|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 16 March 2021 |
| **Meeting venue:** | Via Zoom Meeting ID: 965 0758 9841 |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.15pm | Confirmation of minutes of meeting of 16 February 2021 |
| 1.30pm | New applications (see over for details) |
| 1.30-1.55pm  1.55-2.20pm  2.20-2.45pm  2.45-3.10pm  3.10-3.20pm  3.20-3.45pm  3.45-4.10pm  4.10-4.35pm  4.35-5.00pm | i 21/NTA/33  ii 21/NTA/34  iii 21/NTA/35  iv 21/NTA/36  *Break (10 minutes)*  v 21/NTA/37  vi 21/NTA/38  vii 21/NTA/40  viii 21/NTA/41 |
| 5.00pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Mrs Kate O'Connor | Lay (consumer/community perspectives) | 29/01/2020 | 29/01/2021 | Present |
| Dr Kate Parker | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Ms Rochelle Style | Lay (ethical/moral reasoning) | 14/06/2017 | 14/06/2020 | Present |
| Ms Catherine Garvey | Lay (the law) | 19/03/2019 | 19/03/2022 | Present |
| Dr Sotera Catapang | Non-lay (observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Michael Meyer | Non-lay (health/disability service provision) | 11/02/2020 | 11/02/2023 | Present |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Karen Bartholomew.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 16 February 2021 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **21/NTA/33** |
|  | Title: | Hydrolysed meat in residential aged-care |
|  | Principal Investigator: | Miss Xiaojing Wu |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 05 March 2021 |

Xiaojing (Sharon) Wu and Anna Miles were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. A study to test a hydrolysed meat product in aged care facilities with elderly residents with dysphagia. The trial will last for 6 weeks and will assess if higher protein meal is more palatable than the usual fresh cooked pureed food and has nutritional benefits in the study population.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that the application was previously declined because the researchers wanted to include participants who are not competent to consent but their argument for best interest case did not support this.
2. The Committee asked how significant the proportion of the population they wish to study who will come into the category of severe cognitive impairment. The researcher confirmed that only a small number fit into this category and that 90% of the group will have some element of cognitive impairment but will be able to give supported consent.
3. The Committee asked for confirmation on the number of age care facilities that the researchers intend to include in the study. The researchers confirmed that two facilities will be included in the study. The Committee stated that facilities involved in the study will need to be very clear in terms of the identifiable information that they can provide the research team on the participants and the process for this. For example, access to and use of identifiable data for secondary purposes (i.e. research) needs to be part of the consent, supported consent or the subject of a waiver.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted that the Researcher has resubmitted the application with inclusion of age-care facility patients with severe cognitive impairment, who will not be able to consent to participation. The Committee asked how participating in the study could be considered in the best interests of those recruited who cannot consent. The researchers stated that participation would provide a benefit from the greater nutritional content and palatability of the hydrolysed meat (higher protein) and improved safety due to texture of the product which makes it easier to swallow and reduces the prospect of choking. The researchers further stated that they have run tests and held focus groups with the results supporting these claims. The Committee stated that the documentation submitted for this application needs to reflect the researcher’s verbal argument for best interests for the portion of participants who cannot consent and resubmitted to the HDEC for review.

Please amend protocol to reflect updated best interest argument for severe cognitive impairment and upload the data and analysis evidencing this (specifically summary results of palatability focus group and increased safety data).

1. The Committee noted that the protocol makes no distinction between degree of impairment where supported consent might be possible, and those who are severely impaired where consent is not possible (and best interests case applies). The Committee asked how the supported consent process will work. The researcher clarified that it will be a combination of a speech therapist who has the skills to enable understanding in those who are compromised; and a family member who will have the best knowledge of the individual’s specific communication and comprehension style. The Committee requested that this process be included in the protocol.
2. The Committee requested that the researchers document the procedures for determining capacity of participants to consent; who will qualify for supported consent and who will qualify for best interests’ case. The supported consent procedure should include who will be assisting them to consent. The procedure for severely impaired people should include how the clinical managers will assess and sign off for best interests on an individual basis, including seeking an opinion from family on what the potential participant would want if arguing best interests.
3. The Committee noted that the study involves hands on engagement with facilities staff and participants at the age-care facilities. However, the Committee stated, there is insufficient information for facility staff on the practicalities involved, what they will be required to do as well as what the process is for them to share resident’s information with researchers.

The Committee recommended developing a terms of engagement document describing their role in the study, including a plan for how problems will be managed with facility staff when they arise.

1. The Committee asked researchers to clarify what specific participant records they are referring to in the data management plan as “clinical records”. The researchers confirmed that access to records will be restricted to facility care records and GP records. The Committee recommended that the researchers update the documentation to more clearly describe, what records will be accessed, who will access them, why and when.

Please include the information detailed above in all of the information sheets including the newly developed facility staff information sheet.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the various participant information sheets and consent forms to address the matters raised by the Committee
2. The Committee stated that the information sheet for partially impaired participants was a good example of how the information should be set out and suggested using it as a template for the other participant information sheets.
3. Create a separate document for each participant with severe cognitive impairment, taking into account the context of the individual and that participating in the study is in their best interests in accordance with Right 7 (4) of the Code of Patients’ Rights. This document should be signed by the person who is making the decision under Right 7 (4) and record the basis upon which the decision has been made in accordance with that Right.
4. Please ensure all PISs mention that the participant’s GP will be informed of their participation and that the clinical team and GP will be provided with a summary of results. Please detail if it is the individual participant’s results or the results of the study.
5. Please undertake a thorough proofread of all information sheets for spelling, grammar and formatting errors.
6. Please amend the Assent Script to mention accessing the participants medical records (as per the communication impaired PIS), that they can stop at any time, that the GP will be informed, and include risk/s in blood extraction and BIA (pain, bruising etc.).

Residents PIS/CF

1. Please consider using simple language in non-impaired PIS similar to PIS for the cognitively impaired participants which is straightforward but contains reasonable detail.
2. Please include that participants can ask for help from family, whānau, friends and health care provider for their decision making (for non-impaired). Please also include the need to sign the consent form if they decide to participate in the trial.
3. Please amend the resident information sheet to include participant and/or individuals’ rights to correct their data as per National Ethical Standard 12.15a.
4. Please transfer the following statements “Taking part in this study is your choice. There will be no change in your care at home whether you take part or not. If you take part in the study and change your mind later, you can withdraw from the study anytime” to the section on “what are my rights”.
5. Please include the inclusion/exclusion criteria under “who can take part in the study.”
6. Please include the following in “what will participation in the study involve” section;
   * Name of the procedure and its purpose (shown in the picture and other measurements) for participants to understand what is involved in the study.
   * Include Table 1 in the protocol to facilitate understanding of the time frame/schedule of study activities.
   * Specify the risks involved in the procedure like pain or bruising.
7. Please provide more information on the researchers – e.g. some detail about expertise, perhaps a photo given the close engagement they will have with residents.

Facilities PIS/CF

1. Please amend the facilities information sheet to include the role of the facilities staff in the study and how problems will be managed when they arise.
2. Please amend page 3 of facilities information sheet as next of kin cannot consent.
3. Please provide more information about the researchers given the close engagement they will have with facilities staff.
4. Please consider providing more detail about when the researchers will attend (per the communication impaired PIS).
5. Please provide Maori health support contact details on page 6.

Families/Friends PIS/CF

1. Please remove the word “supported” throughout the participant Information sheet and consent form for family/friend.
2. Please check family/friend PIS for copy and paste errors. E.g. page 2 mentions “your aged care facility”.
3. Please update the families PIS and consent form to clarity that they cannot consent and tailor the information to assist with supported consent. E.g. “ I hereby state that I think that my relative/friend would have consented to take part in this study if they had the capacity to decide and I support their participation”
4. Please review the form and amend the statements that refer to the family member taking part in the study as they will not be a participant. E.g. “I understand the research team will advise the facility nurses and *my* GP of any incidental findings of my friend/relative. E.g. “…If *you and your family member agree* to take part in this study”.

Decision

This application was *provisionally approved* by consensus, subject to the following information being received:

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheets and consent forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Catherine Garvey and Dr Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **21/NTA/34** |
|  | Title: | The Feasibility and Acceptability of Match Emoji. |
|  | Principal Investigator: | Mr Russell Pine |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 March 2021 |

Russell Pine was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. The Feasibility and Acceptability of a Casual Video Game with Mental Wellbeing Concepts Among Year 9 and 10 Students. Classroom based recruitment (n=40), game played a few times a week, pre-post pysch/wellbeing measures and game play analytics.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee considered if it was appropriate for the 13-15-year-old participants to consent for themselves rather than gaining consent of parents. The consensus of the Committee (with one member disagreeing) was that is appropriate for the parents to consent and the participants to assent.
2. The Committee asked how any mental health issues identified from the questionnaire results would be followed up. The researcher stated that these participants would be referred to the school counsellor/support, as per usual school process, who have the appropriate skills and process to assess the individual’s needs, and would consult with parents and agree a joint referral to a health professional where required. The Committee was comfortable with this approach and recommended that it is made clear to the participants upfront of this potential procedure.
3. The Committee acknowledged that a data management plan has been developed for this study, however it was uploaded after the agenda cut-off date and has not been reviewed by the Committee.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee asked for clarity on where the participants’ data analytics for the game will be captured, who will have access to it and how the privacy of participants will be safeguarded. The researcher confirmed that the game is on the Unity platform and will not be downloaded using an app store (contrary to the uploaded documentation). The researcher advised that they are working through a more secure approach to keeping the participants’ data unidentifiable to third parties. The approach the researchers now intend to adopt is to download the game to the university database where the participants can access it via a link rather than downloading it individually themselves. Once the participant has accessed the game from the link, they will be given a unique study number, by the researchers, that can be matched to their data usage. The Committee were comfortable with this change in approach to protecting participant’s privacy and requested this change is reflected in the study documentation. Please update the protocol with more information on the Unity platform, the privacy safeguards and the role of any other third party that will have access to the identifiable data.
2. The Committee advised of the requirement to provide an independent peer review for the study protocol. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26). Please provide an independent peer review using the template and guidance on the HDEC website - <https://ethics.health.govt.nz/guides-templates-forms-0/scientific-peer-review-submissions-%E2%80%93-guidance>
3. The Committee requested that the protocol and participant information sheets are updated to include the following information about the study;
   1. Detailed information about the game
   2. Where and when the interviews will be conducted, including how the confidentiality of participants will be protected, whether participants can read and correct answers.
   3. Explanation of the cultural aspects of the study, if applicable
   4. The Committee suggested uploading a CV for one of the supervisors involved in the study.
4. The Committee noted that the researcher verbally advised that as well as doing a presentation to year 9 and 10 students, they may also hold a similar event for parents. The Committee agreed this was a good idea and recommended that the researcher ensure the procedures and documentation are completed first. This will enable them to use participant information sheets as a script to ensure the information that is being shared in these forums is accurate and consistent. The Committed requested that the detail on the presentations that both the students and parents will be receiving is provided to them for review.
5. The Committee stated that confidentiality may be slightly more difficult to protect in this study because the kids at school are likely to know who is participating in the research (depending upon who turns up to the presentation and where the interviews will be conducted). The Committee requested that this is made clear to the participants and parents.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee suggested that the Researchers use the HDEC participant information sheet template (<https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>). In particular, it is important to expand on the information concerning the management of participants’ data, and risks
2. Provide more information about the nature of the game.
3. Include where and when the interviews will be conducted and how the confidentiality of participants will be protected, and whether participants can read and correct answers.
4. Provide detail on the presentation that both the students and parents will be receiving.
5. Please make it clear that the completion of the surveys or use of the tool will not result in a medical diagnosis and will not result in treatment.
6. Please outline the mental health referral pathway.
7. Proofread all documentation for spelling and grammatical errors (e.g. replace occurrences of “ascent” with “assent”).
8. PISs should state whether Match Emoji is free.
9. Please correct the statements in the PISs that only the researchers will know the participants names as this is not accurate.
10. Please give the Youthline and other help numbers greater prominence on the forms.
11. Please transfer the confidentiality rider from the footnote to the main body.
12. Data must be kept for longer than five years, please amend this in the forms.

Decision

This application was *provisionally approved* by consensus, subject to the following information being received:

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the various information sheets and consent/assent forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
* Please note that the Data Management Plan, not reviewed by the Committee at the time of its meeting, will be considered and comments made on it, including requiring possible amendments if the Plan does not comply with the *National Ethical Standards for Health and Disability Research and Quality Improvement*.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Rochelle Style and Dr Michael Meyer.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **21/NTA/35** |
|  | Title: | Parapneumonic effusion and empyema: aetiology and clinical outcome evaluation in Canterbury. |
|  | Principal Investigator: | Dr Margot (J.M.) de Koning Gans |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 04 March 2021 |

Margot (J.M.) de Koning Gans and Mike Maze was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. This prospective cohort study aims to assess the current aetiology, participants’’ characteristics, complications, (new) biomarkers, outcomes of treatment, and quality of life in participants with parapneumonic effusion or empyema, to be able to better understand and see the opportunities for improving diagnostics and outcomes in future patients with empyema and parapneumonic pleural effusion.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried whether the biomarker testing would interfere with the participant’s care. The researcher answered that this would not be the case.
2. The Committee noted that the research would be of no individual benefit to the participant.
3. The Committee asked about the recruitment process. The researcher clarified that the treating clinician would approach patients to ask for consent to be involved in the study. The patients will have 72 hours to consider it before being asked to give an answer. Patients will not be approached to partake in the study if they are deemed too unwell.
4. The Committee queried whether elderly and frail participants would have the capacity to consent. The researcher responded that to determine this, the treating clinicians would look at their medical history and screen for warning signs of dementia or delirium. The treating clinicians will then suggest suitable participants to the researchers, factoring in capacity to consent. The researchers would then start a conversation with the patient to ascertain whether the patient completely understands and what the research entails. A decision will be made to include the patient in the research based on the outcomes of this process.
5. The Committee confirmed with the researcher that if microbiology results discovered something of clinical significance, the participant and GP would be informed.
6. The Committee clarified with the researcher that participants would not be receiving individual benefit from providing information and tissue.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted an issue around tissue being stored for future unspecified research at the Christchurch Heart Institutes (CHI) Tissue Bank. This biobank had ethics approval when it was established (Ref# 15/CEN/13), but the National Ethical Standards have since been updated and the biobank may not meet those new ethical standards, especially regarding transparency of its governance, illustrated by the fact that the Committee were unable to find governance information of this biobank via a Google search. The Committee noted that when people have trusted their tissue to be deposited into a biobank, they need confidence in the governance process. The Committee referred to Chapter 15 of the National Ethical Standards for Health and Disability Research and Quality Improvement (<https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/15>) which sets out the ethical standards concerning the use of biobanks..
2. The Committee noted that the researcher could proceed by either:
   1. Removing the optional future unspecified research component from their study. It was agreed that this would be a pity, as it would be a missed opportunity for valuable research.
   2. Amending the optional PISCF to comply with Chapter 15 and section 7.58 of the NEAC Standards as closely as possible, based off what is known about the CHI biobank (including contact details should participants wish further information). The Committee agreed that this would be a reasonable mid-way approach whereby the CHI biobank could be used, even if non-compliant with the new Standards, because it does have ethical approval to operate which has not been revoked.
3. The Committee suggested that the researcher or the HDEC could approach the biobank to see if they can show compliance with the NEAC Standards (particularly Chapter 15) regarding their governance structure, noting that it must be transparent. The Committee cited Auckland Tissue Bank as a good model for transparency and governance. The HDECs will look into reviewing this documentation to assess its compliance with the updated NEAC guidelines.

The Committee requested the following changes to the Participant Information Sheets and Consent Forms:

Optional PISCF for future unspecified research:

1. Please amend to give more detail about compliance with chapter 15 of the NEAC Standards, based off what is known about the CHI biobank
2. Please amend to reflect section 7.58 of the NEAC Standards, including, non- exhaustively:
   1. State whether the donor’s identity and details will remain linked with the sample or whether the sample will be delinked (this is relevant to whether or not incidental findings could be returned and it is also relevant to the optional statement in the CF that upon withdrawal a participant agrees that the information collected up to the point of withdrawal may continue to be used - It may not be able to be withdrawn.)
   2. State that, if a donor consents to a tissue sample being unidentified or delinked, they relinquish their right to withdraw consent in the future
   3. Acknowledge that the donor will not own any intellectual property that may arise from any future research
   4. Acknowledge that the donor’s decision about the consent for use of their tissue sample for unspecified research will in no way affect the quality of a donor’s current or future clinical care.
3. Please clarify the role of identifiers, especially with respect to whether participants can receive results.
4. Please consider the statement (page 2) that all FUR research on the tissue will include Maori representation, especially if the tissue is available to overseas research
5. Please include a section which explains the risks of participating in this kind of research.
6. Please provide a better explanation of the types and scope of future unspecified research in the PIS and ensure consistency with the statements in the Consent Form.
7. Please amend the PIS to note that secondary use of data will occur for research which has received ethical approval and that pooling of data with inter(national) datasets for analysis will be done with ethical approval, as per the protocol.

Main PIS

1. Please clarify that genetic testing will be done on bacteria, not on participants. Please add a consent clause for this.
2. Please amend to note that secondary use of data for will occur for research which has received ethical approval and that pooling of data with inter(national) datasets for analysis will be done with ethical approval, as per the protocol.
3. Please inform the participant that their GP will be informed of findings of clinical significance.
4. Please ensure that all matters which appear in the CF have been clearly explained in the body of the PIS. Matters should not appear for the first time in the CF. For example, it would appear from the CF that there will be data FUR in the main study but the section on it in the body of the PIS which describes this doesn’t comply with Standard 7.57.
5. Please refer to consenting individuals as ‘participants’ rather than ‘patients’, and direct to ‘you’ rather than ‘patients’.
6. Please review for lay-language ‘e.g. contact moments’.
7. Please specify the name and number of questionnaires to be completed by the participants.
8. Please specify that participants’ medical care will not be affected if the decision to withdraw from the study is made.
9. Page 6 – under the heading “Can I find out the results of the study’ – the Māori consultation recommendations have not been adopted – please amend accordingly.

Decision

This application was *provisionally approved* by consensus, subject to the following information being received:

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheets and consent forms, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Sotera Catapang.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **21/NTA/36** |
|  | Title: | TRAIL: A Biorepository for the Pathology Department, Dunedin School of Medicine. |
|  | Principal Investigator: | Professor Michael Eccles |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 March 2021 |

Professor Michael Eccles was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. The researchers wish to establish a tissue biorepository in the Department of Pathology at the University of Otago to (1) ensure the Rare Disease Biobank tissue collection continues; (2) provide better consistency of storage and management of research tissue samples for researchers who have studies which need tissue storage; and (3) improve collection of donor tissue from surgeries and procedures (both historical - approximately 400 formalin-fixed paraffin-embedded human tissue blocks, >1000 slides from human tissues, approximately one whole -80°C freezer of human tissue, morgue and rare genetics clinical material, and specimens collected between 1950 and 1980 from Dunedin Hospital) and future-based). By bringing together these tissues, cell lines and their associated data, they hope to ensure a greater standardization of samples, as well as safeguard the management of the tissues and their associated data.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee commended the researchers for commencing this project and for their efforts in drafting the documentation required for establishing a biorepository.
2. The Committee also noted that the project provides a great opportunity to co-design the repository with Māori. The researchers responded that they are currently looking for a suitable Māori representative to work with in this area.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted that not all of the requirements of Chapter 15 of the National Ethical Standards for Health Research and Quality Improvement have been met and asked the researchers to provide documentation around the governance structures and processes.
2. Given the importance of this biorepository and the potential for its governance processes and documentation to be used as a precedent for other biorepositories in New Zeeland (both current and future), the Committee offered to work alongside the researchers to ensure compliance with the Standards.
3. As a starting point, and pending the outcome of the joint work between the researchers and the Committee, some of the areas which require consideration or amendment are as follows:
4. Please ensure there is greater clarity about the governance and processes for the different ‘functional units’ (as there are for tissue deposited into the Auckland Regional Tissue Bank). In particular, there will be different considerations for Rare Disease (RD) tissue where access will be allowed by external researchers, including some who are overseas.
5. The Committee requested that documentation be drafted which clearly sets out the criteria that will be used in deciding access rules for the repository, especially with regard to releasing RD tissue to external researchers where issues of potential identifiability may be more complex Please note Standard 15.16 which requires governance arrangements, researchers or custodians of biobanks to take special care to identify people whose interests may be especially at risk, and interests that arise from diverse values.
6. Please provide guidelines as to how the Biorepository’s oversight committee will determine these external applications
7. The Committee requested the researcher provides documentation to clarify how and who decides whether a particular use of tissue is compliant with the general kaupapa of the bank.
8. The Committee noted that different participant information sheets and consent forms may also be required for the different functional units.
9. The Committee noted the proposed governance structure requires greater clarity – the documentation suggests there will be: (1) a Biorepository Director (2) a Biorepository Manager; (3) a Biorepository Oversight Committee (said to be an initial establishment group and members of this committee are not necessarily involved in the governance). There should be a separation between the overall governance group and the oversight committee; (4) a Biorepository Governance Group (TBA). This is said to involve individuals representing the SDHB and SCL, consumer and Māori representation. There should also be ethics representation (the protocol says its planned for the oversight committee). No documentation has been provided for the governance group (but TORs have been provided for the Oversight Committee); (4) A biobank research advisory panel (which may be the same as the Biorepository Oversight Committee?) - the PIS says this panel is comprised of NZ biomedical researchers, health experts and members of the community, and will decide if the intended research is a good use of the tissue resources. It will be very important that there are some people external to the University of Otago sitting on this panel – currently the 6 members referred to in the protocol appear to all be in the Pathology Department. Note Standard 15.15 which provides that researchers or custodians of biobanks must involve a range of people with relevant interests when they are developing governance arrangements, in the ongoing management of the biobank and in the periodic review of governance arrangements. (5) An Expert Clinical Review (ECR) panel - TORs have been provided but there are no decision criteria or separate documentation (eg, SOPs) guiding how decisions will be made;)
10. Non-exhaustively, compliance with NEAC Standards 15.13 onwards, requires:
    1. stringent rules of access to the biobank
    2. ways in which researchers will be accountable for complying with requirements addressing access, use and privacy.
    3. auditable records of all researchers who receive access to the biobank, and the purposes of that access.
    4. how researchers or custodians will protect privacy and confidentiality of participants, including how data will be de-identified, assignment of codes etc. and how that will be done
11. The Committee noted that documentation must be publicly available on the website (currently incomplete). Refer Standard 15.19.
12. The Committee noted that references had been made in the documentation to other documents which have not been uploaded onto the portal, for example, Best Practice codes and Codes of Conduct.
13. The Committee noted that some aspects of the documentation regarding consent will need to be more carefully considered and noted, by way of example, the concept of supported decision-making as well as the provisions about reconsenting for children.
14. The Committee requested a data and tissue management plan. The HDEC website has a template that can be adapted or used as guidance (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>)
15. The Committee requested the researcher provides the SOPs of the repository.
16. The Committee requested the researcher is more explicit about the intended use of cell lines, noting that use of some of those cells would need informed consent or ethics approval if informed consent not possible.
17. Please update documentation to note the risks involved in biobanking.
18. The Committee noted that reference is made in the documentation to proposed links with the CSTB and the ATB but no further explanation of what they are has been provided.

Subject to the further documentation which is to be provided and existing documentation which requires amendment, the currently uploaded version of the Participant Information Sheet and Consent Form requires the following amendments:

1. Please provide different PISs for different donor types.
2. Provide more detail around future unspecified research.
3. Please discuss the risks of biobanking (required by Standard 15.8), including
   1. The possibility of re-identification (especially for rare disease participants where codification cannot ensure a zero risk of re-identification);
   2. Data harms including to family and whānau;
   3. The difficulty of withdrawing in the light of global sharing;
   4. The nature of genomic research promoting widespread dissemination and ongoing reuse of data such that different actors and bodies will be responsible to decide on their behalf for future uses and for reviewing and evaluating access requests from external researchers.
4. Please ensure better compliance with Standard 15.9.
5. Please inform participants that if the tissue is made non-identifiable, they may not be able to know what is done with their tissue and, in this situation, they will not have the option of withdrawing consent.
6. Please provide a better explanation of what can happen if identifiable data is provided.
7. Please clarify what is meant by ‘next step’ on page 4.
8. Please provide a Māori tissue statement for tissue that might go overseas and overseas data warning statements, as well as the possibility that there may be no NZ representation on ethics committees overseas.
9. Please ensure PISCFs comply with s7.57 of the Standards.
10. Please discuss the sharing of data, especially genetic data, with other repositories – currently the explanation of genetic studies is insufficient – refer to Standard 14.39 about what is required before seeking consent to genetic research.
11. Improve statements about privacy and confidentiality – see HDEC templates.
12. Please update to ensure compliance with Standard 15.17 (participants have the right to request and receive information from biobanks about their stored tissue and how it is being used) and 15.18 (participants have the right to request that researchers correct mistakes or omissions about their health data).

Consent Form:

1. Please amend regarding the above statements.
2. Please discuss withdrawal of data.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

The Committee suggested the researcher reapplies to Northern A to ensure continuity.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **21/NTA/37** |
|  | Title: | Comparison of dimethyl fumarate capsules under fasting conditions. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern XP IP Pty Ltd |
|  | Clock Start Date: | 04 March 2021 |

Noelyn Hung and Linda Folland were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. This is a bioequivalence study being conducted to compare the rate of absorption and pharmacokinetics (PK) of the drug when taken orally under fasting conditions.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried how long the venous catheter is in place. The researcher responded that this for 32 hours up to 36.
2. The Committee queried if monetary incentive could lead to participants concealing information that would disqualify them from trial enrolment. The researcher stated that this is a factor that they are cognisant of, and consider that the monetary incentive is considered minimum wage and so the risk should not be too high.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please ensure that food allergies (such as coeliac or needing an EpiPen) is an exclusion-criteria stated clearly.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **21/NTA/38** |
|  | Title: | Comparison of dimethyl fumarate capsules under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern XP IP Pty Ltd |
|  | Clock Start Date: | 04 March 2021 |

Noelyn Hung and Linda Folland were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. This is a bioequivalence study being conducted to compare the rate of absorption and pharmacokinetics (PK) of the drug when taken orally with food.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried how long the venous catheter is in place. The researcher responded that this if for 32 hours up to 36.
2. The Committee queried if monetary incentive could lead to participants concealing information that would disqualify them from trial enrolment. The researcher stated that this is a possible factor that they are cognisant of, and consider that the monetary incentive is equivalent to minimum wage and so the risk should not be too high.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please ensure that food allergies (such as coeliac or needing an EpiPen) is an exclusion-criteria stated clearly.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **21/NTA/40** |
|  | Title: | ChildPlayWorks data analysis project |
|  | Principal Investigator: | Ms. Judi Jacobsen |
|  | Sponsor: |  |
|  | Clock Start Date: | 04 March 2021 |

Judi Jacobsen and Jeff Cochran were present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. Observational study of the effect of play therapy on behaviour as assessed by repeat standardized therapist and parent questionnaires. Some data has already been collected by the overseas researcher prior to becoming aware that a New Zealand ethics approval was required.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee queried what adaptations, if any, have been made to the United States Play programme to ensure it is culturally appropriate to Māori. The researcher stated that it has been customized to meet the needs of the individual. The Committee noted that wider cultural input is missing. Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*
2. The Committee stated that there are a number of questions about Māori in the application form which will need to be answered more carefully in the resubmission.
3. The Committee queried the role of the listed principal investigator with the study as no CV was provided. After discussion of the facilitatory nature of the role, the Committee suggested that an academic colleague in New Zealand should be approached to participate as the co-ordinating investigator in the study .
4. The Committee stated that the protocol, which comprises only therapist procedures, is insufficient to meet the requirements of the NEAC Standards. A new protocol should be submitted. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
5. An Independent Peer review was not provided. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).* The Committee recommended use of the template (<https://ethics.health.govt.nz/guides-templates-forms-0/scientific-peer-review-submissions-%E2%80%93-guidance>) from an independent researcher.
6. A robust Data Management Plan is required, especially as video data that identifies both counsellors and child participants is collected. Please refer to the HDEC template for guidance. Use of the template isn’t mandatory but is recommended to be adapted for this study (<https://ethics.health.govt.nz/updates/new-templates-datatissue-management-plans>) The Committee emphasised the importance of safeguards around the video data and referred the researcher to Chapter 12 of the National Ethical Standards (<https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health>)
7. The Committee noted their concern with data that has already been collected without New Zealand Ethics approval being obtained. If this was collected under the submitted information sheet, this is not considered informed consent and needs to be reconsented with an approved HDEC information sheet in order to be included. The Committee further noted that only legal guardians can consent in addition to a child’s assent, and not a general caregiver. The Committee requests that this data not be used until a New Zealand ethics approval is granted.

The Committee requested the following changes to the Participant Information Sheet and Consent Form *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please refer to the HDEC template for guidance as many sections are lacking detail. The Committee suggested the separate parental information/consent and child assents are implemented. <https://ethics.health.govt.nz/guides-templates-forms-0/participant-information-sheet-templates>

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **21/NTA/41** |
|  | Title: | ONL-1204-GA-001: A study on the treatment of ONL1204 in patients with geographic atrophy (GA) associated with age-related macular degeneration (AMD) associated with AMD |
|  | Principal Investigator: | Dr James Howard Borthwick |
|  | Sponsor: | ONL Therapeutics |
|  | Clock Start Date: | 04 March 2021 |

No one was present via videoconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of Study

1. The purpose of the study is to evaluate the safety and tolerability of an experimental new treatment ONL1204 Ophthalmic Solution for geographic atrophy (GA) associated with age related macular degeneration (AMD).

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. Please confirm whether SCOTT approval for both investigational drug and the DARC agent has been given. The Committee further requested clarification if the New Zealand investigators are familiar with using DARC.
2. Rather than an insurance certificate, a full outline of the policy has been uploaded and includes the statement “the insured has offered, and the Research subject has agreed to abide by the Conditions of Compensation.” The Conditions are as set out by the insurer, so the compensation statement contained in the Participant information Sheet may be incorrect and require amendment. It will also be necessary for the investigator to ensure that the conditions of insurance are met in terms of the information required to be given to participants. Please ensure that this covers both of the experimental aspects of the trial and that adequate information around the conditions is included in the information sheet for the participants, rather than relying on the standard (template) compensation statement.
3. The Committee queried if the investigator is doing the majority of the recruitment. Please clarify.
4. The Committee noted that the sponsor can stop the study, but the reasons are not outlined. The Committee further noted that this cannot be for commercial reasons. Please clarify these.
5. Please resolve the inconsistency in Data/Tissue Management Plan (DTMP) about whether the images will contain identifiable information or whether they will be coded (sections 7.1 says imaging reports will be labelled with identifiers; compared to 7.2 and 8.2 and 9.2). Please also include greater detail about how these images will be transferred as the Plan refers to the standard operating procedures of the imaging vendor but does not detail what these are.
6. There is no reimbursement or koha for anything other than travel and meals and the DARC imaging will effectively take up a participant’s whole day, on 7 occasions. Please consider adding a koha to adequately compensate the participants for their time.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

Main PIS/CF

1. For a phase 1b study, it should not be optional in the consent form for the GP to be told about participation.
2. The consent form also makes it optional about continued use of data upon withdrawal but the body of the PIS makes this mandatory. Please correct this inconsistency.
3. Please advise participants whether images will contain identifiable information or not which will be sent overseas.
4. Please include more information about what the DARC procedure involves.
5. The risk that this is experimental is not properly emphasised when there are repeat exposures to DARC imaging.
6. The Committee queried if “geography atrophy” is correct (rather than geographic atrophy) or a typo repeated.
7. Please add treatment or sham time frames into Table [\*]

Optional Genetic PIS/CF

1. This PIS does not meet Standards 7.57 and 7.58 for Tissue and Data FUR and must be significantly amended, including adequate information around risks. The Committee also noted the Standards 14.27 – 14.41 about genetic research should be referred to.
2. The consent form does not match up to what is in the body of the PIS. Please amend for consistency.
3. Please correct the advocacy email to be [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)
4. The Committee queried if there is a possibility of incidental findings that may be clinically significant and whether there is a process for the participant to have these.

Decision

This application was *provisionally approved* by consensus, subject to the following information being received:

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17*
* Please amend the Data and Tissue Management Plan (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 & 14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Catherine Garvey and Michael Meyer

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 20 April 2021, 01:00 PM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 4.30pm