HRCDC
Health Research Consent Declaration Committee

Date: 26th January 2021
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kathy Brickell
Kevin Clarke
Claire Collins
Aideen Hartney
Zubair Kabir
Dan Rea
Barry O'Sullivan
Sheelah Connolly
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions ☒YES

New Applications - For Consideration

Applicant	Ref No.	Title
Laura Gonzalez	20-035-AF1	IV Zanamivir Effectiveness Study
Sharon Glynn	19-027-AF3	Identification of predictive and prognostic biomarkers in triple negative breast cancer
Gerard Bury	19-033-AF3	The Medical Emergencies Responder - Integration and Training Programme Study (MERIT)

Meeting Items

1. **Opening, Welcome**
   The Chair opened the meeting and welcomed the members. In addition, the Chair welcomed the newly appointed members to the HRCDC; Mary Tumelty, John Woods, Barry Lyons and Con Cooney. Roundtable introductions to all members were made.

2. **Apologies**
   Evelyn Mahon, Simon Furney, John Ferguson

3. **Disclosure of Interest**

Application 19-033-AF3: Claire Collins disclosed her current position as Chair of the Irish College of General Practitioners' Research Ethics Committee (ICGP REC). The ICGP REC had provided ethics approval for 19-033-AF3 in 2005 and 2008. It was noted that CC was not a member of the REC at the time ethics approval was granted. There was no conflict of interest that warranted abstaining from this discussion.

4. Minutes of the last meeting

Draft minutes of the 11th December 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Matters arising/actions from previous HRCDC meeting

The Secretariat informed the HRCDC that HRCDC Application 20-032-AF1 (MUMPS Study) has been withdrawn by the Applicant. It was noted that the Applicant has stated they will seek to obtain the consent from study participants. It was further discussed that the Applicant could revert to the HRCDC with a new application if consent could not be obtained.

6. New Applications

Reference ID:	20-035-AF1
Lead Applicant:	Laura Gonzalez
Lead Data Controller:	GlaxoSmithKline Research & Development Ltd
Title:	IV Zanamivir Effectiveness Study
Research Objective:	Despite vaccination and available treatments, seasonal influenza accounts for approximately 3-5 million severe infections and 250,000-500,000 deaths worldwide annually. This study will gain an understanding of the clinical management of complicated influenza in ICUs in Europe. It will also investigate the clinical effectiveness of intravenous (IV) zanamivir (Dectova) in the treatment of patients with complicated influenza in this setting, compared to patients who do not receive treatment with Dectova. The collection of historical data for influenza seasons 2017/18 and 2018/19 will begin after the Site Initiation Visit has been performed at each of the participating sites. The historical part is designed to gain an understanding of the clinical management of complicated influenza in European ICUs. The data collection for the comparative part of the study, for influenza season 2019/20 will begin after the data collection for the historical part is completed and for current influenza season, 2020/21, data collection will start after the season have finished, to ensure the retrospective nature of this study. Both parts will be conducted in patients infected with influenza and admitted to ICU. This study will involve patients in ICU with severe influenza in various tertiary hospitals in the United Kingdom and other countries in the European Union.
Reason for Declaration:	A consent declaration is requested to process personal data from hospital medical records for the purpose of this study (access, collect, pseudonymise, transfer, analyse and store).
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee 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. 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 decision should be deferred pending receipt of further information. **Public Interest** • The HRCDC discussed that there is a degree of public interest in the study as it aims to examine the effectiveness of IV administration of this influenza treatment. • It was noted that the study was mandated by the European Medicines Agency (EMA) as part of the product's marketing authorisation process. The HRCDC discussed that this in itself does not provide a strong public interest case. • From the information provided it was noted that the number of participants to be included in the study from St. James' Hospital (SJH) is relatively small (n=22), and a very small proportion of the total number of study participants from across all the international research sites (n=1100). • It was also queried if other Irish sites will be added to the study which could increase the number of participants and potentially the impact of Irish data on the overall study. • The HRCDC queried the extent to which the personal data of a small number of Irish participants would generate reliable and impactful data to meaningfully contribute to the study's overall objective and findings, and therefore if the public interest in the research study would significantly outweigh the public interest in requiring consent from participants. **Consent** • The HRCDC discussed the Applicant's reasons as to why it is not considered possible to obtain assent/consent from participants. This included the retrospective design of the study and the risk of data biasness. In addition, it was discussed that the small sample size could be reduced if there was a requirement to obtain consent, and consent was not given by participants. • The HRCDC also noted that the 2020/21 flu season, for which data will be collected and processed, is currently underway, potentially limiting the time available for obtaining hospital assent/consent. • However, having regard to the relatively small number of participants in both the historical and comparative cohorts, and that participants from the current flu season will be included in the study, the HRCDC was of the view that there would likely be opportunities to obtain consent, deferred consent, or relative

assent, at some point in the study's timeline and that reasonable efforts to consent participants could be made.
- The HRCDC also commented that the Irish arm of study did not appear to consider implementing an assent/consent process for the 2020/21 flu season. It was queried if the study was designed retrospectively to ensure inclusion of all participants treated with IV zanamivir and mitigate the need to obtain consent.
- Furthermore, the HRCDC queried if consent was being obtained from participants at other study sites outside of Ireland.

Patient and Public Involvement (PPI)
- The HRCDC noted that the Applicant has not considered PPI for the study. While it is acknowledged that the study is mandated by the EMA, the HRCDC was of the view that PPI continues to be an important data protection safeguard where it is not possible to obtain consent for data processing.

Transparency
- The HRCDC discussed that the transparency measures in place for this study were inadequate. It was noted that the study would be publicly accessible on the EU Post Authorisation Safety Study Register, however, it was the view of the HRCDC that it would be unlikely that participants would be aware of this Register or to be informed of the study, the use of their personal data or how to exercise their data protection rights.
- The HRCDC also commented that transparency measures are an important data protection measure in situations where consent cannot be obtained.
- The HRCDC was also of the view that some participants would wish to know that their data to be processed in this way.

Data flow and Access to data
- From the information provided, elements of the data flow, including access to identifiable personal data was not clear.
- For example, it was not clear at what point data is transferred by SJH to the Clinical Research Organisation (CRO)/Study sponsor for analysis. It was also not clear what is meant by collecting and processing '*Associated metadata of hospitalisation*' as referenced in the application form.
- In addition, it was not clear who will have access to personal identifiable data. Specifically, is was not clear if identifiable and/or confidential data within the study identification log and the medical records will be accessed by non-hospital personnel, including for monitoring purposes.
- It was also noted that access to the study identification log is provided to the Principal Investigator (PI), however the hospital researcher and the CRO researcher are noted as PIs.
- Furthermore, the application noted that pseudonymised data will be processed by the data controller at their sites outside of the EEA. While the Applicant outlined the legal basis of this transfer, including for inter-company transfers, the HRCDC commented

	that more information on these data processing activities could have been provided. **Participant opt-out** • The HRCDC discussed the Applicant's statement that if the medical notes expressed the patients desire not to participate in any research that their records will not be used. • The HRCDC queried how SJH was capturing this decision within the medical records at the time a patient is admitted to hospital and if these patients are excluded from the study in practice **Processing Agreements** • It was highlighted that the study had already commenced in the UK but had not yet begun in Ireland. It was further noted that the CRO had authorisation to act on behalf of the Sponsor, GSK, and to enter into relevant agreements with parties such as the hospital sites. • The HRCDC noted that the agreements submitted by the Applicant where focused on the UK research sites and/or UK tailored templates and not specifically tailored to the study to be conducted in Ireland.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	The HRCDC request further detailed information on the following queries, which should be addressed collectively by both Principal Investigators of the data controllers: **Query 1.** For the purpose of determining the significance of the public interest case, the Applicant is requested provide the HRCDC with further information as follows; i) elaborate on how the data to be collected and analysed from the very small number of St. James' Hospital participants, would contribute meaningfully to the objectives and findings of the wider multi-site study, and ii) considering the small number of Irish participants that would be recruited, comment on whether it is it planned to expand the study to include other hospital sites in Ireland and therefore increase the number of Irish participants included in the study. **Query 2**. The HRCDC acknowledged that the retrospective study design may limit the opportunity to obtain consent. However, the HRCDC are of the view that opportunities for consent, or attempts to obtain consent, exist, and should be made where practicable. Given the small number of participants from St. James' Hospital (n=22), the HRCDC are of the view that it should be possible to obtain relative assent and/or participant consent from the 2020/21 flu season cohort, and that reasonable attempts should be made to obtain participant consent from living study participants treated during the past flu seasons that are within the scope of this study. The Applicant is therefore requested to provide the HRCDC with

	information on what protocols can be practically implemented to obtain assent/consent from: i) the 2020/21 flu season cohort, and ii) the previous flu season cohorts; 2019/20, 2018/19, 2017/18. When responding to this question, the Applicant is also requested to: i) confirm if assent/consent has been sought from participants in other research sites outside of Ireland, and ii) provide more information on how St. James' Hospital, through the medical records, is capturing a patient's decision that they do not wish to be included in research, as referenced in Part F, Section 1 of the application form. **Query 3.** Following Query 2, the HRCDC is of the view that, at the very minimum, the Applicant should greatly enhance transparency measures so that all participants may be provided with clear information about the study, the use of their personal data and how to exercise their data protection rights, including the right to withdrawal. Correspondingly, the Applicant is requested to provide details as to what specific transparency measures can be implemented to provide this important information to participants. **Query 4.** The Applicant is requested to consider how the level of Patient and Public Involvement can be enhanced within this study by engaging with representative groups, for example, ICUsteps. Consideration should also be given to what PPI engagement may be undertaken at different stages of the study and on issues such as participant consent and enhanced transparency measures. **Query 5.** From the information provided, the data flow and who will have access to personal, identifiable data are unclear. For example: - The application states that only the Principal Investigator (P.I) will hold/have access to study files and the study identification log; an OXON employee is noted as the P.I in Part A, Section 2, while Dr Martin-Loeches of St. James' Hospital is noted as the P.I. elsewhere in the application. - For monitoring purposes, the Applicant states that the OXON Contract Research Associates (CRAs) may access identifiable sensitive data, including the identification log and medical records. - However, it also states that the CRAs will not see any confidential patient data unless the patient specifically consents to this. Correspondingly the HRCDC requests the Applicant to confirm if: i) personnel from OXON or the Sponsor will have access to identifiable data from the medical records or the identification log, whether for monitoring purposes or otherwise, and ii) if the data transferred by St. James' Hospital to OXON/Sponsor for analysis is non-identifiable to the recipient when undertaking the analysis.

	Query 6. Please confirm what is meant by the collection of '*Associated metadata of hospitalisation'* as outlined in PART B, Section 4 of the application form. **Query 7.** The HRCDC notes that the clinical study agreement template provided is not tailored to or in the context of the study to be conducted in Ireland. For example, reference is made to the participating organisation, St. James' Hospital, as a 'NHS organisation'. Please confirm that the required agreements with the Irish site will be tailored/amended to accurately reflect the study to be conducted in Ireland.

Reference ID:	19-027-AF3
Lead Applicant:	Sharon Glynn
Lead Data Controllers:	National University of Ireland Galway (NUIG) Galway University Hospital (GUH)
Title:	Identification of predictive and prognostic biomarkers in triple negative breast cancer
Research Objective:	Triple Negative Breast Cancer (TNBC) is an uncommon form of the disease accounting for only 15% of breast cancers. TNBC is itself a diverse group of invasive breast cancers with some TNBCs following an indolent course but the majority have a more aggressive course with poor outcome where almost all recurrence and death occurs within five years after diagnosis. Despite advances in other areas of breast cancer, patients with TNBC still have very limited treatment options and there are no predictive biomarkers. This study aims to identify biomarkers of TNBC that can be used to predict response to treatment and survival, and thus improve the outcome for patients with TNBC. To do this, it is necessary to evaluate the biomarkers within the tumour tissue from patients who were diagnosed with TNBC that is also linked to treatment and outcome data at 5-8 years from diagnosis.
Reason for Declaration:	A declaration is requested to process the personal data associated with tumour tissues that are surplus to diagnostic requirements, from a cohort of 160 patients for the purpose of this study (collection, including of follow-up data, pseudonymisation, transfer, analysis and storage). These patients were diagnosed with TNBC at Galway University Hospital prior to the introduction of the Health Research Regulations in 2018.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) 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.

	The Chair highlighted that this is an AF3 application and therefore relates to a study that commenced prior to August 2018. It was also noted that a consent declaration is made for the use of personal data only and does not extend to the use of bio-samples. 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** • The HRCDC was of the view that the application demonstrated that the study has a strong degree of public interest. **Consent** • The HRCDC discussed the Applicant's rationale for why it is not possible to obtain the explicit consent of participants. Such reasons included that participants still receiving follow-up care are receiving care across multiple health institutions, making the ability to seek consent more challenging. Lack of resources, the potential to cause distress and that the study investigators do not have direct contact or a relationship with the participant where also cited by the Applicant. The data risks that could arise in re-identifying the participant to obtain their consent was also noted. • The HRCDC discussed that a lack of resources and wishing to avoid participant distress are not sufficient reasons in themselves for not attempting to seek consent. • Furthermore, while it was noted that some of the research team in GUH and NUIG may not have a direct relationship with the participant, other study co-investigators who are hospital clinicians may do. • It was also highlighted that the number of participants included in the study is relatively low (n=160) and that follow-up data will continue to be collected for those whose treatment had not concluded. • The HRCDC therefore discussed whether it was possible and appropriate to obtain consent from living patients, in particular where they are still receiving follow-up treatment. The HRCDC also commented that participants would likely be interested in knowing that their personal data and samples are being used for this study. • It was also queried if attempts had been made to try and obtain consent previously. • On balance, while there is a strong degree of public interest in the study the HRCDC was of the view that the Applicant should explore the potential for, and practicalities of, implementing a consent process for living participants. **Public and Patient Involvement (PPI)** • The HRCDC noted the Applicant's response with regards PPI including experience in general patient outreach. However, the

HRCDC was of the view that further PPI activities specific to this study, should be undertaken.
- Specifically, it was discussed that the views of public and patient representatives could assist in examining what possible consent process(es) could be implemented.

Transparency
- The HRCDC discussed that transparency measures for this study where inadequate therefore, if consent was not possible to obtain, then at minimum enhanced transparency measures specific to this study should be implemented.
- It was the view of the HRCDC that transparency measures should provide information to participants about the study, the use of their personal data and how to exercise their data protection rights, including the right to withdrawal.

Research Ethics Committee (REC) Approval
- It was noted that the study had received research ethics approval in 2014, prior to the introduction of the Health Research Regulations in 2018. It was further noted that the ethics approval for the study was granted by the Chairperson of the REC and did not require full committee approval at that time, given the nature of the study.
- The HRCDC was of the view that the ethics approval for the study should be renewed through a full ethics committee review process.

Identification log/Master list
- It was noted that the identification log which is used to re-identify the participants is held by GUH, and is not shared with its joint data controller, NUIG.
- The HRCDC commented that it is appropriate that the identification log does not leave the GUH site and should not be disclosed to another party, including NUIG.

Data Minimisation
- It was noted that participant date of birth is transferred from GUH to NUIG. The HRCDC queried whether the date of birth was necessary and commented that using minimal data such as age or year of birth would help to further protect the participant's identity.

Other
- From the information provided there did not appear to be a mechanism in place for participants to exercise their data protection rights.
- It was highlighted that a joint controller arrangement between GUH and NUIG is in process. Although the information provided outlined that other agreements are executed between the parties (e.g. a material transfer agreement and data transfer agreement),

	the HRCDC commented that the joint controller arrangement must also be in place that reflects requirements under GDPR.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 8th August 2018 and shall be valid until 31st December 2027, or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** The HRCDC requests the Applicant to make significant efforts to obtain the consent of as many of the living participants as possible. For participants where it is not feasible to obtain consent, the Applicant is subsequently requested to outline what additional transparency measures will be implemented to inform those participants about this study, the use of their personal data within the study and how they can exercise their data protection rights, including the right to withdraw. For the participants that cannot be consented, transparency measures should look beyond general measures and consider more participant-targeted approaches. In meeting this condition, the Applicant should also consider engagement with Patient and Public Involvement groups for consultation on the implementation of consent practices and enhanced transparency measures for these participants. The Applicant must report to the HRCDC on the progress of meeting this condition within 3 months of the of the HRCDC decision letter. The continuation of the consent declaration is contingent on the Applicant reporting on this condition satisfactorily. **Condition 2.** From the information provided to the HRCDC, it was not clear what mechanisms are in place to enable participants to exercise their data protection rights, such as making a 'subject access request'. Linked to Condition 1, the Applicant is requested to have an appropriate transparent procedure in place whereby study participants can exercise their data protection rights, if participants wish to do so. **Condition 3.** It is acknowledged that the study received research ethics approval in 2014 by the Chairman of the REC and was not required to go through full committee approval at that time. The Applicant is requested to renew the Research Ethics Committee (REC) approval for this study from Galway University Hospital and revert with confirmation of this approval within 3 months of the date of issuance of the HRCDC decision letter. Confirmation must be provided that the REC approval covers the study as outlined in the HRCDC application form. *NOTE: The HRCDC reserves the right to amend the consent declaration should the outcome of the REC process result in amendments to the study that are relevant to the HRCDC's decision*.

	Condition 4. It is a condition of this declaration that the joint controller arrangement between GUH and NUIG, as referenced in the application form, is fully implemented in accordance with GDPR requirements. Confirmation that this condition has been met is to be provided to the HRCDC as soon as possible, and no later than 3 months from the date of issuance of the HRCDC decision letter
HRCDC Recommendations:	**Recommendation.** In line with the principle of data minimisation, the Applicant is asked to consider if participant date of birth can be replaced with year of birth or age.

Reference ID:	19-033-AF3
Lead Applicant:	Gerard Bury
Lead Data Controller:	University College Dublin
Title:	The Medical Emergencies Responder - Integration and Training Programme Study
Research Objective:	The Medical Emergencies Responder - Integration and Training (MERIT) programme began in 2005 with the aim of equipping and training at least 500 general practices in Ireland to manage out-of-hospital cardiac arrest (OHCA). To survive OHCA, Cardiac Pulmonary Resuscitation (CPR) and defibrillation must be provided to patients within minutes. Early care by trained and equipped providers is therefore vital. Over 500 general practices now participate in MERIT and since 2015, the MERIT3 project has also enrolled more than 200 doctors who are text alerted by the HSE National Ambulance Service (NAS) to OHCA in their immediate areas. Doctors provide standard clinical care to patients, monitoring the impact of that care is a key component of understanding how it can best be provided. The research component of MERIT is prospective case reporting with follow-up data from an independent national registry to determine survival. The study objectives including monitoring the incidence, content and impact of the clinical care provided by participants during resuscitation.
Reason for Declaration:	A consent declaration is required as it is considered not feasible to obtain participant consent due to the emergency nature of the out-of-hospital cardiac arrest. A consent declaration is therefore required for the collection of clinical information on each out-of-hospital cardiac event and survival data provided to the MERIT study by (i) participating doctors in General Practices and (ii) the out-of-hospital cardiac arrest registry and the subsequent analysis and storage of this data until the point it is anonymised.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) 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.

	The Chair highlighted that this is an AF3 application and therefore relates to a study that commenced prior to August 2018. 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** • The HRCDC was of the view that the study has a strong degree of public interest. **Consent** • The HRCDC discussed the reasons outlined by the Applicant for why it is not possible to obtain participant consent or deferred consent. Specifically, the emergency nature of the out-of-hospital cardiac arrest (OHCA) event, which data is collected about, and that the data controller of the study is not provided with identifiable patient information such as name or address. • The HRCDC also commented that, given the systems in place, it would likely be very difficult to identify where the participant is treated after their OHCA, to follow-up and obtain consent. • It was highlighted that participants included in the study would, in most cases, not be known to the treating doctor making deferred consent difficult to obtain. • However, the Applicant noted that it may be possible to obtain deferred consent via the treating doctor, in the limited situations where the participant is already known to that doctor. • The HRCDC was therefore of the view that the Applicant should explore if and how a deferred consent model could be practically implemented with these doctors so that individuals may have the opportunity to consent or withdraw from the study. **Transparency** • The HRCDC was of the view that insufficient transparency measures have been implemented and therefore should be greatly enhanced to inform participants and the public about the study, the potential use of their data and their data protection rights. The HRCDC commented that fliers in the GP's offices could be useful. It was also commented that the case study document submitted by the Applicant could be a useful component in a wider communications programme. • It was emphasised that strong transparency measures are particularly important where it is not possible to obtain consent. **Research Ethics Approval** • The HRCDC noted the Applicant's response confirming that the REC approval in place covers the study described in the HRCDC application.

	• The HRCDC also noted that the most recent full REC approval was granted in 2008, before the introduction of the Health Research Regulations in 2018. • It was discussed that REC approval should now be renewed for the following reasons i) the methodologies set out in the REC and HRCDC applications differ, and ii) the length of time that has passed since the most recent ethical approval in 2008. **Public and Patient Involvement** • The HRCDC noted that the Applicant had not referenced any PPI activities and was of the view that the study should undertake PPI activities, including engagement with relevant representative groups. • It was emphasised by the HRCDC that PPI is considered an important data protection safeguard in situations where consent cannot be obtained. **Assigned Case Numbers** • The HRCDC noted the confirmation provided by the Applicant that the pseudonymised National Ambulance Service (NAS) case number assigned to each participant and used to determine their outcome via the OHCA Register, can be deleted once their follow-up survival data is collected. The Applicant confirmed that this would render the data for that OHCA case irrevocably anonymised. • The HRCDC was of the view that the NAS case number should be deleted at this point. **Other** • The HRCDC queried whether the Applicant had considered other, secure ways of transferring data to UCD, the data controller of the study. For example, it was noted that data from the defibrillator, if used, is transferred by post. • Based on the information provided, it was not clear what agreements/arrangements are in place between UCD and the relevant data providers, being the general practices and the OHCA Registry. • The HRCDC noted the declaration being sought is for an indefinite period of time. It was discussed that a time limit could be applied or the consent declaration would be subject to the HRCDC's right to review the consent declaration at each Annual Review.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 8th August 2018 and shall be valid for an initial 10yrs or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner. The Applicant may request an extension to the consent declaration by way of submitting an amendment request to the HRCDC for consideration.

Conditions Attached:	**Condition 1.** The HRCDC requests the Applicant to examine if a deferred consent process can be practicably implemented for participants who are known to the doctors who treated them for the out-of-hospital cardiac arrest event. The Applicant should engage with relevant parties on this topic, including the doctors themselves. As part of this condition, consideration should also be given to undertaking a feasibility or pilot exercise. The Applicant is requested to report to the HRCDC on the potential to implement a deferred consent process within 3 months of the date of this declaration. **Condition 2.** For participants whose consent cannot be obtained, the Applicant is requested to enhance transparency measures so that participants and the public are sufficiently informed about this study, the use of their personal data within the study and their data protection rights, including the right to withdraw. The Applicant must report on the transparency measures implemented as part of the Annual Review. **Condition 3.** Public and patient involvement (PPI) is considered an important activity by the HRCDC and is viewed as a key data protection safeguard in situations where the participant cannot provide consent. PPI helps to create a more patient-centred approach by ensuring that the perspective of patients and their families are taken into account. Furthermore, PPI also provides a valuable way of enhancing the level of transparency, which itself is an important data protection principle. It is a condition of this declaration that the study undertakes PPI or engagement activities for the reasons outlined above. Progress to meet this condition is a reporting requirement as part of the Annual Review. *(The Applicant may also wish to consider engagement with PPI groups with regards fulfilling Conditions 1 & 2)* **Condition 4.** The Applicant is requested to renew the Research Ethics Committee approval for the study from the Irish College of General Practitioners and revert with confirmation of this approval within 3 months of the date of issuance of the HRCDC decision letter. Importantly, confirmation must be provided that the renewed/updated approval covers the study as outlined in the HRCDC application form. *NOTE: that the HRCDC reserves the right to amend the consent declaration should the outcome of the REC process result in amendments to the study that are relevant to the HRCDC's decision*. **Condition 5.** It is a condition of this declaration that the necessary data sharing/transfer agreements are in place between the relevant parties, including between the Data Controller, UCD, and the providers of the study data. The Applicant is requested to confirm that all necessary agreements are in place when confirming acceptance (or otherwise) of the HRCDC's decision.

	Condition 6. It is a condition of this declaration that the National Ambulance Service case number, received for the purpose of the MERIT study, is deleted by the data controller once the required follow-up/outcome data has been collected.
HRCDC Recommendations:	**Recommendation.** The Applicant is asked to review the current methods of data transfer and consider if alternative, more secure methods can be used. For example, are there other, secure alternatives to transferring the defibrillator data by the postal system.

7. Annual Reviews of Declarations

The Secretariat received and reviewed 3 Annual Reviews in advance of the meeting of which all 3 where deemed to be complete:

- 19-013-AF3: Omega-3 Study
- 19-014-AF2: COLOSSUS Study
- 19-064-AF3: Discussion Forum use for Public Health Surveillance Study

8. Activities/Events

- The Secretariat informed the HRCDC of the 13th National Annual Data Protection Conference held online on the 27th and 28th of January 2021 (https://conference.dpo.ie/). Details were provided should a member wish to attend.

9. Any other Business

- The HRCDC where provided with a link to a publication relating to HRCDC application 19-004-AF2 (REMAP-CAP Study). https://www.medrxiv.org/content/10.1101/2021.01.07.21249390v1.full.pdf
- The Secretariat provided updates on the CSO COVID19 Data Hub which will be accessible to health researches in the near future. The HRCDC where informed that the HRCDC application has been adopted specifically for studies wishing to solely access this Data Hub and where a consent declaration would be required. This would be circulated to the HRCDC for information purposes.
- The HRCDC where informed that the amendments to the Health Research Regulations were signed by the Minister for Health on January 21st and that guidance materials on these amendments are available at https://hrcdc.ie/guidance/.
- The Secretariat also discussed that further communication activities will be undertaken to inform Applicants of the amendments and ask them to identify what actions they wish to take, if any, with regards to their HRCDC application and/or consent declarations made. In addition, the Secretariat will monitor and respond to queries about the amendments.
- The HRCDC were reminded that the next meeting will be on 2nd March 2021

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