HRCDC
Health Research Consent Declaration Committee

Date: 12th November 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Kevin Clarke
Sheelah Connolly
John Ferguson
Simon Furney
Aideen Hartney
Zubair Kabir
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Genevieve Osanife (Secretariat)

Quorum for Decisions ☒ YES

New Applications - For Consideration

Applicant	Ref No.	Title
INOTREM S.A.	20-030-AF1	Efficacy, Safety and Tolerability of Nangibotide in Patients with Septic Shock. A Randomized, Double-blind, Placebo Controlled Dose Selection Study
Ignacio Martin-Loeches	20-031-AF1	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
Geraldine Boylan	19-024-AF2	Development of a Real Time Seizure Detection Algorithm for Neonates
Eugene Dempsey	19-072-AF2	Multimodal Assessment of Newborns at risk of Neonatal Hypoxic Ischaemic Encephalopathy – The MONItOr Study

Meeting Items

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

2. **Apologies**
   Claire Collins, Malcolm Kell, Barry O'Sullivan

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

4. Minutes of the last meeting

Draft minutes of the 13th October 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Matters arising

- The HRCDC was informed that the Applicant's for studies 19-040-AF3 and 20-029-AF1, that were considered at the previous meeting, have requested an extension to provide more information as requested by the HRCDC. The HRCDC discussed and agreed the proposed timelines for receiving responses from the Applicants.
- The HRCDC was informed that an appeal has been lodged with the Department of Health regarding application 20-021-AF1.

6. New Applications

Reference ID:	20-030-AF1
Lead Applicant:	INOTREM S.A.
Lead Data Controller:	INOTREM S.A.
Title:	Efficacy, Safety and Tolerability of Nangibotide in Patients with Septic Shock. A Randomized, Double-blind, Placebo Controlled Dose Selection Study (The 'ASTONISH' Study)
Research Objective:	The study is a Phase IIb clinical trial (under the remit of S.I. 190 of 2004 and Directive 2001/20/EC). The trial is a double-blind, placebo-controlled dose-selection, multinational, multi-centre trial to evaluate the efficacy of two doses of nangibotide on organ dysfunction (Sequential Organ Failure Assessment; SOFA score) in patients with septic shock in relation to their soluble TREM-1 (sTREM-1) plasma levels (patients with high sTREM-1 levels at baseline and all patients). The main purpose of this trial is to obtain more information on how effective and well tolerated nangibotide combined with standard of care is in patients with septic shock, compared with standard of care alone. This trial also intends to investigate the clinical effectiveness of two doses of nangibotide in terms of organ dysfunction and reversal of shock.
Reason for Declaration:	A declaration is required to collect, store and process personal data of participants with septic shock that lack decision-making capacity, for the purpose of the ASTONISH study.
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 conditional declaration should be made. **Public Interest**

	• The HRCDC discussed that the study had a strong degree of public interest as it relates to the treatment of septic shock. **Public and Patient Involvement (PPI)** • As with previous applications, the HRCDC emphasised the importance of PPI as an important data protection safeguard, where PPI provides views and preferences regarding the research, on behalf of participants where they are unable to provide consent. It was noted that PPI could be undertaken at any stage of a study, for example engaging with PPI groups to inform the dissemination of findings. • The HRCDC noted that the Applicant had not referenced any PPI activities and therefore was of the view that the study should undertake PPI activities by engaging with relevant groups such as the HSE's Surviving Sepsis group. **Obtaining Assent and Consent** • The HRCDC noted from the information provided that where consent cannot be obtained from the participant who lacks decision making capacity, assent will be obtained from a relative, or in certain circumstances the study doctor. • It was further noted that when the participant regains capacity, they are asked to provide consent to continue in the study. • It was discussed that obtaining assent from the study doctor would not be usual practice in Ireland. The HRCDC was therefore of the view that it is more appropriate to obtain assent only from an appropriate relative or proxy individual who understands the will and preference of the participant. • Where the participant lacks decision-making capacity for a prolonged period, it was further commented that the study should seek to re-affirm proxy assent at an appropriate point in time, including after hospital discharge. • The HRCDC was also of the view that the assent/consent process to be implemented, should take into account the impact that COVID-19 restrictions may have and therefore the study should appropriately adapt their assent/consent protocol where appropriate. **Study Information Leaflets and Consent forms** • The HRCDC was of the view that while the study information leaflet and assent/consent forms provided the appropriate type of information, the information was extensive and used overly technical and legalistic language, which may be difficult and confusing for the participant and/or their relative to follow. For example, it was noted the study schedule was included in the information leaflets which would not be typically included. • The study information leaflet and assent/consent forms provided were combined into in a single document. The HRCDC was of the view that the study information leaflet should be provided separately and that the documents used to obtain (i) assent and (ii) consent/deferred consent should not be combined together

	but instead provided as distinct and separate documents for clarity. • The participant's data protection rights, specifically the right to withdraw from the study was discussed. The HRCDC found this information to be unclear and was of the view that further information and transparency on their data protection rights should be provided to the participant and/or individual providing proxy assent. • The HRCDC also noted that the study information leaflet appeared to be generic in nature and not tailored for the Irish hospital sites and without the hospital logo • The HRCDC noted that the study also provides for consent options for the future use of samples and data. For the purpose of ensuring clarity for participants, it was discussed whether consent to process data outside the scope of the study should be more clearly differentiated. • For the benefit of the study and the participant, on balance it was the view of the HRCDC that consideration should be given to reviewing and amending the study information leaflet and assent/consent forms and that this process should involve consulting with the relevant Irish hospital and local Principal investigator. • It was noted that there are a number of third parties, including those based outside Ireland, involved in the study. The HRCDC discussed that the Applicant should ensure that this is transparent to participants and/or the individual providing proxy consent. **Data Controller & Data Processors** • The HRCDC discussed the relationship between the data controller of the study and the Irish hospital sites. It was noted that the Applicant had confirmed that the Irish hospitals are not joint data controllers and are providing pseudonymised data to the data controller for the purpose of the study. The HRCDC queried whether the Irish sites would be considered data processors in this study. • It was discussed that the designated roles of each party are based on the factual circumstances within the study and therefore a party cannot choose to be a data controller or processor. • The HRCDC noted that there are clinical trial/study agreements in place between the data controller of the study and the Irish hospital sites, that incorporate data protection terms and conditions. The HRCDC discussed that it is the responsibility of the data controller and the parties involved in the study to ensure that robust and appropriate agreements/arrangements are in place to govern the processing and use of personal data. **Data minimisation & Storage** • The HRCDC noted that the personal data will be archived for up to 25 years after the study concludes. It was discussed whether this time-period could be minimised.

	• Furthermore, it was queried how much demographic data would be collected for this study. • The HRCDC emphasised that it is important that only the minimal amount of data required to conduct the study is collected and stored and that the Applicant should ensure they are complying with the principle of data minimisation. **Other** • References by the Applicant to potentially providing redacted copies of the medical records, as well as death certificates, to the data controller was noted. The extent to which this information would be redacted was queried by the HRCDC. • It was noted that the data controller/sponsor has employed a designated research company to conduct the study on their behalf. • A single Research Ethics Committee (REC) approval was provided for both of the Irish hospital sites. It was commented that this is standard practice for studies investigating medicinal products. • The HRCDC discussed the number of participants who would be recruited at the St. James' Hospital site and the total number of participants internationally; however, it was not clear how many are to be recruited at the Galway Hospital site. • The HRCDC also commented that it was not clear who was doing the study's follow-up activities.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 12th November 2020 and shall be valid for 25 years after the completion of the study, until 31st October 2047, or upon confirmation that explicit consent has been obtained or the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**NOTE:** It is acknowledged that this is an international multi-site study. The HRCDC has reviewed and considered the application for a consent declaration in the context of the Irish regulatory framework and clinical practices. The Applicant must therefore ensure that the practices conducted within this study are aligned and consistent with relevant Irish legislation and practices. **Condition 1:** 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 lacks decision-making capacity to 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 when designing and conducting the study and determining the most appropriate method of obtaining consent/assent. 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. Examples of

	possible groups to engage with include ICUSteps and the HSE's Surviving Sepsis Group. (https://www.hse.ie/eng/about/who/cspd/ncps/sepsis/contact/) Progress to meet this condition is a reporting requirement as part of the Annual Review. **Condition 2:** It is a condition of the declaration that the scope of the declaration will only cover the processing of personal data where proxy assent is obtained from an appropriate individual who understands the will and preference of the participant. Correspondingly and for the avoidance of doubt, the scope does not therefore extend to the processing of data where assent has been obtained from the study doctor. *Note for context:* It is acknowledged that the Applicant sought to obtain assent from the study doctor in specific circumstances where proxy assent was not possible. In attaching this condition, the HRCDC considered that obtaining assent from the study doctor is not usual practice within Ireland and that the study doctor would not be the most appropriate individual to understand the participant's will and preferences. **Condition 3**: It is a Condition of this declaration that deferred consent is obtained from participants who regain decision-making capacity. Where participants have been discharged from hospital and still lack decision-making capacity, it should be determined at an appropriate point in time whether they have regained capacity and, where possible to do so, to obtain their consent for data processing. As part of the Annual Review, the Applicant must report the number of participants where deferred consent has been obtained and the number of participants where consent has not been obtained. **Condition 4.** Where a participant continues to lack decision-making capacity for a prolonged period of time and where proxy assent remains in place, the HRCDC requests that the Applicant should seek confirmation from the individual who provided assent, that they wish for the participant's personal data to continue to be processed as part of the research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned. **Condition 5.** To ensure clarity and transparency for participants and/or their proxy/relatives, the HRCDC requests that the study information leaflet and assent/consent forms are reviewed and/or amended as follows, where appropriate: - minimise, where possible, the degree of technical and legalistic language to improve readability and are comprehensible. - tailor the content of documents to reflect the study being conducted in Ireland, for example, by using of Hospital logos;

	- the participant and/or relative/proxy should also be provided with appropriate contact details of the Irish hospital should they have any queries and/or wish to exercise their data protection rights; - consider whether the study information leaflet provided should separately to the assent and consent forms. In addition, the documents used to obtain (i) assent and (ii) consent/deferred consent should not be combined together but instead provided to participants and/or their relative as distinct and separate documents; - the participant's data protection rights, specifically the right to withdraw, should be clearly set out within a separate section of the information leaflet. Where it is not possible to delete the participant's personal data when consent is withdrawn, then the reasons for this should be clearly outlined. - in line with information in the application form, outline that data will be destroyed after the archiving period rather than anonymised, as is currently stated. - More generally the Applicant should ensure that information provided to the participant and/or their relative is consistent and aligns with the data processing activities to be undertaken and ensure that any consent obtained for the future use of data is compliant with data protection legislation. The study information leaflets, and assent/consent forms must be reviewed and amended, as appropriate, prior to the enrolment of participants in the study. The HRCDC also request confirmation that the Irish hospital sites and local Lead Investigator have reviewed and approved the use of the amended consent/assent documents. **Condition 6.** The Applicant must ensure compliance with the principle of data minimisation. Please discuss with the relevant data protection officers to ensure that only the minimal amount of data, including demographic data, is collected and only stored for as long as is necessary. Please confirm what specific demographic data is being collected when responding to confirm acceptance or not of the HRCDC's decision. **Condition 7.** It is assumed that the study's follow-up activities are to be undertaken by the Irish hospital and not the data controller/sponsor or other third party. Please confirm that this understanding is correct when responding to confirm acceptance or not of the HRCDC's decision.
HRCDC Recommendations	**Recommendation 1.** The Applicant should consider differentiating consent for processing data for future research from the consent for the core ASTONISH study. In the interest of ensuring clarity for participants, the Applicant should give consideration to obtaining consent for future research via a separate consent document.

	Recommendation 2. Consideration should be given as to how proxy assent and subsequent deferred consent will be sought given the ongoing COIVD-19 restrictions. **Recommendation 3.** The Applicant should review that the terms and conditions of all legal agreements governing the processing and sharing of data between the data controller/sponsor of the study and the Irish hospital sites, to ensure they met the requirements under GDPR.

Reference ID:	20-031-AF1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St James' Hospital, Dublin
Title:	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
Research Objective:	Septic shock is a disease of the microcirculation. The microcirculation is a network of small blood vessels (< 100 µm diameter), which consists of arterioles, capillaries and venules. The microcirculation is structured such that every cell has at least one capillary adjacent to it for the purpose of passive diffusion of oxygen from the blood into the cell, and maintenance of organ function. In septic shock there is an inadequate flow of red blood cells through capillaries. This leads to an inadequate supply of oxygen to tissues, and the development of organ failure. Resuscitation with intravenous fluids partially corrects this pathology. The research objective is to evaluate which fluid is better for improving perfusion of the microcirculation in septic shock - Crystalloid (compound sodium lactate or 0.9% saline) or 20% albumin (Grifols).
Reason for Declaration:	A consent declaration is requested to process the personal data of participants, who lack decision-making capacity to provide consent, for the purpose of this study. Processing includes the collection, pseudonymisation, analysis and storage of personal data.
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 conditional declaration should be made. **Public Interest** • In determining the degree of public interest, the HRCDC discussed whether the study was likely to contribute to developments in current knowledge and/or practice for the treatment of sepsis.

- On balance, and based on the information provided, it was the consensus of the HRCDC that there was level of public interest in undertaking this study.

Research Ethics Committee (REC) Approval

- The HRCDC noted that the study had received provisional REC approval, subject to queries being addressed by the Applicant, regarding the study design and administrative/clerical procedures. The responses to the REC's queries were provided to the HRCDC.
- The HRCDC discussed that full REC approval must be in place and confirmation to this effect should be provided to enable the consent declaration to come into effect.

Public and Patient Involvement (PPI)

- It was noted that no PPI activities were outlined by the Applicant.
- The HRCDC emphasised the importance of PPI and discussed that the study should carry out PPI activities, including by engaging with groups such as, for example, ICUSteps and the HSE's Surviving Sepsis group.

Assent and Consent Process

- It was clarified by the Applicant that proxy assent will be obtained from a family member, or appropriate individual prior to conducting the study and processing data. It was further noted that this aligns with the information outlined in the provisional REC approval letter.
- When the participant regains capacity, deferred consent to continue in the study will be sought. The HRCDC discussed that deferred consent should always be obtained where the participant regains decision-making capacity.
- Where the participant lacks decision-making capacity for a prolonged period, it was further commented that the study should seek to re-affirm relative assent at an appropriate point in time, including after hospital discharge.
- The HRCDC was also of the view that the assent/consent protocol should be appropriately adapted, to take into account the impact that COVID-19 restrictions may have.
- The HRCDC also discussed the feasibility of the proposed timeframe of obtaining assent or consent within 2 hours to subsequently begin to process data.
- Should the protocol change in the future, for example by allowing for deferred assent from a relative/proxy, it was discussed that the Applicant should submit an amendment request to the HRCDC.

Study information leaflet and Assent/Consent forms

- To further differentiate from the relative assent form, it was commented that the documents used to obtain deferred consent when the participant regains capacity could make it clearer to the participant that they have already been enrolled into the study on

	the basis of relative/proxy assent and therefore are being asked to provide consent to continue in the study. • The HRCDC also noted that the documents contain two different names/titles for the study and should therefore be amended for consistency. • Furthermore, it was highlighted that the study information leaflet explicitly references 'deferred assent', whereas the application form references to prior assent from a relative. The leaflet also incorrectly states that research is conducted by Trinity College Dublin and that data is destroyed after 5 years, rather than anonymised as indicated in the HRCDC application from. • Overall, the HRCDC was of the view that the content of the study information leaflets, and assent/consent forms should be consistent and ensure that they accurately reflect the study and data processing activities to be undertaken. **Other** • The HRDC queried how participants are randomised to one of the treatment groups outlined in the study protocol. It was highlighted that randomisation is done by a software programme. • It was noted that Excel will be used to analyse the data. The HRCDC queried how effective data analysis could be run via Excel. • The timelines for the destruction of paper records was not clear
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 12th November 2020 and shall be valid until 31st December 2022 and for 5 years thereafter (until 31st December 2027) or upon confirmation that explicit consent has been obtained or the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1:** The consent declaration shall only become effective upon confirmation that full research ethics committee (REC) approval has been granted. Once obtained, evidence of full REC approval should be provided to the HRCDC as soon as possible. In addition, the declaration has been made on the basis that relative/proxy assent is obtained prior to the enrolment of the participant in the study and the subsequent processing of their data; this aligns with the information outlined within the provisional REC approval letter. Should this protocol change such that a deferred relative/proxy assent protocol is used, then the Applicant should submit an amendment request for HRCDC consideration, subject to obtaining the relevant REC approval. **Condition 2:** 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 lacks decision-making capacity to 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 when designing and conducting the study and determining the most appropriate

	method of obtaining consent/assent. 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. Examples of possible groups to engage with include ICUSteps and the HSE's Surviving Sepsis Group; (https://www.hse.ie/eng/about/who/cspd/ncps/sepsis/contact/) Progress to meet this condition is a reporting requirement as part of the Annual Review. **Condition 3:** Where a participant continues to lack decision-making capacity for a prolonged period of time and where next-of-kin assent remains in place, the HRCDC request that the following actions should be taken as an additional safeguard: i) the Applicant should seek confirmation from the relative/proxy who provided assent, that they wish for the participant's personal data to continue to be processed as part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned. ii) where participants have already been discharged from the hospital and prior to assent being reaffirmed, it should also be determined whether the participant has re-gained capacity and, where possible to do so, to obtain their consent for data processing. The Applicant must report on this as part of the Annual Review, including the number of participants where deferred consent has been obtained, and where deferred consent has not been obtained. **Condition 4.** To ensure clarity, transparency and consistency of information for participants and/or their relatives/proxy, the HRCDC requests that the study information leaflet and assent/consent forms are reviewed and/or amended as follows: - To further differentiate from the relative assent form, the documents used to obtain deferred consent when the participant regains capacity, should make it clearer to the participant that they have already been enrolled into the study on the basis of relative assent and therefore are being asked to provide consent to continue in the study; - remove inaccurate references to 'relative's deferred assent' and that 'Trinity College Dublin' is conducting the study; - aligned with the information in the HRCDC application form, outline that data is anonymised within 5 years, rather than destroyed as is currently indicated in the study information leaflet; - both 'study title' and 'name of study' are provided and are not the same. Please ensure that the title/name of study is consistent throughout the documents. - more generally the Applicant should ensure that information provided to the participant and/or their relative is consistent and

	aligns with the study and data processing activities to be undertaken. The study information leaflets, and assent/consent forms must be reviewed and amended prior to the enrolment of participants in the study and confirmation provided to the HRCDC when this is completed.
HRCDC Recommendation:	**Recommendation 1.** Consideration should be given to how the relative assent and subsequent deferred consent protocol will be implemented in the context of the ongoing COIVD-19 restrictions. **Recommendation 2.** It should be ensured that there are robust protocols in place for the shredding/destruction of paper records.

Reference ID:	19-024-AF2
Lead Applicant:	Geraldine Boylan
Lead Data Controller:	University College Cork (UCC)
Title:	Development of a Real Time Seizure Detection Algorithm for Neonates
Research Objective:	Seizures occur in 5-13% of very low birth weight babies and 1-2 per 1000 babies born at full term and are regarded as a major risk factor for death or subsequent neurological disability. These seizures are clinically difficult to diagnose and are often a marker of important underlying conditions that require urgent diagnosis and treatment. The characteristics of neonatal seizures have so far proved challenging for automated seizure detection methods. The use of Near-infrared spectroscopy (NIRS) in the first few days in neonates have been recommended. This simple and reliable technology permits bedside measurement of acute changes in the most immature and unstable neonates requiring intensive care. Simultaneous video and electroencephalogram (EEG) is the best tool for diagnosing seizures but requires highly specialised technical and medical personnel to acquire and interpret the studies; there is a need to develop an automated, effective and simple to use seizure detection system at the cot side; this study aims to develop a neonatal seizure detection algorithm (code).
Reason for Declaration:	UCC holds the residual databank of EEG recordings, lesser number of NIRS recordings and clinical data that constitutes personal data from participants who consented to participate in the study at Cork University Maternity hospital. A consent declaration is sought for; i) the continued processing of the personal data (pseudonymisation, analysis and storage) for the purpose of this research study and within the scope of the consent that was previously obtained; and ii) a fully anonymised version of the pseudonymised study dataset
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 reminded the members that the Applicant had obtained consent compliant with the previous Data Protection legislation, under the Health Research Regulations, a public interest case is not an applicable factor in the HRCDC decision making process. 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. **Re-consenting and Transparency** • The HRCDC discussed the Applicant's response as to why reconsenting was not feasible, namely that the study had concluded follow-up activities with participants, the number of participants involved, as well as other challenges including change of contact information. • On balance, and based on the information provided by the Applicant, the HRCDC accepted the rationale for not seeking to formally re-consent participants. • The HRCDC was of the view that transparency measures should be enhanced so that participants are made aware of their data protection rights, how they can withdraw their consent and their data if they wish and to receive other general updates regarding the use of their data and the study itself. The HRCDC discussed that the study website and information leaflets sent to participants could be beneficial ways of improving transparency. **Scope of the Declaration** • The HRCDC noted the Applicant's response to a query from the Secretariat, where the Applicant referred to creating a fully anonymised version of the pseudonymised study dataset. in addition to research activities already consented for. Based on the information provided, it was noted that the purpose for creating an anonymised database is for the transfer to collaborative third parties, including commercial parties, for (i) work to be conducted under the scope of the original consent or (ii) work related to the scope of the original consent. • The HRCDC discussed request for the declaration to extend to the creation of an anonymised version of the database. Where the research activities fall under the scope of the original consent it was noted that this would be covered by this declaration. It was commented that it is the responsibility a data controller to determine whether the research undertaken are within the scope of consent already obtained. • However, it was the view of the HRCDC that the creation of an anonymised dataset for research that is not within the scope of the consent already obtained, will not fall under the scope of this declaration.

	• The HRCDC noted that the anonymisation processes, research activities and future recipients accessing the anonymised database were not detailed in the application form and was only highlighted in supplemental information provided by the Applicant. • Subject to ethical approval, a separate consent declaration application, maybe submitted if it is determined by the Applicant that anonymisation of the data for the creation of a separate database falls outside the scope of consent obtained. **Data Agreements** • It was noted that UCC also hold anonymised data collected from a sister study undertaken in the UK by University College London (UCL). It was discussed that the consent declaration applies only to personal data collected in Ireland. • The HRCDC discussed the information provided by the Applicant, which confirmed that legal agreements in place between UCC and UCL were compliant at the time of study commencement. It was also discussed that should data be transferred from UCL to UCC in the future, that appropriate agreements in accordance with current data protection legislation should be in place. • It was noted from the information provided that the anonymised data from UCL has already been transferred to UCC. • The HRCDC commented that it is the responsibility of the parties involved to ensure that the appropriate and relevant agreements are in place governing the processing of data. **Public and Patient Involvement (PPI)** • The level of PPI undertaken within the study was acknowledged. The HRCDC commented that a relatively strong level of PPI was undertaken during the lifetime of the study. **Research Ethics Committee (REC) approval** • A copy of the REC amendment approval letter from Bristol REC was provided as part of the application form. The HRCDC queried why REC amendment approval has sought and granted from the Bristol REC rather than the relevant London REC.
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 30th April 2044 (25 years after the last follow-up session was completed) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** It is a condition of the declaration that the scope of the declaration covers the processing of data within the scope of the original consent previously obtained. For the avoidance of doubt, the scope does not extend to any other processing activity that is outside the scope of the original consent. *Note for Context:* Specifically, the Applicant should determine if the proposed creation of an 'anonymised dataset' for research is within

	the scope of the consent already obtained. If it is determined by the Applicant that anonymisation of the data for the creation of a separate database falls outside the scope of consent previously obtained, an application for a consent declaration, maybe submitted for HRCDC consideration. **Condition 2**. The Applicant is requested to enhance transparency measures and information is available on the data protection rights of participants , including how they can withdraw their consent and their data from the study if they wish to do so, as well as the duration of data storage. Transparency measures should also provide participants with updates regarding the use of their data and the study's progress. Strong consideration should be given to forwarding a letter or information leaflet describing the above data protection rights to the study participants and providing clear information on the study website. Efforts made to implement enhanced transparency measures are a reporting requirement of the Annual Review. **Condition 3.** The Applicant is requested to ensure that required and robust agreements or contractual arrangements governing the processing of data are in place where required. The data protection officer and/or legal office should be consulted on this matter. **Condition 4**. In your response to confirm acceptance or non-acceptance of the HRCDC's decision, clarification must be provided as to why research ethics committee (REC) amendment approval was sought and provided from the NHS Bristol REC, rather than the London based REC.

Reference ID:	19-072-AF2
Lead Applicant:	Eugene Dempsey
Lead Data Controller:	University College Cork
Title:	Multimodal Assessment of Newborns at risk of Neonatal Hypoxic Ischaemic Encephalopathy – The MONItOr Study
Research Objective:	Some babies require resuscitation when they don't cry or move after delivery. This may occur when a baby has had a difficult or stressful time during labour or delivery, associated with an interruption of the blood and oxygen supply to the baby's brain. If severe, this can lead to altered brain function in the first few days after birth, with seizures and decreased conscious level. This is known as hypoxic-ischaemic encephalopathy (HIE). Therapeutic hypothermia ('Cooling') is now standard of care for all babies with moderate to severe HIE. At present there is no single test to tell whether a baby has had a significant injury or not. By conducting a series of investigations, this study is trying to establish the degree of the injury, if present, and the long-term impact on development so that interventions can be developed, and outcomes improved. The main objectives are to document the early neurophysiological changes which occur in the first 6-12 hours following birth in infants

	with HIE and to establish whether the evolution of physiological changes in combination with blood biomarkers can predict outcome as defined by the development of seizures, MRI abnormalities and neurological assessment at discharge and outcome at 18-24 months.
Reason for Declaration:	The applicant is seeking a declaration as the original study information leaflet and consent form are not considered compliant under the HRRs for the following reasons: - They do not outline UCC as sponsor and the data controller - They do not outline the duration of the storage of the data The study team plan to re-consent active participants to an updated, compliant consent form, however it is anticipated that not all participants can be re-consented. A consent declaration is requested for the continued processing of data (collection, pseudonymisation, analysis and storage) for the purpose of this research study and within the scope of the consent that was previously obtained.
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 reminded the members that the Applicant had obtained consent compliant with the previous Data Protection legislation, under the Health Research Regulations, a public interest case is not an applicable factor in the HRCDC decision making process. 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. **Re-consenting** • The HRCDC acknowledged that strong efforts are being made by the Applicant to re-consent participants at their follow-up study visit and discussed that declaration is therefore only required for participants who are not contactable. The HRCDC was also of the view that the Applicant should report on the numbers of participants where it was not possible to obtain re-consent. **Scope of the declaration** • The HRCDC noted the Applicant's response regarding the future use of data outside the scope of the consent obtained that a separate declaration may be required. • It was discussed that it was important for the relevant data controllers to determine if any future study using data is within the scope of consent, otherwise a new declaration or amendment would likely be necessary.

	• The HRCDC also queried if the scope of the consent declaration would include participants who may have withdrawn from the study; it was noted that the number of participants who have withdrawn was very low. • It was discussed that a declaration cannot be made to override the withdrawal of participant consent and therefore the scope will not extend to this cohort. **Re-consenting documents** • Copies of the updated GDPR compliant study information leaflets and assent/consent forms were provided by the Applicant. • The HRCDC was of the view that 'yes/no' tick-box options would be preferable to tick-only boxes on the consent forms as this would help to ensure clarity for both the participant and the study.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until 31st December 2021 and for 25 years thereafter, until 31st December 2046 or upon confirmation that explicit consent has been obtained or the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** Strong efforts to obtain re-consent as outlined in the HRCDC application should be continued to be made by the Applicant. As part of the Annual Review the Applicant is expected to report on the number of participants who have re-consented and the number of participants who have not re-consented. **Condition 2**. The scope of the declaration is for the processing of data of (i) participants whom the study is unable to re-consent and (ii) participants who have withdrawn from the study but have provided consent for the continued processing of their data after withdrawal. For the avoidance of doubt the scope of the declaration does not extend to participants who have or may withdraw from the study in the future but do not provide consent for the continued processing of their data. **Note:** A consent declaration cannot be made to override the withdrawal of consent. Data controllers who wish to continue to process personal data of participants who have withdrawn from the study, are responsible for ensuring they are compliant with data protection legislation, including the derogations outlined within the GDPR, for example Article 17 and informing participants of what shall happen to their data should they withdraw from a study. The Data Protection Officer should be consulted where necessary.
HRCDC Recommendations:	**Recommendation:** The HRCDC recommend the use of 'Yes/No' tick boxes, instead of 'tick-only' boxes in the updated GPDR compliant consent form used to obtain re-consent. The use of 'Yes/No' boxes are considered by the HRCDC as a more effective way of ensuring ensure clarity for both the participant and the research team.

7. Annual Reviews

The Secretariat has received 4 Annual Reviews in advance of the meeting. Of these 19-015-AF2 and 19-031-AF2 were deemed completed and 2 were deemed partially completed;

Regarding 19-006-AF3, the HRCDC was informed that Condition 3, the publication of the annual report, was in progress.

Regarding 19-013-AF2, the Applicant confirmed that data no longer resides with a data processor and therefore the relevant condition has been met. A copy of a final approved privacy notice remains outstanding and has been requested.

8. Activities

The Secretariat informed the HRCDC of the Irish Health Research Forum's (IHRF) 'Advancing Genomics in Ireland' event that was also held on the same day as this HRCDC meeting. The HRCDC were provided with an agenda for this event and a corresponding IHRF discussion paper also entitled 'Advancing Genomics in Ireland'. The Secretariat confirmed that the event will be recorded and that the HRCDC will be provided with the link to watch when available.

9. Any other Business

- The HRCDC were informed that the Health Research Board (HRB)'s 2025 strategy under development, incorporates the function of the Secretariat which is supported and hosted by the HRB.
- The Chair requested the HRCDC to indicate their preference dates and times for HRCDC meetings in 2021, which will be finalised by year end.
- It was discussed that the Secretariat are awaiting responses to queries from Applicant's regarding HRCDC applications, where consent was not obtained prior to the Health Research Regulations regarding the HRCDC AF3 category application. While acknowledging the impact of COVID-19, it was discussed that where responses remain outstanding for a considerable period, the application should be scheduled for consideration at a HRCDC meeting without receiving their responses. Before their application is scheduled for decision, the Applicant will be contacted first and provided with a final request to respond.
- The Secretariat informed the HRCDC that amendments to the Health Research Regulations are due to be signed shortly and that guidance material to accompany the amendments are in development.
- The Secretariat informed the HRCDC of its engagement with the HRB and Central Statistics Office regarding researcher access to COVID19 health data and the consent declaration process.

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