



## HUMAN RESEARCH ETHICS COMMITTEE

### APPROVAL NOTICE

Dear Professor Michael Gradisar,

The below proposed project has been **approved** on the basis of the information contained in the application and its attachments.

**Project No:** 4236

**Project Title:** The role of REM Fragmentation in the relationship between sleep-related problems and separation anxiety for middle childhood

**Primary Researcher:** Professor Michael Gradisar

**Approval Date:** 19/04/2021

**Expiry Date:** 31/12/2021

**Please note:** Due to the current COVID-19 situation, researchers are strongly advised to develop a research design that aligns with the University's COVID-19 research protocol involving human studies. Where possible, avoid face-to-face testing and consider rescheduling face-to-face testing or undertaking alternative distance/online data or interview collection means. For further information, please go to <https://staff.flinders.edu.au/coronavirus-information/research-updates>.

**Please note:** For all research projects wishing to recruit Flinders University students as participants, approval needs to be sought from Professor Clare Pollock in her capacity as Deputy Vice-Chancellor (Students). To seek approval, please provide a copy of the Ethics approval for the project and a copy of the project application to the Office of the Deputy Vice-Chancellor (Students) via [dvcsoffice@dl.flinders.edu.au](mailto:dvcsoffice@dl.flinders.edu.au).

#### RESPONSIBILITIES OF RESEARCHERS AND SUPERVISORS

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##### 1. Participant Documentation

Please note that it is the responsibility of researchers and supervisors, in the case of student projects, to ensure that:

- all participant documents are checked for spelling, grammatical, numbering and formatting errors. The Committee does not accept any responsibility for the above mentioned errors.
- the Flinders University logo is included on all participant documentation (e.g., letters of Introduction, information Sheets, consent forms, debriefing information and questionnaires – with the exception of purchased research tools) and the current Flinders University letterhead is included in the header of all letters of introduction. The Flinders University international logo/letterhead should be used and documentation should contain international dialling codes for all telephone and fax numbers listed for all research to be conducted overseas.
- the HREC contact details, listed below, are included in the footer of all letters of introduction and information sheets.

*This research project has been approved by Flinders University's Human Research Ethics Committee (Project ID 4236). If you have any complaints or reservations about the ethical conduct of this study, you may contact Flinders University's Research Ethics & Compliance Office via telephone on 08 8201 2543 or by email [human.researchethics@flinders.edu.au](mailto:human.researchethics@flinders.edu.au).*

##### 2. Annual Progress / Final Reports

In order to comply with the monitoring requirements of the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)* an annual progress report must be submitted each year on the anniversary of the approval date for the duration of the ethics approval using the HREC Annual/Final Report Form available online via the ResearchNow Ethics & Biosafety system.

**Please note** that no data collection can be undertaken after the ethics approval expiry date listed at the top of this notice. If data is collected after expiry, it will not be covered in terms of ethics. It is the responsibility of the researcher to ensure that annual progress reports are submitted on time; and that no data is collected after ethics has expired.

If the project is completed *before* ethics approval has expired please ensure a final report is submitted immediately. If ethics approval for your project expires please either submit (1) a final report; or (2) an extension of time request (using the HREC Modification Form). For student projects, the Low Risk Panel recommends that current ethics approval is maintained until a student's thesis has been submitted, assessed and finalised. This is to protect the student in the event that reviewers recommend that additional data be collected from participants.

### 3. Modifications to Project

Modifications to the project must not proceed until approval has been obtained from the Ethics Committee. Such proposed changes / modifications include:

- change of project title;
- change to research team (e.g., additions, removals, researchers and supervisors)
- changes to research objectives;
- changes to research protocol;
- changes to participant recruitment methods;
- changes / additions to source(s) of participants;
- changes of procedures used to seek informed consent;
- changes to participant remuneration;
- changes to information / documents to be given to potential participants;
- changes to research instruments (e.g., survey, interview questions etc);
- extensions of time (i.e. to extend the period of ethics approval past current expiry date).

To notify the Committee of any proposed modifications to the project please submit a Modification Request Form available online via the ResearchNow Ethics & Biosafety system. Please open the project, then select the 'Create Sub-Form' tile in the grey Action Menu, and then select the relevant Modification Request Form. Please note that extension of time requests should be submitted prior to the Ethics Approval Expiry Date listed on this notice.

### 4. Adverse Events and/or Complaints

Researchers should advise the Executive Officer of the Ethics Committee on 08 8201-3116 or [human.researchethics@flinders.edu.au](mailto:human.researchethics@flinders.edu.au) immediately if:

- any complaints regarding the research are received;
- a serious or unexpected adverse event occurs that effects participants;
- an unforeseen event occurs that may affect the ethical acceptability of the project.

Yours sincerely,

Hendryk Flaegel

*on behalf of*

Human Research Ethics Committee  
Research Development and Support  
[human.researchethics@flinders.edu.au](mailto:human.researchethics@flinders.edu.au)

Flinders University  
Sturt Road, Bedford Park, South Australia, 5042  
GPO Box 2100, Adelaide, South Australia, 5001

[http://www.flinders.edu.au/research/researcher-support/ebi/human-ethics/human-ethics\\_home.cfm](http://www.flinders.edu.au/research/researcher-support/ebi/human-ethics/human-ethics_home.cfm)

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*Proactively supporting our Research*