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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 June 2021 |
| **Meeting venue:** | Via Zoom 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 11 May 2021 | |
| 10.30am | New applications (see over for details) | |
| 10.30-10.55am  10.55-11.20am  11.20-11.45am  11.45am-12.00pm  12.00-12.40pm | | i 21/STH/126  ii 21/STH/130  iii 21/STH/137  Break (15)  iv 21/STH/139 |
| 12.40pm | Substantial amendments (see over for details) | |
| 12.40-1.20pm | i 20/STH/162/AM01 | |
| 1.20pm | 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 | Apologies |  |
| 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 | 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 Sarah Gunningham.

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 11 May 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/126** |  |
|  | Title: | Prospective Interventional Cohort Study examining the impact of HPI algorithms on duration of hypotension and associated perioperative outcomes in the emergency general surgical population. |  |
|  | Principal Investigator: | Dr Patrick McKendry |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 27 May 2021 |  |

Dr Patrick McKendry 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.

Paul Chin raised a potential conflict of interest. After discussion, the Committee deemed this was not significant enough to exclude the member from discussion.

Summary of Study

1. An interventional study of arterial blood pressure monitoring in patients undergoing emergency bowel surgery. The study aims to use hypotension prediction index, an algorithm using waveforms from routinely placed invasive arterial line featuring Acumen HPI device to predict hypotensive events. 60 New Zealand participants: 30 to receive standard arterial blood pressure monitoring PLUS Acumen monitoring/algorithm 30 participants who had only standard arterial blood pressure monitoring (retrospective cohort/

Summary of resolved ethical issues

1. The Committee asked for clarity on the device and how it relates to standard of care in surgical theatres. The Researcher responded that standard of care is to use a device (arterial lines/canula) that monitors blood pressure in the radial artery during surgery. He added that Acumen HPI is a piece of software used with the standard of care treatment that provides additional data.

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 it is not clear if it is a new device or not and that having an independent peer review undertaken on the study may clarify this point.
2. The Committee requested clarify on whether the Acumen HPI would constitute a new medical device by medical regulators. The Researcher responded that he does not consider it to be as the HPI is essentially the same device currently being used with updated software.
3. The Committee queried why peer reviews have not been provided to HDEC. The Researcher responded that peer reviews have only just been completed by colleagues who have raised concerns with the current protocol and have suggested improvements to address these. The Committee advised that peer reviews are an essential aspect of the ethical review and HDEC need to see this constructive feedback and how the researchers have responded to it. The Committee added that the independent peer review provided would need to comply with *National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26.* For guidance, please see the Scientific Peer Review Template available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
4. The Committee stated that the study is clearly still in the design phase, with the peer review feedback not yet addressed by the Researcher. As the study is missing key information, it is not ready for HDEC review, and therefore the application would be declined today. The Committee suggested using the remaining time to advise the Researcher on the issues with the current application that would need to be addressed for resubmitting. The Researcher agreed with this approach.
5. The Committee require the supply of a data management plan appropriate to the study to ensure the safety and integrity of participant data. This may either be incorporated into the protocol or a separate plan, but it must be study-specific and comply with the *National Ethical Standards for Health and Disability Research and Quality Improvement, Standard 12.15a.* For guidance, please see the Data Management Plan template available on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
6. The Committee advised that information on the prevalence and outcome of this illness in Māori compared with non-Māori New Zealanders is required (application question p.4.1). The answer provided in the application form is very brief and should include existing statistics on the condition in Māori. Please bear this in mind when resubmitting this application and any future applications. (*National Ethical Standards for Health and Disability Research and Quality Improvement, standards 3.1 – 3.6).*
7. The Committee stated that relevant Māori cultural issues for this research are missing from the application (question p.4.2). Please bear this in mind when resubmitting this application and any future applications.
8. The Committed advised that the Researcher must collect ethnicity data unless there is a valid justification for not doing so and suggested using New Zealand census sub-headings for this. (*National Ethical Standards for Health and Disability Research and Quality Improvement, standard 9.20).*
9. The Committed noted that consent for this study is required from patients about to undergo emergency surgery and asked what the justification is for using this high-risk population group rather than the lower risk elective surgery group. The Researcher responded that he intended to show the greatest outcomes with the smallest number of patients. This group have high number of post op complication and usually have ups and downs in blood pressure as opposed to a controlled elective surgery group.
10. The Committee advised that studies have been approved in the emergency surgery population previously and the key to approval is to adequately justify that it is the right population for this study to be performed with and that the Researcher has thought through all the issues and mitigated risks. For example, considering the best way to manage the consenting process given the patients are being admitted into ED and will be highly distressed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, standard 6.2).*
11. The Committee suggested one way of reviewing the application more favourably is to make it clear to the patient that they have option to reconsider after the surgery and withdraw and their data removed.
12. The Committee advised that, given the Committee are now familiar with the study, the Researcher my choose to resubmit the application to this Committee for review when it is ready.

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

1. Please revise your data management section and describe and distinguish between information that will be coded and that which will remain identifiable. For guidance, see the ‘What happens to my information’ section of the PIS/CF template on the [HDEC website](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc).
2. Please simply the parts of the PIS/CF that use complex medical language. Please use plain English that your everyday lay person (someone without medical knowledge) could understand. For example, developing a very basic description of what the Researcher is testing would be helpful. For guidance on what to include for participants, please see the PIS/CF template on the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/).
3. Please update the PIS/CF to include information for the control group audience (once the protocol has been finalised).

Decision

This application was *declined* by consensus, as the Committee did not consider that the study meets the National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1 – 3.6, 6.3, 1.15 – 7.17, 9.10, 9.25, 12.15.

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| **2** | **Ethics ref:** | **21/STH/130** |  |
|  | Title: | IRIS study |  |
|  | Principal Investigator: | Dr Eileen Mc Manus |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 17 May 2021 |  |

Dr Eileen Mc Manus, Dr Jan Schepel and Dr Deepak Sadani were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. A randomised pilot study of two treatments for patients with severe Guillain Barre syndrome (GBS). A New Zealand-only study with 50 participants to be recruited from 3 centres (Waikato, Wellington and Auckland). Intravenous Immunoglobulin G given every day for 2-5 days versus therapeutic plasmapheresis given 5 to 7 times over 10-14 days over 6 months. The results of this study could guide clinical decisions in acutely unwell GBS patients, lead to improved recovery times, shorter stay in HDU and reduce cost of admission.

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 for clarity on who has overall responsibility for the study (i.e. the coordinating investigator) as the application form and participant information sheet list different people. The Researcher confirmed that the coordinating investigator for the study is Dr Jan Schepel.
2. The Committee noted that while the study is described as a pilot/feasibility study, it is implied that this study will be able to compare the efficacy of the two different treatments in these 50 participants (25 in each group) and requested clarity. The researcher confirmed that, after advice from their statistician that it is not possible to answer this question yet, the study was revised as a feasibility study to identify if there any findings that would merit further investigation.
3. The Committee noted the intention to enrol participants from emergency departments. Given that these participants will be seriously unwell and about to be admitted to ICU, the Committee asked for more information about how they will be consented and supported during the time they are considering whether to be in the study.
4. The Researcher responded that with acute GBS, it is rare to end up in ICU within the first 48 hours as patients are admitted to hospital early due to the symptoms they experience. The standard of care procedure is to consult the on-call neurologist within an hour of patients presenting with acute GBS symptoms. At this point the study investigator (neurologist) will evaluate whether or not the patient meets the inclusion criteria and provide the information sheet to the patient if they do. The patient is then given time to consider their participation and discuss it with family.
5. The researcher added that that they have separated the roles (i.e. study neurologist is different to the neurologist providing clinical care) to ensure there is no conflict of interest with regards to the patient/doctor relationship and avoiding any undue influence.
6. The Committee queried if procedures such as nerve conduction studies, lumbar punctures and spirometry will be performed more frequently in this study than in standard clinical care. The Researcher responded that no, the procedures are part of standard of care treatment and there will be no extra procedures required for the study.
7. The Committee noted the Researcher’s confirmation that there are no reproductive risks for women of childbearing potential, or sexually active men in this study and that pregnant women are not excluded from taking part in the study. If there are none and it is not an exclusion criterion, please amend the consent from and information sheet to state this.
8. The Committee asked for clarity on how participants who are not responding to the assigned treatment will be managed. The Researcher advised that those participants not responding to treatment will be withdrawn from the study and referred back to clinicians for standard of care treatment.
9. The Committee noted the Researcher’s confirmation that all three participating sites use both study treatments as standard of care treatments interchangeably and that the two treatments are considered equal around the world.

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 providing more detailed information about the procedures and risks of side effects from each treatment in the PIS/CF. While the Committee acknowledged that patients may have been advised in a different (e.g. clinical) context, it remains important to fully disclose possible side effects to participants in the study context. (e.g. “There is a 2 in 5 chance of…”).
2. The Committee noted the Researcher’s confirmation that participants who are withdrawn for lack of efficacy will be recorded as a treatment failure. The Committee requested that it is made clear to the participant that if they withdraw at that point, the data collected about them prior to withdrawal will be retained.
3. The Committee asked at what point researchers would consider they have lost equipoise for the study, for example if the data shows a significant proportion are failing to respond to one treatment over the other. The Researcher advised, that yes, if significant discrepancy between treatments arises, they would address that. The Committee recommended that the protocol is updated to state that data will be actively reviewed on an ongoing basis and should a significant discrepancy be identified; the research team should consider terminating the study.
4. The Committee noted that the protocol states “patient information will be identifiable to local researchers”. The Committee requested that the data held by the research team locally (even at site level) is de-identified as soon as practical to mitigate the risk of a privacy / confidentiality breach. The investigators may retain a separate log linking identifiers to participant ID numbers. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.4, 12.11).*
5. The Committee recommended the data management section is reviewed as the protocol states study data will be maintained for at least 3 years, when it should be 10 years.

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

1. While the PIS/CF is generally well explained, it may be too lengthy and detailed for patients who are seriously unwell. Please review the form with this in mind.
2. Please review the statement that the study will be "looking at these different treatments to see which is the most effective” and frame it as an exploratory study comparing two treatments so that people are not mislead that there will be a definitive answer regarding efficacy.
3. Please remove the formal study title from the first page as the lay title is sufficient.
4. Please remove or amend the clause in the consent form regarding reproductive risks.
5. The assessments performed by investigators are described in very technical terms on page 4. Please simplify and summarise in lay terms what is involved for participants who may not know what a normal neurological investigation is.
6. Please amend the statement about expected benefits. E.g. “We don’t know if there will be any benefits to this treatment and is why we are doing this study to compare the different treatments”. More detail is needed on how the participant will be looked after if they don’t respond and whether they will need to withdraw from the study.
7. Please include more detail on the risks (side effects and adverse reactions) of the two study treatments as mentioned earlier by the Committee (pages 4 and 5).
8. Please consider the use of diagrams to help summarise what participation will involve and to help explain which tests are specific to this study (pages 3 to 4).
9. Please review and amend the 'information' section to be applicable to the study and remove irrelevant information. For example, there is no sponsor, and it is difficult to justify preventing access to other study-specific information during the study.
10. Please include information about hepatis/HIV tests if these are being done as part of the study rather than as standard of care (mandatory or optional). If study-specific, please advise that hepatis, HIV and COVID are notifiable diseases and therefore it is mandatory that the Medical Officer of Health and GP are informed of confirmed positive results.
11. Please remove the optional yes/no tick boxes on the consent form (page 9) as these are mandatory.
12. Please proofread the final document carefully to ensure consistency and accuracy in grammar, spelling, punctuation, and formatting.

Decision

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

* 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).*

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| **3** | **Ethics ref:** | **21/STH/137** |  |
|  | Title: | EDP 721-001: A Study to Evaluate EDP-721 in Healthy Subjects and in Combination with EDP-514 in Patients with Chronic Hepatitis B Virus Infection |  |
|  | Principal Investigator: | Prof Edward Gane |  |
|  | Sponsor: | Pharmaceutical Research Associates Ltd (NZ) |  |
|  | Clock Start Date: | 27 May 2021 |  |

Dr Christian Schwabe 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.

Devonie Waaka declared a potential conflict of interest, and the Committee decided to include her in the discussion and decision.

Summary of Study

1. An international first in human study of new medicines for chronic hepatis B, enrolling 114 participants in 3 countries (80 in New Zealand). The aim of the study is to evaluate the safety, tolerability, and pharmacokinetics of single and multiple ascending doses of EDP-721 in healthy people (Part 1); and to assess the safety, tolerability, pharmacokinetics, and antiviral activity of EDP-721 in combination with EDP-514 in patients with chronic hepatitis B virus infection (Part 2).

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 participation in this non-therapeutic study will affect the ability of HBV patients to enrol in other therapeutic trials. The Researcher confirmed that it will not restrict participants entry into other therapeutic trials.
2. The Committee noted that an exclusion criterion states, “Before the first dose of study drug, subject has received any vaccine, an investigational agent or biological product within 28 days”, including COVID-19 vaccine. Given this potentially interferes with standard healthcare of the participant, the Committee requested justification for going ahead with this study now rather than waiting until the majority of the population has been vaccinated for COVID-19. The Researcher advised that as the Part 1 study (involving healthy population) is reasonably short it should not interfere with participants having the vaccination before or after participation. He added that Part 2 of the study (involving patient population) will not happen until later in the year and it is expected that these participants will have already been vaccinated.
3. The Committee advised that there cannot be equipoise for a non-therapeutic trial involving placebo because the risks of receiving investigational medicines are inherently greater than the risks of receiving placebo. Please bear this in mind for future applications.

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 a justification for why Part 2 cohort are not being reimbursed for the time and inconvenience of being involved in the study as Part 1 cohort are. The Researcher advised that the normal practice is to ensure equity of reimbursement for all participants, however this is still in negotiations with the funder.
2. The Committee requested confirmation of the reimbursement for Part 2 in the Researcher’s response.
3. The Committee noted that the Part 2 study is still in the design phase as it will be determined by Part 1 and the Researchers were expecting to submit a substantial amendment with the supporting documentation at the completion of Part 1.
4. The Committee advised that being asked to assess a full protocol without all relevant study documentation, for example missing core participant information sheets (PIS/CFs), makes it difficult for the Committee to adequately review the study as a whole. It is the strong preference of the HDEC to have all core PIS/CFs relating to an application submitted with the original application and amendments to these documents made as required.
5. The Researcher responded that he acknowledges the HDECs feedback and will revert back to submitting all PIS/CF documents together.
6. The Committee requested that the Researcher ensures that the web and radio adverts clearly state the clinical trial is of an investigational drug.

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

1. Please provide the Part 2 PIS/CF as a track changed document based on the Part 1 MAD PIS/CF, to enable ease of review given that it was not able to be reviewed in tandem with the originally submitted PIS/CFs.
2. Please review margins, allowing more separation between the footer and the body text.

PIS/CF SAD

1. Please explain cholecystectomy and gastrectomy in lay terms on page 5.
2. Please add “until the end of the study” to the concomitant medication restrictions on page 6.
3. Please introduce the consent clause about opting out of receiving study results in the body of the information sheet (e.g. “…if you don’t wish to receive this, you will have an option to opt out in the consent form”).

PIS/CF FE and MAD

1. Please make changes noted in SAD PIS/CF as they also apply to this document.
2. Please delete “you will be told which cohort you are in” from page 3 of the FE PIS/CF as it is already stated on the previous page.

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).*

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

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| **4** |  | **Ethics ref:** | **21/STH/139** |  |
|  |  | Title: | HDClarity study |  |
|  |  | Principal Investigator: | Dr Richard Roxburgh |  |
|  |  | Sponsor: | UCL Huntington's Disease Centre |  |
|  |  | Clock Start Date: | 27 May 2021 |  |

Richard Roxburgh and Christina Buchanan 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 main purpose of this study is to collect cerebrospinal fluid (CSF), the fluid that surrounds the brain and spinal cord, from people with Huntington’s disease (HD) for future unspecified research. There are currently no treatments available that stops the relentless progression of HD to disability and early mortality. CSF can be used to provide information about the brain and the nervous system that is impossible to obtain in any other way. A further specific feature of this study is that the patient’s clinical state at the time that the CSF is taken will be recorded in detail, which will allow the samples to be interrogated for biomarkers.

Summary of resolved ethical issues

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

1. The Committee discussed whether consent via Enduring Power of Attorney (EPOA) was required for this study, as it seems that currently all in the study would be capable. After discussion with the researcher, the researcher stated they would be removing EPOA from the application and study.
2. The peer review states that cellularity of the CSF will be assessed locally but the Committee could find no mention of this in the Participant Information Sheet (PIS). The researcher clarified that this would not happen locally, as the local clinical laboratory cannot perform the required cellularity test.
3. The Committee asked the researcher to clarify the consenting procedures to ensure separation of clinical and research roles. The researcher stated a research team member not providing clinical care is the primary contact for them to receive study information.

Summary of outstanding ethical issues

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

1. As Māori participants may be enrolled in the study in the future, formal consultation is required even if no participants are in the potential participant pool at this time. This is particularly important where the study centres on the collection of tissue for genetic research, and the sending and storing of tissue overseas.
2. The Committee asked how much of the future research is specific to HD and related disorders, and what might be unspecified. The researcher clarified they are not collecting DNA so there is no genetic component, and that all future research will be related to HD. The Committee noted the protocol leaves future research very broad and states that samples will be made available for similar as well as ‘other’, which is unspecified. This needs to be made clear in the PIS as page 2 only states they will be shared for related research.
3. The Committee stated a data and tissue management plan is required to satisfy the Committee that privacy, integrity, safety and confidentiality is protected. 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. This can be incorporated as part of the protocol or as a standalone document.
4. The Committee noted that there will be local analysis of routine blood tests. As this could result in abnormal results of potential clinical significance, informing a participant’s General Practitioner (GP) of such results should be mandatory. This is currently optional in the PIS.

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

1. Please state whether individual results will be able to be returned or direct participants to the website to find the general research results.
2. Please state clearly that no genetic testing will be undertaken on tissue as part of this study.
3. Please state that the participant is already in the enrolHD study, and that researchers are asking if the participant wishes to be involved in this extra study.
4. Make it clear that samples may also be shared for future medical / scientific research unrelated to HD.
5. Explain why 2MT Software and BioRep SRL would need access to identifiable records. Sharing of identifiable information should be with the smallest number of groups possible, for very defined reasons.
6. Review the [HDEC PISCF template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) regarding access to identifiable information and amend accordingly.
7. On page 11, it states that CDHI has access but does not explain why. Please amend accordingly.
8. Replace the HDEC review statement with that in the HDEC PISCF template.
9. Make it clear that the authorised representative cannot consent to initial study involvement.
10. Under Discomforts and Risks, the Committee queried if it is necessary to separate them out as Discomforts and Risks. Please review and amend.
11. Remove signature of representative as that is being removed for New Zealand.
12. Please amend ACC statement in line with the HDEC template, i.e. “eligible to apply”.
13. Please include a statement that participants withdrawing from the study will be asked by the researcher about whether they also withdraw consent for the ongoing retention / use of stored samples.

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 supply a data and tissue management plan to ensure the safety and integrity of participant data and tissue. 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, 14.16&14.17).*
* 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 Dr Devonie Waaka.

## Substantial amendments

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| **1** | **Ethics ref:** | **20/STH/162/AM01** |  |
|  | Title: | Residential care staff use of relational and suppo |  |
|  | Principal Investigator: | Mrs Christianah Adesina |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 04 May 2021 |  |

Christianah Adesina and Catherine Cook were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Observational study of supportive interventions for dementia patients who 'like to walk' (wander). Dementia patients and carers will be observed by the researcher, and will complete questionnaires about wandering. Southern HDEC approved this study in January 2021 on the basis that all participants would provide informed consent. This amendment submission seeks to allow Enduring Power of Attorney (EPOA) to consent for residents who are unable to provide independent informed consent.

Summary of resolved ethical issues

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

1. The researcher described that the progression of the disease is different per resident, and some may have the ability to still write, some may have the ability to still read, and some do not have it at all. Some can verbally consent, some cannot. After summarising the introduction to the study, some residents have varying difficulty depending on their respective needs. Some may be able to provide informed consent but unable to communicate their consent. The Committee stated that in particular they are primarily concerned with how capable someone is of providing informed consent. Enduring Power of Attorney (EPOA) should only be used when a resident lacks capacity to consent, rather than lack the ability to communicate their consent. The Committee queried how the researcher will determine capacity to consent. The researcher responded that people who are in this agitated walking phase of dementia have a blurred capacity to consent, and anybody requiring rest home or hospital level care is in a heightened state of not being able to manage their own lives. It is quite unpredictable. The researcher feels it is most appropriate to involve the EPOA in the consenting process as it’s not possible to absolutely determine the person has capacity to consent. Family members are likely to be around and could be disturbed if they are not consulted about study participation.
2. The Committee noted that this is a low risk observational study that takes place in the public spaces of the residential care facility and were satisfied that the study does not constitute a medical experiment.
3. The Committee further noted that the principal risk consideration for participants is data harm (privacy or confidentiality breach). Appropriate data safety measures are in place as per the approved application to mitigate this risk.
4. The Committee agreed with the point raised by the researcher that there is strong evidence that people with dementia like to be included in research.
5. Given these points, the Committee agreed that the argument put forward by the researcher for allowing activated EPOAs to provide consent on behalf of participants who lack capacity to provide independent informed consent was valid.
6. The Committee noted, however, that EPOA could not be used for a participant who has capacity to provide independent consent. Further, if any participant who is enrolled under an activated EPOA consent indicates in any way - either verbally or through their behaviour - that they do not wish to participate, the researcher must respect that.

Decision

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

* Please ensure all points raised by the Committee and incorporated into the conduct of the study, with documentation amended accordingly.

## 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:** | 13 July 2021, 10:00 AM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

The following members tendered apologies for this meeting.

* 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.

The meeting closed at 1.20pm.