HRCDC
Health Research Consent Declaration Committee

Date: 28th May 2024
Location: Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Aideen Hartney (Deputy Chairperson)
Alyson Bailey
Sheelah Connolly
Zubair Kabir
Dan Rea
John Woods
Susan Smith
Paul Stynes
Aisling McMahon
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Sharon O'Toole (TCD) & Antoinette Perry (UCD)	19-045-AF2/AMD2	The Gynaecological Biobank (formally the DISCOVARY Bioresource); collaboration with University College Dublin entitled 'Investigating the role of NKAPL in acquired chemoresistance in high-grade serous ovarian cancer'.

New Applications – For consideration

Applicant	Ref No.	Title
Dr Vincenzo Russotto	24-007-AF1	International observational study on airway management in operating room and non-operating room anaesthesia (STARGATE)

Meeting Items

1. **Opening**
   The meeting was chaired by the Deputy Chairperson, Aideen Hartney opened the meeting and welcomed the members. The Chairperson welcomed and introduced Dr Aisling McMahon as a new member of the HRCDC.

2. **Apologies**
   Brigid McManus (Chairperson), Evelyn Mahon, Kathy Brickell, Cornelius Cooney, Patricia O'Beirne, Mary Tumelty (Maternity Leave), Simon Furney, Barry Lyons, Caroline Byrne (Secretariat).

3. Disclosure of Interest

- **24-005-AF1 (Lung Health Check Pilot):** The HRCDC noted that Susan Smith (SS) had previously informed the Committee that she has worked with the researcher involved in this study, however she is not directly involved in the Lung Health Check Pilot. It was previously considered that there was no conflict of interest.
- **Chairperson approval 23-020-AF1/AMD1 (Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland: 2020 – 2022):** Zubair Kabir (ZK) noted that he has previously worked with the researcher involved in this study, however he is not directly involved in this study. It was considered that there was no conflict of interest.

4. Minutes of the last meeting

Draft minutes of 30th April 2024 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

Further to the general point discussion on 24-003-AF1 on 30th April HRCDC meeting, it was commented that the Secretariat's discretion on whether a new application could be considered by the HRCDC if common issues in the study information leaflets that were previously raised have not been fully addressed, would apply to any new application submitted for consideration. It was agreed that such Secretariat discretion should also extend to the issue of public and patient involvement (PPI), including whether PPI engagement has been undertaken in advance of submitting an application to the HRCDC.

6. 24-005-AF1: Applicant response to Conditions.

- In advance of the meeting, the HRCDC were provided with a note from the Secretariat on the Applicant's response to Condition 3 that requested changes to the study information leaflets with regards the optional collection of biosamples from patients attending their screening appointments.
- In their response, the Applicant provided additional information on the purpose of collecting the optional biosamples, which is to analyse for biomarkers to better detect lung cancer, describing this activity as an integral part of the Lung Health Check pilot. The Applicant also proposed the changes they will make to the study documentation as per Condition 3; specifically, they proposed providing further clarify on the purpose of collecting the optional biosamples, unbundling this information into a separate section of the study documentation, and using a separate consent page for the collection and use of samples for the biomarker analysis.
- The HRCDC discussed that the Applicant had provided much more clarity with regards the purpose of collecting and processing bio samples within this pilot screening study and it was the consensus of the HRCDC that the response to Condition 3 was deemed acceptable.

7. Chairperson Approvals

- **21-010-AF1/AMD1 *(AVERT DOSE).*** The HRCDC were informed that amendment request 21-010-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers (i) the change in data controller to the Florey Institute of Neuroscience and Mental Health, with all the named Irish hospital sites now data processors, (ii) the addition of Mayo University Hospital as a study site and (iii) to extend the duration of the consent declaration to 30th June 2025.
- **23-020-AF1/AMD1 *(Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland: 2020 – 2022).*** The HRCDC were informed that

amendment request 23-020-AF1/AMD1 was approved via the Chairperson approval process. The amendment request covers the extension of the consent declaration by 6 months to 31st December 2024.

8. Amendments

Reference ID:	19-045-AF2/AMD2
Lead Applicant:	Sharon O'Toole (TCD) & Antoinette Perry (UCD)
Lead Data Controller:	Trinity College Dublin (TCD) St James's Hospital Dublin (SJH) University College Dublin (UCD)
Title:	The Gynaecological Biobank (formally the DISCOVARY Bioresource); collaboration with University College Dublin entitled *'Investigating the role of NKAPL in acquired chemoresistance in high-grade serous ovarian cancer'*
Research Objective:	See HRCDC Meeting minutes of 14th December 2021 and 30th January 2024.
Purpose of Amendment:	Trinity College Dublin and St James's Hospital, the joint controllers of the bioresource/biobank, are aiming to undertake a new collaboration with University College Dublin, using the personal data and associated samples from approximately 100 patients that are held by the bioresource. This collaboration is titled: '*Investigating the role of NKAPL in acquired chemoresistance in high-grade serous ovarian cancer'*. The amendment is therefore sought to cover the processing of personal data from the bioresource/biobank for this new gynaecological cancer research collaboration. TCD, SJH and UCD are confirmed joint controllers on this specific collaboration.
HRCDC Comments:	The Chairperson introduced the amendment, and the Secretariat provided an overview of what is covered by the original consent declaration made for 19-045-AF1 and an overview of this specific collaboration that is the subject of this amendment request. The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment request should be approved. The HRCDC commented that this new collaborative study was in the public interest. It was also noted that UCD would return unused samples to TCD/SJH and delete the personal data obtained from the biobank at the end of this collaborative study in September 2029. It was discussed that this amendment would be valid until September 2029, however the consent declaration previously made for the biobank will continue until 2031, as per the original HRCDC decision. The HRCDC further discussed that this amendment would only cover this specific collaboration; other future studies would need to apply separately to the HRCDC for consideration; it was noted that this would be outlined in the scope of the decision letter. In addition to the transparency measures outlined in the amendment form, including providing information on this

	collaboration via the TCD biobank website, it was commented that the researchers should consider implementing further transparency measures, for example by providing a link to the TCD website on other suitable websites. On data security, the HRCDC noted the measures that will be in place to store and transfer data, including the use of secure platforms and passwords. It was also discussed that the required data agreements and arrangements should be in place prior to data and biosample transfer. The HRCDC also discussed and commented on the number of a participants who will be included in this collaboration and the scope of the amendment.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** The required appropriate data and material agreements, including joint controller arrangements, must be put in place between the parties for this specific collaborative study; personal data and associated biosamples cannot be transferred prior to the necessary agreements being implemented. **Condition 2.** The study website should be updated to inform and provide information on this new collaboration between St James's Hospital, Trinity College Dublin and University College Dublin. This aligns with Condition 6 of the original consent declaration *(Please also see Recommendation 1)*
HRCDC Recommendations:	**Recommendation 1.** In addition to providing information on this collaboration on the TCD website, the researchers could consider exploring and implementing further transparency measures to inform participants and the public about this study, for example by proving a link to the TCD study webpage on other suitable websites such as other ovarian cancer groups or similar groups.

9. New Applications

Reference ID:	24-007-AF1
Lead Applicant:	Dr Vincenzo Russotto
Data Controllers:	University of Torino
Title:	International observational study on airway management in operating room and non- operating room anaesthesia (STARGATE)
Research Objective:	More than 230 million major surgical procedures are carried out under general anaesthesia each year worldwide. The safe management of the airway remains a major challenge in these patients, while complications arising from these procedures can be very severe, and can include, low blood pressure, low oxygen levels, leading to cardiac arrest, severe brain injury and even death. Researchers do not have robust data on the frequency of major complications arising from management of the airway in people undergoing major surgical procedure.

	The primary aim of the STARGATE study is to assess the current incidence of major adverse events during advanced airway management in anaesthesia in patients undergoing planned or emergency surgery performed in the operating room or in other locations within the hospital (such as radiologic suites, and the emergency room). The secondary aim of STARGATE is to assess the current practice of airway management during anaesthesia worldwide.
Reason for Declaration:	This study involves the processing of personal data of prospective patients who will be treated in the hospital. The Applicant outlines why it is not considered feasible or appropriate to obtain explicit consent for this study which includes the practical challenges to obtain consent given that eligible participants will be identified and enrolled at multiple different locations in the hospital and also due to concerns relating to scientific value and potential study bias.
HRCDC Comments:	***The minutes of the discussion for this application will be updated and published once the HRCDC have completed their deliberations.***

10. Annual Reviews

For Discussion: 23-003-AF1 (CADY Sub-study/MACE)

- The HRCDC were provided with a Secretariat note on the Applicant's Annual Review response to Condition 3 which related to enhancing the level of transparency for this study.
- The Applicant outlined that, following the PPI engagement feedback it has received, other methods of communicating with participants such as through media or social media channels would not be appropriate. The Secretariat also noted that Cancer Trial Ireland (CTI) website does not provide clear information on this sub-study.
- The HRCDC were asked to consider whether, based on the PPI feedback, the study does not need to further enhance transparency measures and that Condition 3 could be deemed to be met, subject to providing information on the sub-study on CTI's own website.
- The HRCDC noted the PPI feedback and commented that it related and referred to enhanced transparency measures such as media and social media accounts which would not be targeted at the participants involved in this sub-study. The HRCDC agreed that measures such as these would not need to be implemented, however, to meet Condition 3 the sub-study should be noted on other relevant websites such as cancer patient or other cancer group websites. It was discussed that this could include providing a link on other relevant websites to the CTI's on sub-study webpage.

The Secretariat also received 8 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 20-006-AF1 (A randomized double-blind placebo-controlled trial of Intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness)
- **Ref ID:** 19-023-AF1 *(Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis)***
- **Ref ID:** 20-035-AF1 (IV Zanamivir Effectiveness Study)
- **Ref ID:** 19-027-AF3 (*Identification of predictive and prognostic biomarkers in triple negative breast cancer)*

- **Ref ID:** 22-001-AF1/CSO *(Study of the impact of lifestyle factors on COVID-19 outcomes)*
- **Ref ID:** 20-010-AF1/COV *(COVID IYON study)***
- **Ref ID:** 21-010-AF1 *(AVERT DOSE)*
- **Ref ID:** 20-039-AF1 *(A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock)***

***Consent Declaration no longer required.*

11. Overview of annual review process

The Secretariat provided an overview of the process for requesting and review consent declaration Annual Reviews and outlined proposed changes to improve and streamline this process. The HRCDC noted this information and approved the new process.

12. Activities report and events of interest.

The Secretariat presented on the recent information sessions for researchers held by the Secretariat. Five in person events were held and representatives from many of the research institutes in Ireland attended. Feedback was generally positive from the researchers.

The Secretariat also circulated a report of its activities for April and May 2024 to the HRCDC in advance of the meeting.

****The Chairperson closed the meeting****

Following the closure of the meeting, the HRCDC attended a presentation from the Department of Health on the latest developments of the European Health Data Space (EHDS).