HRCDC
Health Research Consent Declaration Committee

Time: 10.30 – 14.00
Date: 29th April 2019
Location: Department of Health, Meisian Plaza, Baggot Street, Dublin

Minutes of the Meeting

HRCDC Attendance

Name	Present
Brigid McManus (Chair)	Yes
Evelyn Mahon (Deputy Chair)	Yes
Alyson Bailey	Yes
Kevin Clarke	Yes
Claire Collins	Yes
Sheelah Connolly	Yes
John Ferguson	Yes
Simon Furney	Yes
Bert Gordijn	Yes
Aideen Hartney	Yes
Zubair Kabir	Yes
Barry O Sullivan	Yes
Dan Rea	Yes
Emily Vereker (Secretariat)	Yes
Jonny Barrett (Secretariat)	Yes
Shirley Murphy (Secretariat)	Yes

Quorum for Decisions

☒**YES**

Applications for consideration at this meeting

Applicant	Ref No.	Title
David Williams (Lead) Warren Conolly	19-001/AF3	Irish National Adverse Events (INAES-2) Study

Meeting Items

1. **Opening**

   The Chair opened the meeting, welcomed the members and further welcomed Dr John Ferguson who was absent from the Induction meeting, March 27th. The attendees participated in a short introduction about themselves around the table. It was agreed that meetings would be scheduled on an annual basis, each calendar year.

2. **Apologies**

   Ms. Kathy Brickell and Dr Malcom Kell were not present.

3. **Disclosure of Interest**

The Secretariat (EV) highlighted that the that the Conflict of Interest Policy has been circulated to the HRCDC. The HRCDC was reminded that all members must complete the Annual log form to record any potential interests as that may relate to the duties of the HRCDC. The HRCDC were further requested to complete the disclosure of interest form in the event there was a potential or actual conflict regarding a specific application submitted to the HRCDC. This should be completed, signed and returned to the Secretariat. There were no disclosures of interest recorded today for this meeting.

4. Minutes of the last meeting

The Chair advised the HRCDC that speaking notes from Teresa Maguire (Department of Health) have been included in the latest version of the minutes that was circulated to the HRCDC. The members were reminded that minutes will be published on the HRCDC website. The minutes were agreed by the HRCDC. A member asked about the process of managing social media and press queries. EV stated that any engagement with the media or reference to the HRCDC and/or Health Research Regulations will be captured in the Activities Report for the HRCDC.

5. New Applications

Reference ID:	19-001/AF3
Applicant:	David Williams
Title:	Irish National Adverse Events Study
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:	The Secretariat (JB) provided an overview of the study and the documentation that was provided by the applicant. JB explained the validation process and that all relevant correspondence between the Secretariat and applicant had been included in the review pack for the HRCDC. There was a wide ranging and detailed discussion by the HRCDC. Pseudonymisation of the data and existence of the master list and when this would be destroyed to ensure the data becomes anonymised was discussed. The data access and review process was discussed.

	It was noted that a public interest case has been outlined by the applicant and why it is not possible to obtain consent. The volume of records being reviewed was discussed and why obtaining consent may bias and distort the study and render it not comparable to the initial INAES-1 study. The importance of keeping comparability between the two INAES-1 was recognised. However, the need for patients to be aware of their data being used was equally recognised. The importance of the study in determining adverse events and of research in hospitals in the interest of patients and hospitals was noted. Additionally, the importance of how the study would be communicated publicly in line with the previous INAES-1 study was highlighted. The safeguards in relations to data was discussed. To help determine whether the public interest significantly outweighs the requirement for explicit consent the HRCDC has requested more information from the applicant on a number of aspects: Consent: to the HRCDC requested confirmation on the number of charts to be reviewed as part of the study and additional clarity on why it is not feasible or appropriate to obtain consent from the data subjects who were selected for the study; specifically, this relates to the applicant's statement that obtaining would create inherent bias that would weaken the research. Data minimisation: The HRCDC requested further details on what personal data is/will be processed and why this level of data is required to achieve the research objectives (data minimisation principle). Master list destruction: The HRCDC noted that master link is used to link data from the Hospital In-Patient Enquiry system and the medical records of patients in the hospitals, using a unique Study ID number. The HRCDC has requested further information on the process of destroying the Master list, including who is responsible for this action, when it would occur and notification of when the master list would be destroyed. Public & Patient Involvement: The HRCDC has requested details on feedback received, if any, from patient and service users on the development and oversight of the study. The HRCDC requested the Secretariat to circulate a 2017 academic paper from the first INAES study that describes the original methodology.
HRCDC Declaration Decision:	**Decision deferred until next meeting (June 13th) pending further information from the Applicant.**
Conditions applied:	N/A
Duration of Declaration:	N/A

Separate from the specific application discussion, the HRCDC discussed the topic of 'incidental findings' that may arise from health research and which may be relevant to the care of the patients. The HRCDC discussed whether it fell within a general remit of the HRCDC to consider

this aspect as part of the general consideration. The HRCDC agreed that this matter should clarified with the Department of Health.

6. Activities Report

EV provided an overview of different meetings and events attended by the Secretariat over the last month. An activities report (hard copy) was handed out to the HRCDC members.

7. Update on Amendment to the Regulations

EV updated the HRCDC on the Amendment to the Regulations, specifically that the deadline for compliance for research projects that commenced before the 8th August 2018 has been extended to the 7th August 2019, with an earlier application submission deadline of 7th July 2019 in place. The Amendment has been signed off by the Minister of Health and details are live on the website. The Chair and other members indicated they would like further clarity from the Department of Health on the approach to be taken for applications for existing research projects that are submitted after the 7th August deadline. The Secretariat and Chair are to liaise with the Department on this topic.

8. Training Needs / Case Studies

Members of the Committee where informed that information and training sessions can be organised on particular areas relating to data protection – any requests or queries should be forwarded to the Secretariat.

9. Standard Operating Procedures

Committee members provided some specific feedback on the SOP document circulated at the previous meeting. These points where noted by the Secretariat and members were asked to forward any other comments or suggested amendments to the Secretariat by email.

10. Expenses

EV advised that the expenses procedure is being finalised by the HRB and the HRCDC members will be contacted shortly in relation to this.

11. Any Other Business

EV highlighted the usefulness of the UK Confidentiality Advisory Group website, which contained detailed minutes of the applications under consideration. EV will send the website url to the HRCDC for their interest.

HRCDC
Health Research Consent
Declaration Committee