Kanton Bern
Canton de Berne

Gesundheits-, Sozial- und Integrationsdirektion
Kantonale Ethikkommission für die Forschung

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Frau
Prof. Dr. med. Petra Stute
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Inselspital Bern
Friedbühlstrasse 19
3010 Bern

Bern, 16. Mai 2023, CA

Approval of the Cantonal Ethics Committee of Berne (KEK Bern)

Project-ID	2023-00209
Project title	No more sleepless nights in perimenopause - an open label, randomized, parallel-group, active controlled intervention study in perimenopausal women with vasomotor symptoms and insomnia to investigate the efficacy of hormone replacement therapy and cognitive behavioral therapy
Master's/Doctoral thesis by	Pavicic, Elena
Main investigator	Prof. Dr. med. Petra Stute
Sponsor	Prof. Dr. med. Petra Stute
Centers	• Prof. Dr. med. Petra Stute, University Clinic for Gynecology, Inselspital Bern, Bern

Decision

☒ The approval is granted with charges
This approval is valid for the announced duration of the study, but for a maximum of 5 years from the date of this decision.

The documents must be revised in accordance with the points below. The changes in the individual documents must be drawn up in correction mode so that both the new and the old information are visible. When uploading the revised documents (1x with correction mode, 1x clean-version) via Basec, the old documents that are replaced by the new documents must be deleted.

Charges: To be fulfilled within 30 days.

1. Patient information: must be fulfilled before using the document.
   a. Ch. 14: Please add the direct number of Ms. Stute.

b. Declaration of consent for further use: Section 9.3 provides information about further use, please add the separate declaration of consent for further use further use in accordance with the current template at www.swissethics.ch (see last two pages of the template).

Classification

☒ Clinical trial according to ClinO Category: A

- ☐ with medicinal products
- ☐ with medical devices
- ☐ with transplant products
- ☐ with gene therapy
- ☐ with genetically modified or pathogenic organisms
- ☐ transplantation
- ☒ other clinical trials according to Chapter 4 ClinO
- ☐ with ionizing radiation

Decision-making procedure

☐ Regular procedure ☐ Simplified procedure ☒ Presidential procedure

The Ethics Committee confirms that it works in accordance with ICH-GCP.

Fees

Amount: CHF 0.- **Tariff code:**

According to the current fee schedule of swissethics. Invoicing follows through the Cantonal Health, Social and Integration Department (GSI).

Information on legal remedies

An appeal against this decision may be lodged with the Directorate of Health, Social, and Integration of the Canton of Bern within 30 days from the date of notification. The appeal period may not be extended. The notice of appeal must be submitted in duplicate to the Directorate of Health, Social and Integration, Rathausplatz 1, Postfach, 3000 Bern 8.

Any appeal, which must be submitted in at least two copies, must contain a request, a statement of facts and evidence, a justification, and a signature; the contested decision and other tangible evidence must be attached.

It must

(a) indicate which decision is requested instead of the contested decision, and
(b) the reasons on which this other decision is requested, and
(c) contain the signature of the appealing party or the person representing them.

The notice of appeal must be accompanied by the evidence, insofar as it is tangible, and the contested decision. (Art. 32 und 60 ff. des Gesetzes vom 23. Mai 1989 über die Verwaltungsrechtspflege [VRPG; BSG 155.21]).

Copy to

☐ BAG
☒ DLF
☐ Others

Prof. Dr. med. Christian Seiler
President KEK Bern

Dr. sc. nat. Dorothy Pfiffner
Vice President
Head of Scientific Secretariat

Appendix:
- Duties of the sponsor/investigator or project leader
- Possible decisions and their significance
- Submitted documents 05.05.2023

Appendix

Responsibilities of the Sponsor/Principal Investigator

Submission of Documents: revised documents and new documents related to the study/project should be submitted exclusively via the BASEC web portal, on the appropriate form page of the relevant application. Obsolete documents should be removed, and date and version information should be updated accordingly. The changes made must be submitted in tracked changes mode and additionally as a 'clean' version. Study information and consent forms, the protocol, and amendments must be submitted in searchable PDF files, with scanned documents undergoing OCR (optical character recognition). The signed and dated cover letter must include responses to any questions posed by the Ethics Committee. Revised documents must also be sent to other relevant authorities if involved.

Note: The responsible Ethics Committee reviews the information and consent forms in one of the official languages: German, French, or Italian. Consent forms in other languages are only acknowledged by the Ethics Committee. The sponsor or project management is responsible for the correct translation.

Reporting obligations: The legally binding notification or approval requirements to the Ethics Committee for substantial amendments, early study termination, adverse events, etc., must be complied with (Federal regulations). The final report must be submitted to the Ethics Committee no later than one year after study completion.

Registration obligations: The sponsor must register the clinical trial in a WHO Primary Registry or the U.S. National Library of Medicine's registry (clinicaltrials.gov) and then enter this number in the BASEC portal. The transfer of required data to the Swiss National Clinical Trials Portal (SNCTP) can be automated after Ethics Committee approval and applicant consent. Information about the clinical trial is publicly accessible in both registries. Additionally, swissethics publishes limited information such as the title, project type, and lead Ethics Committee of all applications approved by the cantonal Ethics Committees on swissethics.ch (except for Phase I studies).

Possible Decisions and Their Meanings:

The approval is granted: The project can proceed according to the approved research plan and within the applicable legal regulations. Further approval requirements (Swissmedic/BAG) must be observed.

The approval is granted with charges: The project can start according to the approved research plan and within the applicable legal regulations. The conditions must be met, and the application documents updated within 30 days. Further approval requirements (Swissmedic/BAG) must be observed.

The approval can not yet be granted: The project cannot start yet. The following conditions must be met or questions answered, and the revised documents resubmitted to the Ethics Committee. The Ethics Committee will review the revised documents and grant approval if the conditions are met or the questions satisfactorily answered.

The approval is not granted: The project cannot proceed in its current form. Resubmission is possible.

The application will not be considered: See reasons stated above, e.g., not responsible or not requiring approval.

Documents submitted for the main center

Prof. Dr. med. Petra Stute, University Clinic for Gynecology, University Hospital Bern, Bern, Switzerland

Document	Doc. date	Version
1. Cover letter		
cover-letter-response-sleepless-05-05-23.pdf	31/03/2023	
2. Synopsis of the study plan		
see doc/cat: 4, page/ref: 10		
3. Participant information sheet and informed consent (ICF)		
v2-studieninformation-sleepless-31-03-23.pdf	31/03/2023	2
v2-studieninformation-sleepless-31-03-23-mit-track-changes.docx	05/05/2023	1
generalconsent-inselspital-31-03-2023.pdf	31/03/2023	1
4. Study plan (protocol), signed and dated		
v2-study-protcol-sleepless-31-03-2023.pdf	31/03/2023	2
v2-study-protocol-sleepless-31-03-2023-with-track-changes.docx	05/05/2023	1
4a. Monitoring plan		
see doc/cat: 4, page/ref: 18		
5. CRF (Case Report Form)		
crf-sleepless-02-03-23.docx	03/02/2023	1
6. Investigator's CV, dated		
cv-stute-sleepless-02-03-23.pdf	03/02/2023	
7. Investigator's proof of GCP training		
v2-gcp-prof-stute-sleepless.pdf	31/03/2023	
9. Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator		
financing-sleepless-03-02-23.pdf	03/02/2023	
11. Other documents handed over to study participants		
v2-other-documents-handed-to-participants-sleepless-31-03-2023.zip	31/03/2023	2
12. Details on nature and scope/value of compensation for participants		
There is no compensation for the participation in this study		
14. Information on secure handling of biological material and personal data, and in particular on the storage thereof		
see doc/cat: 4, page/ref: 18		
39. Miscellaneous / Varia		
dissertationsvereinbarung-elena-pavicic.pdf	05/05/2023	1