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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 09 November 2021 |
| **Zoom details:** | https://mohnz.zoom.us/j/96507589841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10:30-10:55am | 2021 FULL 11557 | Correlating molecular alterations in low grade ovarian serous carcinoma to patient outcomes in New Zealand | Dr Mak Sarwar | Dr Sarah Gunningham & Dr Devonie Waaka |
| 10:55-11:20am | 2021 FULL 11233 | A study of safety, reactogenicity and immune response of the repeat vaccination against RSV when given to female participants of 18- 49 years of age during their subsequent uncomplicated pregnancy. | Dr Rebecca Griffith | Mr Dominic Fitchett & Ms Amy Henry |
| 11:20-11:45am | 2021 FULL 11279 | M20-466 Moderate to Severe Rheumatoid Arthritis: A Phase 2b, Dose-Ranging, Safety and Efficacy Study of ABBV-154 | Dr Douglas White | Mr Anthony Fallon & Dr Devonie Waaka |
|  | *Break* |  |  |  |
| 12:00-12:25pm | 2021 FULL 11239 | Exploring implementation of the F-words for Child Development with an organisation in Aotearoa New Zealand | Dr Margaret Anne Jones | Mr Dominic Fitchett & Ms Amy Henry |
| 12:25-12:50pm | 2021 FULL 11615 | ED Elderly Head Injury Outcomes, ED-EM-HI Study | Dr Devin Faragasso | Mr Anthony Fallon & Dr Devonie Waaka |
| 12:50-1:15pm | 2021 FULL 10996 | AG10-304: Extension Study and Safety Monitoring of Acoramidis (AG10) in Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) | Dr Hugh Goodman | Dr Sarah Gunningham & Ms Amy Henry |
|  | *Break* |  |  |  |
| 1:30-1:55pm | 2021 FULL 11481 | M20-371 Moderate to Severe Crohn's Disease: A Phase 2 Safety and Efficacy Study of ABBV-154 | Dr. Benjamin Griffiths | Mr Anthony Fallon & Dr Devonie Waaka |
| 1:55-2:20pm | 2021 FULL 11098 | Study of WVE-004 in Patients with C9orf72-associated ALS or FTD | Professor Tim Anderson | Dr Sarah Gunningham & Ms Amy Henry |
| 2:20-2:45pm | 2021 FULL 11336 | A study investigating a new ocular implant, PA5346 Latanoprost FA SR Ocular Implant. | Prof Anthony Wells | Mr Dominic Fitchett & Dr Devonie Waaka |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |  |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |  |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Apologies |  |
| Mr Anthony Fallon | Lay (consumer/community perspectives) | 13/08/2021 | 13/08/2024 | Present |  |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |  |
| Ms Amy Henry | Non-lay (observational studies) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members following a karakia by Ms Amy Henry, noting that apologies had been received from Associate Professor Mira Harrison-Woolrych.

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 12 October 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2021 FULL 11557** |
|  | Title: | Correlating molecular alterations in low grade ovarian serous carcinoma to patient outcomes in New Zealand |
|  | Principal Investigator: | Dr Mak Sarwar |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2021 |

Dr Mak Sarwar and Dr Bryony Simcock 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 study will look at tumour tissue from women previously diagnosed with low grade ovarian serous carcinoma and analyse the underlying mutations. These will then be correlated with patient age and outcome to determine if there is any predictive value to the various mutations regarding how these patients will fare.

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 how many cases the researchers are expecting. The researchers stated that there will be approximately 30 to 35.
2. The Committee asked who the Co-ordinating Investigator (CI) for the study is. The Committee noted that Mak Sarwar is listed as the CI; however, the form was signed by Peter Sykes as CI. The researcher advised that Mak Sarwar is the CI. Peter Sykes signed the form due to technical issues that arose when signing the form in the online system.
3. The Committee asked if individual results could result in recommendations for treatment options for any participants. The researchers stated that some patients may be eligible for research trials in New Zealand. There are also some unfunded treatments available in private care.
4. The Committee noted that the submission form incorrectly stated that mandatory genetic analysis will not be performed; however, it will be performed. The researchers agreed that this was an error.

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 some participants are deceased and therefore will not be providing consent. Please explain why consent will not be sought from family/whānau for use of deceased individuals’ tissue and provide justification for waiver of consent. Please refer to paragraphs 14.8 to 14.15, and 15.25 of the [NEAC Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/14-human-tissue/) for guidance.
2. The Committee referred to the Data Management Plan (DMP). Please ensure that issues such as management of privacy breach, consultation, ownership of rights etc. are covered. The Committee recommended reviewing the HDECs [DMP template](https://ethics.health.govt.nz/assets/HDEC-data-only-management-template-Oct-2021.docx) for guidance to address the missing information. Please also ensure compliance with paragraph 12.15a of the [NEAC Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/).
3. The Committee referred to the Tissue Management Plan submitted. Please state explicitly where tissue will be analysed and stored for study purposes. Please also ensure that tissue used for research purposes is de-identified; it may be re-identified if required to return results of clinical significance, or at study conclusion on return to the participant’s clinical slide collection.
4. The Committee requested more information on return of individual results. Please explain whether the tests may result in findings that are clinically significant and actionable, and/or clinically significant but non-actionable. Please state the options for participants regarding return of these results. Please formalise processes for these in the study documentation (Protocol and PIS/CF).
5. The Committee noted that all participants in the current study are women with previous cancer who have been under the care of a specialist team. Please ensure that the initial approach regarding participation in research is made by a member of each woman’s clinical team, rather than a 'cold call' from a researcher.

The Committee requested the following changes to the PIS/CF:

1. Please change the font colour – the black font on the blue header is difficult to read.
2. Please ensure that the document is written in clear lay language. Please explain what a mutation is, and what the ‘Illumina TS-15 solid tumour panel’ is.
3. Please explain that the study benefits will likely arise in future. The study may not directly benefit participants.
4. The Committee asked if the researchers intend to undertake Future Unspecified Research (FUR), in which case a separate PIS/CF would be required. There are currently two contradictory statements in the PIS/CF. The researchers confirmed that they do not intend to undertake FUR. Please clarify this in the PIS/CF.
5. On page 2, please state that the study has been approved by the Southern HDEC. Please note that recruitment to the study should not commence prior to ethics approval.
6. On page 2, please replace ‘you have been chosen’ with ‘you are invited’.
7. On page 2, please include a sentence about why the original tissue is stored (i.e. that it needs to be stored in case it is required clinically).
8. Please include more information on tissue management and what is being done with the samples. Please inform participants that DNA will be extracted and analysed.
9. Please clearly state the timeframe for this study and period of collection (2008 – 2021).
10. On page 3, as noted earlier, please provide more information about return of results, and the difference between actionable and non-actionable results. If there is a chance that a poor prognostic genetic marker may be identified that is not actionable, please make this clear too.
11. On page 3, please note that health information should be retained for *at least* 10 years following the end of the study. Currently, there is a statement that ‘Results of the study will be stored on a secure laboratory computer and retained for, up to but not exceeding, ten years by the lead investigator’.
12. On page 3, the following statement appears to conflict with later portions of the document: ‘There is no current intention for future use of the data, however consent would be sought in this event’. Please review and amend accordingly.
13. On page 3, please include a cultural statement regarding the use and storage of tissue, and state whether a karakia is available on disposal of samples. Please also include this information in the DTMP.

**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 PIS/CF, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17).*
3. 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 2019, para 9.7*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Dr Devonie Waaka.

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| **2** | **Ethics ref:** | **2021 FULL 11233** |
|  | Title: | A study of safety, reactogenicity and immune response of the repeat vaccination against RSV when given to female participants of 18- 49 years of age during their subsequent uncomplicated pregnancy. |
|  | Principal Investigator: | Dr Rebecca Griffith |
|  | Sponsor: | GlaxoSmithKline Biologicals SA (GSK) |
|  | Clock Start Date: | 27 October 2021 |

Dr Rebecca Griffith, Bree Stenton, and Renz Cawaling 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. The study aims to evaluate the safety, reactogenicity, and pregnancy outcomes of repeat vaccination (in a subsequent pregnancy) with the new RSVPreF3 vaccine on mothers and infants. The study also aims to demonstrate non-inferiority of immune responses following the administration of repeat RSVPreF3 vaccination, when compared to the first dose.

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 how new participants would be recruited. The researcher stated that there are two routes of recruiting participants. First, mothers who have participated in the two previous studies are already on the research team’s contact list. Another route is through referrals (new participants) from midwives.
2. The Committee referred to the e-diary and asked whether the participant’s lead maternity carer/general practitioner would be notified if any concerning medical information arises from the questionnaire (for example, the headache severity scale may identify preeclampsia). The researcher advised that they receive a notification to site for these situations in real-time. They follow up with the participant in the first instance relatively quickly; however, they would advise the participant to seek healthcare help in the usual way.
3. The Committee asked if a translation service will be made available for participants. The researchers stated that this is not currently available. In the previous studies, all information has been delivered in English.

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 highlighted that the study must be registered with a clinical trials registry approved by the World Health Organisation. Please ensure that this is done before commencing any recruitment activity in New Zealand.
2. The Committee asked if the reimbursement amount calculated for ‘reasonable time’ related to study participation is $100.00 across all New Zealand sites. The researcher confirmed this. The Committee also asked whether travel expenses will be reimbursed in addition to the $100.00. The researcher stated that the amount includes travel; however, they would consider on a case-by-case basis whether to provide additional travel reimbursement. The Committee noted that in areas such as Auckland, reimbursement for travel might be higher than that for time. It appears that the reimbursement would then cover travel and associated expenses rather than reimbursement for time. Please consider this.
3. The Committee asked what would happen for participants who decide that they wish to withdraw consent for optional tissue use after they have completed the study. The researchers stated that at the end of the study, participants need to confirm for their samples to be used for optional research. The Committee asked what the justification is for not allowing withdrawal of consent after this point in time. If the samples can still be re-identified, the consent that participants sign for optional future research is ongoing so they should be able to withdraw consent if possible. Up until the point that the identification link is broken, participants should have the right to withdraw samples for optional future research. The researcher advised that they would obtain and provide more information on this. Please provide more information/justification and clearly state the process for tissue withdrawal, should a participant wish to withdraw consent for optional future research after completing the study.
4. The Committee noted that locality authorisation has been granted for the lead site. The Committee reminded the researcher that locality authorisation should not be signed off without Māori consultation. The researcher advised that sign-off was done in error. Please provide evidence and summarise the outcome of Māori consultation at the site and any changes requested to the Participant Information Sheet and Consent Form (PIS/CF) as a result.

The Committee requested the following changes to the PIS/CF:

1. On page 1, please use a simple lay-language study title above the formal title. Please also use this for lay title on the CF and the Future Unspecified Research PIS/CF.
2. On page 1, please delete the generic statement regarding ethics approval; a New-Zealand specific statement is already included on page 20 and can be moved earlier in the document if required.
3. On page 2, please provide an estimate of the number of New Zealand participants.
4. Please include more information about the purpose of the study, with more background information, and expand on the aspect of looking at subsequent pregnancies and whether immunity is passed onto the baby etc.
5. Please include more information about the screening process.
6. On page 11, please delete the statement that increased health checks are a benefit of study participation. These checks are performed to benefit the Sponsor, not the participant.
7. On page 11, please include a clear statement that phone and video consultations will not be recorded.
8. On page 21, please explain what is meant by documents being videoed. Identifiable data may be viewed over a secure portal; however, should not be able to be downloaded by those reviewing the data externally. Please clarify this.
9. On pages 24 and 26, please delete references to nasal swabs if they are not going to be part of the study. Nasal swabs are mentioned for the first time in the CF but not the body of the PIS or Protocol.

**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 PIS/CF, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Ms Amy Henry.

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| **3** | **Ethics ref:** | **2021 FULL 11098** |
|  | Title: | Study of WVE-004 in Patients with C9orf72-associated ALS or FTD |
|  | Principal Investigator: | Professor Tim Anderson |
|  | Sponsor: | Wave Life Sciences UK Limited |
|  | Clock Start Date: | 28 October 2021 |

Tim Anderson and Laura Paermentier 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. The purpose of this study is to determine if the study drug, known as “WVE-004”, is safe and well tolerated in the treatment of Amyotrophic Lateral Sclerosis (ALS) or Frontotemporal Dementia (FTD) when compared with a placebo control treatment. A multicentre, randomised, double-blind, placebo-controlled, phase 1b/2a study for an experimental drug.

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 the researcher’s clarification that 5-10 participants across New Zealand will potentially be recruited.
2. The Committee noted the researcher’s clarification that the participants with mild dementia who will be recruited into this study, will have the capacity to provide informed consent. He confirmed that they will not be enrolling people into this study who are unable to consent for themselves.
3. The Committee asked for clarification on the need for lumbar puncture for placebo participants. The researcher explained the justification is to understand if any changes or adverse events are due to the study product or the lumber puncture procedure and that having a placebo group means they will be able to understand adverse events through a smaller cohort. The researcher explained that lumber puncture procedures have improved over recent years and are now much better tolerated by patients.
4. The Committee noted the researcher’s comment that the sponsor is planning an open label extension study of two years.
5. The Committee noted that the researchers provided a pregnancy PIS/CF and explained that these documents are reviewed only if and when a participant/partner becomes pregnant during the study to ensure the information provided is fit-for-purpose at the time it occurs. If this situation occurs, the researchers are to submit the pregnancy PIS/CF as an amendment to the study application through the post-approval pathway.

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 recommended the future research unrelated to the study question should be optional and have a separate form. Please remove reference to optional future research from the main PIS/CF and add it as an addendum to the main PIS/CF.
2. The Committee requested clarification on how the researchers will identify the volunteers for the dummy MRI scans. The Committee clarified for the researchers that best practice is to use volunteers outside of their workplace to mitigate potential pressure to take part in the study, which may be present due to the employer-employee relationship. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para* *11.23 – 11.24).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) in addition to those mentioned above:

MAIN PIS/CF

1. Please explain the role of the participant’s support person and how he / she will be selected, to ensure that nomination of an appropriate support person can be made.
2. Please explain what biomarkers are, in lay language, the first time the term is used.
3. Please check that HIV testing is mentioned with the hepatitis testing if this is intended.
4. Please avoid using the term “Early Termination visit” and replace it with language less unsettling.
5. Please ensure participants are informed of their right to receive a lay summary of the study results when available in the body of the information sheet, not just on the consent form.
6. Please amend the Period 1 instructions, as it reads that sentinel participants will have an additional lumber puncture on day 3 (page 6).
7. Please include estimated number of New Zealand participants (page 3).
8. The GP notification of participation in a study of this nature should be mandatory. Please delete statements indicating that this is optional (e.g. page 15).
9. Please clarify whether stopping any medication is a requirement of participating in this study as the PIS/CF states, ‘Early termination includes (additional medication that is not allowed during the study)’.
10. Please include consent to allow study partners to provide information about the participant’s health and wellbeing.
11. Please ensure the coded data required for future research does not include date of birth and replace it with year of birth if needed.

STUDY PARTNER PIS/CF

1. Please remove the black box warning.
2. Please replace the statement, “It is possible that you may not personally benefit’ with ‘you will not personally benefit’.
3. Please state what happens if the study partner withdraws from the study, for example whether the participant must then also withdraw if a replacement study partner is not found.

MRI PIS/CF

1. Please update the body of the information sheet to advise that participants will either get payment or results of the scan – whichever option the researchers choose to go with.

Future Unspecified Research PIS/CF

1. Please add ‘genetic’ to the title of the PIS/CF.

**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 Sarah Gunningham and Ms Amy Henry.

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| **4** | **Ethics ref:** | **2021 FULL 11239** |
|  | Title: | Exploring implementation of the F-words for Child Development with an organisation in Aotearoa New Zealand |
|  | Principal Investigator: | Dr Margaret Anne Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 October 2021 |

Margaret Anne Jones and Julia Hill 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. The study explores the tailored implementation of the F-words for Child Development at an organisational level and is a pilot hybrid type III mixed-methods case evaluation. The study aims to:
   1. examine and track the tailored strategies being used to implement the F-words at an organisational level and determine the effectiveness of these strategies, and
   2. explore the perceived impact of the F-words on health service providers; whānau, parents/caregivers; and tamariki/children and/or rangatahi/youth.

Summary of resolved ethical issues

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

1. The Committee requested clarity on how ethnicity and disability type data will be presented to mitigate the risk of identifying participants with rare disabilities or belonging to minority ethnicity groups. The researcher clarified that their top priority is to ensure the privacy and confidentiality of participants and the results will be reported generally for these smaller groups to avoid identifying participants in publications.
2. The Committee noted that the hui at the conclusion of the research has implications for participants being made aware of the identity of the other participants. The researcher explained that hui attendance is expanded beyond participants, mitigating the risk of identification.

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 the researcher’s clarification that the age range of tamariki-rangatahi participants is 5 – 16-year-olds. Please update the study documentation accordingly.
2. The Committee noted the researcher’s confirmation that the implementation team will develop a blueprint of strategies to support standard care which will be delivered across the course of the study. The Committee stated that because the researchers will be delivering something that is not standard care, the study is an intervention rather than observational as stated. Please ensure this is amended in the study documentation.
3. The Committee queried the recruitment methods that will be used to enrol whānau and tamariki-rangatahi participants. The researcher clarified that the initial approach to the families will be made by an administrator at the organisation, who will send a group email to people who attend the organisation with the study invitation attached. The Committee recommended the initial email contact to the prospective participants is made from the clinical institution rather than a researcher that the person does not know. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7c).*
4. The Committee advised that it is best practice to ensure that when sending group emails (whether for recruitment or not) to ensure that the email addresses are not visible to recipients.
5. The Committee requested that parents and children are not informed of the koha for young people during the informed consent process; it is best mentioned once the interview has been completed. This will mitigate the risk of young people being incentivised to take part in order to receive the gift. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20).*
6. The Committee stated that the email script for the whānau is overly technical and may dissuade people from participating. Please amend the script to be more lay-friendly. Please also make it clear in the email scripts that the coordinating site is in Canada.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) in addition to those mentioned above:

ADULT PIS/CFS

1. Please ensure there is a statement of reassurance that participating in the research will not affect services, and information will not be shared with clinicians.
2. Please review the 'What happens to my information section' of [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) and incorporate relevant components into the PIS/CF. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.16).* This section should align to the information in the data management plan and address risks of data being sent overseas, future use of data if relevant, and what happens to the audio recordings following transcription (this has only been included in the Older Child form).
3. Please delete ACC statement if not applicable to this study (e.g. focus groups and interviews).
4. Please add the HDEC approval statement, and the HDEC, HDC and Māori cultural support statements and contact details. For guidance, please refer to the HDEC’s PIS/CF template linked above.
5. Please state whether data will be shared with other researchers or used for future research related to 'F-words'.
6. Please include a statement about rights to correct the transcript. E.g. “You have the right to request access to your information held by the research team such as the transcript. You also have the right to request that any information you disagree with is corrected”.

OLDER CHILD ASSENT FORM

1. Please revise the document to reduce sentence length and increase the font size.
2. Please use a simple lay title
3. Please delete the ACC statement if there is no risk of study related injury.
4. Please make it clear data will be sent to Canada.
5. Please state whether data will be shared with other researchers or used for future research related to 'F-words'.
6. Please include a statement about rights to correct the transcript. E.g. “You have the right to request access to your information held by the research team such as the transcript. You also have the right to request that any information you disagree with is corrected”.
7. Please state that the youth can say no to participation even if the parents want them to take part.
8. Please include cultural support details and amend other contact details to include HDEC and HDC statements. Please see PIS/CF template linked above.

YOUNGER CHILD ASSESNT FORM

1. Please state that the youth can say no to participation even if the parents want them to take part.
2. Please add field for child’s name.

**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 Mr Dominic Fitchett and Ms Amy Henry.

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| **5** | **Ethics ref:** | **2021 FULL 11615** |
|  | Title: | ED Elderly Head Injury Outcomes, ED-EM-HI Study |
|  | Principal Investigator: | Dr Devin Faragasso |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 October 2021 |

The principal advisor was not 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 primary aim of this observational study is to determine if elderly patients who appear well to an emergency department doctor after a minor head injury are in-fact at low risk of dying, needing neurosurgery, or needing ICU admission, over the next 30 days.

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 stated that the approach set out by the researchers for obtaining consent is not a valid option as it does not meet the suitable processes for obtaining consent detailed in the *National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.1 – 7.8)*. The options available to the researchers are to obtain opt-in informed consent or apply to HDECs for (and be granted) a blanket waiver of consent for re-use of data.
2. The Committee stated that a waiver of consent may be justifiable, but only if the research team restricts collection of data to that available in the clinical record (i.e. additional information cannot be sought from patients, whānau, or aged care facilities). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.47).*
3. The Committee stated that should a waiver of consent not be applied for or granted, the processes regarding enrolment of non-consenting adults must be formalised and a justification for their inclusion provided. The response regarding enrolment of participants using the 'best interest' argument is unclear. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
4. The Committee stated that the participant information sheet and consent forms (PIS/CFs) are not fit-for-purpose as currently written and require significant revision if informed consent is to be sought. For guidance, please use the [HDEC’s PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc). The Committee clarified that PIS/CFs would not be required if a waiver of consent was granted. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
5. The Committee advised that receiving a copy of study results cannot be considered reimbursement for participation. This is applicable only if a waiver of consent is not granted.
6. The Committee stated that the protocol requires significant revision to reflect the consent process that will be pursued for this study and requested the following additional changes *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7)*:
   1. Please remove mention of Kaupapa Māori methodology as contrary to what is stated, this methodology has not been used.
   2. Please remove the 30-day phone call (and other contact with the patient) should the study operate under a waiver of consent.
7. The Committee stated that the data management plan appears to have been cut and pasted from a template or earlier study, contains prompters rather than specific information in a number of sections, and references ADHB and children's data. The plan requires thorough modification to appropriately reflect the data management requirements of this study. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

**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 recommended the researcher re-apply to the Southern HDEC as they have reviewed this initial application and will have more context for the re-application.

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| **6** | **Ethics ref:** | **2021 FULL 10996** |
|  | Title: | AG10-304: Extension Study and Safety Monitoring of Acoramidis (AG10) in Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) |
|  | Principal Investigator: | Dr Hugh Goodman |
|  | Sponsor: | Eidos Therapeutics, Inc. |
|  | Clock Start Date: | 27 October 2021 |

Liz Low and Melissa Kirk 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. The aim of this study is to assess safety and tolerability of acoramidis in participants with symptomatic transthyretin amyloid cardiomyopathy (ATTR-CM).

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 if there would be compassionate access to the drug following the extension study due to limited treatment options. Please clarify this with the Sponsor if there are any plans for this.
2. The Committee noted that the Sponsor’s declaration needs to be signed on the application form.
3. The Data and Tissue Management Plan (DTMP) states that tissue will continue to be used if a participant withdraws, but this is contradicted in the participant information sheet which says it can be destroyed on request. Please correct for consistency.

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

1. Please check that the font is consistent.
2. Please use blood volumes in millilitres only.
3. On page 2 for statement “Your consent to collect your vital status may not be withdrawn unless local laws or regulations do not allow this”, please remove “unless local laws or regulations do not allow this.”
4. Please also check what laws, if any, apply to the similar statement to the above on page 12 about samples that have been collected and amend/remove as necessary. If there are any New Zealand laws that are applicable, please refer to these.
5. Please state on page 13 whether collected data would be retained and used for future related research.
6. Please provide information about withdrawal of data.
7. Please include a statement that participants will be told about any new information related to the study / study drug that could impact their health or desire to continue in the study.
8. Please review for unnecessary repetition, such as pages 3, 4, 11 regarding study procedures and pages 6 and 7 regarding reproductive risks.
9. The Committee noted that the trial cannot be stopped for commercial reasons by the Sponsor. It suggests this on page 10, please amend.
10. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
11. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study). Contacting the GP and withdrawal of already collected data are not considered optional in the PIS

**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 Sarah Gunningham and Dr Devonie Waaka.

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| **7** | **Ethics ref:** | **2021 FULL 11481** |
|  | Title: | M20-371 Moderate to Severe Crohn's Disease: A Phase 2 Safety and Efficacy Study of ABBV-154 |
|  | Principal Investigator: | Dr. Benjamin Griffiths |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 28 October 2021 |

Marina Dzhelali 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 main aim of this study is to assess the efficacy, safety, and tolerability of ABBV-154 in comparison with placebo in subjects with moderately to severely active Crohn’s Disease (CD) who had inadequate response to or were intolerant of prior biologics.

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 the extent of mandatory genetic biomarkers versus optional, as it was unclear in the study documentation. If any genomic analysis is required to fulfil study objectives, it should be restricted to the drug / disease to answer the aims of the study. Please ensure statements in each participant information sheet (PIS) is specific to the requirements of participation. Currently, the statements in the main and optional PIS are identical and are very broad.
2. Please confirm that any safety results that will not affect the blind will be made available to participants.
3. The Committee noted that investigators may be the potential participant’s clinician. Please ensure there are steps outlined in the study documentation on how recruitment and consent can be handled by someone in the research team who is not part of their direct care, after the initial approach regarding study participation is made.
4. The Committee noted the response to ionising radiation questions in the application form were incorrect as the study requires Chest x-ray and dual-energy x-ray absorptiometry (DEXA) scans that are not otherwise required for standard of care.
5. The Committee noted the following about the Data and Tissue Management Plan (DTMP):
   1. Section 6.1 states that participants will be notified only in the event of a Notifiable Privacy Breach. The Committee expects that participants are informed of any breaches of privacy, unless there is a valid reason for not doing so. Replace the applicable bullet point with the [HDEC DTMP template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) text.
   2. Section 12.1 states that participants are informed of the possibility of clinically significant but non-actionable findings in the PIS/Consent Form (CF), and that their wishes regarding return of results are recorded in the PIS/CF. Clarify where this information is in the PIS/CF, and which tests may produce clinically significant but non-actionable findings, if any.
6. Pregnancy PIS/CFs should be submitted in the event of a pregnancy and should be submitted as an amendment. They are not reviewed/approved as part of this submission.

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

Main PIS/CF

1. Provide an explanation on intravenous and subcutaneous in lay terms the first time these terms are used.
2. Please ensure the following are amended to be New Zealand specific:
   1. Information regarding infectious disease testing and notifiable diseases.
   2. Remove reference to state laws
   3. Remove PPD testing if it is not planned at NZ sites.
3. Please provide blood volumes in millilitres only (remove cups / teaspoons / tablespoons).
4. Explain in simple lay language what biomarker and PK samples are the first time they are referenced (page 5)
5. Schedule of assessments should be simplified as much as possible such as specifying questionnaires, blood tests and urine tests.
6. Home visit section is duplicated, remove one (page 13 and page 14).
7. Please remove “also described as the AIDs virus” on page 15.
8. Please include a sentence about the equivalent radiation for the scans (e.g.., equivalent to a year’s worth of background radiation)
9. Contraception section is technical. Please re-write in lay language and give New Zealand context.
10. Personal data, identifiable data and coded data are not well distinguished, with ‘personal data’ being used to describe identifiable data in some places and coded data in others. Please replace with terms such as identifiable, de-identified, etc.
11. The Committee noted that the study cannot be stopped for commercial reasons, please amend. Further, the Committee noted if the study is stopped early because drug is found to work, they would want assurance that participants who have shown benefit from the drug would not be withdrawn early from treatment as a result
12. Page 3 talks about being re-randomised to one of *the* two treatment groups. Please remove “the” as it could be inferred as groups already known.
13. Please advise that karakia is not available at time of tissue disposal.
14. Page 21, statement “Non-live vaccines, such as various COVID-19 vaccines, is not known.” is not entirely clear what this is referring to and is possibly missing a few words. Please amend.
15. Please clarify that “You may have to pay for some medicines according to hospital policy.” will not apply to any medication required as part of the research.
16. Please state if virtual visits are recorded.
17. Give all participants the option of receiving a summary of study results when available (optional Consent Form item)
18. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
19. Delete signature space for legally authorised representative.

Optional PIS/CF

1. It is not clear why the participant's local doctor should be informed about participation in this aspect of the study; it involves no additional risk and no results will be provided to the participant (page 2). Delete if not mandatory.
2. Combine the two sets of bullet points about the purpose of the research (page 2 & page 5) and delete repetitive statements. Retain the information about genes and DNA, and clearly explain whether or not the research may involve analysis of the person's entire genetic code (whole genome analysis).
3. Please simplify the schedule of assessments. This should simply be the visits when the optional blood tests will be completed. The distinction between the different assays is technical and unnecessarily complicated.
4. The optional wearable device sub-study does not seem to be related to the Future Unspecified Research (FUR) tissue information. Clarify who will be invited and whether only those donating samples for FUR will be participating in the device sub-study. Amend the title, and state that they can take part in one, the other, or both.
5. Please provide a brief description of the watch characteristics, such as if it can connect to the internet, has Bluetooth, any form of tracking or camera capability, etc. This information should be in DTMP too.
6. The Committee queried if there really is a risk of anaemia with the collection of 34 mL of blood. Delete if not relevant.
7. There are clearly no health risks associated with withdrawing from this optional FUR. Delete the statement regarding this (page 6).
8. Include a clause in the Consent Form stating that the participant acknowledges that future research will include genetic research.
9. Delete signature box for legally authorised representative.
10. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).

**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 update the data and tissue management plan to ensure the safety and integrity of participant data and tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Anthony Fallon and Dr Devonie Waaka.

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| **8** | **Ethics ref:** | **2021 FULL 11279** |
|  | Title: | M20-466 Moderate to Severe Rheumatoid Arthritis: A Phase 2b, Dose-Ranging, Safety and Efficacy Study of ABBV-154 |
|  | Principal Investigator: | Dr Douglas White |
|  | Sponsor: | AbbVie Inc. |
|  | Clock Start Date: | 27 October 2021 |

No researchers 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. The primary objective is to assess the safety, tolerability, and efficacy of ABBV-154 versus placebo on background methotrexate (MTX) for the treatment of subjects with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to at least one prior biologic and targeted synthetic disease-modifying antirheumatic drug (b/tsDMARD).

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’s justification for use of placebo did not address whether the inclusion of a placebo arm is ethical in the study. However, on review of the Protocol and other study documents, the Committee accepts that this appears to be justified for the study. Please confirm what patients would usually be offered should they choose not to participate in the trial, and whether the placebo period could result in significant deterioration.
2. The Committee noted the restrictions placed on publications. Please summarise the restrictions placed on the publications and state whether the Sponsor can prevent publication of study results.
3. The Committee noted that the researchers intend to use advertisements. Please submit these as an amendment when they are available.
4. The Committee noted that the explanation regarding mandatory biomarkers on the Participant Information Sheet and Consent Form (PIS/CF) on page 10 is broader than that in the Protocol. Please clarify what mandatory biomarker analysis is restricted to and whether it involves DNA analysis.
5. The Committee cannot grant study approval in the absence of sponsor authorisation of the submission. Please ensure that this is undertaken as part of the response to provisional approval.
6. Please confirm whether the study is registered with a World Health Organisation approved clinical trials registry. For example, the EU Clinical Trials Register (EU-CTR).
7. Please note that pregnancy follow-up PIS/CFs are to be submitted as an amendment only in the event of a participant or partner pregnancy. Accordingly, the Pregnancy Follow-up and Pregnant Partner Authorisation documents have not been reviewed or approved by the Committee with this submission.

The Committee requested the following changes to the Data and Tissue Management Plan (DTMP):

1. Section 6.1 states that participants will be notified only in the event of a Notifiable Privacy Breach. The Committee expects that participants are informed of any breaches of privacy, unless there is a valid reason for not doing so. Please replace the applicable bullet point with the relevant text from the HDECs [DTMP template](https://ethics.health.govt.nz/assets/HDEC-data-tissue-management-template-Oct-2021.docx).
2. Section 8.4 does not address future use of tissue. Please amend accordingly.
3. Section 12.1 states that participants are informed of the possibility of clinically significant but non-actionable findings in the PIS/CF, and that their wishes regarding return of results are recorded in the PIS/CF. Please clarify where this information is in the PIS/CF, and which tests may produce clinically significant but non-actionable findings.

The Committee requested the following changes to the main PIS/CF:

1. Please review the document for spelling mistakes and grammar errors. Please also delete any repetitive statements.
2. On page 2, please explain what 'b/tsDMARDs' means in simple lay language.
3. On page 2, the treatment arms are incorrect; the first four Rx arms are not 'or placebo'. Please amend. Please also explain the ratio 1:1:1:1:1 in lay terms ('you have a 20% chance of being in each group').
4. On page 3, please state the estimated number of New Zealand participants.
5. On pages 4 and 10, please include New Zealand-specific information about notifiable diseases. Tuberculosis is notifiable. Please also note that New Zealand does not have 'state laws'.
6. Please delete blood volumes given in tablespoons; use mLs only.
7. On page 4, please explain in simple lay language what biomarker samples are the first time they are referenced. Please also amend page 10 to more accurately reflect mandatory biomarker usage per section 3.7 of the Protocol.
8. On page 9, please provide a statement regarding karakia under cultural considerations.
9. On page 10, please delete 'also called the AIDS virus'.
10. On pages 11 to 12, please provide frequencies for the categories of adverse events.
11. On pages 13 to 14, there are two sections about interactions with other medications. Please combine and delete redundant text.
12. In reference to page 17, please explain to the Committee what photos, video, or voice recordings will be collected during the study.
13. On page 17, please confirm that the following statement is incorrect and delete it from the PIS/CF: ‘The Sponsor may not accept the compensation claim if the injury was caused by ABBV-154’.
14. On pages 19 and 20, the distinction between personal data and coded data is confusing; it is very unclear when identifiable data is being referred to. Please separate access to and use of identifiable data from coded data.
15. On page 20, please make it clear that the participant can access safety/screening results during active study participation where these will not impact blinding.
16. On page 21, as this is a therapeutic study, the study should not be stopped for commercial reasons. If the drug has been 'found to work', ensure participants on active treatment and receiving benefit are not withdrawn early from treatment. Please amend the PIS/CF accordingly.
17. On page 22, please give all participants the option of receiving a summary of the overall study results once available.
18. Please remove optional tick boxes from mandatory consent clauses in the Consent Form.
19. Please delete the signature space for a legally authorised representative in the Consent Form.

The Committee requested the following changes to the Optional PIS/CF:

1. On page 1, please use lay language in the short title.
2. In reference to page 2, please explain to the Committee why the participant's local doctor should be informed about participation in this aspect of the study; it involves no additional risk, and no results will be provided to the participant. Please delete if not required.
3. On pages 2 to 4, please combine the two sets of bullet points about the purpose of the research and delete repetitive statements. Please retain the information about genes and DNA on page 1, and clearly explain whether or not the research may involve analysis of the person's entire genetic code (WGA).
4. On page 4, the Committee queried whether there really is a risk of anaemia with the collection of 34 mL of blood. This is not noted as a risk in the main PIS/CF. Please delete if not relevant.
5. On page 6, there are clearly no health risks associated with withdrawing from this optional Future Unspecified Research. Please delete the statement regarding this.
6. Please explain to the Committee the rationale for including optional tick boxes for participating in the research (if ‘no’ is ticked, the participant cannot participate in the study).
7. Please include a clause stating that the participant acknowledges that future research will include genetic research.
8. The statement regarding SMS messages does not appear appropriate for this form. Please explain why it is required or delete.

**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 PIS/CF, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17).*
3. 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 2019, para 9.7*).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Anthony Fallon and Dr Devonie Waaka.

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| **9** | **Ethics ref:** | **2021 FULL 11336** |
|  | Title: | A study investigating a new ocular implant, PA5346 Latanoprost FA SR Ocular Implant. |
|  | Principal Investigator: | Prof Anthony Wells |
|  | Sponsor: | PolyActiva Ply Ltd |
|  | Clock Start Date: | 28 October 2021 |

Bonnie Menzies and Dr Russell Tait 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. The purpose of this study is to assess the safety and tolerability of 100 ng/day PA5436 Latanoprost FA SR Ocular Implant in adults with open angle glaucoma (OAG) or ocular hypertension (OHT) and assess the period of biodegradation of 100 ng/day PA5436 Latanoprost FA SR Ocular Implant in adults with OAG or OHT. The study will enrol 6 adult participants.

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 if the research team considered having a single site in order to minimise potential risks with device training. The researcher responded that two sites were selected due to issues observed overseas with single-sites and COVID-19. After discussion, the Committee was assured of extensive training procedures in place and was satisfied with the response.

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 if there would be any risk in ocular pressure not being monitored during the washout period, and whether participants would be made aware of symptoms indicating increased pressure. The researcher responded that the washout period can be adjusted per participant with monitoring. The Committee stated that if participants are being informed of what to look for, please include this in the participant information sheet (PIS).
2. The Committee noted that for this type of study, notification to the participant’s usual doctor of abnormal results means they can be confident that appropriate follow-up is in place. Please amend documentation to make it clear that notification to the participant’s GP is mandatory.
3. Please ensure authorisation of the application is provided by the Sponsor in Ethics RM
4. The Committee noted the following about the Data and Tissue Management Plan (DTMP):
   1. Section 7.1 states that screening and safety lab samples and results will be labelled with identifiers; the PIS/Consent Form (CF) and application form state they will be labelled with ID number only. Clarify what is intended and amend documentation accordingly.
   2. Notifiable diseases are not screened for during this study; please delete the final bullet point of Section 8.1.

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

1. Please review for lay language. For example, simplify exclusion criteria significantly, simplifty pressure readings (use 24 - 36 mmHg if it is felt the exact measurements are required), replace technical terms in last bullet point of page 6 with 'examine the study eye', 'broken down' instead of 'biodegraded', 'breathing rate' instead of respiratory rate, 'blood and urine safety tests' instead of 'samples collected for the assessment of your health status' etc.
2. Please delete the stigma risk paragraph - it is not required for this type of study (page 15)
3. Permanent change in eye colour is listed as a special precaution by Medsafe. Update risk to include permanent darkening of the colour of the iris.
4. Delete optional tick-box for GP notification of abnormal results; this should be mandatory (Consent Form)

**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 update the data and tissue management plan to ensure the safety and integrity of participant data and tissue *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Devonie Waaka.

General business

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

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| **Meeting date:** | 14 December 2021 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Mr Anthony Fallon
* Dr Devonie Waaka

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 2.35pm