

Human Ethics Application Conditional Approval

03/10/2022

ATTENTION: PROF Felicity Baker

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

Reference 2022-24870-32866-5

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,

Thank you for responding to queries raised by the HASS 1 ethics committee.

The Committee agreed to approve your application with conditions on the basis that it meets the requirements of the <u>National Statement on Ethical</u> <u>Conduct in Human Research (2007, Updated 2018)</u>. Please see below the **Summary Details for the Approved Human Ethics Project** and **Conditions of Approval**. It is your responsibility to ensure that all people associated with the Project are made aware of what has been approved.

Desk-based elements of your Project and face-to-face research can commence now, as can data collection that can be conducted online or via telephone, subject to necessary approvals or amendments to ethics applications. Please contact us via the Correspondence tab if you have any questions or require further assistance.

Yours sincerely,

MR Tim Mattingsbrooke

Research Ethics Officer

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Summary Details for the Approved Human Ethics Project:

Project TillMusic 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:022-24870-32866-5Approval
Date:0310/2022Expiry Date:0310/2025Responsible
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Project PROF Felicity Baker Supervisor

DR Tanara Vieira Sousa, PROF Efstratios Skafidas, DR Jeanette Tamplin, A/PROF Jenny Waycott, DR Amit Lampit, DR Libby Flynn, MS Zara Thompson, DR Ryan Kelly, PROF Robyn Woodward-Kron, Miss Dianna Vidas, MS Alissa Westphal, PROF Nicola Lautenschlager, Miss Other Investigators Rebecca Moorhead, MRS Hayley Antipas, MS Phoebe Stretton-Smith

Documents Table:

Consent form A	MATCH_DMP_2022_07_04_v3		
		04/07/2022	3
	A_MATCH_Study3_PLS&Consent_Resident	21/07/2022	1
Consent form A	A_MATCH_Study3_PLS&Consent_Guardian	21/07/2022	1
Consent form A	A_MATCH_Study3_PLS&Consent_CareStaff	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	B_MATCH_Study3_Stage1_UNIT_Observation&AdverseEventForm	21/07/2022	1
Questionnaire(s) and/or C survey instrument(s)	C2_MATCH_Study3_Stage2_AgitationEventForm	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	D1_MATCH_Study3_Stage3_MusicInventory	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	D2_MATCH_Study3_Stage3_PreTrialAssessment_CareStaff	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	E1_MATCH_Study3_All_OtherForms_Resident	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	E2_MATCH_Study3_All_Medication_Resident	21/07/2022	1
Questionnaire(s) and/or E survey instrument(s)	E3_MATCH_Study3)_All_OtherForms_CareStaff	21/07/2022	1
Questionnaire(s) and/or C survey instrument(s)	C1_MATCH_Study3_Stage2_Screening_Resident	22/07/2022	1
Full protocol (for medical N research)	MATCH_Protocol_study3_V1_22Jul22	22/07/2022	1
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian	22/07/2022	1
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_resident	22/07/2022	1
Consent form A	A_MATCH_Study3_PLS_Consent_CareStaff_V1.1	05/08/2022	1.1
Consent form A	A_MATCH_Study3_PLS_Consent_Guardian_V1.1	05/08/2022	1.1
Consent form A	A_MATCH_Study3_PLS_Consent_Resident_V1.1	05/08/2022	1.1
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian_V1.1	05/08/2022	1.1
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_resident_V1.1	05/08/2022	1.1
Full protocol (for medical N research)	MATCH_Study3_Protocol_V1.1	05/08/2022	1.1
Other 1	1st_review_Comments_	05/08/2022	1
Other A	Amendment_9September2022	09/09/2022	1
Consent form A	A_MATCH_Study3_PLS_Consent_CareStaff_V1.2(stages1&3)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_PLS_Consent_CareStaff_V1.2(stage2)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_PLS_Consent_Resident_V1.2(stages1&3)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_PLS_Consent_Resident_V1.2(stage2)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_resident_V1.2	13/09/2022	1.2
Consent form A	A_MATCH_Study3_PLS_Consent_Guardian_V1.2(stages1&3)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_PLS_Consent_Guardian_V1.2(stage2)	13/09/2022	1.2
Consent form A	A_MATCH_Study3_Stage3_ConsentConfirmation_guardian_V1.2	13/09/2022	1.2
	MATCH_Study3_Protocol_V1.2_reviewed	13/09/2022	1.2
Other P	Participation_Agreement_MACS_email	13/09/2022	1
Other T	Trial site letter agreement - MATCH_MACS	13/09/2022	1
Other F	Response to HASS 1 Comments	13/09/2022	1
Other external approvals		20/09/2022	
Other external approvals		20/09/2022	
	Response to HASS 1 Comments v3	20/09/2022	
	MACS_signed_agreement	20/09/2022	
	MonashHealth	20/09/2022	
	Trial site letter agreement - Non-TGA trials_Monash	20/09/2022	

Conditions of Approval:

Due date of Condition 03/01/2023

Condition details Register and upload the Residential Aged Care – HammondCare endorsement/approval letter when you receive it on 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.