To the editors,

Re: Manuscript ID: 74772

This is a letter to request a waver of written consent for all participants whose medical data was included in data analysed for this manuscript.

Data was collected as a retrospective audit from a prospectively recorded unit database of all liver transplant recipients. All data is de- identified.

Ethical Approval was obtained from the Austin Health Human Research Ethics Committee (HREC).Written informed consent was not a requirement for this audit. Please find below the application for an Audit application form stating that implied consent was utilised and that written informed consent was not obtained. Please also find below the final approval form for this application based on the National Statement.

Thank you for your understanding, Yours sincerely

Dr Penelope Hey, on behalf of all authors
Liver Transplant unit, Austin Health,
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Austin HEALTH

AUSTIN HEALTH OFFICE FOR RESEARCH

QUALITY IMPROVEMENT ACTIVITY OR AUDIT APPLICATION FORM

Description of proposed activity

☒ Audit
☐ Quality Improvement Activity
☐ Unsure

Type of Research Project

☒ Single Site
☐ Multi-Site
Please list all sites:

Section 1: General Information

1.1

Reference Number	AUDIT: *(Office Use Only)*	RISKMANQ: *(Please insert RiskmanQ ID for QI applications)*
Project Title	The use of DEXA body composition assessment to predict outcomes following liver transplantation	
Short Title/Acronym *(if applicable)*	DEXA and post-transplant outcomes	

1.2 Austin Health Principal Investigator

Title & Name	Dr Penny Hey
Position	Gastroenterologist
Department	Gastroenterology
Qualifications	MBBS FRACP
Office Mailing Address	
Austin Health Phone Number	0413798425
Austin Health E-mail Address	Penny.hey@austin.org.au
Alternative E-mail Address	Pennyhey8@gmail.com
Relevant Research Experience (Please attach CV)	

1.3 Additional Personnel (add additional tables if required)

Title & Name	
Position	
Department	
Qualifications	
Office Mailing Address	

Phone Number	
E-mail Address	
Role in this Project	
Relevant Research Experience (Please attach CV)	

1.4 Student Investigator (if applicable)

This section is relevant to students who are not employees of Austin Health and who will be accessing health, personal or sensitive information from Austin Health including that from medical records towards obtaining their Degree. Please complete the details below:

Name	
Role in this project	
University	
Supervisor at Austin Health	
Postgraduate qualification being completed	
Phone Number	
E-mail Address	
Agreement being submitted	

1.5 External Applicant (if applicable)

This section is relevant to a person who is not an employee of Austin Health and who will be accessing health, personal or sensitive information from Austin Health including that from medical records. Please identify the position and the organisation that you are affiliated with below:

Name	
Role in this project	
Organisation	
Phone Number	
E-mail Address	
Agreement being submitted (if applicable)	

1.6 Documents for review

Please list all the related documents including their version number and date.
E.g. Protocol, Data Collection Tool*, Questionnaire, Consent Form, etc.
***Please include a Data Collection Tool with all audit applications.**

Document name	Version Number	Date
~~Protocol~~ Data collection tool DXA-1	DXA-1	20/12/2021

1.7 Reason for Undertaking this Activity

Higher Degree or Postgraduate Qualification	☐
Please specify which degree (if applicable)	
Part of employee's professional duties/employment with Austin Health	☒
Undergraduate Degree	☐
Vocational or Qualification requirement	☐
Please specify which Vocational or Qualification requirement (if applicable)	

1.8 Approximate project duration

How long is the project expected to take?	☒ less than 1 year ☐ 1 to 2 years* ☐ more than 2 years*

*Where projects are for more than one year, you will be required to submit an annual progress report.

Section 2: Protocol

2.1 Rationale & Objectives (maximum 300 words)

DEXA (Dual-energy x-ray absorptiometry) body composition provides a simple, low radiation and readily available measure of lean mass in patients with chronic liver disease. As part of liver transplant workup, all patients routinely undergo DEXA for bone density assessment, with additional body composition parameters available. There is emerging evidence that low muscle mass as measured on CT scan can predict post-transplant survival. This study aims to evaluate the role of DEXA body composition at transplant assessment at predicting post-transplant outcomes including mortality, bacterial infections, organ rejection and hospital length of stay.

2.2 Methods- include how the activity will be conducted, timelines, number of participants, data collection & analysis (maximum 500 words)

Timeline (Insert information about timeline of the activity)
Data entry: Data will be exported from prospectively collected data stored on the liver transplant database of all patients undergoing workup for liver transplantation. This process including data cleaning will take several weeks, with statistical analysis and writing of the project to follow. The project is expected to be completed within 6 months. Data will be collected for patients worked up between 2002 and 2018 when the Lunar Prodigy DEXA scanner was used.

Data Collection (Please include information about how the activity will be conducted)
Data will be exported from the liver transplant database (filemaker).

Data Source (Please specify data collection source)
Filemaker (liver transplant database).

Primary aims (Insert information about primary aims of this project) 1. To assess whether pre-transplant sarcopenia, defined by low lean mass on DEXA, predicts mortality and graft failure after liver transplantation. 2. To assess whether pre-transplant sarcopenia predicts post-transplant bacterial infections and acute cellular rejection 3. To assess whether there is an association between low lean mass on DEXA and longer hospital and ICU length of stay.
Data Analysis (Please provide brief information about data analysis) Data will be analysed using R software. Survival analysis will be performed using cox proportional hazard regression analysis. Length of stay will be correlated against lean mass parameters.
Data Management (Please include information about how and where the data will be stored) De-identified data will be stored on a password protected excel document, on a password protected Austin Health computer.

2.3

Risks & Burdens The risk and/or burden to participants must be negligible for QI projects. Risk and/or burden include extensive interviews, lengthy questionnaires, persistent reminders, and/or intrusive and personal questions.	
Does the proposed activity impose any additional burden, harm or risk, beyond those associated with routine care?	☐ Yes ☒ No
If yes, please explain.	

2.4

Overlap with Research Activities must not involve a deviation from normal standard care, and must not include the assessment of safety/efficacy of a new intervention or device. Any requirement for additional testing, blood or tissue collection, physical or psychological testing, or longer interviews are not considered quality assurance. Similarly, activities must not involve randomisation, or the use of control groups/placebo.	
Does the proposed activity involve any clinically significant departure from the routine clinical care provided to patients?	☐ Yes ☒ No
Does the proposed activity involve randomisation, inclusion of control groups, or the use of placebo?	☐ Yes ☒ No
Does the proposed activity seek to gather information about the participant beyond that collected as part of routine care?	☐ Yes ☒ No
If yes, please explain.	

2.5

Please answer the relevant question: 1. How are the findings expected to result in a quality improvement; or 2. How will the findings of this audit activity be used?
The findings of this audit activity will aim to be published in a peer-reviewed journal. This aims to improve our understanding on the use of DEXA in defining sarcopenia and predicting patient outcomes.

Section 3: Survey

3.1

Participant Survey or questionnaire (If applicable) If participants are being asked a survey, please answer the following:	
Number of surveys the participant will have to answer	

The estimated total time required to answer the survey(s)	
How survey will be distributed?	
Survey platform to be used (if any) *E.g. Qualtrics or REDCap*	
Will you be interviewing staff members or students?	☐ Yes ☐ No
Copy of survey questions attached	☐ Yes ☐ No
List the name of each survey that will be administered	

3.2

Consent	
Will written informed consent be obtained from participants?	☐ Yes ☒ No
Will verbal and/or implied consent be obtained from participants?	☐ Yes ☒ No
If yes, please include a copy of the Information Sheet, Consent Form or Verbal Consent Script for review	

Section 4: Privacy

4.1

Privacy and Confidentiality Participant's records (medical records, databases, data/tissue banks) used for these activities may only be accessed by those with usual access (through routine clinical care or professional practice) or by those with a directly-related secondary purpose.	
Will participant records/information be accessed by those with routine access through clinical care/professional practice **OR** by those with a secondary purpose which is directly related to the patient's clinical care?	☒ Yes ☐ No
Will the confidentiality of participant records/information be maintained at all times?	☒ Yes ☐ No

4.2

Privacy and Data Storage	
Are the rights, privacy, and professional reputation of any persons or institutions involved free from any risk of infringement?	☒ Yes ☐ No
Will all data collected be non-identified?	☒ Yes ☐ No
Will data be published in a non-identified format?	☒ Yes ☐ No
Will the storage of such information be securely held within the department for a minimum period of 7 years, in a non-identified format?	☒ Yes ☐ No
How will research data be retained? *E.g. Paper copies in locked office or electronic copies, password protected file on secure network.*	Password protected file on a password protected Austin health secure network computer.
How will data be destroyed? *E.g. Secure shredding or secure electronic file deletion.*	Secure electronic file deletion.
How will the findings of this work be disseminated?	☒ Journal article ☐ Conference ☐ Internal presentation (e.g. Research week) ☐ Case study

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Section 5: Intellectual Property Considerations

5.1	Intellectual Property Considerations	
	Is there a possibility of new Intellectual Property being developed from this project?	☐ Yes ☒ No ☐ N/A
	Does the research agreement state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership?	☐ Yes ☐ No ☒ N/A
	Does the Research Agreement describe arrangements for the use of all new intellectual property through the research project?	☐ Yes ☐ No ☒ N/A

Section 6: Study Budget

6.1 Study Budget (if applicable)
If you are receiving funds to support this project, please submit relevant documentation; for example contracts and/or letter from the sponsor.

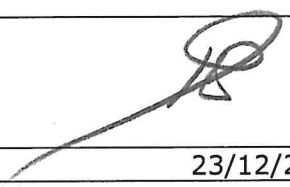
Funding Type	Source of Funding	Funding Amount
Commercially sponsored		
Sponsored, other (e.g. collaborative groups)		
External funding (e.g. NHMRC, Foundations etc.)		
Internal Departmental funding		
Other (specify)		

Which organisation will receive and manage this funding: (Please list organisation details and contact person)	Not applicable.

Section 7: Declaration

Principal Investigator Declaration (This section is mandatory)

- I confirm that the information provided in this application is true and correct and that I agree to adhere to all relevant legislation and guidelines during conduct of this activity.
- I am responsible for maintaining the confidentiality of the medical records accessed and any personal, health or sensitive information contained within those records by the external applicant.

Name of Austin Health Principal Investigator	Penelope Hey
Signature of Austin Health Principal Investigator	
Date	23/12/2021

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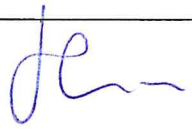
Head of Department Declaration (This section is mandatory)

- I support this research activity being undertaken in my department.

Name of Austin Health Head of Department	Dr Josephine Grace
Signature of Austin Health Head of Department	
Department	CHASMO
Date	24/12/21

Student Investigator Declaration (if applicable)

- I agree to adhere to all relevant legislation and guidelines during conduct of this activity.
- I am responsible for maintaining the confidentiality of the medical records accessed and any personal, health or sensitive information contained within those records.

Name of Student Investigator	
Signature of Student Investigator	
Date	

External Applicant Declaration (if applicable)

In consideration of Austin Health agreeing to allow me to access, use, collect and disclose health, personal or sensitive information from health and medical records or directly from Austin Health patients or employees for the purposes of conducting the above named project, as the case may be

1. I acknowledge that certain legislation relating to patient health care and medical records privacy including the Health Services Act 1988 (Victoria), the Health Records Act 2001 (Vic), the Information Privacy Act 2000 (Victoria), the Mental Health Act 2014 (Victoria) and the Privacy Act 1988 (Cth) impose on me duties of confidentiality.
2. I agree to comply with those requirements as they apply to Austin Health and its patients and that I am not permitted to, and will not, collect, use or disclose to any other person beyond the research team personnel, directly or indirectly, any health, personal or sensitive information about any patient of Austin Health in identifiable format obtained by reason of my participation or connection with my conduct of this project.
3. I agree to maintain the confidentiality of any health, personal and sensitive information from the health and medical records I source. I will not remove any original source material from Health Information Management. I agree to keep confidential any health, personal or sensitive information concerning persons and events that comes to my attention on the Austin Health campuses. Such information includes that concerning the research study noted above and any other information which comes my way, whether it be something I read, something I see, or something I hear.

Name of External Applicant	
Signature of External Applicant	

Date	