HRCDC
Health Research Consent Declaration Committee

Date: 25th January 2022
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions
☒YES

Returning Applications - For consideration

Applicant	Ref No.	Title
Ignacio Martin-Loeches	20-031-AF1/AMD1	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock

New Amendments - For consideration

Applicant	Ref No.	Title
Laura González (OXON) / Ignacio Martin-Loeches (Local Investigator)	20-035-AF1/AMD1	IV Zanamivir Effectiveness Study
Mary McCarron	21-009-AF1/AMD1	Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability

Meeting Items

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

2. **Apologies**

Evelyn Mahon, Simon Furney, John Ferguson, Kathy Brickell, Zubair Kabir, Claire Collins.

3. Disclosure of Interest

There were no disclosures of interest for this meeting.

4. Minutes of the last meeting

Draft minutes of 14th December 2021 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The Secretariat has contacted the National Office for Research Ethics Committees to discuss how Applicants, who are seeking ethics amendment approvals from the COVID-19 National Research Ethics Committee, could be informed that they may also need to consider if a separate consent declaration amendment request should be submitted for HRCDC consideration. It was noted that the National Office for Research Ethics Committees will consider how best to coordinate communications on this matter.

6. Returning Applications:

Reference ID:	20-031-AF1/AMD1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St James's Hospital, Dublin
Title:	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
Research Objective:	See HRCDC Meeting minutes of 14th December 2021
Purpose of Amendment:	See HRCDC Meeting minutes of 14th December 2021
HRCDC Comments:	The Chair introduced the agenda item and reminded the members of the additional information that was requested from the Applicant. The Chair referred to the discussion on this application at the previous meeting and summarised the outstanding matters and the responses provided by the Applicant. Committee members were invited to indicate whether the amendment request should be approved. It was the consensus of the HRCDC that the amendment to the consent declaration could be approved. The decision was based on the following discussion points: **Pulmovista device:** • The HRCDC noted the Applicant's response that the Pulmovista device is a standard of care available in the St. James's Hospital Intensive Care Unit (ICU). • The HRCDC discussed that there was a variance between the response provided and description of the device in the study information leaflet, as being used in routine care. It was agreed that the Applicant should ensure that the description of the Pulmovista device in the information leaflet should be amended to reflect the position in clinical practice for transparency purposes.

	• It was noted from the response provided that no additional data processing associated with the use of this device, will be carried out. The HRCDC discussed that the use of the Pulmovista device was not highlighted in the original HRCDC application form or the study protocol and has subsequently received REC approval. Therefore, for clarity, it was agreed that the scope of the consent declaration should also be amended to include any possible processing of data associated with the Pulmovista device, that maybe used for the purpose of the study. **Assenting protocol** • The HRCDC noted from the responses provided that the typical timeline for obtaining deferred proxy assent was within 72hrs after a participant has presented in hospital and has been enrolled in the study. • It was commented that this timeline of obtaining deferred assent was reasonable. **Exclusion criteria** • The HRCDC noted that a participant's allergy to albumin, one of the study's exclusion criteria, is determined by examining their medical records. It was commented that an allergy to albumin is extremely rare. **Telephone assent** • It was noted that the Applicant is liaising with the research ethics committee with regards ethical approval for the telephone assent protocol. • It was discussed that confirmation that the required ethical approval is in place for the telephone assent protocol, must be provided to HRCDC as soon as possible. • When obtaining assent by telephone, it was further commented that the study information leaflet and assent forms should be sent to the proxy individual for signing, and the signed assent form returned to the study researchers as soon as possible. **Other** • It was noted that the amendments to the study information leaflets and assent/consent documents, highlighted and discussed on 14th December 2021 meeting, should be addressed by the Applicant. • In addition, it was commented that the Data Protection Impact Assessment (DPIA) should be reviewed to identify any new or emerging data protection risks and mitigating actions, and, where appropriate, to consult with the relevant Data Protection Officer on any revisions that are made.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Duration of Declaration:	The Amendment is made commencing 25th January 2022 and shall be valid until 31st December 2022 and for 5 years thereafter until 31st December 2027 or upon confirmation that the data has been

	irrevocably anonymised or destroyed, whichever occurs sooner. (This timeline is in line with the duration of the consent declaration)
Conditions Attached:	**Condition 1**. Confirmation must be provided to the HRCDC that the required research ethics committee approval is in place for the telephone assent protocol. Confirmation must be provided as soon as possible and no later than 25th March 2022. **Condition 2.** When obtaining assent by telephone, the Applicant should ensure that the study information leaflet and proxy assent form is forwarded for signing by the proxy, and that a copy of the signed assent form is returned to the study team for their records, as soon as is practicable. **Condition 3.** The Applicant is requested to ensure that Condition 4 attached to the original consent declaration, is addressed thoroughly and as soon as possible to ensure any inaccurate or inconsistent information is amended in the assent/consent documentation. **Condition 4.** The Applicant is requested to review the study's Data Protection Impact Assessment (DPIA) to identify any potential new or emerging data protection risks and mitigating actions, and, where appropriate, to consult with the data controller's Data Protection Officer on any revisions that have been made.
HRCDC Recommendations:	**Recommendation 1.** Further to Condition 3, the HRCDC recommends that the Applicant reviews the participant and proxy study information leaflets to ensure that the description of the Pulmovista device, transparently and accurately reflects its use in clinical practice in St. James's Hospital. Furthermore, the following observations are also made and should be considered by the Applicant: - page 5 of the participant consent to continue information leaflet states '*If you do not want to be part of the study then we will delete the information from the secure network'*. A statement to this effect, tailored for those who are asked to provide proxy assent, should also be included in the proxy assent documentation, - inaccurate use of '*consent*', as opposed to '*assent*', should be amended in the proxy information leaflet -specifically, page 2 of the proxy information leaflet states '*this process is known as informed consent*') - the following statement in the consent/assent should be revised for clarity, as it could be misinterpreted that personal data from GP records are also being processed for the study: '*I agree to my GP being informed of my participation in the study and providing information from my medical records to the study team as described in this information sheet*.'

7. Amendments

Reference ID:	20-035-AF1/AMD1

Lead Applicant:	Laura González (OXON) / Ignacio Martin-Loeches (Local Investigator)
Lead Data Controller:	GlaxoSmithKline Research & Development Ltd
Title:	IV Zanamivir Effectiveness Study
Research Objective:	Please see minutes of 13th April 2021
Purpose of Amendment:	The amendment is requested to extend the processing of personal data for the study to include the 2021/2022 flu season participant cohort. This is due to the low number of study participants in the previous two flu seasons. As per the previous seasons, the data for the 2021/2022 will be collected retrospectively.
HRCDC Comments:	The Chair provided an overview of the amendment request and requested members to indicate their approval to amend the conditional consent declaration and invited members to comment. It was the consensus of the HRCDC that the conditional declaration could be amended. The HRCDC commented that the conditions attached to the original consent declaration still apply and remain valid. It was noted that this is standard where an amendment to a consent declaration is made. In addition, it was discussed that the Data Protection Impact Assessment (DPIA) should be reviewed and revised, where necessary, to identify any new data protection risks and mitigating actions.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended
Amendment Duration	The Amendment is made commencing 25th January 2022 and shall be valid until 31st August 2022 and for 30 years thereafter or upon confirmation that the personal data has been destroyed or rendered anonymised, whichever is sooner. (This is an extension of the duration of the consent declaration, to reflect that the end of study is now due in August 2022. The original end date was projected as April 2022).
Conditions Attached:	**Condition.** The Applicant is requested to review the study's Data Protection Impact Assessment (DPIA) to identify any potential new or emerging data protection risks and mitigating actions, and, where appropriate, to consult with the data controller's Data Protection Officer on any revisions that have been made.

Reference ID:	21-009-AF1/AMD1
Lead Applicant:	Mary McCarron
Lead Data Controller:	Trinity College Dublin
Title:	Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability
Research Objective:	See minutes of 20th July 2021

Purpose of Amendment:	The amendment request is for the additional processing of personal data of new participants being recruited for the study, from sixteen new disability services.
HRCDC Comments:	The Chair introduced the amendment request and invited the Secretariat to provide an overview of the amendment. The Secretariat outlined the reason for the amendment and highlighted that, of the sixteen additional services noted in the amendment form, 8 of these had provided confirmation that the necessary research ethics committee (REC) approval for the study was in place. It was discussed that the amendment request, if approved, would cover these services, and would not cover the other 8 services until the necessary REC approval for those services are also in place. It was queried if additional information should be sought on 3 of these new services, which were described in the amendment request form as 'exemplar' services, where it was noted that more in-depth research was to be conducted. The Secretariat reminded the Committee that the original HRCDC application had previously provided information on the purpose of the exemplar sites within this study. It was highlighted that undertaking more in-depth research at the exemplar sites is a core part of the study, under the study's 'work package 4'. Based on the information provided, it was the consensus of the HRCDC that the amendment to the consent declaration could be approved, with an appropriate condition attached regarding the new sites where the requisite REC approval remains pending.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration	The Amendment is made commencing 25th January 2022 and shall be valid until 31st December 2022, or upon confirmation that the personal data have been rendered irrevocably anonymised or destroyed, or whichever occurs sooner. (This timeline is in line with the duration of the consent declaration)
Conditions Attached:	**Condition 1.** The amendment to the consent declaration is effective for the 8 services named in the amendment request form, where confirmation has been provided that the requisite research ethics committee (REC) approval is in place. For each of the 8 remaining services named in the amendment request form, the amendment will not be effective until the requisite REC approval is in place to conduct the study at that service. Once this is provided, confirmation of REC approval for that service should be submitted to the HRCDC as soon as possible.

8. Annual Reviews

The Secretariat has received 6 Annual Reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 19-017-AF2 (Tom Fahey: Prescribing in primary care patients aged 70 years or older)

- Ref ID: 19-084-AF1 (Karn Cliffe: 1 Year post-sepsis study)
- Ref ID: 20-036-AF1 (Alistair Nichol: EPO-TRAUMA)
- Ref ID: 19-043-AF3 (Rose Anne Kenny: GRO-TILDA)
- Ref ID: 19-014-AF2 (Jochen Prehn: COLOSSUS Study)
- Ref ID: 20-034-AF1 (Ivan Perry: A Capture-Recapture Study to Estimate the Prevalence of Problem-Opiate Use in Ireland (2015 – 2019))

The Secretariat also informed the HRCDC that a mid-term report for the following study, was submitted and deemed acceptable:

- Ref ID: 21-001-AF1 (Patrick Sheahan, Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)).

9. Activities report

- The HRCDC was provided with a copy of the feedback that was submitted, on behalf of the HRCDC, regarding the Health Information and Quality Authority's (HIQA) public consultation on '*Draft recommendations on a consent model for the collection, use and sharing of health information in Ireland*'.
- The HRCDC were informed of an upcoming event: *'WEBINAR: Informed consent in cluster randomized trials: a guide for the perplexed'* (9th February 2022, https://nuigalway-ie.zoom.us/webinar/register/WN_GeSW4DNgR42W7uEC_IuEPw)

10. Any Other Business

- The Secretariat provided a brief update on the applications submitted to the HRCDC that are pending consideration. It was noted that the Secretariat is awaiting confirmation from a small number of data controllers as to whether applications will be withdrawn or proceed for HRCDC consideration.
- Members were reminded that the next meeting of the HRCDC is scheduled for 8th March 2022. It was discussed that this meeting will likely be held by videoconference.

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