

Human Ethics Application Approval

02/08/2023

ATTENTION: Prof Felicity Baker

7420 - Melbourne Conservatorium of Music
7620 - Fine Arts and Music
The University of Melbourne

Reference Number: 2023-24870-43080-11

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 amendment to your project has been approved on the basis that it meets the requirements of the [National Statement on Ethical Conduct in Human Research \(2007, Updated 2018\)](#).

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, and that other relevant approvals are obtained before work on this project begins.

Please contact us via the Correspondence tab if you have any questions or if you require further assistance.

Kind regards,

Miss Laura Coburn

Research Ethics Officer

Human Ethics Team

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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: 2023-24870-43080-11

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 Amit Lampit, MS Annalise Baulch, PROF Lars Kulik, MR Nestor Stiven Cabello, MS Phoebe Stretton-Smith, MRS Hayley Antipas, Miss Dianna Vidas, PROF Robyn Woodward-Kron, DR Ryan Kelly, DR Libby Flynn, A/PROF Jenny Waycott, PROF Nicola Lautenschlager, MS Zara Thompson, MS Alissa Westphal, PROF Efstratios Skafidas, DR Jeanette Tamplin

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
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

Document Type	File Name	Date	Version
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_Interview	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
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
Other	Study3_Amendment_July23	03/07/2023	1
Full protocol (for medical research)	MATCH_Study3_Protocol_V1.5	26/07/2023	1.5
Other	Study3_amendment_Aug23	26/07/2023	1

Conditions of Approval:

Research projects are usually approved for 1 year (to the anniversary date of the approval). Projects may be renewed yearly upon receipt of a satisfactory annual report, for up to a total of three years. If a project is to continue beyond three years, an extension of one year is available, up to a total of 5 years (3+1+1). If a project extends beyond five years, a new application must be submitted. Please contact our office if you require assistance with this.

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

- Limit of approval:** Approval is limited strictly to the research as submitted in your Project application.
- Variation to project:** Any subsequent variations to the Project must be notified formally to the Committee as an Amendment. These must be approved before they are implemented. If the Committee considers that the proposed changes are significant, you may be required to submit a new application.
- Incidents or adverse events:** Researchers must immediately submit to the Committee an incident report for any incident 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 approval.
- Annual reports and monitoring:** All projects are subject to monitoring at least annually. An annual report must be submitted each year on the anniversary of project approval (progress report), and at the conclusion of the project (final report). If an annual report is not submitted, the conditions of approval for that year will not have been met.

FOR PROGRAM APPLICATIONS: Please ensure that you attach all Student Proposal Forms (to be completed before each student begins their research) to

your annual report submission.

5. **Auditing:** All projects are subject to auditing at any time by the University.