|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 August 2022 |
| **Zoom details:** | 965 0758 9841 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12.00-12.30pm | 2022 FULL 11342 | COG ACNS2021: A Study of a New Way to Treat Children and Young Adults With a Brain Tumour Called NGGCT | Dr Stephen Laughton | Mrs Helen Walker & Dr Patries Herst |
| 12.30-1.00pm | 2022 FULL 12151 | PNOC19 | Dr Stephen Laughton | Dr Cordelia Thomas & Ms Julie Jones |
| 1.30-2.00pm | 2022 FULL 11917 | In Vitro Studies of Drug Absorption Across Human Skin | Dr Noelyn Hung | Dr Cordelia Thomas & Mrs Patricia Mitchell |
|  |  | Break |  |  |
| 2.15-2.45pm | 2022 FULL 12973 | Throm-PED registry | Dr Peter Bradbeer | Mrs Helen Walker & Ms Julie Jones |
| 2.45-3.15pm | 2022 FULL 12970 | Actions of SGLT 2 inhibitors in individuals with stage 4 chronic kidney disease | Professor Robert Walker | Ms Sandy Gill & Dr Patries Herst |
| 3.15-3.45pm | 2022 FULL 12897 | Asthma Review and Management in Community Pharmacy | Dr Alex Semprini | Dr Cordelia Thomas & Mx Albany Lucas |
| 3.45-4.15pm | 2022 FULL 13251 | SEL002: A Study of Sodium Selenate as a Treatment for Probable Behavioural Variant Fronto-temporal Dementia | Dr. Campbell Le Heron | Mrs Helen Walker & Mrs Patricia Mitchell |
|  |  | Break |  |  |
| 4.30-5.00pm | 2022 FULL 12802 | A Study To Evaluate the safety of GDC-1971 In combination with Atezolizumab | Dr Sanjeev Deva | Ms Sandy Gill & Dr Patries Herst |
| 5.00-5.30pm | 2022 FULL 13232 | AROMMP7-1001: A Study to Evaluate the Effects of ARO-MMP7 Inhalation Solution in Healthy Participants and in Participants with Idiopathic Pulmonary Fibrosis | Dr. Alexandra Cole | Dr Cordelia Thomas & Ms Julie Jones |
| 5.30-6.00pm | 2022 FULL 13258 | STRIDE-10 - Clinical trial of V116 in adults 50 years of age or older who have not had a pneumococcal vaccine | Professor Richard Stubbs | Mrs Helen Walker & Ms Julie Jones |
| 6.00-6.30pm | 2022 FULL 12906 | VIR-MHB1-V200-A Platform Study to Evaluate Investigational Therapies in Chronic Hepatitis B Infection | Prof Edward Gane | Ms Sandy Gill & Mrs Patricia Mitchell |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | Present |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Apologies |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members, noting apologies had been received from Ms Jessie Lenagh-Glue and Mx Albany Lucas.

The Chair noted that the meeting was quorate.

The Committee noted 2022 EXP 13004 was withdrawn from the agenda and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 26 July 2022 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2022 FULL 11342** |
|  | Title: | COG ACNS2021: A Phase 2 Trial of Chemotherapy followed by Response Based Whole Ventricular & Spinal Canal Irradiation  (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumour |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | Children’s Oncology Group |
|  | Clock Start Date: | 12 August 2022 |

Dr Stephen Laughton, Dr Olga Ksionda and Paula Murray 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 resolved ethical issues

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

1. The Committee clarified that the details of “what will happen with my information” would pertain only to coded information as corresponding with privacy requirements. Registration to the Children’s Oncology Group (COG) requires information be sent to the group for a study number to then be generated so initials and date of birth would be sent to the group but further identifying information would not be sent to the group.
2. The Committee clarified that future unspecified research (FUR) would be on coded information only.
3. The Committee clarified that the children would be aware that they had a brain tumour and that there would be variation in the ways that the participants would be managed by the research team, which may include obtaining oral assent from the child and not providing the assent document if aspects of the document would cause distress, as may be the case if the child was not yet aware of their diagnosis.

**Summary of outstanding ethical issues**

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

The Committee requested the following changes to the Main Participant Information Sheet and Consent Form (PIS/CF):

1. Please clarify the statement concerning the sending of data to study sponsors as currently the paragraph concerning “what will happen to my information” is unclear. …the right to send personal information overseas…could mean both identifiable and coded information. The sentence from the consent form pertaining to exactly what information will be sent overseas could be added to the PIS for clarity. Please specify that the research team is requesting the consent of participants to send the initials and DOB for registration with COG overseas.
2. Please clarify that “personal information” includes both identifiable and coded information. The current HDEC template clearly distinguishes between identifiable and coded information. We strongly suggest COG templates build that in. In accordance with the NEAC guidelines, the PIS must provide information about the form of data (identifiable, non-identifiable, re-identifiable) used and stored and who will have access to the different forms (pg 76 of NEAC guidelines)
3. The Committee requested that the FUR PIS includes information about who will have access to their samples and coded information.
4. Please refer to the [HDEC PIS](about:blank) template for missing sections, such as data section, and specifically where referencing contraceptive methods which are currently brief.
5. Please note that mention of “copying medical records” is incorrect and should be clarified to be access of study data for auditing purposes.
6. Please note that there is no mention of a COG participant code in “what will happen to my information”. Please amend this.
7. On page 5, the phrasing around describing what will happen if surgery is not an option is overly complex. Please simplify.
8. Please correct references to Auckland District Health Board as this is no longer an entity.
9. Please ensure consent for tissue and data is together in the consent forms.
10. Please amend pregnancy statements to “You should not become pregnant or father a child,” to remove unnecessary gendering.

The Committee requested the following changes to the Future Unspecified Use of Tissue Info and Consent Generic v3 Participant Information Sheet and Consent Form & Future Unspecified Use of Tissue Reconsent 16+ Info and Consent Generic v3 (PIS/CF):

1. The Committee requested that the contraception section of the [HDEC PIS template](about:blank) be included for clarity of expectations of precautions to prevent pregnancy.

The Committee requested the following changes to the ACNS2021 Assent 11-15 years SSH v1:

1. Please soften the phrasing of the introductory paragraph as it is quite affronting in its exclamation of “you have a brain tumour”. This may be troubling for participants that are not fully aware of this or who have been shielded from the full extent of this by their parents.
2. Please amend to provide more information for this age group, particularly with respect to what will happen with their information.

The Committee requested the following changes to the ACNS2021 Assent 7-10 years SSH v1:

1. Please soften the phrasing of the introductory paragraph as it is quite affronting in its exclamation of “you have a brain tumour”. This may be troubling for participants that are not fully aware of this or who have been shielded from the full extent of this by their parents.
2. In the optional testing section, there should be better explanation of the fact that additional samples would be taken at the time of initial testing and therefore that there would be no further samples taken later in the study.
3. Please simplify the assent section and state simply that “If you would like to be part of the study please sign here.”. Please also remove reference to the ‘participant’ here as it has not previously been explained and could be confusing to these younger children.
4. Please remove the statement of HDEC approval as it has no relevance to a child.
5. Please simplify language used in this form so that it is slightly more lay friendly.

The Committee requested the following changes to the ACNS2021 Information Sheet and Consent Form (PIS/CF) Reconsent 16+:

1. Please amend wording of requesting for re-consent “you are now considered to be adult enough” reads as condescending and is unnecessary. It is sufficient to simply say ‘…because you are able to consent for yourself’.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, 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 Dr Patries Herst and Mrs Helen Walker.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2022 FULL 12151** |
|  | Title: | A Randomised, Double-Blinded, Pilot Trial of Neoadjuvant Checkpoint Inhibition followed by Combination Adjuvant Checkpoint Inhibition in Children and Young Adults with Recurrent or Progressive High-Grade Glioma (HGG). |
|  | Principal Investigator: | Dr Stephen Laughton |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 12 August 2022 |

Dr Stephen Laughton, Dr Olga Ksionda and Paula Murray 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 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 scientific review was satisfactory.
2. The Committee clarified that the details of “what will happen with my information” would pertain only to coded information as corresponding with privacy requirements. Registration to the Children’s Oncology Group (COG) requires information be sent to the group for a study number to then be generated so initials and date of birth would be sent to the group but further identifiable information would not be sent to the group.
3. The Committee clarified that the height and weight would be collected at each clinical visit.

Summary of outstanding ethical issues

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

The Committee requested the following changes to the Main Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee suggested describing the clinical activities and then having a visit table to show where and when these would occur for the sake of brevity.
2. The statement “your decision to take part or not, or to take part and then be withdrawn," is not clear and sounds like the participants have no choice in the withdrawal. Please amend this.
3. Please remove the word Parent/Guardian from the sentence "If you do decide to take part, you will be given this Parent/Guardian Information and Consent Form to sign and you will be given a copy to keep" as those over 16 years consent for themselves.
4. The Committee requested that the optional consent for storage of samples be noted in the main PIS once, but then further mention removed as the information is covered in the optional PISCF and is not required in the main PIS.
5. Please correct the following typos:
   1. "Knowing what is involved will help you decide if you want you to take part in the research." (page 1)
   2. "How long will I be in the study? If you/you choose to participate in this study," (page 9)
   3. “If you decide to take part and later change your mind, you are free to withdraw you from the project at any stage." (page 10)
   4. "and discuss with you whether you want you to continue in the research study" (page 16)
   5. "Also, on receiving new information, your Starship Hospital doctor might consider it to be in your best interests to withdraw them from the research study." (page 16)
   6. "WHAT IF I WITHDRAW I FROM THIS RESEARCH STUDY?" (page 16).
   7. "You or you can search this website at any time.” (page 18)
6. Please ensure there is a statement for the reimbursement of study visit related costs.
7. Please ensure that the document is written in first person throughout.
8. Please remove reference to Auckland District Health Board as this is no longer accurate.
9. Please modify clause 13 ". If you leave the study, we will use any information already collected unless you tell us not to." as the consent says that information will be used.
10. Please clarify the statement "The coded information from this study will be sent to the Pacific Paediatric Neuro-Oncology Consortium (PNOC), the collaborative research group conducting this study. PNOC will make sure that any information it receives or discloses is kept as confidential as possible. PNOC may request to review your hospital medical record. " and detail where the PNOC group is based and why they would have access to medical records.
11. Please clarify the forms of data, who has access to data, why and what parts of the data as per the information in the data management plan. Please define each type of data as per the HDEC PIS template as a reference as to what is required. In accordance with the NEAC guidelines, the PIS must provide information about the form of data (identifiable, non-identifiable, re-identifiable) used and stored and who will have access to the different forms (page 76 of National Ethical Standards)
12. Please clarify the statement "In the unlikely event that we learn of a breach of confidentiality, someone from the research team with contact you with additional information. If, at any point during or after this study, you think that you may have been re-identified, please contact us and let us know." As it is unclear as to how participants would be aware of a breach of confidentiality.
13. Please remove "as required by U.S. Law" about clintrials.gov as it is not New Zealand law.
14. Please be clear around what data will be sent where and remove reference to the Privacy Act and US law.
15. Please note that the longest term of document retention is the one that should be referred to in the PIS. At present two different timeframes are given.
16. Please correct the statement “All research involving humans is reviewed by an HDEC.” This is not correct, for a statement on the review done by HDEC please see the HDEC PIS template.
17. Data regarding ethnicity should be collected in the study CRF, not in the PIS/CF, unless it has a direct impact on the participant’s ability to give informed consent, such as would be the case if a specific language was required. Please remove mention of the pharmaceutical manufacturer having access to participant records. There is no basis for the manufacturer to have access to any medical records even for the sake of auditing.
18. Please note that the participants declaration is missing, please include this above the signature.
19. Please note that the researcher’s declaration is missing as well as the name of the researchers taking consent.
20. Please ensure the different forms of data are explained and who has access to the data.
21. Please clarify the data retention period.
22. Please amend the statement “Visit the NCI's Web site at http://www.cancer.gov." as this is too general a referral as there needs to be more specific guidance as to what information may be found on the site.
23. Please note that mention of the protocol being provided at the time for reconsent is incorrect and should state the original PIS will be provided.
24. Please note that the General Practitioner (GP) is introduced in the consent, but not previously. The participant is agreeing that they understand information being given to the GP, but this has not been explained to them in the document. Please amend and ensure that there is an explanation as to why the information would be given to the GP and when.
25. Please correct or remove the statement "Please read the information below and think about your choices. After making your decisions, check “Yes” or “No”, then add your initials and the date after your answer. " as there is no re information that follows the statement.
26. Please remove the HDEC approval from the consent as it is contained within the PIS.

The Committee requested the following changes be made to the PNOC019 Assent Form 7-10 years SSH v1

1. Please remove the statement of HDEC approval from the assent section as this should be in the main information section of the sheet.

The Committee requested the following changes be made to the Future Unspecified Use of Tissue Info and Consent Generic v3 & Future Unspecified Use of Tissue Reconsent 16+ Info and Consent Generic v3:

1. Please include the consent statements as they are currently missing.
2. Please remove the statement of HDEC approval as this should not be in the consent section, but rather in the main information section of the sheet

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, 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 Julie Jones and Dr Cordelia Thomas.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2022 FULL 11917** |
|  | Title: | In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) of drug absorption across human skin |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 August 2022 |

Linda Folland and Dr Noelyn Hung 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 resolved ethical issues

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

1. The Committee clarified that the researchers were trying to find a research nurse to approach the potential participants.

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 documents were quite blunt when mentioning the tissue samples. “Surgical waste” should be re-worded and integrated into a request for the use of the surgically removed tissue in softer language. Please refer to refer to Right 7(9) of the Code of Rights- “That you have the right to decide on return or disposal”, in the wording of this paragraph.
2. The Committee requested that further detail be added to the participant information sheet as to the procedures that will be undertaken. The application did not have sufficient detail as to how participants will be approached and what will happen to the amputated body part, etc., and there needs to be significantly more detail as to this. The Committee further noted that some of this information that is missing in the protocol should also be outlined in the information sheets. Please clarify the variety of tests the skin sample will be used for.
3. The Committee requested further peer review to ensure that the methodology being used is clinically and scientifically appropriate.
4. The Committee requested that there be some significant changes made to the participant information sheets as to the cultural considerations that are present.
5. The Committee queried as to whether the research was a Kaupapa Māori methodology which appears to be incorrectly selected in the application.
6. The Committee queried if it could be possible to provide a karakia for samples to the disposal of samples.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please note that amputation needs to be included in the inclusion criteria.
2. Please include a description of what will happen to the tissue that is collected, how it will be prepared, stored etc.
3. There is a typo at the end of the last line on page 2. Please add the word “to” to this sentence.
4. Please reword the payment section so it is reimbursement of expenses incurred as part of their participation otherwise it would be taxable.
5. Please reword the statement "with your surgeon's recommendation..." as this reads as coercive and should be less leading, consider including a statement that the surgeon has been consulted but that the request is not their clinicians. 3
6. Please note that the statement “you can speak to your surgeon or GP at any time” should be removed as that is probably not practicable, and the GP is not involved.
7. Please include a statement detailing that a request for certain health information from the GP or healthcare provider would be undertaken with the participant’s consent, and ensure that it aligns with the GP statement in the consent
8. Please ensure that there is consistency between the consent forms and the PIS as currently there is no consensus on what will happen in the event the participants would like their samples returned and in what event there will be destruction of samples.
9. Please amend mention of Northern A Health and Disability Ethics Committee to be Central.
10. Please amend the reference to the number of pages, or remove the line as the current number of pages listed does not match the document
11. Please ensure that all abbreviations are listed in full first prior to abbreviating only.
12. Please ensure that the importance of tissue and information to Māori noted in the application is detailed also in the PIS.
13. Please note that on the first page there is a paragraph mentioning different sized patches; this should be removed.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Mrs Patricia Mitchell.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2022 FULL 12973** |
|  | Title: | Observational study of pediatric thrombotic disease: the Throm-PED registry |
|  | Principal Investigator: | Dr Peter Bradbeer |
|  | Sponsor: | Scientific Subcommittee Pediatric and Neonatal Hemostasis and Thrombosis of the International Society of Thrombosis and Hemostasis (ISTH) |
|  | Clock Start Date: | 12 August 2022 |

Dr Peter Bradbeer and Jane Wylie 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 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 children would be aware of what a blood clot or thrombosis is. The researcher indicated that consenting would require this explanation.

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 there was a lack of an independent scientific peer review. Please refer to the [peer review template](about:blank) for guidance.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please amend page 2 where it states, "If you leave the project, we will use any information already collected unless you tell us not to." This is not optional according to the consent form.
2. Please clarify "If you do not have an appointment for the Starship Hospital outpatient clinic, with your permission, we may contact you by telephone or ask your local hospital or GP to share the relevant information." As this permission is covered by the consent, ‘with your permission’ may not be required within this statement.
3. Please include that the General Practitioner (GP) will be notified of involvement in the study within the body of the PIS.
4. Please consider use of the data text from the [HDEC PIS template](about:blank). The PIS does not clearly describe the difference between identifiable and non-identifiable data and who has access. In accordance with the National Ethical Standards, the PIS must provide information about the form of data (identifiable, non-identifiable, re-identifiable) used and stored and who will have access to the different forms.
5. The section about the Privacy Act is not required and can be removed.
6. Please clarify "Organisations that may inspect and/or copy your research records for quality assurance and data analysis-" or remove as necessary as under no circumstances would medical records be copied, even for audit. Please refer to the [HDEC template](about:blank) for guidance.
7. Please specify that there may be future research, refer to the HDEC template for guidance.
8. Please remove the statement on page 3, "You may withdraw your consent for the collection and use of your information at any time," as the sentence following states the same thing correctly.
9. Please specify the data security measures, including where it will be stored, how it will be kept secure, who will have access and why.
10. Please include a description of a registry as can be found in the [HDEC template PIS](about:blank).
11. Please do not refer to ethnic groups when requesting a translator, the language the participant may require an interpreter for is relevant, but ethnicity data should be collected within the study case report forms, not the PIS/CF
12. Please note that the researcher declaration (prior to signature block) and full details section is missing where consent is recorded. Please refer to the [HDEC template PIS](about:blank) for this
13. Please include a cultural statement to address the importance of health information as a Taonga.
14. Please ensure that it is clear to participants that only coded information is taken out of New Zealand and not identifiable information. Personal information is both.The Committee referred the Researchers to the PIS template on the HDEC website (linked above) for how this should be laid out.

The Committee requested the following changes to the Throm-PED Reconsent 16+ v1 230622 Participant Information Sheet (PISCF):

1. Please amend "because you are considered adult enough to sign consents for yourself." to say “because you are now able to provide consent for yourself”.
2. Please note that the consent process is continuous and there should be assessment regardless of age as to the ability of young people to consent. For example, the Researchers could consult the Fraser Guidelines or Gillick Competence.

The Committee requested the following changes to the Throm-PED Assent Form 7-10 years v1 230622:

1. Please amend "You don’t need to do anything because we only put things about your regular treatment." To state that you are ‘collecting information’ rather than to ‘put things’.
2. Please amend the statement "There won’t be any ‘good’ to you from this study" as the term ‘benefit’ was covered in the title and makes more sense
3. Please amend "There are no bad things that could happen, because you do not need to have any different tests or treatment and your information that we will put into the registry will not tell who you are." ‘Not tell who you are’ does not make sense and there is no prior explanation of a registry prior to this statement in the document. Please also define what the “bad things” might be if this language remains.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. 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).
3. Please update the participant information sheet and consent form, 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 Julie Jones and Mrs Helen Walker.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **2022 FULL 12970** |
|  | Title: | Sodium glucose co-transporter2 inhibitor's effect on glucose and sodium clearances in individuals with stage 4 chronic kidney disease |
|  | Principal Investigator: | Professor Robert Walker |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 12 August 2022 |

Dr Luke Wilson 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 resolved ethical issues

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

1. The researcher clarified that the linking to clinical record would be linking identifiable data to coded data and medical records and not linking study set databases.

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 there would need to be a future unspecified research (FUR) participant information sheet should FUR be intended.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please consider altering the pages for the figures to make them landscape for readability as the text is currently too small.
2. Please include that there will only be 6 people recruited.
3. Please include the intention for data collected prior to withdrawal would be used after withdrawal.
4. Please note that blood and urine samples are culturally significant. This should specify the data management sheet as these samples are Taonga, mention of karakia should also be included.
5. Please include the sentence “Participants will be informed of the potential risks and cultural issues associated with sending [and storing] data overseas, and that there may be no New Zealand representation on overseas governance committees” from the data management plan.
6. Please review for typos. E.g., “informed” as “inform”.
7. Please inform participants within the PIS that their General Practitioner may be contacted and why.
8. Please remove all mention of data linking within the PIS and consent sections as this is not relevant to this study.
9. Please remove all headers or references of district health boards as they are no longer technically an entity.
10. Please ensure that the whole document is in first person.
11. Where the participants are informed of reimbursement please be specific and remove mention of “asked to complete” where noting the reimbursement for study involvement.
12. Please note that collection of data pertaining to withdrawal must be with the participants consent.
13. Please make it clear that “further investigation” is not referring to future unspecified research and that there is a clear plan as to the future investigation of biomarkers associated to chronic kidney disease.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, 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 Dr Patries Herst and Ms Sandy Gill.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **2022 FULL 12897** |
|  | Title: | Asthma Review and Management in New Zealand Community Pharmacy - a Single Cohort, Open Label Non-Randomised Pilot Study |
|  | Principal Investigator: | Dr Alex Semprini |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 12 August 2022 |

Dr Alex Semprini and Georgina Bird 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 resolved ethical issues

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

1. The Committee clarified that the Participants and their General Practitioners (GP) would be informed of the change in titration of their drug at the same time.
2. The Committee clarified under what circumstances a GP would be able to interact with the standing order as given to the pharmacists. And clarified what would occur in the event that the GP would disagree with the pharmacists standing order.
3. The Committee clarified there would be a separate and private room for the research questionnaires and consenting to be conducted in.
4. The Committee clarified that the questionnaire and the electronic diary were designed in a way that there was an immediate response available to any severe response or indication of distress.
5. The Committee clarified that the participation and consent forms would be gone through with the pharmacist and electronically consented.
6. The Committee clarified why a translated PIS and interpreters would not be made available to Māori as they are disproportionately affected by asthma.

**Summary of outstanding ethical issues**

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

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please include details of the plans regarding the questionnaire and the electronic diary specific to any severe response or indication of distress. Please specify the expected timeline of response.
2. Please note that participants don't have to be "happy" to attend the pharmacy, it may be more suitable to change this to "willing", or "able".
3. Please amend the statement regarding approval by HDECs as that HDECs only approve the ethical aspects of the study. Please refer to the HDEC template for guidance.
4. Please amend where it states that under "who can take part in the study", "You have been recommended to participate in this study by your doctor," This statement is coercive. Please alter to be less coercive, such as " Your doctor has identified you as someone who may be eligible for this study." Please ensure that all language used to refer to a participant’s GP is consistent.
5. Under “What will participation in my study involve” please specify that a separate room for this study will be available at the pharmacist.
6. Please specify that any changes to the titration of the medication done by the pharmacist will be shared with the GP.
7. Please amend the risk sentence to state that in the event the participants are experiencing any issues and their GP is not available that the participant should call 111.
8. Please include a statement informing participants of the right to access and correct information.
9. Please amend “taking” the inhaler, to “using” the inhaler.
10. Please include information concerning the possibility of falling pregnant during the study the GP will be informed. Please explain what participants should do should they fall pregnant and the reasons that GPs should be informed.
11. Please include nurse practitioners in the list of primary carers should this study be more widely tested.
12. Please remove Study approval by HDEC sentence on page 9 or page 2 as it is repeated.
13. Please note that the Table of identifiable information should more clearly state that study staff includes both pharmacy staff and MRINZ staff. Otherwise, withdrawal by contacting the researchers as MRINZ would not be possible.
14. Under ‘who to contact’, please modify the medical advice to say “Study related medical advice..”
15. Please include that the GP will also be paid for their time in the study.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **2022 FULL 13251** |
|  | Title: | A Phase 2b Randomised Controlled Trial of Sodium Selenate as a Disease Modifying Treatment for Probable Behavioural Variant  Fronto-temporal Dementia |
|  | Principal Investigator: | Dr Campbell Le Heron |
|  | Sponsor: | Alfred Health |
|  | Clock Start Date: | 12 August 2022 |

Dr Campbell Le Heron, Courtney Rowse, Lucy Vivach, Holly Thirwall, and Alice Gordon 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 resolved ethical issues

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

1. The Committee clarified that the support person could be replaced in the event that the caregiver stops participating.

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 there could be an advance directive at the point of consent (As per the Code of Rights, Right 7.5) that if the participant were to later become incompetent they chose to continue in the study and, their original consent would stand. That would remove the issue of proxy consent on behalf of an adult as this is not legal in New Zealand. The Committee noted that competence at the beginning of the study is vital, but continued competence is not necessary.
2. The Committee requested that additional advice or support numbers be provided, not just Healthline.
3. The Committee requested that mention of insurance be removed as this would be covered by ACC.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please ensure there is a statement to inform participants that their caregiver would be requested to answer questions about the participant and provide details of the information that the caregivers would be providing.
2. There should be a bullet point in the CF where participants consent to this information being obtained from their support person.
3. Please include a statement concerning the potential for loss of competence later in the study and make an option for participants to continue in the study in the event they lose competency.
4. Please note that there is Whakamā inherent in this condition and there should be specific acknowledgement of this as well as the fact that the head is tapu.
5. Please include a statement as to the potential for replacement of the caregiver.
6. Please include mention of optional future unspecified research.
7. Please include the option for participants to request a lay summary of the study.
8. Please include a safety plan for risk mitigation in the event that distress occurs as a response to the questionnaires. Please ensure that there is specific details as to the pathways for referral after this distress is identified.

The Committee requested the following changes to the Caregiver Information Sheet and Consent Form (PIS/CF):

1. Please update the NZCR study details in the footers of the document.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, 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 Mrs Patricia Mitchell and Ms Helen Walker.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **2022 FULL 12802** |
|  | Title: | A PHASE Ib, OPEN-LABEL STUDY EVALUATING THE SAFETY, PHARMACOKINETICS, AND ACTIVITY OF GDC-1971 IN  COMBINATION WITH ATEZOLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS |
|  | Principal Investigator: | Dr Sanjeev Deva |
|  | Sponsor: | Genentech, Inc. |
|  | Clock Start Date: | 12 August 2022 |

Dr Sanjeev Deva, Vivian Sun, and Nadia Hitchen 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 resolved ethical issues

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

1. The Committee asked if the future unspecified research forms (FUR) could be combined. The Researcher explained that they can happily combine the two tumour biopsies FUR forms into one. However, the Committee further explained that if the researcher is happy with the current process, they are more than welcome to keep their current processes.
2. The Committee asked about the repository forms and if it is available from the start. The Researcher explained that the repository forms will be given at the start and that most of the samples are based on previous biopsies that the participant has already had and if the participant consents to progression the researchers will give them a progression consent form.
3. The Committee asked about the time difference between the start and the progression consent forms and if participants will have a copy of it due to time difference between the two forms. The Researcher explained that the participants will most likely have multiple copies of all forms as they are going under amendments and must counter sign these forms throughout the study.
4. The Committee asked about the insurance and that it does not seem to be protocol specific. The Researchers explained that the insurance is global and is a significant amount of money that is easily covering participants in the study and the researchers have little concern about insurance and coverage as the insurance company is trustworthy.
5. The Committee asked if the participants would benefit from this product and if it is something that can be obtained after the study is done. The Researcher explained the drug would likely continue to be offered to the participants through a drug compassion scheme.

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 amend identifiable and non-identifiable data by separating and explaining in lay language where possible under the data section. In accordance with the National Ethical Standards, the participant information sheet must provide information about the form of data (identifiable, non-identifiable, re-identifiable) used and stored and who will have access to the different forms.
2. Please list who the 'appropriate authority' is for HIV and Hepatitis testing. i.e., notifiable to the Medical Officer of Health.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. The side effects of azetolizumab are under two different paragraphs on page 12 and page 10, please amend by putting the side effects under one paragraph.
2. The dose-findings participant information sheet currently says there are 36 pages, please amend to 28 pages or remove this line and only use the footer information, which should say ‘X of Y pages’.
3. Please add an optional bullet point about receiving a lay summary of the results once completed. The participants should not have to go to a website to find their results.
4. The participant information sheets for: optional tumour biopsy, optional tumour biopsy at progression and optional tumour biopsy at progression New Zealand need to include the following: “what will happen with the information gained from my samples”.
5. Please include more information about the drug after the trial is completed by including wording that explains where and how the participant can access the drug after the trial is completed.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **2022 FULL 13232** |
|  | Title: | A PHASE 1/2A STUDY EVALUATING THE EFFECTS OF ARO-MMP7 INHALATION SOLUTION IN HEALTHY SUBJECTS AND PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS |
|  | Principal Investigator: | Dr Alexandra Cole |
|  | Sponsor: | Arrowhead Pharmaceuticals, Inc |
|  | Clock Start Date: | 12 August 2022 |

Dr Alexandra Cole 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 resolved ethical issues

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

1. The Committee asked about MMP7 levels. The Researcher explained that MMP7 levels are what is causing the damage, as low levels of MMP7 will not cause any damage although that is not widely known and that there is no prolonged effect on the MMP7 levels.
2. The Committee asked about the reserves and potential payment. The Researcher explained that if the reserves come in and stay overnight and do not get dosed in the morning because they are not needed, they will receive a payment for staying overnight which is around $250. However, those that do not stay overnight will not get payment. The Researcher explained that if the participants do act as a reserve, they will bring them into the next cohort to dose.
3. The Committee asked to confirm that the insurance protocols will last until 2024. The Researcher explained they will get it clarified from the sponsors but is almost certain that is correct.
4. For future applications, please include in the application form how common this condition is for Māori, or if you cannot acquire statistics for this, please state there are no statistics for Māori regarding this condition.

Summary of outstanding ethical issues

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

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please amend page 4 and explain to participants why the MMP7 level matters and explain MMP7 in lay language.
2. Please amend page 5 by removing the apostrophe in ECGs.
3. Please amend page 15 that refers to GP and then on page 16 it refers to "usual doctor" Please use the same expression to avoid confusion.
4. Please amend the consent forms as they refer to "other Health providers" and "current provider" this wording is not in the participant information sheets, please use the same expression to avoid confusion such as GP.
5. Please include more information about payment, stay time, and how the reserve works for potential participants.

**Decision**

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

* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **2022 FULL 13258** |
|  | Title: | A Phase 3, Randomized, Double-blind, Active Comparator-controlled Clinical Study to Evaluate the Safety, Tolerability, and  Immunogenicity of V116 in Pneumococcal Vaccine-naïve Adults 50 Years of Age or Older. |
|  | Principal Investigator: | Professor Richard Stubbs |
|  | Sponsor: | Merck Sharp & Dohme LLC |
|  | Clock Start Date: | 12 August 2022 |

Professor Richard Stubbs 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 resolved ethical issues

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

1. The Committee noted not a closed meeting as the minutes are not discussing scientific details of the study. The Researcher agreed to this.

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 $5million NZD aggregate for insurance was lower than they would expect to see. They acknowledged the lower risk of a Phase 3 study, but given the number of participants in New Zealand, they requested to check if this could be increased to the standard $10million.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. On page 12, the following sentences are contradicting and require rectifying; "If the trial team gives you a device, you will need to return it at your last trial visit.” and “You may keep the items even if you do not complete the entire trial.”
2. On page 14, there is a typo that should read ‘or’, not ‘of’ between “your GP of family doctor”.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **2022 FULL 12906** |
|  | Title: | VIR-MHB1-200- A Platform Study Evaluating the Efficacy and Safety of Investigational Therapies in Participants with Chronic Hepatitis B Infection (PREVAIL) |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Vir Biotechnology, Inc. |
|  | Clock Start Date: | 12 August 2022 |

No one was present via videoconference for discussion of this application as the Committee notified the applicant ahead of time that there were few comments and had nothing for discussion.

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 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 the inclusion of the Māori data sovereignty template statement in participant information.

Summary of outstanding ethical issues

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Page 1 of the Main PIS states “This form has been reviewed and approved by an Independent Review Board (IRB) or Ethics Committee (EC).” Please delete the reference to IRB.
2. Please tighten language around informing study doctor before starting or stopping any medication to state “when practical or as soon as possible.”

**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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

|  |  |
| --- | --- |
| **Meeting date:** | 27 September 2022 |
| **Zoom details:** | To be determined |

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.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 6.00pm