hospital on the HRCDC amendment request form

	<p>must be submitted to the HRCDC as soon as practicable. The amendment will not be in effect until this condition is met.</p> <p>Condition 2. Appropriate joint data controller arrangements must be in place between RCSI, Beaumont Hospital and St James's Hospital.</p>
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7. New Applications

Reference ID:	22-011-AF1
Lead Applicant:	Professor Iracema Leroi
Data Controllers:	Trinity College Dublin
Title:	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia
Research Objective:	<p>NSE-Cog Residential Care will compare a Sensory Support Intervention for Residential Care (SSIRC) to Care as Usual (CaU) in Residents with Dementia (RwD) with hearing and/or visual impairment. The study will ascertain feasibility, acceptability, and tolerability of the intervention. It will explore whether the intervention may be effective in improving quality of life and other outcomes and evaluate cost-effectiveness.</p> <p>Approximately 10 homes will participate, 5 will receive the intervention and 5 will receive CaU. RwD in the intervention arm will receive hearing and vision assessments and aids to assist. Staff in the intervention nursing homes will receive general training in sensory cognitive health. Selected staff, Sensory Champions, will receive further training and deliver the SSI-RC. SSI-RC has four levels: Resident, Staff, environment, and referral pathway. Assessment will be carried out in several ways including semi-structured interviews and questionnaires. at the beginning of the study, after 3-months and again after 6-months.</p>
Reason for Declaration:	A consent declaration is required to process the personal data of residents with dementia (i.e., participants who lack decision-making capacity) for the purpose of this specific research study (i.e., collection, transfer, analysis, storage etc.).
HRCDC Comments:	<p>The Chairperson introduced the study and reminded the HRCDC that this study was first tabled at the HRCDC meeting of 6th September 2022, however it was noted that the study had not yet identified the nursing homes/data processors who will be included in this study. The Applicant has since provided an initial list of confirmed nursing homes that will participate in this study.</p> <p>It was noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent.</p> <p>The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the</p>

Applicant, it was the consensus of the HRCDC that a conditional declaration should be made.

Public interest case

- The HRCDC discussed the aims and objectives of the study and the study methodology. It was queried whether the study would produce sufficient findings and it was commented that clearer information on the study's activities could have been provided. However, it was also noted that this is a feasibility study to inform a potentially larger study in the future.
- Based on the information provided by the Applicant, it was the view of the HRCDC that there is a strong public interest case and that it would not be feasible to obtain explicit consent for this study.

PPI engagement

- The HRCDC discussed the Applicant's response on the public, patient and carer involvement (PPI) activity undertaken. It was noted that PPI representatives form part of the Trial Steering Committee and that discussion groups were held previously, which included PPI representatives.
- The HRCDC noted this activity and was of the view that PPI could be further strengthened, in particular, through engagement with the residents with dementia. The HRCDC was therefore of the view that the study should seek the feedback and opinions of the residents recruited to the study.

Transparency and withdrawal of data

- It was noted that the study information leaflets could provide clearer information regarding withdrawing from the study and the processing or deletion of data thereafter. The ability to withdraw from the study should also be made as easy as possible, including providing a contact within the nursing home, not just the Trinity College Dublin research team, if a participant and/or their relative wishes to withdraw from the study.

Data Security

- The HRCDC discussed the responses from the Applicant regarding the transfer of data between the nursing homes and the researchers, including the transfer of physical or hard-copies of the data.
- The HRCDC was of the view that security of the data may not be as robust as it could be and therefore Applicant should examine and strengthen the security of the data, including physical copies and transfer of data, to ensure that it is appropriately protected. In this regard it was discussed that the transfer of physical or hard-copy data from the nursing home to the research team should be reconsidered and data transferred by secure electronic methods only.

Other

	<ul style="list-style-type: none"> • The HRCDC queried the number of nursing homes and participants to be recruited to this study. It was highlighted that the study aims to recruit between 50-60 residents with dementia across 10-12 nursing homes. The HRCDC commented that the Applicant should be requested to provide updates on the number of residents recruited as part of the Annual Review. • It was queried how some of the data would be obtained, for example the resident’s educational background. • It was noted that there is a data processor located in France and that data will be stored in France. It was discussed that this data processor refers to the research software used within this study. It was commented that the Applicant refers to agreements being in place with the French data processor. • It was highlighted that qualitative interviews will not be held with the residents with dementia; these interviews are only undertaken with staff in the nursing homes. It was further noted that the resident study assessments are primarily observation based, with only one assessment requiring direct engagement with the residents. It was also highlighted that access to medical records will be by the nursing home staff only. • It was commented that the Applicant should ensure that only the minimal data required for this study should be processed and that personal data should only be processed for the minimal length of time. • The HRCDC discussed that when recruiting participants for this feasibility trial, that it would be beneficial to request if they would also wish to be included and have their data processed in a larger future study, should this be undertaken. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, including on the assent/consent process, data agreements and arrangements, minor corrections in the study information leaflets and ensuring that local REC approval for each nursing home is sought and obtained where necessary.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 13 th December 2022 and shall be valid until 30 th November 2027 or upon confirmation that the personal data have been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	Condition 1. The Applicant is requested to further enhance the level of PPI engagement within this study; specifically, the Applicant is requested to undertake engagement and discussions with, and seek feedback from, the residents with dementia who will be recruited to the study. This engagement with residents should consider discussions and seek feedback on the development and delivery of the study, the assent/consent process, transparency measures and the dissemination of findings and other relevant matters. PPI engagement with residents with dementia should also

discuss support for and the development of a larger future study that may follow this feasibility study.

Condition 2. It is a condition of this declaration that proxy assent on behalf of a resident who lacks decision-making capacity is sought and obtained from an individual who understands the resident's will and preferences. Further, should the capacity of the resident fluctuate over the course of the study, the study must seek to obtain their deferred consent to continue to process their data. Deferred consent, if the resident regains capacity, should be sought at an appropriate point in time that does not cause undue stress to the resident.

Condition 3. Appropriate data agreements and arrangements must be in place between the relevant parties prior to the processing of personal data for this study. The consent declaration will not be in effect until this condition is met.

Condition 4. The Applicant is requested to seek confirmation that the REC approval obtained from TCD is sufficient to conduct the study at that nursing home. Where local REC approval is required from the nursing home this must be obtained. Confirmation that TCD REC approval is sufficient, or that local REC approval is required and has been obtained, should be provided to the HRCDC as soon as practicable. For the avoidance of doubt, the consent declaration will not be in effect for the nursing home sites where local REC approval is required but has not been obtained, until REC approval is in place.

Condition 5. With regards the study information leaflets and assent/consent forms and withdrawing from the study, the following should be addressed by the Applicant:

- (i) The current information leaflets state 'You can change your mind about your relative taking part in the study and opt out at any time even if the study has started' or 'You can decide to take part or not each time we visit. If you choose not to take part, this will not affect your care or treatment'. It must be clearly outlined to both the resident providing assent/consent and the person providing proxy assent where they lack decision making capacity, what will happen the personal data if their assent/consent or proxy assent is withdrawn, i.e., aligned with the response from the applicant, the data collected will continue to be processed subject to their agreement and it will be deleted if they do not agree. Information should also be provided whether there is a point in time where personal data cannot be deleted/removed.
- (ii) Further to point (i), where a participant wishes to withdraw from the study and/or exercise their data rights, a contact within the nursing home, not just the Trinity College research team, should be clearly provided in the information leaflets for both the

	<p>participant and their proxy. This contact in the nursing home can then liaise and engage with the Trinity College contact.</p> <p>Condition 6. The Applicant is requested to review and strengthen the security of the data collected for this study, in particular the security of the physical copies of data and the methods of data transfer, to ensure they are suitably robust; where practicable, the transfer of physical or hard-copy data from the nursing home sites to the research team in Trinity College Dublin should be avoided and data transferred by secure electronic methods only. The Applicant is requested to reply to this condition and provide details on the robust security of the data as soon as possible and within 2 months. The consent declaration will not be effect until a satisfactory response is provided to the condition by the requested deadline.</p> <p>Condition 7. Aligned with the principle of data minimisation, the Applicant should ensure that only the minimal level of personal data is collected, processed, transferred and stored for the purpose of this study. Consideration should also be given on whether the data can be anonymised or destroyed sooner than November 2027.</p> <p>Condition 8. The study information leaflets and the consent/assent forms for residents with dementia and those providing proxy assent should be reviewed to ensure that they are written in the correct perspective. For example, the statement 'Do I have to take part' in the information leaflet for the relative/proxy should be rephrased as 'Does my relative have to take part'.</p> <p>Condition 9. The Applicant is requested to provide updates on the number of residents with dementia recruited to this study as part of the Annual Review.</p>
<p>HRCDC Recommendations:</p>	<p>Recommendation 1. With regards the study information leaflet and assent/consent and proxy assent forms, the Applicant is recommended to ask the residents with dementia and their relative/proxy, if they would also wish to be included and have their data processed in a larger future study that may follow form this feasibility study.</p>

8. Updated HRCDC Standard operating procedures

- The Secretariat circulated a copy of the updated HRCDC Standard Operating Procedures (SOPs) to the HRCDC prior to the meeting and provided a brief overview of the changes and additions that have been made. The Chairperson requested the HRCDC members for their comments on the SOPs which were noted by the Secretariat. The HRCDC were asked to forward any further comments they had on the SOPs to the Secretariat in advance of the next HRCDC meeting in January 2023. The feedback received will be reviewed and considered by the Secretariat and the latest draft will be tabled at the January 2023 meeting.

- The HRCDC queried whether the consent declaration appeals process has also been reviewed and updated. It was commented that the appeal process is independent of the HRCDC and will be highlighted to the Department of Health.

9. Annual Reviews

The Secretariat has received 3 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-060-AF1**; Austin Stack, '*National Kidney Disease Surveillance System and Quality Assurance Programme*'
 - **Ref ID: 20-013-AF1/COV**; Joe Eustace, '*Solidarity Trial*'
 - **Ref ID: 21-017-AF1/CSO**; Michael O'Callaghan, '*COVID-19 in Ireland: A retrospective analysis of general practice's contribution to testing and assessment*'
- Note:* The Secretariat informed the HRCDC on the progress made regarding Condition 2 (enhanced transparency measures) and that this declaration has expired and that an extension will not be sought by the Applicant.

10. Activities report and events of interest

- The Secretariat circulated the activities report to the HRCDC detailing the events and activities that have occurred since the previous November meeting.
- The following upcoming events of interest and other relevant updates were also noted to the HRCDC:
 - Human Tissue Bill: <https://www.gov.ie/en/press-release/01f22-minister-donnolly-to-publish-the-human-tissue-transplantation-post-mortem-anatomical-examination-and-public-display-bill/>
 - IPPOSI event: '*A Rights-Based Approach to Accessing Health Information*' on Thursday 1 December (recording: https://youtu.be/_I7AVnjoZcA)

11. Any Other Business

- The Secretariat circulated the HIQA public consultation documentation on 'Draft National Standards for Information Management in Health and Social Care' and the proposed consultation responses on behalf of the HRCDC. The HRCDC were asked to forward any additional comments or feedback on this consultation to the HRCDC by Friday 16th December. (<https://www.hiqa.ie/reports-and-publications/consultation/draft-national-standards-information-management-health-and>)
- It was highlighted that 12th April 2022 meeting of the HRCDC, although quorate, was not fully constituted; specifically, the Chairperson and Deputy Chairperson were absent from the meeting and an Acting Chairperson was appointed. The Chairperson and Deputy Chairperson confirmed to the HRCDC that they formally endorse the decisions made by the HRCDC at the April 2022 meeting.
- It was discussed that the HRCDC may benefit from a presentation on the Assisted Decision-Making Act, including the recent developments that have occurred with regards this legislation.
- The Chairperson thanked Marta Pisarska (Secretariat) for her work and contribution within the HRCDC Secretariat and wished her the best of luck in her next role.
- The Chairperson thanked the Committee members and the Secretariat for their work and commitment in 2022 and looks forward to continuing the work of the HRCDC in 2023.

****The Chair closed the meeting****

Following the meeting, the HRCDC attended a presentation on the Health Information Bill and European Health Data Space by Peter Lennon, Department of Health.

APPROVED