HRCDC
Health Research Consent Declaration Committee

Date: 8th November 2022
Location: Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Evelyn Mahon
Alyson Bailey
Simon Furney
Aideen Hartney
Dan Rea
Cornelius Cooney
Mary Tumelty
Barry Lyons
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)
Caroline Byrne (Secretariat)
Marta Pisarska (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Ruben Keane	20-013-AF1/COV/AMD1	Solidarity Plus Trial

New Applications – For consideration

Applicant	Ref No.	Title
Frank Doyle	22-012-AF1	Targeted Review and Amalgamation of Unmapped Major Trauma and Ambulance Data in Ireland: TRAUMA Study

Meeting Items

1. **Opening**
   The Deputy Chairperson opened the meeting and welcomed the members.

2. **Apologies**
   Zubair Kabir, Brigid McManus, Claire Collins, Sheelah Connolly, Kathy Brickell, John Woods, 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 4th October 2022 were circulated in advance of the meeting and were approved by the HRCDC.

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5. Matters arising

A member requested an update on the status of the Annual Review for 19-038-AF1 which was noted on 4th October HRCDC meeting. The Secretariat informed the HRCDC that the Applicant had confirmed that the consent declaration was no longer required and has been withdrawn.

6. 22-008-AF1; Evaluation of policies and practices to support safe and appropriate controlled drug prescribing

- The HRCDC discussed the response to Condition 1 (transparency measures) that was attached to the consent declaration made to 22-008-AF1. The Applicant's response outlined the information that has been provided on the study's website and the other communication activities undertaken, including targeting pharmacists and General Practitioners (GPs). The HRCDC commented that the website was comprehensive and provided detailed information on the study. It was the view of the HRCDC that Condition 1 has been met by the Applicant.
- Notwithstanding this, it was discussed that the website uses quite technical and academic language. It was therefore recommended that the Applicant liaises with public and patient representatives to provide an introduction to the study on the website using layperson's language, and that further website updates and future communication activities should utilise layperson's language where possible.

7. Amendments:

Reference ID:	20-013-AF1/COV/AMD1
Lead Applicant:	Ruben Keane
Lead Data Controller:	University College Cork Department of Health, Ireland
Title:	Solidarity Plus Trial (*updated study name from the 'Solidarity Trial'*)
Research Objective:	Please see minutes of 20th May 2020
Purpose of Amendment:	The amendment request relates to a change in the study's treatment arms and an extension of the duration of the consent declaration, from 5 years from the end of the study to 25 years, as per the new Clinical Trials Regulations.
HRCDC Comments:	The Deputy Chairperson introduced the amendment. The Secretariat provided an overview of the changes made to the study that is the subject of the amendment request. It was highlighted that the trial has added 2 new treatment arms (Infliximab and Imatinib), that are in addition to the 4 treatments outlined in the original HRCDC Application; both the original and the newly added treatments are already marketed medicines. It was noted that study was described as an 'adaptive' or 'platform trial' to examine treatments for COVID-19, where the core trial protocol remains the same but with the treatments to be examined discontinued or added depending on the research findings. The Secretariat highlighted that the 4 original treatments are no longer being investigated as part of this trial in Ireland. It was also discussed that the purpose of the study and the participant cohort continues to be on examining treatments for patients with COVID-19 and that the data processing activities and consent/assent process otherwise remain unchanged. It was

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	further noted to the HRCDC that recruitment to the trial has begun to slow in recent months. The Deputy Chairperson requested each HRCDC member to indicate whether the amendment to the consent declaration should be made. It was discussed that the amendment request was primarily a technical one and that the changes do not relate to new disease areas, participant cohorts or the examination of new un-marketed treatments. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment should be approved. **Study Information Leaflets** • The HRCDC noted that a condition attached to the original declaration requested the Applicant to develop and use separate and distinct information leaflets and assent/consent forms when seeking (i) proxy assent from the participant's relative or friend and (ii) consent to continue for participants who regain decision-making capacity. From the updated study information leaflets provided by the Applicant, it was noted that separate, distinct versions are not used when seeking proxy assent or participant consent. • The Secretariat highlighted that following the HRCDC's decision letter in May 2020, the Applicant outlined a proposal to use a single version of the study information leaflet and assent/consent form, that would include distinctive and clear sections for participants and their relatives. Based on the rationale provided by the Applicant, this approach was deemed acceptable and was noted on 10th June 2020 HRCDC meeting. • It was queried whether the participant who provides proxy assent is automatically forwarded a copy of the information leaflet and assent form. It was discussed that some participants have already been recruited with regards the new treatment arms. It was the view of the HRCDC that the Applicant should confirm that a copy of the study documentation has been sent to those who have provided proxy assent to date, and if not, to ensure this has occurred. Copies of the study documentation should also be sent to the individual providing proxy assent for prospective participants as part of the standard assent procedure.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Duration of Declaration:	The Declaration is made commencing 20th May 2020 and shall be valid for 25 years after the study has concluded. *This is an extension of the duration of the declaration initially made.*
Conditions Attached:	**Condition 1.** The Applicant is requested to ensure that a copy of the study information leaflet and proxy assent form is forwarded to the individual who provides proxy assent on behalf of the participant who lacks decision making capacity; a copy of the study documentation should therefore be provided to the participants (n=9) who have already been recruited to study regarding the two new treatment arms (Infliximab and Imatinib), if not already done

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	so, and a copy also forwarded to the individual providing proxy assent for future prospective participants as a standard study procedure.

8. New Applications

Reference ID:	22-012-AF1
Lead Applicant:	Frank Doyle
Data Controllers:	Royal College of Surgeons in Ireland (RCSI) National Office of Clinical Audit (NOCA) HSE National Ambulance Service (NAS)
Title:	Targeted Review and Amalgamation of Unmapped Major Trauma and Ambulance Data in Ireland: TRAUMA Study
Research Objective:	This study aims to support the development of the national trauma care system in Ireland by combining, anonymising, and then analysing two currently separated datasets. These are, the National Ambulance Service (NAS) electronic Patient Care Record (ePCR) and the Major Trauma Audit (MTA). As this data concerns trauma patients, informed consent was not possible and given the size of the dataset it is considered that retrospective consent to process the data is not feasible. Therefore, the Applicant is applying for a consent declaration to process the data for the purposes of linking and anonymising the datasets. They plan to analyse the anonymised data to map the patient journey from the scene of the incident to discharge from hospital and to identify characteristics that determine the need to bring patients to major trauma centres.
Reason for Declaration:	The declaration is required for the transfer and merging of two personal datasets (the National Ambulance Service (NAS) electronic Patient Care Record (ePCR) & the Major Trauma Audit (MTA)). Once merged the data will be anonymised and transferred for analysis to RCSI. The pseudonymised audit and NAS data obtained for this study by the data controllers will be retained for 5 years after the study concludes.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 Secretariat provided an overview of the application and the scope of the consent declaration, if made. The Applicant has confirmed that RCSI, NOCA and the NAS are joint data controllers of this study. It was also outlined that the merged dataset of the NOCA and the NAS data that is transferred to RCSI for analysis purposes is considered to be anonymised by the parties. The Deputy Chairperson 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.

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Public interest case

- The HRCDC noted the aims and objectives of the study and that the personal data to be processed spans the years 2020-2022. Given the impact of COVID-19 during this timeframe, it was discussed whether the research would provide the most applicable and effective findings compared to if the study was to process data from a period that has not been impacted by the pandemic.
- Based on the information provided by the Applicant, it was the view of the HRCDC that there is a strong public interest case and that it would not be feasible to obtain explicit consent.

Transparency measures and PPI engagement

- The HRCDC discussed the extent of the data to be processed within this study and the importance of ensuring there are sufficient transparency measures.
- The Applicant outlined that a study website is expected to be launched in June 2023 and that study information will be promoted on social media and relevant newsletters. The Applicant outlined that the website would not be launched until after the study has commenced, however it is not expected that RCSI would be provided with the dataset for analysis until after the website is launched. The HRCDC was of the view that data should not be transferred between the parties before the website has been launched. It was commented that the study and the website should also clearly outline the participant's data protection rights, including the right to withdraw and the process for withdrawal from the study, and any limits or derogations to such rights. It was also discussed that other transparency and communication activities should be explored.
- The HRCDC also discussed the level of PPI engagement in the study. It was noted that references were made to having engaged with PPI representatives on identifying the research question, combining the datasets and that PPI contributors will be involved with the study's oversight groups. Based on the information provided, it was not fully clear to the HRCDC who the PPI contributors were, with the contributors being described as 'co-investigator' and 'collaborator'. Given the extent of data to be processed, it was discussed that the study should ensure the inclusion of participant representatives who can provide the perspective on behalf of the participants cohort,

Data minimisation

- It was noted that the Applicant is due to run a pilot study using a dummy dataset, to establish what data is required to achieve the study objectives as well as the merging of the datasets. It was commented that the Applicant should update the committee of the results of the pilot as part of the Annual Review to inform the HRCDC of the final data that is used including if any additional data was required.

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	• Further, the HRCDC discussed that Applicant should ensure that the study adheres to principle of data minimisation principle. **Other** • The HRCDC noted the references made to the Trauma Research Network (TARN) in the application form and queried their role in this study. The Secretariat noted the response from the Applicant confirming that TARN is the system and methodology used to collect data for the National Trauma Audit. While TARN provides a service for the trauma audit, it is not a data controller or data processor in this specific research study. It was discussed that the processing of personal data for the purposes of audit does not fall under the remit of the Health Research Regulations or the consent declaration process. It was also noted that it is up to NOCA to ensure that the relevant agreements are in place with TARN regarding the National Trauma Audit. • It was commented that a formal procedure should be in place regarding participant withdrawal from the study. In addition, it was discussed that where a participant wishes to withdraw their data from this study then their data should be withdrawn where this is possible to do so, in the context of GDPR derogations and the feasibility of withdrawing the data at that point in the study • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, including submitting outstanding signatures, data protection officer feedback, confirmation of final REC approval and that the required data agreements/arrangements are in place.
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 November 2022 and shall be valid until 31st July 2030 (5 years after the study has concluded) or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** It is a condition of this declaration that the study website is launched and adequately promoted prior to the transfer and processing of participant data between the parties, and that there is a sufficient timeframe between the launch of the website and when the transfer of data occurs; for the avoidance of doubt participant data (whether personal/pseudonymised or anonymised data) cannot be transferred between the NAS, NOCA and/or RCSI before the launch of the website. Further to this, the website should provide clear information on the aims and objectives of the study, the data to be processed and clearly outline the participant's data protection rights, including the right to withdraw and how to exercise such rights. The website should also outline any derogations or limitations to data protection rights, if applicable, including at what point data cannot be withdrawn from the study if this is requested by the participant In addition to the study website, the Applicant is also requested to explore what other transparency measures and communications

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	activities could be implemented. *(Please see Condition 2 and Recommendation 1)* ***Note:*** While the transfer of 'real-world' participant data cannot occur before this condition is met, it does not prevent the transfer of the 'dummy dataset' that will be used in the pilot of this study. **Condition 2.** Further to Condition 1, where a participant wishes to withdraw their data from this study then their data should be withdrawn where this is possible to do so, in the context of GDPR derogations and the feasibility of withdrawing the data at that point of the study. When considering a participant's request to withdraw their data, all the joint data controllers (NOCA, NAS, RCSI) should therefore have due consideration on the feasible and practicable steps that can reasonably be taken to remove the participant's data at that stage of the study. **Condition 3.** The Applicant is requested to ensure that PPI engagement continues during the study and that those engaged are participant representatives who can provide the perspective and views of the study's patient cohort (i.e., trauma patients). The PPI engagement undertaken is a reporting requirement of the Annual Review. **Condition 4.** When obtained, confirmation of final and full research ethics committee approval must be provided to the HRCDC. The consent declaration will not be in effect until this condition has been met. **Condition 5.** An authorised signature on the consent declaration application form, and data protection officer feedback on the DPIA, on behalf of RCSI must be submitted to the HRCDC as soon as practicable and no later than 2 months from the date of this declaration. The consent declaration will not be in effect until this condition has been met. **Condition 6.** It is a condition of this declaration that the necessary agreements/arrangements governing the transfer and use of the data for this study are in place between the relevant parties. This includes relevant data sharing agreements and joint controller arrangements. No transfer of data can occur prior to the required agreements/arrangements being in place.
HRCDC Recommendations:	**Recommendation 1.** Further to study website and the withdrawal of data, the Applicant should ensure that a clear protocol is in place with regards participant withdrawal. **Recommendation 2.** The Applicant is requested to inform the HRCDC of the results of the pilot study using the 'dummy dataset' as part of the Annual Review. As part of this the Applicant is requested to inform the HRCDC of the changes, if any, that have made regarding the data used in this study that may arise from the pilot, including whether the study requires the inclusion of additional participant data. In addition, the Applicant is requested to adhere to the data minimisation principle and ensure that only the necessary data is processed for the purpose of this study.

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9. Amendment Procedure draft document

A document outlining a draft procedure with regards HRCDC amendment requests was circulated to the HRCDC in advance of the meeting. The Deputy Chairperson introduced the document, and the Secretariat provided an overview of the proposed procedure. The HRCDC discussed the proposed procedures and its potential impact on data controllers seeking an amendment to an existing consent declaration. It was the view of the HRCDC that the document provides a useful and clear procedure for amendment requests that will also provide clarity to Applicants. The HRCDC approved the procedure.

10. Remaining AF2 Applications

- The HRCDC were provided with summary information regarding the AF2 applications that have been submitted to the HRCDC, and information on those that remain pending consideration following the introduction of the amendments to the Health Research Regulations in January 2021.
- The Secretariat informed the HRCDC that, following the latest correspondence with two pending AF2 applications; 19-046-AF2 and 19-048-AF2, no response has been provided from the Applicants confirming that either (i) a consent declaration is no longer required, and the application is withdrawn or (ii) a consent declaration is required, and the application should proceed.
- The HRCDC discussed the proposal that 19-046-AF2 and 19-048-AF2 should be deemed withdrawn from the consent declaration process and therefore that they would not be considered. It was agreed by the HRCDC that 19-046-AF2 and 19-048-AF2 are deemed to have been withdrawn and it was noted that the Secretariat will inform the Applicants and their data protection officer.

11. Annual Reviews

The Secretariat has received 15 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-004-AF2;** Alistair Nichol, REMAP-CAP
- **Ref ID: 19-013-AF2;** Maeve Rooney, Omega Study
- **Ref ID: 19-016-AF2;** Cara Martin, CERVIVA HPV Primary Screening Pilot Study
- **Ref ID: 19-020-AF2;** Deirdre Murray, BASELINE Study *(the HRCDC were informed of the Applicant's progress on Condition 3 (i.e., reconsenting participants) which has been discussed with the Chairperson and that efforts are being made to progress this condition*).
- **Ref ID: 19-044-AF2;** Mark Little, Rare Kidney Disease Registry and Bioresource
- **Ref ID: 19-077-AF3;** David Galvin, IPCOR Study
- **Ref ID: 20-012-AF1/COV;** Cliona Ni Cheallaigh, COVID-19 Bioresource
- **Ref ID: 20-013-AF1/COV;** Ruben Keane, Solidarity Trial *(the HRCDC were informed that the Applicant's progress on Condition 1 (PPI engagement) was discussed with the Chairperson and a response has been agreed by the Chairperson).*
- **Ref ID: 20-027-AF1;** Ger Curley, Immune Dysfunction in Acute Brain Injury
- **Ref ID: 21-002-AF1;** Alistair Nichol, Mega ROX
- **Ref ID: 21-003-AF1;** Tom Rogers, Investigating the Epidemiology of *Mycobacterium bovis* infection in human
- **Ref ID: 21-007-AF1/COV**; Alistair Nichol, INPBS-COIVD 19
- **Ref ID: 21-009-AF1**; Mary McCarron, Support guidelines for dementia
- **Ref ID: 21-012-AF1**; Norman Delanty, Everolimus for drug-resistant Epilepsies

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- **Ref ID: 21-013-AF1;** Maeve Mullooly, Mammographic breast density and breast cancer outcomes in a population-based breast screening programme

12. Any Other Business

- The HRCDC were provided with an update on the arrangements for the December HRCDC meeting.
- The HRCDC were reminded to complete the poll for meeting dates in 2023 which will be finalised and circulated shortly.

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

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