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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 July 2021 |
| **Meeting venue:** | https://mohnz.zoom.us/j/96507589841  Meeting ID: 965 0758 9841 |

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| **Time** | **Item of business** |
| 10.00am | Welcome |
| 10.15am | Confirmation of minutes of meeting of 08 June 2021 |
| 10.30am | New applications (see over for details) |
| 10.30-10.55am  10.55-11.20am  11.20-11.45am  11.45-12.00pm  12.00-12.25pm  12.25-12.50pm  12.50-1.15pm  1.15-1.30pm  1.30-1.55pm  1.55-2.20pm  2.20-2.45pm | i 21/STH/166 Sarah/Paul  ii 21/STH/155 Helen W/Mira  iii 21/STH/156 Dominic/Paul  *Break (15)*  iv 21/STH/157 Sarah/Mira  v 21/STH/158 Dominic/Paul  vi 21/STH/162 Helen W/Mira  *Break (15)*  vii 21/STH/165 Dominic/Paul  viii 21/STH/152 Helen W/Mira  Substantial amendments (see over for details)  i 20/STH/70/AM09 Sarah/Mira |
| 2.45pm | Meeting ends |

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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 | Apologies |  |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |  |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | Present |  |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |  |

## Welcome

The Chair opened the meeting at 10.00am and welcomed Committee members, noting that apologies had been received from Dr Devonie Waaka.

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 08 June 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/166** |  |
|  | Title: | 208833 (STAPH AUREUS BIOCONJ-001 STG) |  |
|  | Principal Investigator: | Dr Renate Koops |  |
|  | Sponsor: | GlaxoSmithKline |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Renate Koops, Alexandra Romano and Sylvia Pietkiewicz 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 first in human study will evaluate the effects of an investigational vaccine when administered to adults aged 18 to 50 years who have had a recent skin and soft tissue infection (SSTI) caused by Staphylococcus aureus. The purpose of this study is to assess safety and reactogenicity, to perform a preliminary evaluation of clinical efficacy and to explore immunogenicity of GSK Biologicals’ S. aureus vaccine compared to placebo (saline).

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 it is unusual to administer a vaccine *after* an SSTI incident. The researcher responded that this is because SSTIs are recurrent. The vaccine aims to prevent SSTIs in populations who have them on a recurring basis.
2. The Committee queried how much participants will be reimbursed and whether this will be consistent across sites. The researcher responded that the amount is yet to be decided but that consistency across sites would be ensured as best as possible.
3. The researcher agreed to inform the Committee if the data from the 32 healthy volunteers already given the vaccine revealed anything of significance.

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 requested that the researcher makes the advertisement more lay friendly, e.g. by stating “skin infections” rather than “soft tissue infections”

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

1. Please include data of adverse events from the previous study in healthy volunteers.
2. Please make more lay friendly, including lay title.
3. Please make all information in the PIS relevant to the group reading it.
4. On page 10, please remove the statement saying that regular health check-ups are a benefit of the study.
5. On page 23 and 24, please remove talk about nasal swabs as involvement in the study will not include this.
6. Please remove detail of optional future unspecified research (FUR) from the main PIS, e.g. in the ‘what will happen to my samples’ section on page 13.
7. Please clarify you will not be able to access the vaccine after the study.
8. Please use the HDEC [reproductive risk template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx) instead of the current reproductive risk statement.
9. Please clarify that you will be screening for hepatitis (and HIV if applicable) and that these are notifiable to the Ministry of Health if a positive test is returned.
10. Please clarify on page 14 that the tick box for optional FUR is on the optional FUR form, not the main form.
11. Remove background information and repetition that makes the form unnecessarily long.
12. Please reconsider the form structure to improve readability, e.g. the explanation of the study design could be much earlier in the form.
13. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance on the data management section. Please clarify the difference between identified and deidentified data in a New Zealand context.

OPTIONAL FUR

1. On page 2 of the Optional FUR consent form, please give separate headings for related and unrelated research using stored samples.

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 suggestions made by the Committee.

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| **2** | **Ethics ref:** | **21/STH/155** |  |
|  | Title: | (duplicate) (duplicate) Metabolic syndrome in Huntington's disease: A retrospective study. |  |
|  | Principal Investigator: | Dr Eileen Mc Manus |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 20 June 2021 |  |

Eileen McManus was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The researchers will review approximately 50 patients diagnosed with Huntington’s disease for metabolic syndrome. They will review their clinical notes for Huntington’s diagnosis, co-morbidities, and medication. They will collect a weight, height, waist circumference and blood pressure. They will collect bloods e.g., lipid profile and glucose/HbA1C. They also collect clinical data on symptomology and function. Other data regarding age, ethnicity and gender will be obtained.

Summary of resolved ethical issues

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

1. The Committee enquired about recruitment into the study and requested a separation of the roles of the clinician and researcher, so that participants do not feel pressured to partake in the study. The Committee requested that a research nurse introduces the study to the potential participant rather than the clinician, in order to avoid inducement. The researcher reassured the Committee that they have procedures in place for this.
2. The Committee noted that the peer review lacked detail and encouraged the researcher to seek a more detailed peer review in future applications e.g. the Committee needed clarification from. the researcher that they will be collecting data regarding age of entry into the study as well as age of diagnosis.
3. The Committee noted that this application had come to the full committee due to the issue about enduring power of attorney (EPOA). The Committee queried how many participants will have an activated EPOA in place. The researcher responded that this would be roughly between 5-10% per cent of participants. The Committee felt that it was acceptable for the EPOA to sign on behalf of these participants, as it is a low risk observational study that does not constitute a medical experiment.
4. The Committee clarified with the researcher that there will be no future use of data in this study

Summary of outstanding ethical issues

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

1. The Committee queried what would happen if the relevant tests required by the researchers to perform the diagnosis had not been performed, e.g. some of the blood tests. The researcher responded that they will have all blood test data required for most patients, however not all patients will have an HbA1c or lipid profile done. Therefore, the consent form will ask if bloods can be taken. The researcher team also needs to look at height, weight and waist circumference, which will also be included in the consent form.
2. Please update the data management plan in the protocol for accuracy, e.g. where it says that there will be no patient identifiers. Please refer to NEAC 2019 section 12.15.

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

1. Please provide information in the ‘what will my participation involve?’ section, pertaining to the extra blood tests and collection of height, weight and waist circumference
2. The Committee queried the process if metabolic syndrome is diagnosed in some participants. The researcher responded that they will inform the participant and their GP, and offer them treatment. The Committee requested that this information, as well as what diagnosis and treatment will entail, is included in the PIS
3. Please clarify that there will be no control group. Rather, the study data will be compared to data from another study.
4. On page 2 of the PIS, please delete next of kin for who can consent. Please amend to refer to ‘activated’ EPOA.
5. Please include on the CF a place for the EPOA to sign.
6. Under 'rights to access your information', please amend the second paragraph to read 'please ask if you would like to access your results'. The remainder of the information in the paragraph does not pertain to an observational study.
7. Under 'future research using your information' please delete 'if you agree' - other study documentation infers that this is a mandatory component of study participation. If the intention is for future use of data to be optional, a yes/no tick-box should be included in the consent section, with an applicable consent clause.

Decision

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Assoc. Prof Mira Harrison-Woolrych and Dr Sarah Gunningham.

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| **3** | **Ethics ref:** | **21/STH/156** |  |
|  | Title: | Aotearoa Healthcare Equity in Atopic Dermatitis (AHEAD Study) |  |
|  | Principal Investigator: | Dr Georgina Harvey |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Georgina Harvey and Stuart Dalziel 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. Three studies. Using national datasets the researchers will describe the demographics of paediatric (<18 years) AD admissions to hospital (January 2001 to December 2020). Additionally, for children admitted between 2015 - 2019, they will describe dispensing of topical corticosteroids and emollients, as a surrogate for community management, in the year prior to and following the index AD admission. Finally, they will compare the frequency of dispensing for topical corticosteroids and emollients with frequency of dispensing for aged matched children dispensed topical corticosteroids but not admitted to hospital for AD during the same time period. They hypothesize that community dispensing will be lower in Māori and Pasifika children admitted to hospital with AD.

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 the involvement of the researchers in the clinical care of the child participants, noting the possible conflict of interest, especially when recruiting participants. The researcher informed the Committee that they will attempt to mitigate this risk by recruiting participants after rather than before they have received clinical care. The researcher insisted that they cannot find someone else outside of the clinical team to do the recruitment. The Committee requested that the research team employ particular sensitivity during the recruitment process.
2. The Committee noted that the retrospective data includes NHI, which is identifiable. The Committee requested that the NHI is removed from the dataset as soon as possible. The researcher responded that this will occur once the two datasets have been linked.

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 research team are not consenting participants for retrospective use of health data, and that the application does not provide a justification for this. The researcher responded that it will be impossible to approach these participants as they do not have their contact details. He also noted that the public benefit of the research outweighs the risk to the individual. The Committee was willing to grant a waiver of consent on the basis that the justification for this request of a waiver of consent, as per the [*National Ethical Standards for Health and Disability Research and Quality Improvement*](https://neac.health.govt.nz/publications-and-resources/neac-publications/national-ethical-standards-for-health-and-disability-research-and-quality-improvement/)*,* paras 7.47-7.48, is provided in writing to the HDEC.
2. The Committee requested a specific Data Management Plan for each of the three parts of the study, as per the *National Ethical Standards for Health and Disability Research and Quality Improvement,* para 12.15. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) for guidance.
3. The Committee noted a variability in referring to 16-year-old versus 18-year-old participants. Please clarify in the documentation, e.g. page 14 of protocol.
4. The Committee requested details of a full scientific peer review to be provided to HDEC, as per the *National Ethical Standards for Health and Disability Research and Quality Improvement*, para 9.26.
5. The Committee requested reassurance for how the children’s rights will be protected and a clarification of the assent process for children, as per the *National Ethical Standards for Health and Disability Research and Quality Improvement*, paras 6.22 – 6.23. The Committee noted that under NZ law, being under 16 does not mean that a participant is not capable of consenting - informed consent relates more so to competency than it does strictly to age. If participants can understand the study and what they are consenting to, participants under the age of 16 should be given the right to provide their own consent. The researcher responded that most child participants will be very young and therefore unable to have competency to provide consent. If they do not assent, they will not be included in the study, as per standard practice. The Committee requested that the researcher provides in their documentation a procedure for competent child participants to provide their own consent and noted that a peer review should provide specific feedback on the scientific value of studying the guardian/parent viewpoint in the absence of the child/patient viewpoint.
6. The Committee noted that question r2.5 of the online forms talks about retaining health information until the youngest participant turns 18. This should say 10 years after the youngest participant turns 16 years old, and should be reflected where relevant in the PISCF and Protocol/data management plan.

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

1. The Committee noted that the PISCF for the online survey missed many details required to adequately inform participants about the study. Please update to include more information, especially with regard to data management. Please see the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
2. Please provide more detailed information about data management for each part of the study. Please see the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
3. Please provide an ACC statement in the adult PIS, as per the [*National Ethical Standards for Health and Disability Research and Quality Improvement*](https://neac.health.govt.nz/publications-and-resources/neac-publications/national-ethical-standards-for-health-and-disability-research-and-quality-improvement/)*, para 17.1.* Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
4. Please proofread the documents.

Decision

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

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

A final decision will be made by Mr Dominic Fitchett and Dr Paul Chin.

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| **4** | **Ethics ref:** | **21/STH/157** |  |
|  | Title: | CA42750 - Study to investigate safety and efficacy of Obinutuzumab in Patients with SLE |  |
|  | Principal Investigator: | Dr Ketna Parekh |  |
|  | Sponsor: | Roche Products (New Zealand) Limited |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Ketna Parekh, Marina Dzhelali and a sponsor representative 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 current study CA42750 (ALLEGORY) is being undertaken to observe whether obinutuzumab would also have clinically meaningful benefits for systemic lupus erythematosus (SLE) patients with active disease, but without severe lupus nephritis (LN), and to provide long-term data to inform the use of obinutuzumab in SLE. In light of the clinically meaningful benefits and an acceptable safety profile observed with obinutuzumab in SLE patients with severe LN, the Sponsor is undertaking the present study to assess the efficacy and safety of obinutuzumab, a Type II anti-CD20 monoclonal antibody with enhanced B-cell depletion, to address a significant unmet medical need in patients with active, autoantibody-positive SLE.

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 insurance is NZ specific. The researcher responded that yes, it is.
2. The Committee queried whether placebo participants will be eligible for the long-term extension study. The researcher reassured the HDEC that yes, this is the case.
3. The Committee queried whether the access to the study drug after the study is finished will be given by Roche or the NZ Government. The sponsor representative informed the Committee that this would be provided by Roche, subject to certain criteria being met, as outlined in the study protocol and PISCF.
4. The researcher informed the committee that the DNA collection is no longer going to occur. They will amend the PISCF accordingly.

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 whether there is a risk of adverse effect in participants on the placebo having to take other drugs for the duration of the study that they are not needing (methylprednisolone, paracetamol, diphenhydramine). The researcher responded that these are necessary for the participant to receive them as it is a blinded study. The Committee requested that the researcher include in the PIS that these medications may cause side effects, with special consideration for those in the placebo group (who are not receiving any benefit from the study drug).

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

1. Please amend to remove reference to DNA collection.
2. Please state the risk of adverse effects for the non-study drugs that will be taken by participants during the study.
3. Please rephrase the reproductive risk statement to advise participants to use *any* of the contraceptive methods listed rather than *two* methods.
4. Please reduce and condense where possible, e.g. do not need full study title on first page, just lay title is fine. Reduce the large capital letters on first page.
5. Please ensure adequate separation between the main text and the footers.
6. Please make NZ-specific.
7. Please move the cultural statement to an earlier/more appropriate place.
8. Please remove the optional tick boxes from the CF, with the exception of the summary of results tick box.
9. Please separate data use in the data management section of PISCF into de-identified and identifiable.
10. Please reword “pain in extremity” to state “pain in hands and feet”, so as to avoid misinterpretation.

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 suggestions made by the Committee.

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| **5** | **Ethics ref:** | **21/STH/158** |  |
|  | Title: | Window of opportunity trial of Tarloxotinib combined with SBRT in advanced HPV negative head & neck cancer. |  |
|  | Principal Investigator: | Dr Andrew Macann |  |
|  | Sponsor: | Auckland District Health Board |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Andrew Macann, Dr Edbert Wong and Dr Sanjeev Deva 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. Tarloxotinib is a medication that is activated by low oxygen levels and targets a growth receptor important for survival of the head and neck cancer. This research programme is trying to improve outcomes in head and neck cancer by combining Tarloxotinib with a targeted form of radiation therapy called Stereotactic Body Radiotherapy (SBRT) prior to surgery. The primary objective will be to evaluate logistics and safety of Tarloxotinib on its own and in combination with SBRT.

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 it was unclear whether this is a commercially sponsored study and asked the researchers for clarification surrounding the involvement of the drug manufacturer Rain Therapeutics in order to ascertain whether injury as part of this study is covered by ACC. The researchers clarified that Rain Therapeutics are only supplying the drug, but data ownership stays with the research team. Only one investigator on the team has a conflict of interest. The Committee was satisfied with this.
2. The Committee clarified with the researcher that tissue stored for future use will not be used without further/separate consent being obtained. A Tissue Bank consent form will also be signed.
3. The Committee asked how the conflict of researchers being a potential participant’s usual clinician will be managed. The researcher responded that these patients typically go through a multi-disciplinary clinic journey. As this is a window-of-opportunity study, consent happens in a small window, so the person discussing the trial with them would also subsequently be one of their clinicians. There will also be a team of research nurses after they have been identified who follow up to see if they are still interested in order to avoid possible inducement.
4. The Committee noted there would be no reimbursement of expenses and queried if there will be any expenses incurred on top of their usual standard of care. The researcher stated there are more visits than normal and there is some funding for patients who are travelling from Northland to be reimbursed to ensure they are not excluded. The Committee noted that participants should never be out of pocket and reimbursement should be equal across all cohorts. The researcher stated they will implement reimbursements across all cohorts to cover costs.
5. The Committee clarified with the researchers that participants on anti-psychotics, anti-depressants and anti-arrhythmics would be excluded, rather than ceasing these medications to be in the study.
6. The Committee confirmed with the researchers that this study is going to SCOTT for review.
7. The Committee noted that Hepatitis B and C serology is required as part of safety bloods for cohorts being given tarloxotinib, but these tests are not mentioned in the relevant participant information sheet/consent form (PIS/CF). The researchers clarified that these are part of routine standard of care of these 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 stated that the Protocol and Participant Information Sheet have insufficient information covering data management. The Committee stated more information around data management is required to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
2. The protocol should be updated to specify which concomitant medications with an accepted risk of QTc prolongation may be subject to cessation to facilitate study entry (e.g. anti-emetics), and which will be regarded as part of exclusion criteria (e.g. antidepressants).

The Committee requested the following changes to the Participant Information Sheets (PIS) and Consent Forms (CF):

All

1. Please review for repetition and wherever possible, remove repeat sentences.
2. Please proofread for typos, grammar and layout.
3. Please clarify across all cohorts that no research will be done on their tissue in the Tissue Bank without separate consent being obtained for that. Please also state that whole genome sequencing will not be performed.
4. Ensure there is a Yes/No option in the Consent Form for future unspecified use
5. Please ensure the study titles refer to which cohort the PIS relates to avoid giving a participant the wrong form.
6. References to anonymised data needs to be checked and amended if it is meant to refer to de-identified, not anonymised.
7. The Committee asked to consider a new lay-title for the study.
8. Please remove “Withdrawal” from the first heading.
9. The Committee noted that withdrawal from the study doesn’t need to be in writing.

OE-MRI only PIS/CF:

1. Please clarify there may be a small risk of complications that could push back surgery

OE-MRI and Tarloxotinib PIS/CF:

1. Please include a statement about Rain Therapeutics providing the medication.
2. The Committee requested the researcher include the [HDEC reproductive risks template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)

OE-MRI, Tarloxotinib and SBRT PIS/CF:

1. Please include a statement about Rain Therapeutics providing the medication.
2. Please include risks around Tarloxotinib and SBRT as it is outlined in the Tarloxotinib only PIS/CF.
3. The Committee requested the researcher include the [HDEC reproductive risks template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx)

Decision

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

* Please supply a data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
* 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).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **6** | **Ethics ref:** | **21/STH/162** |  |
|  | Title: | NT-0796 single ascending and multiple dose study in healthy adults |  |
|  | Principal Investigator: | Dr. Chris Wynne |  |
|  | Sponsor: | Novotech NZ Ltd |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Chris Wynne 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 first in human study to test the safety, tolerability, pharmacokinetics and pharmacodynamics of NT-0796 in healthy volunteers is in 2 parts - A single ascending dose (SAD) part - with 7 groups of different doses (8 subjects per group - blinded), A multiple dose part (MAD) - with 3 groups (8 subjects per group- blinded) and 1 group (8 subjects - unblinded).

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 participants should not have to wait for HDEC approval to receive urgent information.

Summary of outstanding ethical issues

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

SAD PIS/CF:

1. States 75% chance of receiving active drug, please correct.

MAD/MAD+CSF PIS/CF:

1. States inpatient stay day 1 to Day 3 but provides details up to day 16
2. In the MAD+CSF, please finalise the volume of CSF. Please also include percentages for risk of lumbar puncture.

Pharmacogenetics PIS/CF:

1. Typo on page 1
2. Please provide more information on genes and what they are, how they are shared between family members. Please also state if single gene analysis is being done or whole genome.

Decision

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

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

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| **7** | **Ethics ref:** | **21/STH/165** |  |
|  | Title: | D6401C00008: A Study To Assess AZD9977 in Healthy Participants and Participants with Renal Impairment |  |
|  | Principal Investigator: | Dr Mark Marshall |  |
|  | Sponsor: | Parexel International |  |
|  | Clock Start Date: | 01 July 2021 |  |

Dr Mark Marshall and Courtney Rowse 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 heart and kidneys work closely together, and as a result heart disease and kidney (renal) disease are often accompanied with one another. AZD9977 is a drug being developed as a treatment for heart failure (HF). However, in this study, AZD9977 will be given to renally impaired patients to determine if AZD9977 is safe for HF patients that are at an increased risk of kidney disease.

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 why another 9 healthy controls are needed in this study when there is data from 153 previous healthy controls. The researcher stated they are an active control group.
2. The Committee noted that participants should not have to wait for HDEC approval to receive urgent information.
3. The Committee clarified with the researcher that there is formal data monitoring arrangements, on a periodical basis (internal data committee) to discuss whether cohort 2 and 3 need to progress following 1 and 4. The Committee queried why severe renal impairment patients are being evaluated rather than starting in those with mild renal impairment, as from a safety perspective, the approach is usually to study mild disease first before progressing to study more severe disease. The Committee was satisfied that this aspect of the study would be subject to review by SCOTT to see whether this is scientifically a reasonable approach.

Summary of outstanding ethical issues

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

1. Please amend black box to state “first time in humans with renal impairment”
2. Please define/explain early in the PIS in lay terms what severe renal impairment is.

Decision

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

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

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| **8** | **Ethics ref:** | **21/STH/152** |  |
|  | Title: | Nasal spray for patients with chronic rhinosinusitis undergoing FESS |  |
|  | Principal Investigator: | Professor Richard Douglas |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 01 July 2021 |  |

Professor Richard Douglas and Mr Alejandro Fandino-Reyes 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. Nasal rinsing for patients undergoing nasal surgery is a fundamental aspect of postoperative care. Normal saline solution is the current preferred method. However, a significant number of patients do not seem to respond appropriately. Recently, hydrogels have been used in the postoperative period for patients undergoing sinus surgery with promising results. We want to analyse and compare the rheology of various viscous nasal formulations and create and clinically test a viscous nasal spray.

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 some of the researchers will also be the participant’s clinicians and encouraged separation of the roles to avoid inducement. The researcher confirmed that a research nurse will be the one to consent the participant to avoid any undue influence.

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 this is a first-in-human trial of a new formulation, although active ingredients are approved for use in other licensed products there is potential for absorption. The Committee recommended that the researchers contact Medsafe and get confirmation whether Standing Committee on Therapeutic Trials (SCOTT) review is required.
2. The Committee stated more information around data management is required than what is available in the Protocol and Participant Information Sheet to satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
3. The Committee queried if there are any plans to market this product based on the results of the study. The researcher confirmed that at this point there is not.
4. The Committee noted that ethnicity data would not be collected. Standard 9.10 and 9.20 states all researchers conducting health research in New Zealand must collect good quality ethnicity data unless there is valid justification as to why this is not necessary. Given the uncertainty in the impact of the novel nasal formulation in Maori compared to non-Maori participants, please ensure this is collected as part of this study.

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

1. Please ensure all technical/medical terms have lay terms where possible (i.e. “new” instead of “novel”)
2. Please include a box in bold at the start that states this is the first time this formula is being used in humans.
3. Please include page numbers.
4. Please separate the footers as much as possible from the main body of the text.
5. On page 2, the expected duration of the study is 48 days but the protocol states that follow-up will occur on day 60. There is also a discrepancy of “24 days” and “28 days”. Please reconcile across all documents.
6. Provide more context around after what date results of the study will be available to participants.
7. The Committee requested the removal of the ‘Yes’ tick boxes from the consent form unless it is for a clause that is truly optional.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please supply a data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Assc Prof Mira Woolrych-Harrison.

## Substantial amendments

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| --- | --- | --- | --- |
| **1** | **Ethics ref:** | **20/STH/70/AM09** |  |
|  | Title: | C3671008: A study assessing the safety and effectiveness of an investigational Respiratory Syncytial Virus (RSV) vaccine, in infants born to women vaccinated during pregnancy |  |
|  | Principal Investigator: | Dr Joanna (Jo) Gullam |  |
|  | Sponsor: | Ms Adriana Ioan |  |
|  | Clock Start Date: | 02 June 2021 |  |

Dr Joanna Gullam was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study assesses the investigational RSV vaccine RSVpreF, administered to healthy pregnant women. The study aims to see whether RSVpreF vaccination is effective in protecting infants from RSV, and to see how safe and well-tolerated the vaccine is in pregnant women and their infants. This amendment proposes to remove the lower-age limit to include adolescents who are pregnant.

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 researcher is expecting most of the adolescents to be competent to give their own consent. The researcher responded that the lead investigator at each respective site would meet with a prospective participant who was under 16 in order to ascertain whether the individual is competent enough to give fully informed consent.
2. The Committee noted for future amendments to only submit documents relevant to the New Zealand study sites and the amendment reason.
3. The Committee queried what is the plan for those who are judged to not be competent to give their own consent. The researcher responded that this would be regarded as a “screening failure” and would not be included. The Committee noted that there was an upload of a parental consent on behalf of a minor document. The researcher clarified that this was in error and will not be done in New Zealand, and participants will need to provide consent for themselves. The Committee was satisfied with this approach in excluding those who cannot provide their own consent and asked for the researchers to check that the protocol does reflect this.

Decision

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

* Please check protocol statements regarding the new adolescent population are relevant to New Zealand sites, i.e. that only those who are competent to consent (based on researcher assessment of competence, not age) will be included in this trial.

## General business

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

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| --- | --- |
| **Meeting date:** | 10 August 2021, 10:00 AM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

1. **Review of Last Minutes**

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

The meeting closed at 2.40pm