HRCDC
Health Research Consent Declaration Committee

Time: 10.30am - 17.00pm
Date: 25TH July 2019
Location: Grand Canal Hotel, Grand Canal Street Upper, Dublin 4

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Claire Collins
Sheelah Connolly
John Ferguson
Simon Furney
Aideen Hartney
Zubair Kabir
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions ☒**YES**

Declarations considered at this meeting:

Applicant	Ref No.	Title
David Williams	19-001-AF3	INAES-2
Aideen Hartney	19-009-AF3	Moving in Study

Applications considered at this meeting:

Applicant	Ref No.	Title
Alistair Nichol	19-003-AF3	TEAM
Alistair Nichol	19-004-AF2	REMAP
Alistair Nichol	19-007-AF2	TAME
Alistair Nichol	19-008-AF2	TTM2

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the Members. Caroline Byrne (CB) was introduced and welcomed to the Secretariat. The Chair and Members recognised the contribution of CB's predecessor, Shirley Murphy (SM), in supporting the early establishment of the HRCDC. SM was thanked for the work she had undertaken over the previous months and the HRCDC wished her the best in her future role.

2. **Apologies**
   Prof. Evelyn Mahon, Ms. Kathy Brickell, Prof. Bert Gordijn, Prof. Malcolm Kell and Prof. Barry O' Sullivan were not present.

3. Disclosure of Interest

Dr. Aideen Hartney (AH) disclosed her interest in relation to Agenda Item 4.2 (19-009-AF3, "Moving In Study") and was absent for this part of the meeting.

There was one disclosure of interest by Kathy Brickell (KB) covering each of the four applications for consideration; 19-003-AF2 "TEAM Study"; 19-004-AF2 "REMAP Study"; 19-007-AF2 "TAME Study" and 19-008-AF2 "TTM2 Study". KB was absent for the meeting.

A disclosure of interest form was completed by AH and KB and submitted to the Secretariat for record purposes.

4. Minutes of the last meeting

Draft minutes circulated in advance of the meeting, were discussed and agreed subject to a minor amendment for clarification. The Chair reminded the HRCDC that the minutes will be made available on the website.

5. Validation checklist cross checked with regulations requirements

The Chair introduced the updated validation checklist that will be used by the Secretariat in the application triaging process. JB highlighted changes made which now cross-references the requirements of the Health Research Regulations (HRRs) which are now cited within the document and provided in an accompanying reference list.

It was noted that the validation checklist is intended as a tool for the Secretariat and HRCDC to ensure Applicant's address the requirements outlined HRRs and satisfy the HRCDC, as part of the decision making process, that such requirements have been addressed. The Secretariat will update the website with the new checklist for Applicant's to view.

6. Previous Declarations for discussion:

Reference ID:	19-001-AF3
Lead Applicant:	David Williams
Data Controller:	Royal College of Surgeons in Ireland (RCSI)
Title:	INAES-2
Application Summary:	See HRCDC Meeting minutes 13.06.2019
Points to Discuss:	• The Applicant responded to the HRCDC decision letter of 27th June 2019 confirming acceptance of the HRCDC's decision. The Applicant further requested advice from the HRCDC in relation to the requirement to adhere to the conditions of the declaration once the master list has been destroyed by the end of October 2019, at which point the Applicant stated in the letter that they considered the data to be anonymised.
HRCDC Comments:	• The HRCDC reaffirmed that all conditions of a declaration must be met for the duration of the declaration, including Condition 2, relating to PPI engagement. • The HRCDC noted from the response letter, that the Applicant considered that the data (the subject matter of application 19-001-AF3) will be irrevocably anonymised once the master list has been destroyed. The anticipated date of destroying the master list is October 2019. The HRCDC agreed that it is the responsibility of the data controller to determine when data is deemed anonymised.
HRCDC Decision	• Based on the information provided by the Applicant, the HRCDC agreed to amend the duration of the declaration from 7 years - and amend to 31st October 2019. • The HRCDC clarified that Condition 2 remains unchanged and the Applicant must report on this condition when submitting the Annual

	review, due on the anniversary of the date the declaration came into effect.

Reference ID:	19-009-AF3
Lead Applicant:	Aideen Hartney
Data Controller:	National Disability Authority
Title:	Moving in Study
Application Summary:	See HRCDC Meeting minutes 13.06.
Points to Discuss	• The Applicant responded to the HRCDC decision letter of 27th June 2019. The Applicant outlined the challenges of meeting Condition 1 whereby the HRCDC requested confirmation of an extension of the research ethics approval from St. John of God (SJoG) within a short timeframe of 15 working days. Given the next SJoG Research Ethics Committee (REC) meeting is in September, this condition cannot be met.
HRCDC Comments:	• The HRCDC acknowledged the impracticalities of meeting the deadline to confirm REC approval for the SJoG site, given that the timelines and processes of the REC were beyond the control of the Applicant. As the approval from SJoG has expired the, HRCDC considered that data processing related to this site should not be undertaken until REC approval has been extended.
HRCDC Decision	• The consensus of HRCDC was to amend Condition 1 such the Applicant must provide written confirmation of REC approval to the HRCDC, with no deadline attached. The HRCDC further agreed that until Condition 1 is met, data processing should not be undertaken at the SJoG site.

7. New Applications for consideration

Reference ID:	19-003-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TEAM
Application Summary:	The aim of the TEAM study is to evaluate the effect of early activity and mobilisation during prolonged invasive mechanical ventilation (IMV). Patients who are critically ill are treated in ICUs, and receive IMV to help with their breathing, which is a lifesaving intervention. However, this intervention, confines patients to their beds for long periods of time and is associated with poor recovery of physical function and severe muscle weakness. This is called intensive care unit acquired weakness (ICUAW). Though many patients recover, not all return to the same level of function as before their illness. Exercising patients while they are still receiving IMV, or early mobilisation, has been proposed as a strategy to prevent ICUAW.
Purpose of Application:	A consent declaration is requested as the model for obtaining consent from subjects in this study is initially based on a Relative's Deferred Assent to collect and process the patient's data, followed by obtaining deferred/delayed 'Subject Consent to Continue' to collect and process

	their data. The patient's data will be processed for research purposes at the start of the study without specific explicit consent from the subject as the patient is sedated and is not able to give informed consent upon entry into the study.
HRCDC Comments:	The Chair introduced the research study and highlighted that as 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 for this research study. After discussing the application in detail, based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Patients who do not regain capacity** • The HRCDC had concerns regarding patients who may not regain capacity to provide consent, after a prolonged period of time, and where next-of-kin assent still remains in place. It was noted that the Data Protection Impact Assessment (DPIA) stated that were such a situation to arise, the enrolled patient will continue to participate in the research and subsequently their personal data will continue to be processed. The HRCDC acknowledged this situation has not yet arisen in the research study, as participants have either regained capacity or are deceased. • The HRCDC recommended that next-of-kin assent could be reaffirmed at appropriate time points where patients have been in-capacitated for a prolonged period. Where follow-up activities are undertaken by the Applicant, these could provide opportunities to re-confirm relative assent and thus act as an additional safeguard to further protect the data rights of the patient. **Transfer of Data** • It was noted that an agreement between Monash and SVUH is awaiting execution of the legal agreement, which was scheduled for June 2019. • The HRCDC considered that data transfer agreements must be in place as an appropriate safeguard and that confirmation from the Applicant is required. A declaration will not cover the transfer of data as a form of data processing until such agreements are in place. **Ethical Approval** • It was noted that REC approval is not yet in place at one of the research sites. Any declaration made would not extend to the research site where ethical approval was not in place. However, the Applicant can make a request for an amendment to a declaration at a later date requesting that the declaration scope be extended to include the other research site once research ethical approval has been obtained. • The Secretariat explained that any amendment requests would be considered at a meeting of the HRCDC. As part of the process the Applicant would be required to confirm that the research study scope and

	purpose has not changed and that the relevant safeguards are in place at the new research site. **Consent forms** • The HRCDC commented that the consent forms used by the Applicant could have more clearly set out the separate aspects of the research study and data processing, which may enhance the user experience of consent forms and avoid confusion for the data subject. It was noted that best practice under GDPR, is that consent should be layered if appropriate. **Next-of-Kin Assent** • Some queries were raised regarding the fact that personal data is collected before next-of-kin assent can be obtained; It was noted that next-of-kin consent was obtained within 72hrs of admission. It was considered that under emergency care situations, it may be inappropriate to request next-of-kin assent immediately after patient admission, given the stressful situation for the next-of-kin. It was noted that early data collection was essential as part of the initial screening and randomisation of patients for inclusion in the study, including the generating of a pseudonymised study identification number. Data was not uploaded to the study database until next-of-kin assent was obtained. **Data Retention** • The Applicant referred to the General Clinical Practice (GCP) guidelines as the rationale for why personal data, including the master list, will be retained for 15 years after the conclusion of the study. It was queried whether this 15 year period was appropriate and/or necessary in the context of data protection; particular reference was made to the master list linking patient names and contact details with the study ID number. • The HRCDC recommended that the length of time for data and master list retention be reviewed. **Other discussion points** • It was acknowledged that the Applicant had pro-actively engaged with the Secretariat, to ensure the HRCDC was fully informed of the research study. • The HRCDC acknowledged that the Applicant had submitted four distinct applications for separate research studies for consideration at this meeting. A number of similarities existed across the applications including the model of consent, data retention protocols and reasons for seeking a declaration. Thus, some HRCDC observations on application 19-003-AF2 were applicable to 19-004-AF2, 19-007-AF2 and 19-008-AF2. • The HRCDC acknowledged the complex subject matter of each application and suggested that the application could have simplified the subject matter for ease of review by the HRCDC. • It was acknowledged that whilst there was no requirement to consider a public interest case, the HRCDC did commend the research study as being in the public's interest.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.

Conditions Attached:	The following specific conditions have been attached to the declaration as follows; **Condition 1:** The HRCDC has requested that all appropriate contractual arrangements (legal agreements) must be in place with the relevant institutions, regarding the transfer of personal data for the purpose of the research study. This is a safeguard that the HRCDC has requested and therefore confirmation that these agreements must be provided to the HRCDC. Until this confirmation is received the declaration will not cover the processing activity of transferring data. **Condition 2**: Confirmation of Research Ethics approval from the Tallaght University Hospital site must be provide to the HRCDC, once granted. No data processing can commence at this site until such written confirmation is provided to the HRCDC. **Condition 3:** The HRCDC has requested that, where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the following action should be taken as an additional safeguard: The Applicant should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study 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.
Duration of Declaration:	The declaration is made commencing August 8th, 2018 and shall be valid until 2021 and 15 years thereafter (until August 31st, 2036), or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner.
Other HRCDC observations/ Recommendations:	**Recommendation 1:** The HRCDC recommended a review of the consent forms and patient information leaflets used by the Applicant, to ensure there is clarity for the participants and those assenting on their behalf, regarding all aspects of the research study and data processing. Specifically, the Applicant should consider an appropriate layered consent approach to ensure informed assent and consent is obtained. **Recommendation 2**: The HRCDC has recommended that the 15 year data and master list retention period, be reviewed to determine whether the retention period could be shortened and master list be destroyed within a shorter timeframe. The Applicant is required to report on the review of the data retention policy when submitting the annual review to the HRCDC.

Reference ID:	19-004-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	REMAP-CAP
Application Summary:	This study aims to find the most optimal treatment for severe Community-acquired pneumonia (CAP) in the adult Intensive Care Unit (ICU) population. In comparison to a conventional trail, it combines a number of novel design features and has been termed a Randomised, Embedded,

	Multifactorial Adaptive Platform trail. These features are designed to enhance the efficiency of trial conduct, generate new knowledge more quickly, and improve outcome for participants within the trial
Purpose of Application:	A consent declaration is requested as the model for obtaining consent from subjects in this study is initially based on a Relative's Deferred Assent to collect and process the patient's data, followed by obtaining deferred/delayed 'Subject Consent to Continue' to collect and process their data. The patient's data will be processed for research purposes at the start of the study without specific explicit consent from the subject as the patient is sedated and is not able to give informed consent upon entry into the study.
HRCDC Comments:	The Chair introduced the research study and noted that there were similarities to the research protocols described in 19-004-AF2 and 19-003-AF2. Thus, some of the discussion points would apply to this application, 19-004-AF2. However, it was highlighted that each application should be considered on its own merits, based on the specific information provided. The Chair requested each HRCDC member to indicate whether a consent declaration should be made for this research study. After discussing the application in detail, based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration could be made. It was further agreed that the declaration would mirror the declaration made for 19-003-AF2, including conditions and recommendations, as the discussion points for 19-003-AF2 were applicable to this application. In making this decision the following points were also raised and discussed by the HRCDC: **Study length** • Some reservations were expressed about the 'open-ended' and 'perpetual' nature of the research study questions, as described by the Applicant, which may continue beyond the data collection timeframe. As a point of information, the Secretariat highlighted the section of the application which stated that current expected duration of the study which is linked to the expiration of the current grant. • It was noted that the length of a declaration made would align with the research study duration and any subsequent archiving of the data, and therefore have an exit strategy. It was discussed that if the research study was extended, e.g. by way of additional grant funding, the Applicant may apply to the HRCDC for an amendment to the declaration. **Data transfers** • The HRCDC noted that more institutions are involved in this research study compared to the previous application (19-003-AF2), including those outside the EU. It was noted that multiple partners resulted in an unclear data flow pathway. The importance of appropriate data transfer agreements between the collaborative parties was reiterated. • The HRCDC were not clear from the information provided, whether identifiable personal data, such as patient name, is stored locally and not

	shared with the collaborative parties. The HRCDC requested confirmation from the Applicant that this information is stored locally. **Other discussion points:** • It was stated that the research study methodology is an innovate approach that is not usually undertaken in Ireland and, although a public interest case is not required for this application, as per the Health Research Regulations, they felt that the research was of public value.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Conditions Attached:	The following specific conditions have been attached to the declaration as follows; **Condition 1:** The HRCDC requested that all appropriate contractual arrangements (legal agreements) must be in place with the relevant institutions, regarding the transfer of personal data for the purpose of the research study. This is a safeguard that the HRCDC has requested and therefore confirmation that these agreements must be provided to the HRCDC. Until this confirmation is received the declaration will not cover the processing activity of transferring data. **Condition 2**: Confirmation of Research Ethics approval from sites currently awaiting approval (Beaumont Hospital and University Hospital Galway) must be provided to the HRCDC, once granted. No data processing can begin at these sites until such written confirmation is provided to the HRCDC. **Condition 3:** The HRCDC has requested that, where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the following action should be taken as an additional safeguard: The Applicant should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study 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. **Condition 4:** The HRCDC has requested confirmation that personal identifiable data, such as name, date-of-birth, are stored locally at the Hospital site of the patients, and not transferred to the collaborative parties.
Duration of Declaration:	The Declaration is made commencing August 8th, 2018 and shall be valid until 2021 and 15 years thereafter (until August 31st, 2036), or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner.
Other HRCDC observations/ recommendations	**Recommendation 1:** The HRCDC recommended a review of the consent forms and patient information leaflets used by the researchers, to ensure there is clarity for the participants and those assenting on their behalf, regarding all strands of the research study and data processing. Specifically, the researchers should consider an appropriate layered consent approach to ensure informed assent and consent is obtained.

	Recommendation 2: The HRCDC has recommended that the 15 year data and master list retention period, be reviewed to determine whether the retention period could be shortened and master list be destroyed within a shorter timeframe. The Applicant is required to report on the review of the data retention policy when submitting the annual review to the HRCDC

Reference ID:	19-007-AF2
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital
Title:	TAME Cardiac Arrest
Application Summary:	The TAME Cardiac Arrest Trial is a definitive trial in cardiac arrest patients whose heart has been restarted and who are on a breathing machine in the intensive care unit. This trial will determine whether increasing carbon dioxide to above normal levels [so-called targeted therapeutic mild hypercapnia (TTMH)] during the first 24 hours on a mechanical ventilator in the intensive care unit improves brain recovery at 6 months compared to current standard care.
Purpose of Application:	This research study will involve the collection and processing of patient data prior to the research team being able to obtain consent from the data subject; this is due to the nature of the patient's condition and lack of capacity to provide explicit consent. Instead next-of-kin consent is obtained. A declaration is therefore sought in relation to the processing of personal data until such time that the patient regains capacity and provides explicit consent directly to the research team.
HRCDC Comments:	The Chair introduced the research study and it was again noted that clear parallels could be drawn between application 19-007-AF2 and the previous applications considered (19-003-AF2 and 19-004-AF2). Thus some of the discussion points would again apply to this application, 19-007-AF2. The HRCDC noted the additional 'biobank sub-study' for the collection of blood samples for biomarker analysis. Although the consensus of the HRCDC was that there was a favourable disposition towards making a declaration, there was broad consensus that further information is required from the Applicant. Therefore, a formal decision would be deferred pending receipt of further information from the Applicant. The decision was based on the following discussion points: **Biobank Sub-study** • The HRCDC discussed whether this 'sub-study' should be subject to its own individual HRCDC application given the scope of the processing activities that were related to the sub-study, such as: 1) the collection and storage of the blood samples and 2) the use of the samples for future research. This is set out in the consent forms and patients information leaflets. It was noted the sub-study forms part of the larger TAME research study, where samples are collected from the patients who are taking part in the TAME research study. It was further acknowledged that analysis of the

	bio-samples to investigate biomarkers is a collaboration between the institutions noted as the data controllers for the TAME research study. • The HRCDC discussed the scope of a declaration and confirmed it would be specific to the TAME research study biobank sub-study element within it. A declaration would not cover the further processing of the biobank samples for further research outside of the scope of TAME research study. Consent for any such 'future use' or processing should be sought, or where appropriate subject to a separate HRCDC application. • It was noted that a declaration is only made where explicit consent has not been obtained from the patient; once the patient regains capacity and provides consent or withdraws from the biomarker element of the TAME study then the declaration will no longer be valid. A declaration is only requested to cover data processing up until this point. • The HRCDC considered that the Applicant should provide confirmation that a single declaration for the TAME biobank and biomarker research element is appropriate. **Data Storage:** • The HRCDC were of the view the data processing activities and data flow relating to the biobank and biomarker 'sub-study' was not clear from the information provided. Specifically, where data will be stored, how data will be processed by each collaborative institution noted in the application and future access to the samples and data in the biobank, including whether the data will be transferred out of the Ireland. • It was commented that the language used in the consent form provided a limited explanation of the future use of the biobank samples as it combined the collection and retention of bio-samples as a form of processing with the general term 'future use'. **Consent:** • Further concerns were raised that consent forms were confusing and possibly overly complicated given the separate processing activities. It should be more explicit that there are different research strands within the TAME research study. • It was acknowledged by the HRCDC that the issue of consent form design and compliance was outside the remit of the HRCDC and that legislation provides for the use of broad consent. • It was recommended that future consent forms should be revised to ensure participants are fully consider informed of all research strands within the research study. Additionally, it was considered that participants provide signatures indicating consent to different data processing and research activities.
HRCDC Declaration Decision:	It was the consensus of the HRCDC that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	The HRCDC requested the following information from the Applicant: • Clarity on the governance structures of the biobank and associated data that will be processed. Specifically, details on the storage and retention of data as it pertains to the biobank.

	• Clarity of the transfer of biobank data among the institutions noted and possible future uses (data flow), specifically the Applicant should outline what safeguards are in place regarding data transfers. • The Applicant should confirm that one declaration is can cover processing activity of the biobank sub-study. • It is not clear from the review of the consent forms whether participants or next-of kin are fully informed of data protections rights for the biobank sub-study. Specifically, the HRCDC wish to understand whether the consent forms and information leaflets are deemed to be 'bundling' the biobank sub-study into the main TAME research study.

Reference ID:	19-008-AF2
Applicant:	Alistair Nichol
Title:	TTM2
Application Summary:	The TTM2 Trial is a definitive trial in cardiac arrest patients in the intensive care unit (ICU), whose heart has been restarted and who are in. This study aims to determine whether initial hypothermia (cooling to 33C initially with rewarming to normal body temperature) during post resuscitation care in the intensive care unit improves recovery at 6 months compared to current standard care, in patients who have been resuscitated following an out of hospital cardiac arrest. The findings will allow doctors to make informed decisions about which target temperature is better for patients and potentially promote a shift in clinical practice towards cooling patients with rewarming
Purpose of Application:	This research study will involve the collection and processing of patient data prior to the research team being able to obtain consent from the data subject; this is due to the nature of the patient's condition and lack of capacity to provide explicit consent. Instead next-of-kin consent is obtained. A declaration is therefore sought in relation to the processing of personal data until such time that the patient regains capacity and provides explicit consent directly to the research team.
HRCDC Comments:	The Chair introduced the research study. It was recognised That there were clear parallels between application 19-008-AF2 and the previous application, 19-007-AF2. The HRCDC agreed that the majority of the discussion points and matters raised during the consideration process for 19-007-AF2 are applicable to this application. Although the consensus of the HRCDC was that there was a favourable disposition towards making a declaration, there was broad consensus that further information is required from the Applicant. Therefore, a formal decision would be deferred pending receipt of further information from the Applicant. The decision was based on the following discussion points: **Biobank Sub-study** The HRCDC noted the additional 'biobank sub-study' that involved the collection of blood samples for biomarker analysis. The HRCDC discussed whether this 'sub-study' should be subject to its own individual HRCDC application given the scope of the processing activities that were related to the sub-study. **Data transfer and governance**

	• Whilst the data flow is clearer in this application, however the HRCDC required further clarity regarding the flow of data between the collaborative partners. • The HRCDC had similar queries in relation to the governance of the biobank and access to the biobank and wished for further clarity. **Consent** • The HRCDC considered that follow-up contact with the patient or next-of-kin provides an opportunity for the Applicants to and re-confirm consent going forward for the biomarker and biobank sub-study. • Again, it was considered that the consent form did not distinguish the different elements of the research study sufficiently. However, it was again acknowledged that the issue of consent form design and information leaflet content is outside the remit of the HRCDC. **Research Ethics** • It was noted that the start date of the research study did not appear to align with the date of the Research Ethics approval letter submitted by the Applicant. It was therefore unclear from the REC letter when approval or provisional approval was granted and if the letter provided was the original approval document. The HRCDC stated that the Applicant should confirm when REC approval was granted and provide the relevant documentation.
HRCDC Declaration Decision:	It was the consensus of the HRCDC that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	**Point 1**: Based on the information provided to the HRCDC, the start date of the research study did not appear to align with the date of the Research Ethics Committee (REC) approval letter submitted by the Applicant. It was unclear from the REC letter when approval or provisional approval was granted and if the letter provided was the original approval document. The HRCDC wish to receive confirmation when REC approval was granted and provide the relevant documentation. **Point 2:** Clarity on the governance structures of the biobank and associated data that will be processed. Specifically, details on the storage and retention of data as it pertains to the biobank. **Point 3:** Clarity of the transfer of biobank data among the institutions noted and possible future uses (data flow), specifically the Applicant should outline what safeguards are in place regarding data transfers. **Point 4:** The Applicant should consider if a separate declaration is needed for the processing activity associated with the biobank sub-study and provide clear rationale regarding their decision. **Point 5:** It is not clear from the review of the consent forms whether participants or next-of kin are fully informed of data protections rights for the biobank sub-study. Specifically, the HRCDC wish to understand whether the consent forms and information leaflets are deemed to be 'bundling' the biobank sub-study into the main TTM2 research study.

8. Appeals process:

The Secretariat updated the HRCDC on the appeals process that Department of Health (DOH) had developed. In summary, the Appellant has 30 working days to submit an appeal and any corresponding supporting documents. The DOH have 40 days from the submission of the appeal to establish an independent appeals panel. JB outlined that the appeals process will take the form of a *de novo* process. The HRCDC through the Secretariat will be informed of the decision of the appeal panel by the DOH. The decision will be published on the HRCDC website.

9. Activities Report

EV provided an overview of the Activities Report which was provided to the HRCDC. EV noted that the HRCDC website has been updated with further information to guide potential Applicants. Specific reference was made to the guidance for Applicants.

EV and JB referred to the recent clarification received from the DoH; Applicants can submit an application for a consent declaration where they have made reasonable efforts to re-consent data subjects but where they have received no response.

10. Any other Business

a. FOI Training - The Chair informed the HRCDC that Kevin Clarke (KC) is the appeals officer for FOI decisions being appealed. A second HRCDC member may be appointed as a stand-in appeals officer should KC not be available. The Chair and the Secretariat provided a brief description of the FOI training they had received on July 22nd. The high quality of the training provided was recognised. The Chair informed the HRCDC that the majority of records can be requested under FOI, subject to considerations in relation to personal data and commercial sensitivities. The Chair suggested that the FOI trainer could be invited to present at the next HRCDC meeting.

b. Decision time - JB reminded the HRCDC to sign the iPad usage policy and thanked them for their time and patience during the set-up of the software and devices. JB provided an update on the technical issues that Decision Time are working to resolve. the HRCDC were asked to forward any feedback or issues or suggest any areas they would like to receive training on. Issues with using hyperlinks within Decision Time and working offline were raised at the meeting; Members were informed that an on-site training session is provided as part of the software package and that help videos can be accessed on the iPad. The HRCDC were reminded and encouraged to read the short guidance document that had been forwarded by email. iPads will be updated at appropriate time points.

c. Update on applications logged to date - The Secretariat confirmed that 63 applications have been submitted. The Secretariat are awaiting updates from Applicants on another three applications that were submitted earlier in the year.

d. HRCDC Expenses - The HRCDC were provided with an update on the payment of expenses and Secretariat thanked them for their patience with delays.

e. Training for HRCDC: The Chair suggested that the HRCDC could benefit from presentations from individuals with subject matter expertise, for eg. Biobanking experts, Ethics. The Secretariat will assist with identifying an appropriate speaker for HRCDC training purposes.

11. Date of next meeting

The HRCDC was reminded that the next meeting will be hold on September 10th, 2019, located at the Grand Canal Hotel