

**Date:** 2<sup>nd</sup> March 2021  
**Location:** Videoconference

## Minutes of the Meeting

### HRCDC Attendance

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

**Quorum for Decisions**  YES

### New Applications for Amendments to current Consent Declarations - For Consideration

Applicant	Ref No.	Title
David Galvin	19-077- AF3/AMD1	IPCOR Study
Ignacio Martin-Loeches	19-086- AF1/AMD1	Sepsis Immunosuppression in Critically Ill Patients

### New Applications - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-038-AF1/COV	RECOVERY-Respiratory Support - <b><i>This application was withdrawn in advance of the meeting</i></b>
Bairbre McNicholas	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
Professor Patrick Sheahan	21-001-AF1	Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)

## Meeting Items

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**1. Opening**

The Chair opened the meeting and welcomed the members.

**2. Apologies**

Kathy Brickell

**3. Disclosure of Interest**

Application 21-001-AF1: Zubair Kabir (ZK) disclosed that study's Principal Investigator is a colleague of his but he had no role in this specific study. It was agreed there was not a conflict of interest that required abstaining from the discussion on this application. ZK comments on this application were provided last, after other members comments.

**4. Minutes of the last meeting**

Draft minutes of the 26<sup>th</sup> January 2021 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

**5. Matters arising/actions from previous HRCDC meeting**

The Secretariat provided an update to the HRCDC with regards to HRCDC Application 20-035-AF1 (IV Zanamivir Effectiveness Study). It was noted that responses from the Applicant to the HRCDC's queries remained pending and that an extension has been provided.

**6. Amendments**

Reference ID:	19-077-AF3/AMD1
Lead Applicant:	David Galvin
Lead Data Controller	New Data Controller: University College Dublin (UCD) Current Data Controller: Clinical Research Development Ireland (CRDI)
Title:	Irish Prostate Cancer Outcomes Research (IPCOR)
Research Objective:	See minutes of 25 <sup>th</sup> June 2020.
Purpose of Amendment:	Data collection for this project is completed and the IPCOR dataset is currently held by the data controller CRDI. CRDI will be wound down by the end of April 2021. There is no other dataset of its kind for prostate cancer in Ireland and it is important for cancer research in Ireland that the IPCOR dataset currently held by CRDI would be available beyond the end date of the IPCOR project and the winddown of CRDI. To enable this to happen within an appropriate data governance framework, the dataset must be transferred to another data controller. UCD, one of the CRDI partners, and the institution associated with the Principal Investigator, will become the data controller for the IPCOR dataset. The Applicant requests an amendment to the existing consent declaration for the following: <ul style="list-style-type: none"> <li>- change of data controllership from CRDI to UCD</li> <li>- transfer of the IPCOR dataset to UCD (this includes the clinical data obtained from the National Cancer Registry of Ireland (NCRI) and the patient reported outcomes (PROMs) data)</li> </ul>

	<ul style="list-style-type: none"> <li>- aligned with the original declaration, the continued analysis and processing of the data by UCD for the purpose of the IPCOR study,</li> <li>- the continued storage of data.</li> <li>- obtaining updated survival data from NCRI</li> </ul>
HRCDC Comments:	<p>The Secretariat provided an overview of the reasons for seeking an amendment to the existing consent declaration. The Chair requested each HRCDC member to indicate whether the request for the amendment should be approved.</p> <p>It was the consensus of the HRCDC that the amendment to the consent declaration decision would be made.</p> <p><b>Transparency and Withdrawal of Data</b></p> <ul style="list-style-type: none"> <li>• Aligned with Recommendation 2 of the current consent declaration, when the data is transferred to UCD the HRCDC discussed the importance of ensuring that participants continue to be made aware of the study and that participants can continue to exercise their data protection rights, including the right to withdraw.</li> <li>• The HRCDC noted that the intention was to maintain the IPCOR website and was of the view maintaining and updating the website was important for the study Information on the transfer of the data to UCD should be clearly noted on the website.</li> <li>• It was noted that the Applicant has stated that the IPCOR website has a contact form for participants to use should they wish to withdraw from the study to exercising their data protection rights. However, upon examination of the website it was not clear to the HRCDC where this form was located and therefore how participants can exercise their data protection rights.</li> </ul> <p><b>Research Ethics Committee approval</b></p> <ul style="list-style-type: none"> <li>• The HRCDC discussed whether formal REC approval is required for the transfer and continued processing of the IPCOR from CRDI to UCD.</li> </ul> <p><b>Transfer of data</b></p> <ul style="list-style-type: none"> <li>• The HRCDC discussed that appropriate contractual arrangements governing the transfer and use of data must also be in place between UCD and CRDI and NCRI with regards to the transfer of the IPCOR data to UCD and the provision of updated survival data. This is aligned with Condition 1 of the current consent declaration.</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>• It was discussed that going forward, the NCRI will only continue to retain the link between the NCRI and IPCOR ID codes and no other IPCOR data.</li> </ul>
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration can be amended as requested by the Applicant.
Amendment Duration	The Amendment is made commencing 2 <sup>nd</sup> March 2021 and shall be valid until 31 <sup>st</sup> July 2020 and for five years thereafter (until 31 <sup>st</sup> July 2025) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.

	(This timeline is in line with the duration of the consent declaration)
Conditions Attached:	<p><b>Condition 1.</b> The Applicant must ensure that strong transparency measures, including those outlined in the initial HRCDC application, continue to be implemented by the new Data Controller UCD and, should be further strengthened to ensure that participants can continue to be made aware of this study and how they can exercise their data protection rights. Specifically, it is a condition of this amendment approval that the following actions are undertaken as soon as possible by the Applicant:</p> <ul style="list-style-type: none"> <li>(i) The IPCOR study website must continue to be maintained and updated by the new data controller, UCD.</li> <li>(ii) Information with regards the change in controllership and transfer of data to UCD must be visible and clearly communicated on the IPCOR website.</li> <li>(iii) The IPCOR website and other transparency measures must clearly outline to participants how they can continue to exercise their data protection rights including the right to withdraw from the study. It must be transparent how requests from participants who wish their exercise their data protection rights will be facilitated. This includes the visibility of and ease of access to the contact form on the IPCOR website should a participant wish to withdraw, as referenced by the Applicant.</li> </ul> <p>This condition is a reporting requirement of the Annual Review.</p> <p><b>Condition 2.</b> The HRCDC request confirmation that ethics approval, has been granted to the transfer of the data to UCD. As part of this condition, any requirements arising from the REC review and how these requirements have been met, must be provided to the HRCDC.</p> <p><b>Condition 3:</b> It is a condition of this amendment approval that appropriate contractual arrangements are in place between the new data controller UCD, and CRDI and NCRI with regards the transfer of the IPCOR data to UCD and the provision of updated survival data.</p>

Reference ID:	19-086-AF1/AMD1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St James's Hospital
Title:	Sepsis Immunosuppression in Critically Ill Patients
Research Objective:	See minutes of 2 <sup>nd</sup> March 2020
Purpose of Amendment:	The Applicant requests an amendment to the existing consent declaration to cover additional processing activities to be undertaken by the data processor Dalhousie University in Canada, for the purpose of this study.
HRCDC Comments:	<p>The Secretariat provided an overview of the reasons for seeking an amendment to the existing consent declaration. The Chair requested each HRCDC member to indicate whether the request for the amendment should be approved.</p> <p>It was the consensus of the HRCDC that a decision should be deferred pending receipt of further information.</p>

	<p><b>Scope of additional processing activities</b></p> <ul style="list-style-type: none"> <li>• Based on the information provided, it was not clear to the HRCDC what specific processing activities will be undertaken by the Canadian data processor on the bio-samples and associated data, and how this new activity relates to the original study. Specifically, it was not clear what analysis will be undertaken, what additional data will be generated and if this activity fell within the scope of the original study.</li> <li>• The HRCDC was of the view that in order to fully determine degree of public interest and ensure the research activity was not a new study, further information should be provided by the Applicant outlining the scope of the additional processing activities and how this relates to the study.</li> </ul> <p><b>Research Ethics Committee (REC) approval</b></p> <ul style="list-style-type: none"> <li>• From the information provided, it was not clear if REC approval is in place for the additional data processing activities to be undertaken in Canada. The HRCDC discussed that it would be appropriate to request formal confirmation that ethics approval has been granted and covers this new activity within the existing study.</li> </ul> <p><b>Public and Patient Involvement</b></p> <ul style="list-style-type: none"> <li>• The HRCDC discussed that the consent declaration made for the main study had attached a condition to strengthen the level of PPI however, no response to this condition has yet been provided</li> <li>• It was discussed that the conditions already attached to the consent declaration remain applicable and that this can be re-iterated to the Applicant should the amendment be made.</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>• The HRCDC discussed that transparency measures should be updated where possible, to inform participants and their next-of-kin that biosamples and data may be transferred to Canada as part of the study.</li> <li>• It was also noted that the Applicant had submitted a draft material and transfer agreement. The HRCDC commented that no transfer of data and biosamples should occur until the appropriate agreements governing the transfer and use are in place between the data controller and the data processor. In addition, the data controller will need to take into account the additional requirements for transferring data outside the EEA as outlined in the GDPR.</li> <li>• The HRCDC commented that only the minimal amount of accompanying data should be transferred with the biosamples, in line with the principle of data minimisation.</li> <li>• From the information provided, it was noted that all remaining biosamples, will be destroyed or returned to the data controller, once analysis by the Canadian data processor is complete. All the data generated will also be destroyed by the processor once it has been received by the data controller, St. James' Hospital.</li> </ul>
HRCDC Decision:	The consensus of the HRCDC was that that a formal decision would be deferred pending receipt of further information.

Further Information Requested:	<p>The HRCDC request further detailed information on the following:</p> <p><b>Query 1:</b> The HRCDC was of the view that there was insufficient information provided to determine if the amendment request can be approved. Therefore, to help determine the public interest in the additional processing activities, the Applicant is requested to provide further information clearly outlining the additional processing activities that will be undertaken by the data processor in Canada for the purpose of the Sepsis Immunosuppression in Critically Ill Patients study. Specifically, information is required on the types of analysis that will be undertaken, the data that will be generated by the new processor and how this relates to the objectives of the original study.</p> <p><b>Query 2.</b> The HRCDC must be satisfied that this additional processing activity falls under the remit of the 'Sepsis Immunosuppression in Critically Ill Patients' study and not a new, separate study, and that REC approval is in place for this additional activity. The Applicant is therefore requested to provide formal confirmation that research ethics approval is in place for the additional processing activity to be undertaken in Canada and whether this is covered by way of the original REC approval for the Sepsis Immunosuppression in Critically Ill Patients study or an amendment to this REC approval.</p>
HRCDC Comments	Given the time sensitive nature of this amendment request, the HRCDC discussed that the responses from the Applicant can be considered by written procedure. However, if required the HRCDC can convene an early meeting to make a final decision.

### 7. New Applications

Reference ID:	20-039-AF1
Lead Applicant:	Bairbre McNicholas
Lead Data Controller:	Galway University Hospital
Title:	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock
Research Objective:	Blood pressure (BP) is a vital parameter and maintaining an adequate BP is one of the most fundamental tenets of management of shock. It is a decision that Intensive Care Unit (ICU) clinicians make every time they assess such patients and it is plausible that their decisions regarding BP targets may directly impact on outcomes of those patients. Conventional practice often results in a varying degree of untreated relative hypotension that is inadvertently accepted in real world setting. Minimizing such variation by targeting a patient's own basal BP can be a simple strategy or a management approach that can potentially improve outcomes. This approach has never been tested in a randomized controlled trial (RCT) among ICU patients with shock and is needed to influence strength of recommendations regarding choice of BP targets for vasopressor support. This study will compare standard care to a strategy of targeting patients usual pre-illness blood pressure (BP) during management of shock in ICU. Eligible patients will be randomly assigned to either standard care (control) or a strategy of individualized BP target (intervention). The intervention and the BP

	<p>monitoring in the study will last until a patient is not requiring breathing support or does not require invasive BP monitoring catheters. The choice and the dose of BP-titrating medication will be at the discretion of the treating clinician. Data will be collected on the degree of untreated BP deficit, peak rise in serum creatinine and serum cystatin levels, protocol compliance, recruitment rate, death, and major adverse kidney events (MAKE) during the first 14 days. The study will also collect information on hospital mortality and incidence of any major complications. These clinical outcomes and the data on achieved-BP will be compared in between the two groups to assess feasibility and efficacy of the intervention in relation to the standard care.</p>
<p>Reason for Declaration:</p>	<p>A consent declaration is required to process the personal data of participants who lack the decision-making capacity to provide explicit consent for the purpose of this specific study.</p> <p>Processing activities include access, collection, pseudonymisation and subsequent transfer/uploading of data, including of follow-up data, to the electronic Case Report Form (eCRF) for analysis by the study sponsor University of Newcastle, New South Wales, Australia. The declaration also includes the storage only of personal data for future research purposes.</p>
<p>HRCDC Comments:</p>	<p>The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent.</p> <p>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:</p> <p><b>Public Interest</b></p> <ul style="list-style-type: none"> <li>• The HRCDC discussed the aims and objectives of the study including the small number of participants who will be recruited to the study, a small proportion of which will be recruited from Irish hospital sites. It was commented that the aims, objectives and methodology of the study outlined in the application form, could have been more clearly described by the Applicant. It was also queried if the small number of participants would provide sufficient and meaningful data with regards the management of blood pressure during shock.</li> <li>• From the information provided in the research protocol document, the HRCDC noted and discussed that this was a feasibility study to inform a future RCT on blood pressure management.</li> <li>• Considering the nature of the research area and that the study aims to inform a larger, future research trial, on balance it was the consensus of the HRCDC that there was a strong public interest case for undertaking this study.</li> </ul>

## **Research Ethics Committee (REC) Approval**

- The HRCDC noted that REC approval from Galway University Hospital was granted by the Chair of the REC which was to be ratified at the next REC meeting. It was discussed that it would be appropriate to request the Applicant to confirm that formal ratification has occurred.
- It was further noted that REC approval for two other research sites, Beaumont Hospital and St. Vincent's University Hospital remained pending. The HRCDC discussed that the consent declaration can only cover the research sites where REC approval has been granted.

## **International transfer of data**

- The HRCDC discussed the roles of the Australian parties within this study, which includes the University of Newcastle as the study sponsor, the sponsor's monitor and the George Institute for Global Health as the data custodian. It was noted that the Secretariat had sought further clarity on the roles of the Australian parties, however the HRCDC commented that the Applicant could have more clearly outlined the roles of the Australian parties, the extent of data transferred outside of Ireland and the safeguards and legal basis for such transfers.
- From the information provided by the Applicant, it was noted that the Australian parties are not joint controllers of this study and that their roles focus on the aggregation and analysis of study data.
- It was further highlighted by the Applicant that the data collected and pseudonymised at the Irish sites and subsequently transferred for analysis, is anonymised to the recipient and that no access to personal, identifiable information is provided to the Australian parties.
- On the legal basis for the transfer of data outside of the EEA, the HRCDC noted the references made to transferring data on the basis of public interest, approved codes of conduct, standard contractual clauses and contracts between the Irish sites and the University of Newcastle in Australia. The HRCDC discussed that the appropriate legal basis and contractual arrangements must be in place between the relevant parties transferring study data, including to parties located outside of the EEA, and that contractual arrangements should include terms and conditions and ensure the anonymity of the participants.

## **Withdrawal of consent**

- The HRCDC discussed the protocol in place should the individual providing proxy assent, or the participant, wish to withdraw from the study and the options for what will happen their personal data in such a scenario. From the information provided, it was noted that if assent/consent is withdrawn then the data will be destroyed or that permission will be requested to continue to retain and use the pseudonymised collected up to that point.
- The HRCDC also queried if the next-of-kin and, in particular, the participant when they regain capacity, would feel undue or unintentional pressure to permit the continued processing of the data

already collected if they wished to withdraw, given the small number of participants involved and the impact their withdrawal may have on the study.

- The HRCDC commented that information on withdrawing from the study and options for what will happen the personal data should be consistent and clear in all study documentation provided to both the next-of-kin and participants and that particular care should be given to avoid pressurising participants to permit the continued processing of their data if they wish to withdraw from the study.

### **Study Information leaflets**

- The HRCDC discussed the study information leaflets and assent/consent forms submitted by the Applicant and was of the view that these documents should be revised to add clarity and transparency for participants and/or their relatives, to ensure consent/assent is fully informed.
- For example, the study information leaflets state that the intervention is within the standard of care and treatment. The HRCDC commented that if there are identifiable risks associated with this treatment such as risks associated with high blood pressure, these risks should be outlined to relatives and the participant. It was commented that the 'Surviving Sepsis' guidelines should be used to identify and comment on any potential risks.
- It was also noted that the terms 'assent' and 'consent' are used interchangeably and incorrectly at times in information leaflets. Similarly, the terms 'personal data' and 'pseudonymised data' are used interchangeably,
- Other areas highlighted by the HRCDC that require clarity included information provided on the storage of data for future use and the number of study participants to be recruited.
- The HRCDC commented that the assent form should ascertain the participant's will and preference as to whether they wish to be included in a research study.
- The HRCDC was also of the view roles and responsibilities of the Australian parties should be clearly outlined, including clarity on the type of data that is transferred.

### **Patient and Public Involvement and Transparency**

- The HRCDC discussed that PPI in research is considered an important data protection safeguard. Obtaining and drawing from PPI perspectives and experiences can inform and improve data protection measures such as transparency of the study and participants data protection rights.
- From the information provided, it was noted that PPI activity had commenced to seek perspectives from patients that had been treated in the ICU, regarding research. The HRCDC queried if PPI could be leveraged to explore enhancing more general transparency measures within the ICU setting.

### **Data Minimisation**

	<ul style="list-style-type: none"> <li>• Considering the principle of data minimisation, the HRCDC discussed whether the 15 year data retention period was necessary and if it could be reduced</li> <li>• In addition, the HRCDC was of the view that the minimal amount of data should be transferred to Australia for analysis for the purpose of this of this study.</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>• The HRCDC queried whether this study would fall under the recent amendments that were made to the Health Research Regulations. The Secretariat noted that it is up to the data controller to determine if their study falls under any of the amendments or if a consent declaration is required.</li> </ul>
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Decision	The Declaration is made commencing 2 <sup>nd</sup> March 2021 and shall be valid until 2 <sup>nd</sup> March 2022 and for 15 years thereafter (until 2 <sup>nd</sup> March 2037) or upon confirmation that explicit consent has been obtained or the personal data have been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	<p><b>Condition 1.</b> The HRCDC notes that Research Ethics Committee (REC) approval for this study has been granted by the Chair of the Galway University Hospital (GUH) REC, which is to be formally ratified at the next meeting of the REC. It is a condition of this consent declaration that full REC approval must be granted by the GUH REC for this consent declaration to come into effect. Any matters raised or actions required by the GUH REC must be addressed by the Applicant and any responses provided to the HRCDC. Evidence of full REC approval from Galway must be provided to the HRCDC as soon as possible in order for the consent declaration to become effective.</p> <p><b>Condition 2.</b> Linked to Condition 1, this consent declaration only covers data processing at the research sites that have been granted full REC approval. Confirmation of full REC approval from Beaumont Hospital and St. Vincent’s University Hospital, that currently remains pending, must therefore be provided to the HRCDC once available, for the consent declaration to cover these sites.</p> <p><b>Condition 3.</b> All appropriate contractual arrangements must be in place with the relevant parties to govern the transfer and use of data for the purpose of this research study. Robust terms and conditions should be set out to safeguard the anonymity of the research participants. For international transfers of data to Australia, the data controller must also ensure that such transfers are done in compliance with Chapter V of the General Data Protection Regulation (GDPR). It is advisable to consult with the Data Controller’s DPO on this matter to ensure the appropriate legal basis for international transfer of personal data is used</p> <p><b>Condition 4.</b> In line with the principal of data minimisation, only the minimal amount of data required for the purpose of this study should be transferred for analysis to the Sponsor and the data custodian in</p>

Australia. No identifiable data should be transferred to, or accessed by, these parties, such that the data remains fully anonymised to the recipient. The Applicant is also requested to consider whether the data retention period of 15 years is necessary and can be reduced to a shorter timeframe.

**Condition 5.** The Applicant must ensure clear and consistent information is provided to the individuals providing assent on behalf of the participants that lack decision-making capacity, and the participant with regards withdrawing from the study and the options available for what will happen their personal data should they wish to withdraw. Given the small numbers of participants in this study, particular care should also be given to avoid unduly or unintentionally pressurising participants or their assenting relatives to permit the continued processing of personal data if they wish to withdraw from the study.

**Condition 6.** The HRCDC requests that the study information leaflets, and assent/consent forms are reviewed and amended to ensure clarity, transparency and consistency of information for participants and/or individuals providing assent. In this context the following observations were made by the HRCDC:

- (i) For correctness, *relative or next-of-kin 'consent'* for data processing should be replaced with *'assent'*, when referring to a proxy individual providing assent on behalf of the research participant. Correspondingly *'consent'* should only be used when engaging directly with the research participant. It is important to ensure these terms are not used interchangeably. Assent is an important data protection safeguard but has no lawful basis for data processing.
- (ii) References to 'your relatives' data should be removed where appropriate from the participant's study information leaflet,
- (iii) Different information on the storage and future use of data is outlined, with one document referring to future research relating to lung infections and the other future research on sepsis. The Applicant should ensure that clear, informed and consistent information is provided to both participants and individuals providing assent with regards the storage and processing of data for future research and the areas of research that maybe undertaken,
- (iv) It is noted that there are references to the University of Newcastle, Canberra as opposed to New South Wales. The roles of the Australian parties within this study and extent of the data that will be transferred to Australia should be clear and consistent,
- (v) The information leaflets state that 'pseudonymised' and 'personal' data will be shared/transferred to Australia, however other sections state that 'personal data/information' will not be shared. Under GDPR pseudonymised data is considered personal data. It should be clearly outlined that pseudonymised or coded/de-identified data, is provided to the parties in Australia, and shall be anonymised to the recipient,

	<p>(vi) Amend the information leaflets to state that 50, not 30, participants will be included in this study</p> <p>(vii) The assent form should be positively framed to ask the individual providing assent if the will and preferences of the research participant are known and whether they would wish to be included in the research, as opposed to asking if they are aware of any objections,</p> <p>(viii) The Applicant is requested to ensure that the relevant potential risks of the study have been appropriately outlined in the study information leaflets. Specifically, the HRCDC discussed that there are likely to be identifiable potential risks from high blood pressure that could be outlined. The relevant 'Surviving Sepsis' clinical guidelines should be used to identify and comment on any potential risks.</p>
Recommendation	<p><b>Recommendation 1:</b></p> <ul style="list-style-type: none"> <li>The HRCDC recommends that the Applicant continues to engage with PPI representatives to leverage their perspectives and experiences to inform and improve upon data protection measures such as greater transparency measures within the ICU setting in general.</li> </ul>

Reference ID:	21-001-AF1
Lead Applicant:	Prof. Patrick Sheahan
Lead Data Controller:	South Infirmary Victoria University Hospital (SIVUH) St. James' Hospital, Dublin (SJH)
Title:	Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)
Research Objective:	<p>There is currently no international consensus on the optimal approach to Human Papilloma Virus (HPV) testing in oropharynx squamous cell carcinoma (OPSCC - throat/tonsil cancer) and at least a minority of patients are misclassified as having HPV positive disease. Accurate assignment of HPV status in OPSCC is essential given the improved prognosis of patients with HPV associated tumours, divergence in staging for HPV positive and negative cases and potential differences in patient management.</p> <p>The College of American Pathologists (CAP) currently recommends the use immunohistochemistry (IHC) as a method to test for the p16 protein biomarker for HPV in OPSCC. However, they acknowledge that in low prevalence populations this approach may be suboptimal. In contrast the Royal College of Pathologists (RCPath) in the UK recommend additional testing of all p16 positive cases, usually performed by DNA in-situ hybridization (ISH). This approach can greatly improve overall testing specificity but has significant cost and resource implications. The main concern with the use of p16 IHC alone in moderate prevalence populations such as Ireland and the UK is the risk of false positive results.</p> <p>The objective of the study is to establish the optimal approach to HPV testing for OPSCC in Ireland, the analysis will be based on comparison of survival outcomes and cost effectiveness of the testing approaches. Involvement of the 2 biggest Head and Neck Cancer Centres in the</p>

	country (SJH and SIVUH) will ensure that the study is adequately powered and consequently based on the results a national recommendation/guideline for HPV testing in OPSCC will be developed. The study will predominantly take the form of a retrospective chart review, but with the additional step of retrospective HPV RNA in situ hybridization (ISH) testing of the p16 positive cases, which will be performed on existing tissue blocks. This is a new test which only became commercially available in Ireland in 2020 and reportedly has very high sensitivity and specificity.
Reason for Declaration:	A consent declaration is required as the Applicant states it is not feasible to obtain the explicit consent of participants. The data processing activities for the above referenced study includes access, collection, pseudonymisation, transfer and storage of personal data. Once the data collection is completed the data will be irrevocably anonymised prior to statistical analysis.  The data to be processed is that already obtained for care and treatment and data associated with and generated from pre-existing bio-samples. Follow-up survival data will also be collected during the course of the study.
HRCDC Comments:	<b><i>The minutes of the discussion for this application will be updated and published once the HRCDC have completed their deliberations.</i></b>
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.

## 8. Annual Reviews of Declarations

The Secretariat has received 3 Annual Reviews in advance of the meeting of which all 3 were deemed to be complete:

- 19-022-AF2: TILDA
- 19-038-AF3: The Genomic Basis of Alzheimer's disease in Ireland
- 19-043-AF3: TILDA GRO

## 9. HRCDC Annual Activities Report for 2020

The Secretariat provided a draft of the HRCDC's 2020 Annual Report for submission to the Minister for Health, a requirement under the Health Research Regulations. In advance of finalising the report before submission to the Minister, the Committee were invited to submit feedback and comments.

## 10. Activities Report

Emily Vereker (EV) provided an overview of the Activities Report which was provided to the HRCDC.

## 11. Any other Business

- The HRCDC were informed of a recent publication from the European Data Protection Board (EDPB); 'Publication of opinion on GDPR as it applies to Health Research'. It was noted that the EDPB references consent as a suitable data protection safeguard.  
[https://edpb.europa.eu/sites/edpb/files/files/file1/edpb\\_replyec\\_questionnaire\\_research\\_final.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_replyec_questionnaire_research_final.pdf)

- The HRCDC were provided with a letter from the Minister for Health in relation to the appointment of new members to the Committee and acknowledging the work of the HRCDC to date. Members of the HRCDC appreciated the positive feedback and thanks received from the Minister.
- The Secretariat informed the HRCDC of the decision made by the Office of the Information Commissioner's (OIC) regarding an FOI request that was submitted to the HRCDC in 2020 (<https://www.oic.ie/decisions/right-to-know-clg-and-hea/index.xml>)
- The Secretariat noted that responses have been received from some Applicants whose application are consideration by the HRCDC. Specifically, after considering the recent amendments to the Health Research Regulations, some 'AF2 Applicants' have confirmed that a consent declaration was still required. The Secretariat highlighted that in cases where the study had not obtained consent that was compliant under the previous data protection legislation, that the Applicant will be requested to outline a public interest case as is required under the Regulations. Subject to the number of new applications submitted and the responses from Applicants, it was noted that the HRCDC will aim to consider AF2 applications at the next available meeting where possible.
- The HRCDC where informed of two upcoming events that may be of interest:
  - National Office for NRECs: Webinar on a National System of Research Ethics Review (11<sup>th</sup> March 2021, 11:00am-12:00pm)
  - The Royal Irish Academy: The role of Irish Bioethics: (re(building) trust and reasonable discourse in medicine, science and technology (15<sup>th</sup> April 2021, 11:25pm-17;30pm)

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