HRCDC
Health Research Consent Declaration Committee

Time: 10.30 – 17.00
Date: 13th June 2019
Location: Schoolhouse Hotel, 2-8 Northumberland Road, Ballsbridge, Dublin 4

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus - Chairperson
Evelyn Mahon - Deputy Chair
Alyson Bailey
Kathy Brickell
Kevin Clarke
Sheelah Connolly
John Ferguson
Simon Furney
Bert Gordijn
Aideen Hartney
Zubair Kabir
Malcolm Kell
Barry O Sullivan
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Shirley Murphy (Secretariat)

Quorum for Decisions

☒YES

Applications considered at this meeting

Applicant	Ref No.	Title
Warren Connolly RCSI /Beaumont	19-001-AF3	Irish National Adverse Events Study
Aideen Hartney/ Caroline O'Nolan	19-009-AF2	Moving In Study
Michael Farrell/ Beaumont / GMI	19-006-AF3	Contribution of Whole Genome Sequencing to Brain Tumour Biology

Meeting Items

1. **Opening**
   The Chair opened the meeting, welcomed the members and further welcomed Dr Malcolm Kell who was absent from the Induction meeting, March 27th and the previous HRCDC meeting, 29th April.

2. **Apologies**
   Dr Claire Collins was not present.

3. Disclosure of Interest

There was one conflict of interest in relation to application number 19-009-AF3 "Moving in Study" by Dr Aideen Hartney. Dr Hartney was absent for this part of the meeting when the application was under review. A conflict of interest form was completed by AH and submitted to the Secretariat for record purposes.

4. Minutes of the last meeting

Minutes from April 29th meeting of the HRCDC were agreed. The Chair reminded the HRCDC that the meeting minutes will be published on the HRCDC website. In response to a query, it was confirmed that the approach in general would be that comments will not be attributed to individual Committee members.

5. SOPs

The HRCDC agreed the Standard Operating Procedures (SOPs), which will be published on the HRCDC website. The SOPs will be reviewed at year end. The Secretariat provided a copy of the Declaration Decision Letter Template, highlighting the standard conditions that will be included in each letter, which are aligned to the Regulations and the SOPs. The HRCDC approved these standard conditions.

6. Activity Report

The Secretariat provided an overview of the Activities Report and highlighted the meetings and events the Secretariat participated in since the April 29th meeting. The HRCDC discussed the communication channels for the upcoming deadline in relation to 'transitional period' projects. The Secretariat stated that they will liaise with relevant stakeholders to communicate the deadline, such as the Dept. of Health and Data Protection Commission.

7. Previously reviewed applications

Reference ID:	19-001-AF3
Lead Applicant:	David Williams
Data Controller:	Royal College of Surgeons in Ireland (RCSI)
Title:	Irish National Adverse Events Study (INAES)
Application Summary:	This study (INAES-2) proposes to determine current rates of adverse events in Irish acute hospitals and to establish whether the implementation of the Clinical Programmes has influenced overall adverse event frequency. INAES-2 will also be able to compare adverse event rates with those reported in the recently updated National Incident Management System (NIMS). A key goal of INAES-2 is to provide the Irish healthcare sector with a data collection tool capable of being used by hospitals and frontline staff to determine local adverse event prevalence rates with a view to quality improvement. In total up to 3200 data subjects are/will be randomly selected from 8 hospital sites using the HIPE database; 200 surgical and 200 medical inpatients from each hospital. Data will be collected from the patients' medical records.
Purpose of Application:	Patient information from existing healthcare records is required for the purpose of this study. Information collected will be in relation to the admission and any relevant injuries/adverse events of patients in hospitals. Clinical Data will be used for research purposes. The Application submitted is seeking a consent declaration for the purpose of obtaining personal data from hospital healthcare records of randomly selected admissions across eight hospital sites
HRCDC Comments:	At the previous HRCDC meeting of April 29th, the HRCDC requested further information from the Applicant. A response letter from the Applicant was

	circulated by the Secretariat in advance of the meeting, to the HRCDC for consideration. The HRCDC was reminded that a decision should be considered based on weighing up the public interest case with the data protection rights of the subjects, on balance with the requirement to obtain consent and to consider the impact if a declaration is or is not made. An overview of the Applicant's response to the queries was provided. It was noted that the appropriate safeguards were in place and assurances that data will be anonymised once the master list was destroyed. The Chairperson referred to the extensive discussions at the previous meeting of April 29th and proposed that based on the information received, and subject to no objections, a declaration could be made and any conditions discussed. The Chair asked members to indicate if they did not agree that a declaration should be made. Comments from the HRCDC were as follows; Some minor concerns were raised by the HRCDC members who believed a declaration should be made: • Public/Patient involvement (PPI): It was considered that the Applicant response on the PPI query did not sufficiently answer the question raised by the HRCDC at the April 29th meeting. • Master list: It was noted that the hard copy of the master list would be destroyed. However, it was also questioned whether an electronic copy existed and if a statement to this effect should be requested from the Applicant. The Secretariat clarified to the HRCDC that a condition of a declaration could include information from the Applicant that the master list has been destroyed in both physical and digital formats. • It was queried whether anonymised data from the INAES-2 study combined with other data sets could identify an individual. The Secretariat confirmed that any declaration made, would be specific for the INAES-2 project and does not allow for the subsequent transfer of data to third parties. • Although supporting a declaration, it was the view of one HRCDC member that the selection bias rationale for not obtaining consent only produced a low-risk to the project due to the method of oversampling and collecting data from a relatively small number of hospital sites • One member commented that a public interest case did exist, although it was not significant. However, the risks to the data subjects were very low and the study would produce beneficial findings. • It was noted that personal data would be anonymised once the master list has been destroyed – the timing of this activity will help inform the duration for any Consent Declaration. **Support for a Declaration:** • The majority of the HRCDC were broadly satisfied with the responses from the Applicant in relation to the previous queries on consent, data minimisation and destroying the master list. • It was felt that overall the public interest did outweigh the need to obtain explicit consent.

	• It was considered that the study findings would help to increase awareness among the medical community into an important area and that more studies like this should be undertaken. **Setting a precedent** • In making a declaration decision it was re-emphasised that this should not set a precedent for future waves of 'INAES' studies. The Secretariat and the Chair confirmed no precedent would be set; each project is considered on a case-by-case basis. HRCDC members requested that this be communicated to Applicants in a general statement via the HRCDC website.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows**;** **Condition 1.** The HRCDC requested written confirmation that the Master list (including all hard and soft electronic copies) associated with source personal data, has been destroyed, as soon as this occurs; and **Condition 2.** As part of the Annual Review report to the HRCDC, the Applicant is requested to provide specific information on the PPI during the lifetime of the study and outline any issues considered and addressed as part of that involvement.
Duration:	7 Years after submission of the final INAES-2 report or publication, whichever comes last.
Other Observations/ Recommendations	The following recommendations are to be communicated to the Applicant in the decision letter: • No precedent set: Each application is considered on its individual merits. It should be noted that any future consent declaration being sought for next waves of 'INAES' studies, that application will be viewed on its own merits. Therefore, the Applicant should not view this decision for 19-001-AF3, as a precedent for future applications. • For future applications, the HRCDC recommends the Applicant consider condition 2 when designing the future waves of 'INAES' studies.

8. New Applications

Reference ID:	19-009-AF3
Lead Applicant:	Dr. Aideen Hartney
Data Controller	National Disability Authority
Title:	Moving in Study
Application Summary:	The National Disability Authority (NDA) is undertaking the 'Moving In Study' to evaluate costs and benefits of new models of disability services and compare them to older models of service. The study will collect data based on interviews with participants. The study will involve between 500-600 data subjects and is expected to end in Q1 2020.
Purpose of Application:	Many of the participants in the study have limited capacity to provide consent. A declaration is requested to enable the continued processing of personal data already obtained via i) proxy consent or ii) direct consent using

	'Easy Read' but non-GDPR compliant consent forms and Patient Information Leaflet (PIL). A declaration is also sought in respect of future study participants who may not have the capacity to provide consent that is GDPR compliant.
Comments:	The Chair introduced the project and requested each HRCDC member to indicate whether a Consent Declaration should be made for this project. All members agreed that a Consent Declaration should be made following detailed discussion on a number of key areas: **Consent and proxy consent:** • The HRCDC agreed with the applicant's case that obtaining GDPR compliant explicit consent from the majority of the study participants is not possible due to their level of capacity and the requirements under GDPR. It was commented that the decision on the level of capacity was subjective. The response of the applicant that the capacity to provide informed consent is determined based on the participant's cognitive impairment, communication difficulties and support needs, observations and interactions with the participant and after considering the views of staff and or family members and any other relevant information was highlighted. • The HRCDC acknowledged the applicant's effort in trying to obtain explicit consent that is aligned with GDPR. This included redesigning the PIL and consent form on two occasions, further to legal advice received. The applicant was commended for obtaining explicit consent compliant with GDPR directly from a small number of participants who had capacity to do so. Similarly, they were commended for continuing to provide 'easy-read', non-GDPR compliant PILs and consent forms to participants with further reduced capacity, even though a declaration is requested to cover this cohort of participants. • The HRCDC acknowledged and discussed the absence of a legal framework that allows proxy consent to be used for participating in health research. It was highlighted that only those with a legally appointed guardian can provide legally recognised proxy consent and that the process for undertaking this process can be long and costly to most families/institutions. • The HRCDC noted that proxy consent was obtained from the service providers, which may reflect personal family situations of adults with disabilities. It was stated that the role of the proxy consent provider could have been explained in more detail within the application. • It was commented that collecting data from the service provider in cases of proxy consent, may create a methodology risk in relation to data collection and biasness of findings. The risk that the proxy consent could be treated as a 'tick-box' exercise was raised, potentially undermining and weakening the study. **Public interest case** • It was determined that there was a strong public interest case in this research which outweighed the requirement to obtain explicit consent as the project was conducting important research in an area of significant

	relevance to policy makers and it also had the potential to impact the lives of participants. • The HRCDC commented that research with the potential to impact the lives of participants should involve those very same participants whenever possible. The research aims to support people living with disabilities and include them in the decision making process. This is uncommon in the research field due to issues of capacity and legal authorities. **Disclosing risks to participants** • Although in favour of making a declaration one member of the HRCDC would have preferred more details on the procedures undertaken if the researcher uncovers a risk to the data subject, eg cases of bullying and/or abuse. • The Secretariat and other HRCDC members referred to the information provided by the applicant on this matter; Any case of bullying and/or abuse would be raised with the service provider and, if it is not satisfactorily dealt with, then further action will be taken by the research team. **Publication of findings** • Some HRCDC members noted that the data will be retained until the publication of the final report, after which it will be anonymised – however a timeline or estimate for publication of this final report was not provided. **Type of data to be collected** • Some HRCDC members commented that a clearer description of the qualitative and quantitative data to be processed as part of the study could have been provided. • The Secretariat pointed to the response to the query letter provided by the applicant that detailed more information on the type of data collected in the study. **Public and Patient Involvement** • HRCDC members commented that the response in relation to public/patient involvement was satisfactorily provided by the applicant including that individuals living with a disability sit on the NDA board that oversees the study and that the project's advisory committee includes a representative from a disability service provider; this is in the context that PILs and consent forms are also provided to the study participants and is relevant to the principle of transparency. **Safeguarding the data** • Some HRCDC members noted that data will be transferred electronically to the NDA and queried if this created a risk of data exposure. • The Secretariat highlighted that applicant states that pseudonymised data is transferred via email - Master List and 'FACE' word documents are stored separately. **Research Ethics approval letter**

	• Some HRCDC members noted that a Research Ethics Approval letter was time-limited and had subsequently expired. • HRCDC requested that the applicant provides further clarity on this issue which will be communicated though the HRCDC decision letter.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows; **Condition 1.** The Research Ethics approval received from St. John of God was time limited for 1 year, granted on 25th November, 2016. The HRCDC quested confirmation that an extension to the ethics approval has been sought and is currently valid. Confirmation is required within 15 working days upon receipt of this letter; and **Condition 2.** The HRCDC requested written confirmation once the Master list (hard and electronic copies) and FACE word file have been destroyed, thus confirming the data has been rendered anonymised.
Duration:	Until the data has been anonymised as described in the application via the destruction of the 'FACE' word files and Master code sheets
Other observations/ recommendations	Finally, in addition to the Conditional Declaration made, the HRCDC have requested the Applicant address the following matters; • The HRCDC requested the Applicant to confirm that in the event any abuse/bullying/historical harm is disclosed during the course of the interview, and where the researcher is not clear as to whether this had been reported, that the researcher/interviewers themselves will ensure relevant authorities are notified. • The Information Sheet provided to participants states "*The answers you give will not change the service you get now or in the future*". In its discussion the HRCDC considered that while understanding the need to reassure participants of no negative impact from refusing involvement in research, the information sheet may not fully inform the participant that the research may lead to positive service changes. The HRCDC recommended that this comment is revised to avoid this potential misinterpretation.

Reference ID:	19-006-AF3
Lead Applicant	Michael Farrell (Beaumont) & Hannah Moran (GMI)
Data Controllers	Beaumont Hospital & Genomics Medicine Ireland
Title:	The contribution of Whole Genome Sequencing to Brain Tumour Biology
Application Summary:	The research project aims to establish a brain tumour information system (BTIS) which will enable researchers to interrogate biologic and genetic data, across a range of tumour types. The data will be generated from two sources: 1. From archival brain tissue and 2. From the associated clinical data. The data will be processed by 1. Beaumont Hospital and 2. Genomics Medicine Ireland.
Purpose of Application:	The project aims to use archival brain tumour tissue from 9,000+ patients, which extends back over a ~30 year period. Of these archival tissue samples,

	it is estimated only 15% of these individuals (herein after referred to as data subjects) are living. The Applicants are seeking a declaration for the purpose of processing personal data of living data subjects, where consent cannot be obtained and until such time that the data will become anonymised.
Comments:	The Chair introduced the project and requested each HRCDC member to indicate whether a Consent Declaration should be made for this project. After discussing the application in detail, based on the information provided by the Applicants, it was the consensus of the HRCDC that no Consent Declaration should be made based on the following interlinked grounds; **Consent** • The HRCDC were of the strong opinion that explicit consent of living data subjects, should be sought for the purpose of using their personal data for this project. The HRCDC did not accept the case made for the impossibility of doing this and believed that it should be possible for the data controllers to identify which data subjects are not deceased using patient records and available public records to subsequently try to seek their explicit consent. • Furthermore, the nature of the data processing activity relates to whole genome sequencing, carried out by the joint data controller (Genomics Medicine Ireland; 'GMI'). The HRCDC were of the view that the involvement of a 'for-profit' organisation processing personal data introduces a higher risk that data subjects may have a deeper concern for their privacy rights. This therefore introduces a higher risk to the privacy rights of the data subject with implications for data transparency and fairness of processing. The HRCDC were therefore of the view that explicit consent from data subjects should be obtained or, at minimal attempts made to obtain consent, even if this is challenging. • The HRCDC further commented that the number of samples included in the study may not necessarily correlate directly to the number of data subjects - multiple samples could be from a single patient thus lowering the number of data subjects further. • Treating clinicians could be involved in obtaining consent • A lack of resources is not a sufficient reason in itself for not seeking the explicit consent of data subjects - the HRCDC recognised that it may be difficult, but should be an achievable task. • Supporting documentation submitted with the application referenced a study stating that data subjects are happy for archived diagnostic tissue to be used for health research if samples are not used for commercial purposes. HRCDC viewed this as a contradiction as a commercial entity was involved in this project. **Public interest** • The HRCDC recognised the value of developing a Brain Information System (BTIS) and benefits to society. The HRCDC further considered GMI's use and future permissions to currently unknown international third parties to access the duplicated BTIS, under the control of GMI. Safeguards on such unknown transfers to third parties for unknown purposes are unclear, potentially increasing the risks to the data subjects.

	• From the information supplied to the HRCDC, it was not evident that GMI's use and commercialisation of the BTIS would directly and significantly benefit the public. The HRCDC questioned the direct benefit back to patients whose data has been used to underpin the research, considering the high cost of drugs that may be developed. **Transparency and fair processing** • The HRCDC considered the information in the application and additional information sought by the Secretariat regarding transparency and privacy notices. • The HRCDC considered that this core principle of data protection was not adequately addressed, as there is no clear public notice outlining the role of either data controller in the establishment of the BTIS on either data controller's website. More specifically, there is no transparent public notice detailing GMI's subsequent use and provision of access of BTIS data to third parties. • The low level of transparency potentially creates a high risk to data subject confidence and trust; the HRCDC contended that it is likely that unless explicit consent was obtained, individuals would not expect their data to be used in this way; shared with GMI for genetic sequencing and subsequently shared by GMI via their duplicate database to other third parties for purposes that could include non-health research. **Patient & Public Involvement** • The HRCDC considered the efforts made to engage with PPI representatives and the engagement with Brain Tumour Ireland was acknowledged. • However, the HRCDC was of the opinion that more specific efforts to engage individuals should have been made to ensure robust PPI engagement, in particular in relation to the role of GMI as a joint data controller and the establishment of a duplicate BTIS database. **Other discussion points**: • It was acknowledged that GMI are receiving data that has already been pseudonymised in Beaumont and which has been de-linked to the original patient record. When receiving the data GMI are adding their own unique identifiers. • It was acknowledged that tumour somatic DNA, not germline DNA, will be extracted, and correspondingly analysed by GMI, after which the bio-samples will be returned to Beaumont Hospital. As part of the duplicate database GMI will retain a copy of the tumours genetic sequence and other anonymised clinical data. • The HRCDC commented that the study had not been peer-reviewed. • It was recognised that private companies often play a role in modern healthcare development. • It was recognised that a childhood equivalent BTIS has already been established in Beaumont. • It was acknowledged that a 'consent waiver' was previously granted by the relevant Research Ethics Committee

	• It was recognised that the response from the applicant that there would be a data gap if only including samples obtained via consent as of August 2018. • The HRCDC noted the terms and conditions of the legal contract between Beaumont and GMI. The Secretariat highlighted a clarification, provided by the Applicant, regarding future access to Hospital data. The Applicant confirmed that this contract was only relevant for future prospective sample collection, where explicit consent would be sought from donors. GMI will never have access to patient records. **Summary:** Give all the matters considered above, the HRCDC was not satisfied that the public interest significantly outweighed the requirement for explicit consent of data subjects.
HRCDC Declaration Decision:	The consensus of the HRCDC was that no Consent Declaration should be made.
Conditions applied:	N/A
Duration:	N/A
Other observations/ recommendations	N/A

9. Any other Business

- **FOI Requests -** EV advised the HRCDC of the procedure of any FOI requests. The Secretariat have drafted up a FOI policy that will be signed off and published. HRCDC member, Kevin Clarke, agreed to act as FOI 'appeals' officer.
- **HRCDC Observers -** As the HRCDC are considered newly established the Chair advised that she will not be agreeing to external observers during the initial HRCDC meetings to enable the HRCDC to continue to embed and effectively implement its protocols and procedures for considering applications.
- **iPads / Reading Room -** During the lunch break a member of the IT team set-up iPad security for each member. The HRCDC were advised on any queries they had in relation to the iPads. The Secretariat and IT provided an update on the procurement of the Reading Room software that will eventually be installed on the iPads and the benefits they can expect once this has been completed.
- **Publication of Minutes / Applications on Website -**The HRCDC were reminded that under the Health Research Regulations, and as outlined in the SOPs, a summary of submitted applications, HRCDC decisions and minutes of meetings will be published on the HRCDC website; no issues were raised.
- **Expenses -** SM advised that HRCDC expenses were being processed and will take 10 working days.
- **Meeting Arrangements -** The Chair discussed the round table approach at this meeting and it was agreed that this format worked well and will continue to be used at future HRCDC meetings. The Secretariat asked for feedback on their processes and procedures in supporting the HRCDC's work. The HRCDC were satisfied with the processes to date. It was suggested that, in the interest of time before a scheduled meeting, valid applications are forwarded to the HRCDC for consideration once they have been 'triaged' by the Secretariat. The Secretariat will aim to trial this for the next scheduled HRCDC meeting and will discuss with the Chair in advance.