

Human Ethics Application Conditional Approval

21/02/2023

ATTENTION: PROF Felicity Baker

3582 - Melbourne Conservatorium of Music 6599 - Fine Arts and Music The University of Melbourne

Reference 2023-24870-36694-8

Project Title: Music Attuned Technology for Care via eHealth – MATCH: Exploratory and Proof-of-Concept Study in the Residential Aged Care Setting and Determining Digital Markers of Agitation (Study 3)

Dear PROF Felicity Baker,

Your application for an amendment to your Project has been considered by an Executive Committee. You have been approved with conditions to proceed with the Project in line with the amendments on the basis that it meets the requirements of the <u>National Statement on Ethical Conduct in Human Research (2007, Updated 2018)</u>.

Any original conditions attached to your Project remain applicable. It is your responsibility to ensure that all people associated with the Project are made aware of what has been approved.

Please get in touch with us via the Correspondence tab if you have any questions or require further assistance.

Yours sincerely,

MR Tim Mattingsbrooke

Research Ethics Officer

Human Ethics Team Office of Research Ethics and Integrity | Research, Innovation & Commercialisation Level 5, Alan Gilbert Building, 161 Barry Street The University of Melbourne, Victoria 3010, Australia T:(03) 8344 8662

E: timm@unimelb.edu.au

Summary Details for the Approved Human Ethics Project:

 Project Title:
 Music Attuned Technology for Care via eHealth – MATCH: Exploratory and Proof-of-Concept Study in the Residential Aged Care Setting and Determining Digital Markers of Agitation (Study 3)

 Reference Number:
 2023-24870-36694-8

 Approval Date:
 03/10/2022

Expiry Date:	03/10/2025
Responsible Human Ethics Committee	HASS 1
Project Supervisor	PROF Felicity Baker
Other Investigators	Dr Ajay Castelino, DR Tanara Vieira Sousa, DR Libby Flynn, MS Zara Thompson, DR Ryan Kelly, PROF Robyn Woodward-Kron, Miss Dianna Vidas, MS Alissa Westphal, PROF Nicola Lautenschlager, MRS Hayley Antipas, MS Phoebe Stretton-Smith, PROF Efstratios Skafidas, PROF Lars Kulik, MR Nestor Stiven Cabello, DR Jeanette Tamplin, A/PROF Jenny Waycott, DR Amit Lampit
External Investigators	Dr Den-Ching Angel Lee

Documents Table:

Document Type	File Name	Date	Version
Other	MATCH_DMP_2022_07_04_v3	04/07/2022	3
Consent form	A_MATCH_Study3_PLS&Consent_Resident	21/07/2022	1
Consent form	A_MATCH_Study3_PLS&Consent_Guardian	21/07/2022	1
Consent form	A_MATCH_Study3_PLS&Consent_CareStaff	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	B_MATCH_Study3_Stage1_UNIT_Observation&AdverseEventForm	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	C2_MATCH_Study3_Stage2_AgitationEventForm	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	D1_MATCH_Study3_Stage3_MusicInventory	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	D2_MATCH_Study3_Stage3_PreTrialAssessment_CareStaff	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	E1_MATCH_Study3_All_OtherForms_Resident	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	E2_MATCH_Study3_All_Medication_Resident	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	E3_MATCH_Study3)_All_OtherForms_CareStaff	21/07/2022	1
Questionnaire(s) and/or survey instrument(s)	C1_MATCH_Study3_Stage2_Screening_Resident	22/07/2022	1
Full protocol (for medical research)	MATCH_Protocol_study3_V1_22Jul22	22/07/2022	1
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian	22/07/2022	1
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_resident	22/07/2022	1
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.1	05/08/2022	1.1
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.1	05/08/2022	1.1
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.1	05/08/2022	1.1
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian_V1.1	05/08/2022	1.1
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_resident_V1.1	05/08/2022	1.1
Full protocol (for medical research)	MATCH_Study3_Protocol_V1.1	05/08/2022	1.1

Document Type	File Name	Date	Version
Other	1st_review_Comments_	05/08/2022	1
Other	Amendment_9September2022	09/09/2022	1
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.2(stages1&3)	13/09/2022	1.2
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.2(stage2)	13/09/2022	1.2
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.2(stages1&3)	13/09/2022	1.2
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.2(stage2)	13/09/2022	1.2
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_resident_V1.2	13/09/2022	1.2
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.2(stages1&3)	13/09/2022	1.2
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.2(stage2)	13/09/2022	1.2
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian_V1.2	13/09/2022	1.2
Full protocol (for medical research)	MATCH_Study3_Protocol_V1.2_reviewed	13/09/2022	1.2
Other	Participation_Agreement_MACS_email	13/09/2022	1
Other	Trial site letter agreement - MATCH_MACS	13/09/2022	1
Other	Response to HASS 1 Comments	13/09/2022	1
Other external approvals	MACS_signed_agreement	20/09/2022	1
Other external approvals	MonashHealth	20/09/2022	1
Other	Response to HASS 1 Comments v3	20/09/2022	3
Other	MACS_signed_agreement	20/09/2022	1
Other	MonashHealth	20/09/2022	1
Other	Trial site letter agreement - Non-TGA trials_Monash	20/09/2022	1
Other	Study3_Amendment_Additional_Staff_Interview_Oct22	17/10/2022	1
Questionnaire(s) and/or survey instrument(s)	D_MATCH_Study3_Stage1&3_ManagementStaff_IInterview	17/10/2022	1
Questionnaire(s) and/or survey instrument(s)	D_MATCH_Study3_Stage3_Residents_PostTrialInterview	17/10/2022	1
Full protocol (for medical research)	MATCH_Study3_Protocol_V1.3	07/11/2022	1.3
Other	Response to HASS 1 Comments v4	07/11/2022	4
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.3(stage2)	07/11/2022	1.3
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.3(stages1&3)	07/11/2022	1.3
Consent form	A_MATCH_study3_PLS_Consent_Management_Staff_V1.0	07/11/2022	1.0
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.3(stage2)	07/11/2022	1.3
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.3(stages1&3)	07/11/2022	1.3
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.3(stage2)	07/11/2022	1.3
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.3(stages1&3)	07/11/2022	1.3
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian_V1.3	07/11/2022	1.3
Consent form	A_MATCH_Study3_Stage3_ConsentConfirmation_resident_V1.3	07/11/2022	1.3
Consent form	A_MATCH_Study3_PLS_Consent_CareStaff_V1.4(stage2)	06/02/2023	1.4
Consent form	A_MATCH_Study3_PLS_Consent_Guardian_V1.4(stage2)	06/02/2023	1.4
Consent form	A_MATCH_Study3_PLS_Consent_Resident_V1.4(stage2)	06/02/2023	1.4
Full protocol (for medical research)	MATCH_Study3_Protocol_V1.4	06/02/2023	1.4

Document Type	File Name	Date	Version
Questionnaire(s) and/or survey instrument(s)	C_MATCH_Study3_Stage2&3_MusicQuestionnaire_V1.1	06/02/2023	1.1
Questionnaire(s) and/or survey instrument(s)	C_MATCH_Study3_Stage2_MusicPlaylistsForm	06/02/2023	1
Other	Study3_Amendment_6Feb23	06/02/2023	1

Conditions of Approval:

Due date of Conditio	n 21/05/2023
Condition details	When you receive the approval letter from Residential Aged Care - HammondCare, don't forget to register and upload it onto Infonetica.

Research projects are normally approved to the anniversary date of the approval. Projects may be renewed yearly for up to a total of three years upon receipt of a satisfactory annual report. If a project is to continue beyond three years, two optional extensions of one year each (3+1+1) will need to be applied for. Anything beyond five years will need a new application to be submitted.

Please note that the following conditions also apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

- 1. Limit of Approval: Approval is strictly limited to the research submitted in your Project application.
- 2. Variation to Project: Any subsequent variations to the Project must be notified formally to the Committee for consideration and approval before they are implemented. If the Committee considers the proposed changes significant, you may be required to submit a new application.
- 3. Incidents or adverse events: Researchers must report immediately to the Committee anything that could affect the ethical acceptability of the Project, including adverse effects on participants or unforeseen events. Failure to do so may result in suspension or cancellation of the approval.
- 4. Monitoring: All projects are subject to monitoring at any time by the Committee.
- 5. Annual Report: An annual report must be submitted each year on the anniversary date of the approval and at the conclusion of the Project. Ethics approval will lapse if an annual report is not submitted.
- 6. Auditing: All projects are subject to audit by members of the Committee.