|  |  |
| --- | --- |
| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 10th May 2022 |
| **Zoom details:** | https://mohnz.zoom.us/j/9481145912 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Assigned Lead Reviewers** |
| 10:30am – 11:00am | 2022 FULL 11858 | Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries | Dr Frank Weilert | Mr Dominic Fitchett & Dr Devonie Waaka |
| 11:00am – 11:30am | 2022 EXP 12392 | Evaluation of Youth Primary Mental Health and Addiction Services - Access and Choice Initiative | Dr Adrian Field | Mr Anthony Fallon & Associate Professor Nicola Swain |
| 11:30am – 11:50am |  | ***Break 20 minutes*** |  |  |
| 11:50am – 12:20pm | 2022 FULL 12705 | Evaluation and validation of the body surface gastric mapping (BSGM) device for use with Young People aged 5-18 years with symptoms or a diagnosis of an Upper Gastrointestinal Functional Disorder | Ms Gayl Humphrey | Mr Dominic Fitchett & Ms Amy Henry |
| 12:20pm – 12:50pm | 2022 FULL 12479 | Optimising heat therapy for treating high blood pressure | Dr Kate Thomas | Mr Anthony Fallon & Ms Amy Henry |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assoc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Absent |
| 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 |
| Associate Prof Nicola Swain | Non-lay (intervention & observational studies) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 10:00am and welcomed Committee members.

The Chair noted the absence of Associate Professor Mira Harrison-Woolrych but noted it was not necessary to co-opt another member for the meeting.

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 12th April were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **2022 FULL 11858** |
|  | Title: | Feasible, safety and utility of Endoscopic ultrasound-guided PPG measurement (EUS-PPGM) in patients undergoing liver resection and major intra-abdominal surgeries |
|  | Principal Investigator: | Dr Frank Weilert |
|  | Sponsor: |  |
|  | Clock Start Date: | 28th April 2022 |

Dr Stephanie Yung and Dr Frank Weilert were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the accessing of the portal vein would carry no increased risk of bleeding than in routine Fine Needle Aspirations (FNA). Please include this information in the information sheets.
2. The Committee clarified that the study in Adelaide was a sister study that was separate, but that data would be shared for the sake of combining for publication.
3. The Committee clarified that the participants would not be recruited by the study team and the surgeon would only contact the patient and provide the PIS once they had been forwarded to the study. The consenting would be on-site prior to the operation and study team would be informing participants as necessary to understand the procedure.
4. The Researcher clarified that the scientific peer reviewer was not an investigator and had been listed in the protocol in 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. Please remove the provider of the scientific peer review from the protocol as per the request of the Committee.
2. The Committee would like the researcher to provide their medical indemnity for review.
3. Please ensure the study is registered in a WHO-approved clinical trial registry prior to commencing recruitment activities.

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

1. The Committee noted that there was an abundance of technical language and images that would need to be amended and reviewed for lay language and the overly technical or specialist aspects removed for clarity.
2. Please state that the study doctors have experience with the EUS-PPGM procedure and state the approximate number of procedures undertaken at the study site.
3. Please specify that the result of the EUS-PPG could impact on the decision to proceed with their scheduled surgery.
4. Please clarify whether participants would still undergo trans-jugular (TJ) measurement if they do not take part in the study (p8).
5. Please remove “If you agree” as the future use of coded data is not optional (page 10).
6. Please ensure the information about the study being stopped matches that in the protocol (page 11).
7. Please delete the Yes/No box from the General Practitioner (GP) notification clause in the consent form as this should not be optional.
8. Please review for typos and grammatical errors (i.e. on p5 “our very experience endoscopist”, mixing tenses, etc).
9. Please explain conditions and terms used in the risk section on page 6.

The Committee requested the following changes to the Protocol:

1. Section 10 of the data management plan (DMP) states 'we will only be collecting data for a small group of patients receiving their medical care through specialised cancer pathway'; the protocol discusses liver cancer and colorectal cancer but does not limit study inclusion to adults receiving specialist cancer care. Please specify in the eligibility criteria that study entry is restricted to adults with a confirmed cancer diagnosis and liver lesions.
2. Please amend to include informed consent procedure and timing; screening/ eligibility procedures (including whether these are collected as a study procedure or whether standard of care samples results will be used); and all time points for scheduled in-person or remote participant contact.
3. Please address safety monitoring and study stopping criteria adequately.
4. Please clarify the sample size and amend as required.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please identify appropriate data governance policies / standard operating procedures required at the locality (Waikato DHB) and reference these.

**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 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 Dr Devonie Waaka and Mr Dominic Fitchett.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **2022 FULL 12392** |
|  | Title: | Evaluation of Youth Primary Mental Health and Addiction Services - Access and Choice Initiative |
|  | Principal Investigator: | Dr Adrian Field |
|  | Sponsor: | Ministry of Health- Manatū Hauora |
|  | Clock Start Date: | 28th April 2022 |

Dr Adrian Field, Dr Alicia Crocket and Ms Isobel Freeman 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.

Associate Professor Nicola Swain declared a potential conflict of interest related to this application; however, the Committee was happy that this would not impact her assessment and as such they took full part in the review process.

Summary of resolved ethical issues

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

1. The Committee clarified that any type of advertising would need to be provided for review, but that this could be provided as an amendment to the study.
2. The Committee clarified that, should a child wish to participate but the whānau states the child should not take part, the researchers would not enrol the participant in the study. The researcher further noted that, if the young person was able to provide independent consent, the young person would be asked for permission to approach the whānau regarding the young person’s or the whānau’s participation. If permission is not given, the whānau will not be approached.

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 further Māori consultation be undertaken by an independent body. This consultation should adequately cover the primary localities as identified by the researchers as Auckland and Hamilton.
2. The Committee noted that the peer review provided was not independent or scientific and was not sufficient to be considered for review. Please refer to the [HDEC peer review template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx) and use this to provide an independent scientific review of the study.
3. The Committee requested the rationale for compulsory parent/guardian consent for 12–15year-olds, as the NEAC standards allow for the ability for young people to give independent informed consent if competent. The Committee stated that the clinician upon referral should provide guidance as to whether the young person has the capacity to consent. This should be detailed in the protocol. The Committee noted that all referrals for rangatahi interview should be through the clinicians, not self-referral through the survey completion, as this ensures competence to consent is assessed for all potential rangatahi.
4. The Committee recommended a clinician be added to the study staff. The clinician should be available to assess / implement follow-up of potentially significant disclosures made by participants and should also be available to debrief interviewers to prevent undue risk to the interviewer.
5. The Committee noted that the survey was described as anonymous but carried contact details in the event the participant elected to be entered into a prize draw or be contacted for interview. The Committee requested identifiable information be entered using a separate link, to ensure survey data is truly anonymous.
6. The Committee noted that as the survey will now be anonymous, there is no need for supervision by parents/guardians. They requested this be clearly documented in the protocol and other relevant study material.

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

1. Please specify any actions that may be taken in the event of information being incidentally disclosed that may require mandatory notification or warrant clinical follow-up.
2. Some important information is introduced in the assent / consent section of the forms. Please ensure all material is introduced in the body of the information sheet.
3. Please state where in-person interviews will be conducted.
4. Please state that a small koha will be provided.
5. Please state whether the parent / guardian will have access to the rangatahi's interview transcript.
6. Please provide a list of contacts for support in events of distress.
7. Please include risk of privacy breach in all documents.
8. Please include more fulsome information regarding access to and use of data.
9. Please include the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) contact details, including Māori cultural support details.
10. Please specify if support people may attend with the participants.
11. Please specify if the participant’s General Practitioner (GP) may be contacted in the event of a significant disclosure requiring clinical follow-up.
12. Please ensure there is a confidentiality statement for group interviews.

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

1. Please review and amend to ensure that there is sufficient information provided for informed consent to be given. The Committee recommended using the HDEC PISCF template for this purpose.
2. Please utilize a secondary link for the survey prize draw to protect the anonymization of data.

The Committee requested the following changes to the Protocol:

1. Please consider including an estimated number of participants for each cohort.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please note where the log linking identified information to participant identification numbers will be stored. If this will not be necessary, please state as such.
2. Clarify what demographic data will be collected from service providers and MOH staff, and whether this may be sufficient to identify individuals in some instances. Describe processes in place to mitigate this risk.
3. Please address any applicable institutional data governance policies.
4. Please address the potential for future use of data.
5. Please note that full date of birth should not be included as this is an indirect identifier.
6. Please change the sentence under the bullet points of "Anonymous/Anonymised data" to read "Anonymous/Anonymised data may be included..." currently reads as De-identified
7. Please consider addition of reasons for not informing someone of a privacy breach allowed under the act.

**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 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 Nicola Swain and Mr Anthony Fallon.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **2022 FULL 12705** |
|  | Title: | Evaluation and validation of the body surface gastric mapping (BSGM) device for use with Young People aged 5-18 years with symptoms or a diagnosis of an Upper Gastrointestinal Functional Disorder |
|  | Principal Investigator: | Dr Gayl Humphrey |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 28th April 2022 |

Dr Gayl Humphrey and Professor Greg O’Grady was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried how the potential of commercialisation forming a conflict of interest would be managed. The conflict would be managed by Uniservices and through declaring the conflict to participants and in any published reports.
2. The Committee queried the peer review comment around recruitment and the Researcher explained that the modes of advertisement are likely to be sufficient for the older age groups, however they recognise that there may need to be more direct recruitment for the younger (<7 years old).
3. The Committee clarified that where a young person is capable of providing informed consent this should be prioritised over an assent where the parents will consent on their behalf. The Committee noted that it is not semantics to request consent in capable young people alongside parent consent where parental consent for the child may be preferable.

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 clarified that this was a feasibility study in the paediatric field and formed part of a PHD programme, and that the results will inform further larger paediatric studies. However, it was noted that the device was currently awaiting regulatory approval by the FDA and a company has been established for commercialisation purposes. The Committee decided that on balance this should be considered a commercial study and that there would need to be commercial indemnity and availability of ACC-level compensation in event of injury. This will need to be supplied.
2. The committee requests that the amount of money given as reimbursement be removed from the advertising material given there are children involved, and that the Koha be made appropriate for young children where applicable, for example a book or a toy voucher. The parents may still be reimbursed for travel.
3. .

The Committee requested the following changes to the Protocol:

1. Please note that if serious concerns are noted from the anxiety/quality of life scales and/or after discussion with the participant and their parent/guardian, the GP should be notified as a mandatory component of study participation. Please amend the protocol and PISCF accordingly.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please refer to the NEAC standards para [12.15](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/) to ensure all aspects of data use and management are considered and amend the DMP accordingly. Ensure information regarding privacy breach, future use of data, and data access is addressed.
2. Please include information on the potential use of data for future commercial interests.
3. Please note that health information must be kept for at least 10 years after the youngest child has reached the age of 16. This needs to be stated across all documentation.

The Committee requested the following changes to the Assent Forms 5-10 years:

1. Please provide detail as to the food and drink provided.
2. Please standardise font size.
3. Please review for use of 'my' and 'your' to describe the participant.
4. Please remove the full informative table from under header and replace with lead doctor name and phone number.
5. Please re-word 'help doctors and nurses find out what is wrong sooner'; as this makes it appear there is a problem with the child, and many are healthy controls.
6. Please delete information not critical for the age range (study funding; scintigraphy test result; withdrawal of data; retention of data etc)

The Committee requested the following changes to the Assent Forms 11- 15 years:

1. Please amend to make this age appropriate.
2. Please use the 16–18-year-old sheet for members of this group who can comprehend more detailed information, i.e., for all young persons considered competent to provide informed consent.
3. Please provide detail as to the food and drink provided.
4. Please review for use of 'my' and 'your' to describe the participant.
5. Please amend 'You can ask to have my information removed up to 4 weeks after each cycle'.
6. Please check to ensure that “cycles” is explained.

The Committee requested the following changes to the 16–18-year-old Participant Information Sheet and Consent Form (PIS/CF):

1. Please note that the 16–18-year-old document should contain all the information provided in the Whānau document.
2. Please include compensation in event of injury statement.
3. Please clarify why the 16–18-year-olds must be accompanied by a family member.
4. Please make it clear that the participants will not get a copy of their individual results (and why).
5. Please state that participants can choose to receive a lay copy of study results.
6. Please provide better information regarding use of data (what is collected, identifiability, access, sharing, future use, ownership rights, potential commercial application, rights to access and correct data, risk of privacy breach, GP notification of significant abnormal mental health results etc). It is recommended the researcher refer to the HDEC PISCF template for guidance.
7. Please provide named Māori cultural support details. Many young people may not have a kaumātua to talk to.
8. Please remove the yes/no options to contact a general practitioner (GP) as this should not be optional. For this section, please see the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
9. Please review for typos.
10. Please provide detail as to the food and drink provided.
11. Please provide Māori cultural support details. Many young people may not have a kaumātua to talk to.

The Committee requested the following changes to the Whanau participant information sheet and consent form:

1. Please include compensation in event of injury statement. Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for this.
2. Please make it clear that the participants will not get a copy of their individual results (and why).
3. Please state that participants can choose to receive a lay copy of study results.
4. Please provide better information regarding use of data (what is collected, identifiability, access, sharing, future use, ownership rights, potential commercial application, rights to access and correct data, risk of privacy breach, GP notification of significant abnormal mental health results etc). It is recommended the researcher refer to the HDEC PISCF template for guidance.
5. Please review for typos.
6. Please provide detail as to the food and drink provided.
7. Please provide Māori cultural support details. Many young people may not have a kaumātua to talk to.
8. Please remove yes/no options to contact a general practitioner (GP) as this should not be optional. For this section, please see the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/)

The Committee requested the following changes to the 16-18-year-old Pictogram Participant Information Sheet and Consent Form (PIS/CF):

1. Please remove “tummy” from lay title.
2. Please note that there is no need to repeat explanations, i.e., “pictograms (images)”.
3. Please review for repetitive information throughout.
4. Please provide more information as to data management processes.

The Committee requested the following changes to the 11-15-year-old Pictogram Participant Information Sheet and Consent Form (PIS/CF):

1. Please replace the title with pictogram specific title or remove entirely.
2. Please note that this form seems targeted at a younger age group than 11-15 years old (i.e., the use of terms such as “tummy”) – please use the 16-18 form for competent young persons of any age and reserve this form for those young person’s unable to provide informed consent (in this age bracket).
3. Please note that health information must be kept for 10 years and not 6 as stated on page 2.

The Committee requested the following changes to the 5-10-year-old Pictogram Participant Information Sheet and Consent Form (PIS/CF):

1. Please replace the title with pictogram specific title or remove entirely.

The Committee requested the following changes to the Whanau pictogram participant information sheet and consent form:

1. Please remove “tummy” from the lay title.
2. Please note there is no need to repeat explanations, i.e., “pictograms (images)”.
3. Please include more data management information as can be found in the [HDEC PISCF template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc)

**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 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 Ms Amy Henry.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **2022 FULL 12479** |
|  | Title: | Optimising heat therapy for treating high blood pressure |
|  | Principal Investigator: | Dr Kate Thomas |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 28th April 2022 |

Dr Kate Thomas and Dr Brendon Roxburgh 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 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 scientific peer review be provided.
2. Please change "appears to be an effective therapy" to a "might/may be..." in the advertising material.
3. The Committee requested that registration in a WHO-approved clinical trial registry is completed prior to commencing recruitment activities

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

1. Please ensure that any information in the consent form has first been addressed and included in the PIS.
2. Please specify whether retention of tissue for future is mandatory; whether it may involve genetic / genomic testing; and how long samples may be retained for. If it is mandatory, please remove tick box options.
3. Please ensure that general practitioner (GP) notification in the event of a significant abnormal finding is a mandatory component of study participation. This should be reflected in the PISCF.
4. Please replace words such as 'subjects' and 'patients' with 'participants' and 'people' throughout the document.
5. Please include information about the initial visit, as presumably this will include an informed consent discussion and signing of written consent. Clarify that people may be excluded from taking any further part on the basis of answers provided in the health history questionnaire.
6. Provide more information about the environment, particularly with regards:
   1. The number of people who may be in the spa at the same time
   2. What clothing should be worn in the spa.
   3. How private the spa area is (for example, might there be other people not involved in the study in the area).
   4. Whether there are areas to shower and change after the spa
7. Please address risk of privacy breach.
8. State that the participant, and the participant's GP, will be informed in the event of a significant abnormal result.
9. Please include information as to whether a clinician would be on site.
10. Please provide more detail on issues regarding privacy and availability of gender-matched research team members
11. Please ensure that information of the weigh-in and if this will be clothed as necessary.

The Committee requested the following changes to the Protocol:

1. Please define 'recently' in terms of commencement of anti-hypertensive therapy. It may be preferable to state that all anti-hypertensive medication must be stable for at least XX weeks prior to enrolment.
2. Please clarify how anti-hypertensive medication compliance will be assessed during the study period, as non-compliance may significantly impact primary study endpoints.
3. Please clarify how 'blood and plasma volume' will be ascertained by blood sampling (this used to involve administration of radio-labelled albumin / iodine)
4. The Committee requested that the researcher provide more clarification around the 'mini-interview' or exit questionnaire.

The Committee requested the following changes to the Data Management Plan (DMP):

1. Please specify future use of tissue and data, including what this may be used for and who would have access to this data.
2. Please ensure only age and year of birth is included with de-identified data.
3. Section 12.2.2 references future unspecified tissue research. Per other study documentation this is not planned; please delete.
4. Please ensure that is a participant withdraws from the study, he or she is specifically asked whether the data / tissue collected prior to withdrawal can continue to be used. This should also be clearly stated in the PISCF.

**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 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 Anthony Fallon and Ms Amy Henry.

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 14th June 2022. |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 12:50pm.