HRCDC
Health Research Consent Declaration Committee

Date: 26th May 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kevin Clarke
John Ferguson
Aideen Hartney
Zubair Kabir
Barry O' Sullivan
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions ☒**YES**

New Applications - For Consideration

Applicant	Ref No.	Title
Maccon Keane	20-015-AF1/COV	The ESMO-CoCARE Registry for patients with a Malignancy who are diagnosed with COVID-19
Jack Laffan	20-001-AF1	A Retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database
Gerry McElvaney	19-025-AF2	Irish National AATD Registry (Alpha-1)

Meeting Items

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

2. **Apologies**
   Kathy Brickell, Claire Collins, Sheelah Connolly, Malcolm Kell, Simon Furney

3. **Disclosure of Interest**
   There were no disclosures of interest for this meeting.

4. **Minutes of the last meeting**
   Draft minutes of the 30th April HRCDC meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. **New Applications**

HRCDC
Health Research Consent Declaration Committee

Reference ID:	20-015-AF1/COV
Lead Applicant:	Maccon Keane
Lead Data Controller:	European Society For Medical Oncology (ESMO)
Title:	The ESMO-CoCARE Registry for patients with a Malignancy who are diagnosed with COVID-19
Research Objective	The European Society for Medical Oncology (ESMO) has launched an international collaborative registry, ESMO-CoCARE, to further the understanding of the COVID-19 and its impact on the care and management of cancer patients who are diagnosed with COVID-19. This is part of a global initiative, in collaboration with the CCC19 (COVID-19 & Cancer Consortium), to pool real-world data and thus rapidly accumulate knowledge, which will inform and provide guidance on the clinical management of these patients. The purpose of this international registry is: i. The identification of factors potentially associated with disease severity; ii. The development of a tailored risk assessment strategy for cancer patients; iii. To provide a means of proposing recommendations for cancer patient management that are based on reliable, real-world observations.
Reason for Declaration	A declaration is requested for the following data processing activities to be carried out in Ireland for the purpose of the ESMO-CoCARE Registry: i. The collection and pseudonymisation of existing patient data from medical records at the hospital by staff in that hospital, and ii. The uploading/transferring of pseudonymised data to ESMO-CoCARE Registry by the hospital staff
HRCDC Comments:	An overview of the study was provided by the Secretariat. The study's data governance and data controller arrangement between the controllers of the Registry and Hospital sites was discussed and the HRCDC agreed that further clarity should be sought regarding what data controller entity or entities a decision would issue to. The HRCDC was of the view that the application could be considered at the meeting, however, should the HRCDC determine that a declaration could be made, it would not be possible to issue a formal decision until confirmation is received from the Applicant on data governance and the data controller arrangements. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application in detail, and based on the information provided by the Applicant, it was the consensus of the HRCDC that no Consent Declaration should be made based on the following discussion points:

	Public Interest & Consent • The HRCDC discussed the objectives of the Registry and the participating role of the Irish Hospital sites and patients. The HRCDC was of the view that there was a degree of public interest in the ability of Irish patients and health practitioners to participate and benefit from the inclusion of their data in the International Registry. • From the information provided, the HRCDC noted that the Irish cohort numbers of participants across all hospital sites was relatively low and includes retrospective and prospective patients. • The HRCDC discussed the rationale for not obtaining explicit consent to use personal data of participants for the Registry. It was noted that the Applicant wished to avoid potential distress caused to participants and that obtaining consent could impact the feasibility of including data from the Irish cohort of patients in the Registry. However, in the context of this specific patient cohort and nature of the study, and the expected requirement for explicit consent, there was no evidence set out in the application as to why seeking consent would be distressing and therefore the HRCDC considered that obtaining participant consent is an appropriate safeguard. • It was further discussed that a patient-clinician relationship already exists, which further supports the feasibility and importance of seeking explicit consent. • The HRCDC was of the view that it could be possible and appropriate for the Applicant to obtain participant consent. **Transparency & Data Protection rights** • The HRCDC discussed the lack of clarity as to the ability of a participant to withdraw their data from the Registry, given the data controllers of the Registry are international. It was also considered that more information on withdrawing from the Registry should be provided through the transparency notices. **Patient & Public Involvement (PPI)** • It was discussed that public and patient involvement for the study had not been considered possible by the Applicant. However, the HRCDC considered it possible to communicate with patient advocacy groups or equivalent eg. email or telephone means. • The HRCDC considers PPI in health research an important safeguarding element, where no explicit consent is being sought, to ensure a PPI perspective is reflected in the overall study. The HRCDC notes the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSSI), setting out the importance of understanding the patient perspective during the COVID-19 pandemic. **Summary:**

	• When weighing up the aforementioned points of discussion, the HRCDC was of the opinion that public benefit and interest in research study did not significantly outweigh the data protection rights of participants and mitigated the requirement to obtain explicit consent. This view was coupled with the view that there was insufficient evidence of strong data protection safeguards as required under the Health Research Regulations. **Future HRCDC Application** • It was discussed that the refusal by the HRCDC to make a declaration, does not preclude the Applicant from submitting a revised application, seeking a consent declaration for the processing of personal data for some participants who may lack decision-making capacity, or where potential participants have been lost to follow-up and where demonstrable attempts have been made to consent these individuals. • If another application is submitted on these grounds, then the Applicant would be expected to clarify data transfer governance, the data controller(s) arrangement, in addition to the other points outlined by HRCDC, such enhanced PPI and revising the study information leaflets and other transparency notices. • It must be clear what data controller is seeking a consent declaration and additionally, how a consent declaration can be implemented in Ireland, where international data controllers are involved. A participant in a study should not be disadvantaged in any way and should be afforded the same level of benefit/protection with an international data controller, as with an Irish data controller.
HRCDC Declaration Decision:	The consensus of the HRCDC was that no Declaration should be made.

Reference ID:	20-001-AF1
Lead Applicant:	Jack Laffan
Lead Data Controller:	Royal College of Surgeons in Ireland
Title:	A Retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database.
Research Objective	It has been long known that the faster a patient receives emergency treatment during a severe heart attack, the better the outcome. Different treatments exist to open blocked arteries. In Ireland, since 2013, there is a compiled national heart attack registry based on an integrated emergency care system. Despite this, the follow up of patient's actual outcomes has never been studied. This study aims to identify patients who suffered severe heart attacks in 2013/2014, and for whom accurate time intervals pre-treatment were recorded (first 999 call, first ambulance contact, time of arrival to hospital etc). The study involves accessing patient electronic records to determine the distance patients lived from the nearest specialist emergency capable heart attack hospital to determine whether this had any effect on time delays, and on 5-year all-cause mortality.
Reason for Declaration	A consent declaration is requested to:

	i. Re-identify patients of interest from a pseudonymised database from the national heart attack register. ii. Once re-identified, to access the medical records of the patients of interest in their original treating hospitals and collect no more than 3 data fields.
HRCDC Comments:	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 Applicant, it was the consensus of the HRCDC that a consent declaration could be made. The following points were discussed; **Public Interest and Obtaining Consent** • The HRCDC discussed that study and rationale for examining all-cause mortality and benefit of assessing the effects of treatment with distance from the hospital, could have been more clearly articulated within the application form. • The HRCDC also considered the Applicant's rationale for not seeking to obtain participant consent due to the large number of patients who meet the study's inclusion criteria. • On balance the HRCDC acknowledged the rationale for not seeking consent. In addition, given the limited personal data being processed, the HRCDC was of the view that the public interest in this study significantly outweighed the requirement to obtain explicit consent. **Transparency** • The HRCDC discussed the transparency measures to be implemented, including the Applicant's response on whether patients are informed about the National Heart Attack Registry. • The HRCDC was of the view that it was unlikely that participants would be sufficiently informed of the study and how their personal data will be used. • Therefore, it was considered appropriate for the study to implement greater transparency measures as a suitable condition to protect the study participants. • The HRCDC also discussed that the Applicant should consider how the dataset, if anonymised, could be shared with researchers for the benefit of further scientific research. **Data risks** • The HRCDC discussed the researchers approach to identity eligible patients by reviewing patient charts at each hospital. • It was considered that, on balance, the data protection risks in this study design appeared to be minimal. The HRCDC discussed the importance of the protecting personal data stored on the laptop device by robust encryption and password protection security techniques. **Research Ethics Approval** • The HRCDC noted the Applicant's response that research ethics committee (REC) approval is also required from the

	individual hospital sites. It was discussed that a consent declaration will only cover data collection at hospital sites where REC approval is in place. **Public and Patient Involvement (PPI)** • The HRCDC discussed that of PPI should be enhanced to ensure that the perspective of the patient is considered.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing May 26th, 2020 and shall be valid for six months (until 31st November 2020) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner
Conditions Attached:	The following conditions have been attached to the Declaration as follows: **Condition 1:** The Applicant is requested to ensure that appropriate and robust security measures are implemented when transferring, recording and storing personal data. Specifically, this includes measures such as encryption techniques and passwords to protect personal data on the study laptop. **Condition 2:** The Applicant is requested to implement robust transparency arrangements to inform participants and their families about this study and the use of their personal data. The communications plan as outlined in the study's Data Protection Impact Assessment form should be implemented. Transparency measures should also outline how participants can exercise their data protections rights, including the ability to withdraw from the study if they wish to do so, including what will happen to their personal data in such a situation. Transparency arrangements should be implemented in advance of commencing the study at each site. The implementation of robust transparency arrangements is a reporting requirement as part of the Annual Review. ***NOTE:*** Further information on providing transparent information can be found on the Data Protection Commission's website; https://www.dataprotection.ie/en/organisations/know-yourobligations/transparency. It is advisable to discuss this with your institutions Data Protection Officer (DPO). **Condition 3:** The HRCDC considers PPI in health research an important safeguarding element, where no explicit consent is being sought, to ensure a public/patient perspective is reflected in the overall study. The Applicant is requested to enhance the level of public and patient involvement (PPI) in the study, and in advance of commencing the study. If there are constraints using normal means to engage with PPI representatives and advocacy groups in light of the ongoing coronavirus situation, the Applicant is advised to engage by alterative means such as email and videoconference as appropriate.

	Condition 4: The Applicant must inform the HRCDC when research ethics approval has been granted at each of the five hospital sites. For the avoidance of doubt the scope of this consent declaration is only valid for data processing at hospital sites that have received research ethics approval. **Condition 5:** Appropriate contractual agreements or suitable arrangements, as required, must be in place between the data controller RCSI and the organisations involved in the study that are providing access to personal data for the purpose of the study. It is advisable to discuss this with your institution's DPO and legal office's as required. **Condition 6:** The Applicant is requested to consider how the dataset collected for this study could further benefit the public and patients by being made accessible to the wider research community in a de-identified and controlled manner. The Applicant is requested to report on this condition as part of the Annual Review.

Reference ID:	19-025-AF2
Lead Applicant:	Gerry McElvaney
Lead Data Controller:	Alpha-1 Foundation Ireland
Title:	Irish National AATD Registry (Alpha-1)
Research Objective	Alpha-1 is a genetic condition with a high prevalence rate in Ireland; 1 in 25 Irish people are affected which can cause lung, liver and skin disease. The Alpha-1 registry in Ireland was established in 2005 to collect information on Alpha-1 individuals. The registry is part of the spectrum of clinical care and research at the National Centre of Expertise for Alpha-1 antitrypsin deficiency (AATD) at Beaumont Hospital. It records medical and demographic information of patients with the aim of i) increasing the level of understanding of the condition, ii) helping to inform and improve clinical care and iii) providing early access to new treatments via clinical trials
Reason for Declaration	A consent declaration is being sought for registry participants who were consented prior to May 2019. Though approved by Beaumont Hospital REC in 2005 and meeting the standard of consent standard at that time, the 2005 National AATD Registry Patient Information Leaflet (PIL) and consent form were not considered compliant under General Data Protection Regulations (GDPR) and Health Research Regulations (HRRs).The scope of declaration being sought will cover the processing of personal data of individuals (~530) who consented prior to May 2019. Processing activities within the scope of the declaration being sought: - Collection and storage of data - Anonymisation of the data for sharing with third parties - Sharing of anonymised data with Earco.eu - Use of data in research studies

	- Retention of data indefinitely (*unless otherwise withdrawn by the participant*)
HRCDC Comments:	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 Applicant, it was the consensus of the HRCDC that a conditional declaration should be made; **Public Interest** • Although a public interest case is not applicable for this application, the HRCDC was of the view that the registry was of public interest as it focuses on research into a rare disease. **Re-consent** • The HRCDC noted the Applicant's response that participant consent has been obtained and is in line with the previous data protection legislation. • The HRCDC also discussed the Applicant's rationale for why it is not possible to re-consent existing participants; namely that participants had provided consent under the previous legislation and that the number was participants was significant. • The new consenting protocol for prospective participants was discussed and considered relatively robust and clear. **Transparency:** • The HRCDC noted that a number of engagement and communication activities are undertaken by the Alpha-1 Foundation Ireland each year. The HRCDC commented that such activities, including conference events, could provide opportunities to obtain re-consent or, at minimum, further enhance the level of transparency and publicity, which the HRCDC considers important given the extent of personal data that is collected for and held by registry. • The HRCDC was of the view that the registry should further enhance the level of transparency and publicity. This includes providing information on how participants can exercise their data protection rights. • In addition, the HRCDC commented that the registry's website and public events should be used to inform and update participants and their families on the registry's activities and the use of the data that has been collected. **Public and Patient Involvement (PPI)** • The HRCDC noted and acknowledged the strong level of PPI within this study and commented that this provides some additional data protection safeguards. **Transfer of data** • The HRCDC queried the transfer of data to third parties, including the potential for the transfer of anonymised data to a European registry as described in the application form. It was

	noted that the Applicant states that third parties will receive anonymised data. • It was discussed that where data is transferred, including data that is anonymised to the recipient, that a contractual agreement or arrangement as appropriate should be in place governing this transfer with terms and conditions ensuring the anonymity of participants.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing May 26th, 2020. The Declaration has no expiry date but shall be valid until confirmation that the data has been rendered anonymised or destroyed.
Conditions Attached:	The following conditions have been attached to the Declaration as Follows: **Condition 1:** The Applicant is requested to further enhance and implement transparency arrangements to ensure that participants, their families and the public are fully informed about the registry and the use of personal data. The transparency measures should clearly outline the type of data collected and how participants can exercise their data protection rights (and steps to withdraw from the registry if they wish to do so, including what will happen to their personal data in this scenario). The Applicant is requested to consider activities such as publicising updated information on the registry's website as well as providing information at the foundation's annual conference or other events, as appropriate. The implementation of robust transparency arrangements is a reporting requirement as part of the annual review. ***NOTE:*** Further information on providing transparent information can be found on the Data Protection Commission's website; https://www.dataprotection.ie/en/organisations/know-yourobligations/transparency. It is advisable to discuss this with the institutions Data Protection Officer (DPO). **Condition 2:** The Alpha-1 Foundation Ireland is required to do the following; i) Where data is transferred from the registry to third parties, the data controller of the registry must ensure that that a contractual agreement or arrangement as appropriate should be in place governing this transfer with terms and conditions ensuring the anonymity of participants. ii) Where data from the registry is to be shared with the European registry, the HRCDC requires clarity on the relationship between the both parties and confirmation that that a contractual agreement or arrangement as appropriate should be in place governing this transfer with terms and conditions ensuring the anonymity of participants data agreement is in place should be provided to the HRCDC.

6. Any other Business

i) The Chair and EV provided an overview of the discussion with the Office of the National Research Ethics Committee on the topic of consent and next-of-kin assent. It was noted that main points of discussion were:
- relative assent Vs consent from a legal appointed representative
- consent and assent protocols
- information content within study/participant information leaflets
- the importance of public and patient involvement in the consent process and development of information leaflets

The HRCDC were informed of an aim to produce a FAQ or guidance document on this topic to assist researchers.

ii) The HRCDC and Secretariat discussed the processing of applications and existing capacity in this area. The Secretariat also highlighted the estimated number of COVID-19 applications awaiting responses and review.

The Chair closed the meeting.

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