1 Information Summary

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1	**General information and aim of the study** This is a non-clinical study to understand the fundamental mechanisms of sleep, wake, and intermediate stages, especially under high sleep pressure. We use EEG, a passive recording device that measures the electrical activity produced by your brain, and we compare these signals across different times of day and activities. In particular, we aim to determine whether parts of the brain can selectively fall asleep. For practical reasons, this study will be conducted entirely in English, although you can always ask for help in understanding instructions and questionnaires to the experimenter.
2	**Participant selection** We are looking for participants who are young, healthy, who sleep without difficulty and habitually follow average sleep-wake schedules. You must be willing to answer a lot of questions about yourself, your lifestyle, eating, drinking, and drug habits. It is recommended that you have a decent understanding of English.
3	**Study procedure** 1) Online screening with provisory digital consent 2) Definitive study consent 3) In-person questionnaires 4) Adaptation night in the lab (so you get used to the EEG cap) 5) 1 week wearing a wrist movement tracker and filling in daily sleep reports 6) A 4h night sleep in the lab with EEG 7) 24h awake in the lab with EEG a. Cognitive tests b. Staring at dots for a while c. Watching TV d. Only eating snacks (instead of 3 large meals) 8) The following night sleep with EEG, as long as you want 9) Debriefing questionnaire From first meeting to the end: 9 days Time in lab: 9h + 36h
4	**Rescheduling or early termination of the experiment** If anything affects your sleep (or could potentially affect your sleep) in the one month prior to the experiment or early-on in the experiment, this does not disqualify you from continuing, but please reschedule the experiment after you have completely recovered from this event. If the interference is too severe, the experiment will have to be aborted. You will be compensated partial amounts for the time already invested.
5	**Burdens** The following are the most uncomfortable aspects of the experiment. Please be sure you are willing and capable of withstanding them before agreeing to participate: - Stay awake for 24 hours after only 4 hours of sleep. - Wear EEG electrodes for 36 hours continuously, also while sleeping. - The electrodes will leave little marks on your skin for 24h after being removed. - Sticking to a strict schedule regarding when to fall asleep and wake up for a week, and not having anything scheduled early in the mornings (requiring and earlier alarm) or late in the evening (delaying sleep) - Abstaining from coffee or other caffeinated beverages while in the lab, and avoiding coffee in the afternoons the week before - Abstaining from alcohol, drugs, and partying the entire week of the experiment - Conducting boring tasks for extended periods of time

	- Eating the same set of snacks at 3h intervals during the 24h awake period.
6	**Benefits** The results of this study could benefit clinicians by establishing an objective biomarker for sleepiness and sleep pressure, without needing to rely on subjective sleepiness ratings.
7	**Rights** Your participation in this study is entirely voluntary. At any point you can choose to withdraw, without needing to provide a reason. In this case, your data will still be evaluated. You may ask questions at any time.
8	**Obligations** If you decide to participate, please follow the rules and instructions. Most importantly: - Be honest when answering questionnaires - Inform the experimenter about any adverse event that could affect your sleep or wellbeing during the course of the experiment - Do not drink coffee in the afternoons during the week of the experiment - Do not drink any alcohol or attend parties during the week of the experiment - Don't engage in activities that result in poor sleep around the time of the experiment (e.g. travel across time zones, overnight camping) - Be prepared to reschedule if anything happens that affects your sleep
9	**Risks** If you have sensitive skin, you may suffer skin irritation. If you have a psychiatric or medical condition, it is unknown what the effects of prolonged wakefulness will have. For this reason, it is important that you understand your own limitations before agreeing to participate.
10	**Results** If you wish, the experimenters can provide you with the final results and eventual publication derived from this study. Should the data analyses of your EEG reveal any potential medical condition (e.g. epilepsy), we will consult a medical expert and further inform you.
11	**Confidentiality of personal data** For this study we will collect personal data, which will be immediately coded to provide anonymity. The participant code will only be available to the principal investigator and research coordinator. The coded EEG data will be made publicly available to be used in other studies, for which you will be asked to provide separate consent. We comply with all legal provisions of the Data Protection Act.
12	**Compensation for participants in the study** For the completion of the whole study, you will be compensated 400 CHF. Should the experiment be aborted for whatever reason, partial compensation will be provided.
13	**Responsibilities** The University Children's Hospital of Zurich will be responsible in case you were to suffer damage as a consequence of the study.
14	**Study funding** The study is financed by the HMZ flagship grant "SleepLoop" and operating funds of Prof. Huber.
15	**Contacts:** You may ask questions at any time. Sophia Snipes PhD student Office address: Attenhoferstrasse 45, 8032 Zurich

	Mobile number: + 41 79 155 62 64 Email (regular but not urgent communication): sophia.snipes@kispi.uzh.ch Principal investigator: Prof. Reto Huber Steinwiesstrasse, 75 CH-8032, Zurich Email: reto.huber@kispi.uzh.ch Phone: +41 (0)44 266 81 60
16	**List of substances** This section gives many examples of caffeinated drinks, drugs and medication that you are not permitted to take during the experiment. If you require medication, you are not eligible to participate.

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Identification of Local Sleep Events in Wake EEG

The study is supervised by: Prof. Reto Huber

Dear Sir/Madam,

We kindly invite you to participate in a research project on sleep and sleepiness. This document presents the research project in detail, and a summarized version will also be provided. If any terms aren't clear, please refer to either the Glossary at the end, or feel free to ask the informing investigator directly.

Detailed information

1. General information and aim of the study

The study focuses on how the EEG changes with increasing time awake, how this relates to the EEG during sleep, and subjective feelings of sleepiness. Previous evidence suggests that under high sleep pressure (from staying awake longer than usual), parts of your brain selectively and briefly fall asleep. We want to find an exact biomarker for such a local sleep event.

This study is carried out in compliance with Swiss legislation. It has been examined and approved by the competent cantonal ethics committee.

This is a fundamental neuroscience experiment, not a clinical or medical trial. It will be conducted entirely within Zurich, and will last at most 2 years from start to finish, in which time we aim to collect data from around 30 participants. Your participation will span no more than 9 days.

2. Participant selection

Participants are screened so that they are very similar among each other, without introducing confounding elements that might bias the results. Furthermore, they must be able to handle the conditions of the experiment, without it being too different from their regular sleep-wake rhythms.

You must be:

- Between the ages of 18 and 25
- Healthy
- An average chronotype (not extreme morning or evening type)
- A good sleeper

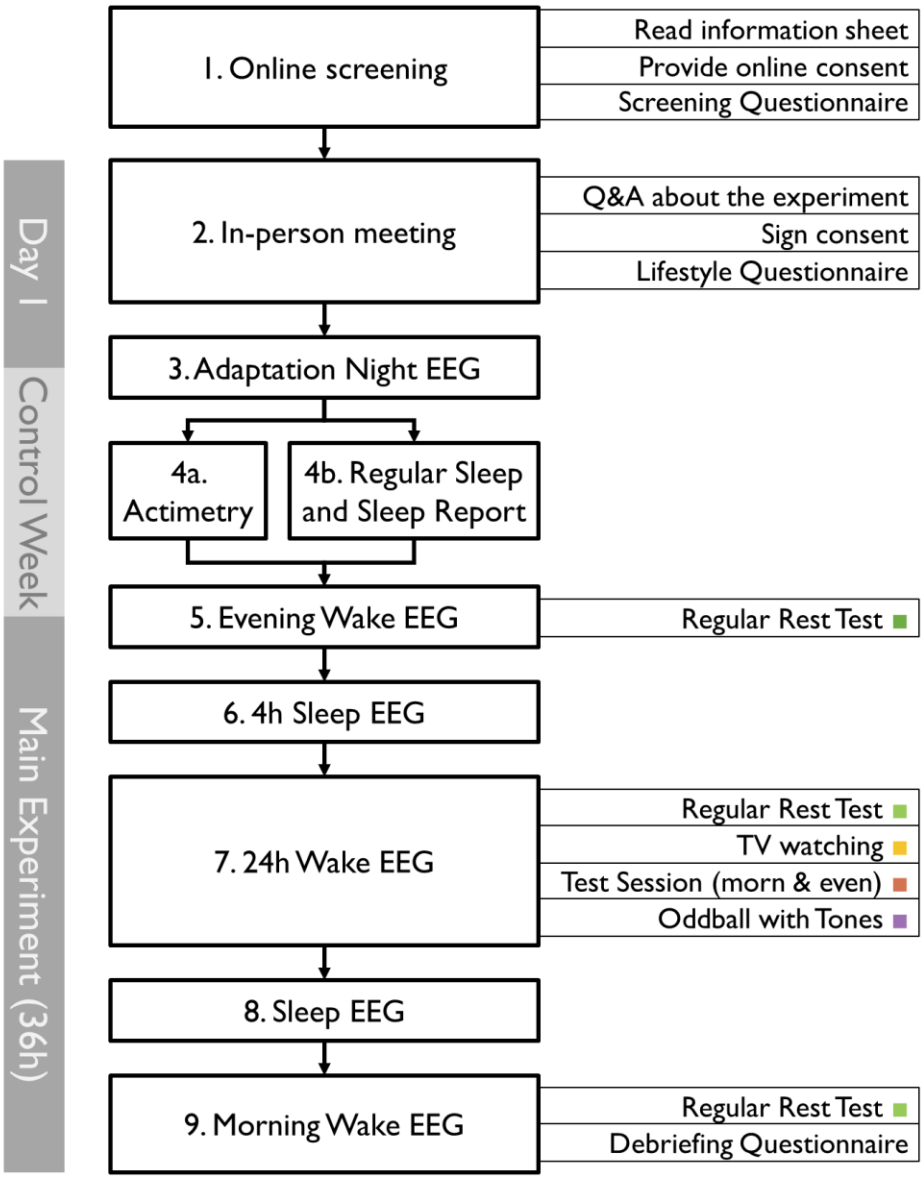
You will be excluded if you have or have done any of the following:

- Been diagnosed with or strongly suspected of having a psychiatric or medical condition
- Have any learning disorders
- Have sensitive skin
- Currently in a period of stress, or generally being vulnerable to stress
- Currently required to wake up more than 2h before preferred wakeup time, or go to sleep 2h later than preferred
- Any sleep disorders, daytime sleepiness, or any other sleep complaints
- Nap regularly
- Pregnant
- Heavy consumer of:
    - Caffeine
    - Alcohol

- Regular consumer of:
  - Drugs (see list at end of document)
  - Nicotine
- Currently taking medication
- Any past experience with:
  - Frequent drug use
  - Severe addiction and/or withdrawal
  - Alcoholism
- Substantial experience with
  - Shift work
  - Time zone travel
  - Sleep deprivation

3. Study procedure

The following figure outlines the study procedure you will have to follow, and the tests involved at each stage.



1. **Online screening**: By now you should have already completed the online screening procedure. Once you have signed this consent form, please provide the experimenter with the 3-word code you received at the end of the questionnaire. This will allow us to de-anonymize your answers and include them in the study. If you forgot the code, you will need to re-do the questionnaire.

2. **In-person meeting:** During your first meeting with the experimenter, read this information sheet, ask any questions, and then, if you feel comfortable participating, please sign the formal consent form. After this, you will be given an additional questionnaire, the **Lifestyle Questionnaire,** asking you for more details about your eating, drinking, and sleeping habits, as well as other questions about yourself. If there's any chance you might be pregnant, we will ask you to quickly do a pregnancy test. Lastly, you will be asked to establish with the experimenter a bedtime and wake up time that you find natural and can comply with for 1 week leading up to the main experiment.

3. **Adaptation night:** Either the same day you sign consent, or shortly after, you will need to come to the lab for a night measurement. You will be equipped with the EEG electrodes, and asked to sleep within the agreed upon time window. This is to let you get used to the new sleeping environment well before the main experiment, and to confirm that you do not have any sleep problems.

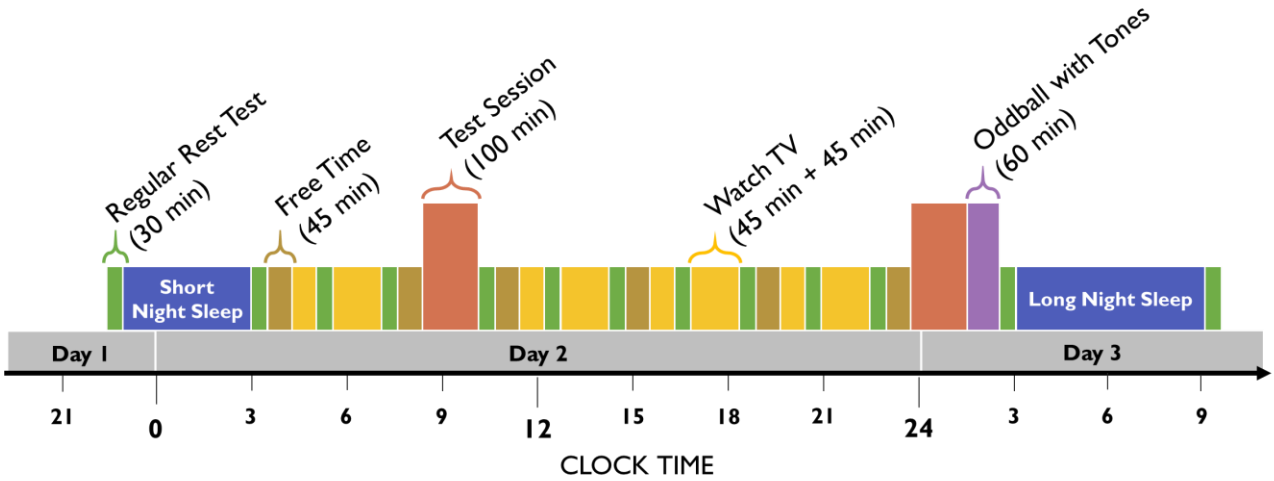
4. **Controlled sleep week**: for 7 days before the experiment, including the adaptation night, you are asked go to sleep and wake up at the same pre-specified times, and avoid any behaviour that could affect your sleep (listed in *Obligations*). Every morning right after waking up, you will be provided a **Sleep Report** to fill out, which asks you about the quality of your sleep, any dreams you might remember, mood, and your activities from the day before. During this week, you will be given an actimetry watch to wear, essentially a watch that records your wrist movement. This is to help keep track of your sleep and wake up times, as well as any potential naps in the middle of the day (which you should not take). If at the end of the week, the sleep-wake cycle was not sufficiently regular, you can try again another week.

Main Experiment

5. **Evening EEG**: when you come to the lab for the main experiment, you will start with a **Regular Rest Test**, which involves focusing on your breath for some time, then staring at a fixation dot. During this time, you will have your head in a chin rest, and an eye-tracker will measure any eyelid closure and pupil size. At the end, you need to answer questions about your experience. This sequence you will do every 2 hours the next day, and is used to systematically keep track of changes in resting state over time. <u>During all EEG recordings, there will be a microphone recording audio</u>, to keep track of everything that happens.

6. **Short Night Sleep EEG**: You will go to sleep at the regular hour, this time wearing the EEG. At the midpoint of your sleep, around 4 hours later, we will wake you up.

7. **24h wake EEG**: During this time, you will follow the schedule depicted in the timeline below.



a. You start with a Regular Rest Test, described in Point 5.

b. Then you will have around 40 minutes of **Free Time** "disconnected" from the EEG computers (the electrodes still on your head, but neither EEG nor audio will be recorded) to do what you want. For the whole day, you won't get any large meals, but instead a small plate of food that is the same for every Free Time period, which will occur once every 3 hours. You can choose which foods beforehand.

c. Once in the morning, and once in the night, you will conduct a **Test Session**. This will consist of a mixture of different tasks and resting states we use to compare different types of EEG signal, and see how they change with sleepiness. These are cognitive tasks, such as an Oddball in which you will be presented a series of changing stimuli, and have to click a button as soon as you notice a special deviant stimulus.

d. The rest of the time, you will be watching a **TV series** of your choice. You will be seated comfortably, and while we appreciate it if you don't move much (we will still be recording EEG), it is more important that you are comfortable.

e. The day will end with a 1-hour **Oddball test**, in which you need to indicate the change of a stimulus with a keypress, while pink noise tones play in the background. After one last Regular Rest Test, you can go to sleep.

8. **Long Night Sleep EEG**: you will get to go to sleep at the same time you woke up (e.g. 3AM), and sleep in until you naturally wake up.

9. **Morning**: you will do one last Regular Rest EEG, then will have the EEG taken off, and will be free to shower and get ready to leave. We will have you fill out the final **Debriefing Questionnaire**, asking you about your experience, then you'll get paid and can go home.

4. Rescheduling and Early Termination of the Experiment

To ensure that your sleep is as normal as possible, it is important that enough time has passed between an event that impacts your sleep, and the main experiment. If any of the following have occurred recently, please make sure that the Adaptation Night is scheduled at least 25 days from then.

- Taken any drugs
- Got seriously sick (e.g. flu) or injured (e.g. broken arm)
- Travelled across 2 or more time zones
- 5 or more consecutive nights of poor sleep, for whatever reason
- Sleep deprivation (staying awake longer than 20 hours)
- Sleep restriction (sleeping less than 6 hours a night for at least 3 consecutive nights)

Before the Adaptation Night, please be sure to have recovered completely from any of the following, usually within 4-5 days. Furthermore, if any of these occur during the week of the experiment, please inform the experimenter and reschedule.

- A cold or similar small illness (can still go to work)
- Get a vaccine
- Drink alcohol so much you can't walk / passed out
- Menstruation
- Exams
- Smoke/vape/nicotine patch
- Festival or other exhausting event
- Long trip
- Terrible night of sleep

You may be excluded from the rest of the study before completion. This will happen for only one of the following reasons:

1) You choose to withdraw
2) A medical condition or other disqualifying element is revealed, and you no longer meet the screening criteria
3) An external event interrupts the schedule or causes a significant loss of data, such as equipment malfunction or experimenter error
4) You do not follow the rules in section 8, *Obligations*, resulting in unreliable data.

5. Burdens

There are some aspects of the experiment that you might find too burdensome. Please make sure you're willing to withstand the following:

- Staying awake for 24 hours after only 4 hours of sleep. You will be monitored by the experimenters to make sure you don't doze off. You will be tired. This is similar to what you would experience when traveling across time zones needing to stay awake, or skipping a night to study or party, but you will not have stress or excitement keeping you awake.
- Wearing an EEG net for 36 hours continuously, also while sleeping. Some people find having something constantly on their heads irritating and sleeping with the electrodes is uncomfortable. The electrodes will leave little marks on your skin for 24h after being removed. These are just pressure marks that fade progressively with time, but maybe don't plan to go to a job interview the next day.
- Sleeping in the lab. In addition to the EEG, some people find sleeping in a new environment difficult. If this is the case for you, it's best if you don't participate.
- Sticking to a strict schedule on when to fall asleep and wake up for a week. This is a burden if you have to reschedule events that might interfere with your sleep pattern, or if you find it difficult to go asleep at a specific time rather than whenever you feel like it.
- Abstaining from coffee or other caffeinated beverages while in the lab, and limiting coffee in the week before. Ideally, you already don't drink much coffee, but if you need coffee in the afternoon, this might be particularly a problem for you.
- Abstaining from drugs, and partying the entire week of the experiment. We're sorry if participating in this experiment has a negative impact on your social life.

- Conducting boring tasks for extended periods of time. This affects some people more than others, but especially when sleepy, you might find yourself getting irritated trying to stay awake while doing nothing.
- Eating the same set of snacks at 3h intervals instead of 3 normal meals during the 24h awake.

6. Benefits

Outside of monetary compensation, there are no immediate direct benefits for your participation. If everything goes well, we should be able to identify a reliable marker for sleep pressure that can be used in clinical settings, although further population-specific studies would be needed. Of particular interest to us would be using such a marker in children, to compare region-specific brain development and sleep.

7. Rights

Participation in this study is voluntary. If you do not intend to participate in the study, or decide later to withdraw, you do not have to in any way justify your decision. In order to not invalidate the value of the time spent on the study until then, data collected up to that point will still be evaluated. In this case, after analysing your data, it will be completely anonymized. This means that the decoding code will be destroyed in such a way that no one will be able to trace the origin of the data and samples.

You can ask at any time any questions you want about the study. For this purpose, please contact the research coordinator.

8. Obligations

If you decide to participate in the study, you will need to:

- Follow the instructions.
- Answer all questionnaires honestly.
- Inform the experimenter of any changes to your health or schedule that could interfere with the experiment; it is not necessary to specify what.
- Reschedule the experiment if anything interferes with your sleep or health before the experiment (see section 4, *Rescheduling*).
- During the control week:
  - Don't consume caffeine in the afternoon, after 4PM (coffee, caffeinated soft drinks, energy drinks, black or green tea, etc.).
  - Do not drink more than 2 portions of caffeinated beverages per day (e.g. only 2 coffees, or 1 double espresso, or one coffee and one Red Bull).
  - Do not drink any alcohol, or take any drugs, or smoke anything at all.
  - Don't have any early morning activities that require you to set an earlier alarm than planned.
  - Avoid parties or other events that might delay your sleep schedule.
  - Wear the actimetry watch the whole time, but especially while sleeping. If the data shows periods of more than 2h when it wasn't worn, and you didn't inform the experimenter, you may be disqualified from continuing the experiment.
  - Every morning before breakfast, fill out the Sleep Report. It is important that you do so before doing anything else because we ask about dreams, whose memory fades very quickly. It is acceptable to be up to 2 hours late.
  - Contact the experimenter if you have any doubts if something is ok to do, and carefully report things that happened that you suspect could be relevant.
- During the main experiment, please:
  - Arrive on time to the appointment. You will have a lot to do, and serious delays would require rescheduling the whole experiment.

- Sleep when asked and stay awake when asked. We understand that this is intentionally difficult, and it does require some effort on your part.
- Go to the toilet and take care of other needs during the Free Time periods, not elsewhere in the experiment. These are meant as unrecorded times for your benefit; deviating from the scheduled activities could invalidate the whole experiment.
- Follow the instructions, engage in the tasks, and ask questions if anything is unclear.

9. Risks

There are no risky procedures involved in this study if you are a healthy young participant without skin problems. Some people react negatively to the conductive gel used for the EEG, but these are individuals who tend to have multiple skin allergies, eczemas, etc. The effects of prolonged wakefulness are well documented in healthy people, but have different, often unknown, effects in patient populations.

10. Results

During the study, the project investigator / management will inform you of any new developments that could affect the benefits of the study or your safety and, consequently, influence your consent. You will be informed in case of incidental findings (e.g. epileptic activity) that may indicate a medical condition. If you do not wish to be informed, you may not participate in this study.

If you wish to be kept updated about the results of the experiment, just ask the investigators, and they will email you the final conclusions of the study.

11. Confidentiality of personal data

Coding and confidentiality

As part of this study, personal data (e.g. name, address, date of birth) will be collected and will be coded. “Coding” means that all data that could identify you are replaced by a randomly generated code. The decoding code will always remain encrypted within the institution. Only a few people will have access to your uncoded data and only to perform tasks necessary for the project. All persons who are in possession of the data in the study are bound by confidentiality. People who do not know the code will not be able to draw any conclusions about your identity. For publication, we will render publicly available your individual coded EEG data, actigraphy data, and non-sensitive questionnaire data (e.g. handedness, gender). The data cannot therefore be traced back to you. Your name will never appear on the Internet or in a publication. Data protection regulations are respected and you as a participant have access to your data at any time.

Data publication

It is possible that your data will be used later for other studies. For this "re-use" and online publication, we invite you to sign a separate consent, which you will find at the end of this document. If you do not agree to have your data re-used and published, then you may not participate in this study. We believe it is important for research publications to be fully transparent, and therefore data to be freely available for other research groups to analyse.

Inspections

It is possible that the study could be subject to inspection. This verification could be done by the ethics committee or the institution that organizes the study. The project management will eventually have to make your personal and medical data available for the purposes of these checks. Your name will not be published in any report or publication, nor in printed form, nor on the Internet.

12. Payments for study participants

For participation in the complete study, you will be paid 400 CHF.
You may be paid 10 CHF for only completing the Lifestyle Questionnaire. If the Adaptation Night reveals a sleep condition that disqualifies you from participating, or you realize you do not wish to participate anymore, you will be paid 50 CHF.

If an external event, experimenter error, or you wish to abort the experiment after the first experiment night recording, you will be paid 100 CHF.

If the 24h wake period is too much for you, and you choose to go to sleep earlier, you will be paid in total 200 CHF. Expenses such as transport costs generated by participation in the study will be paid.

13. Responsibility

If, as a result of the study, you suffer injury, the University Children's Hospital of Zurich will be responsible. The conditions and the procedure are governed by the law. If you have suffered any injuries, please contact the project management.

14. Study funding

Funding (salary costs and experimental costs) are provided by the HMZ flagship grant "SleepLoop" and operating funds of Prof. Huber.

15. Contacts

In case of doubts, fears or emergencies that may arise during or after the study, you can contact Sophia Snipes at any time, or if more appropriate, the principal investigator, Prof. Reto Huber.

Sophia Snipes
Email (preferred): sophia.snipes@kispi.uzh.ch
Email (urgent): snipes.sophia@gmail.com
Phone (really urgent): +41 79 155 62 64

Prof. Reto Huber
Steinwiesstrasse, 75
CH-8032, Zurich
Email: reto.huber@kispi.uzh.ch
Phone: +41 (0)44 266 81 60

16. List of substances

When referring to "Drugs", "medication", and "caffeinated drinks", use the following lists as guides. They are not exhaustive, so apply your own judgement for items not listed, or ask the experimenter.

Drugs

- Marijuana/hashish
- Heroin/opium
- Cocaine
- Meth/amphetamines
- MDMA, GHB, "ecstasy"
- LSD, mescaline, psilocybin ("magic mushrooms")
- Steroids

Medication

(We use medication as exclusion criteria both because of the effects of the drug and the underlying disease being treated.)

- Anything prescribed by a doctor
- Over the counter drugs used as a stimulant or sleep-enhancer such as:
  - Valerian
  - Melatonin
  - Nyquil®
  - Benadryl®
  - Antihistamines
  - Methylphenidate

Medication exceptions:

- Prescribed creams for limited external use (but if you are treating a skin problem, you may react adversely to the overnight EEG)
- Contraception

Caffeinated drinks

High caffeine content (max 2 servings per day during the controlled week before the main experiment)

- Coffee
- Red Bull
- Monster

Low caffeine content (max 4 servings per day)

- Green or black tea
- Iced tea
- Coca Cola / Pepsi
- Mountain Dew
- Guarana
- Decaffeinated coffee
- Hot chocolate (and cold chocolate drinks)

Other caffeinated foods

Please avoid consuming too much of these, and treat them with the same rules as "low caffeine drinks"

- Tiramisu
- Caffeine gum
- Chocolate, especially dark
- Coffee/chocolate ice cream
- Some cereal energy bars

Glossary

Actimetry watch: this is a device you wear like a watch that measures your wrist acceleration, comparable to commercial products like the Apple Watch or Fitbit.
Principal investigator: prof Reto Huber
Research coordinator/ coordinating investigator: Sophia Snipes
Informing investigator: Sophia Snipes or an assistant researcher.

EEG: electroencephalography, a passive recording technique for measuring electrical signals produced by your brain.
HMZ: Hochschulmedizin Zürich

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Declaration of written consent for participation in a study

Carefully read this form. Do not hesitate to ask questions if something is not clear to you or if you want an explanation.

BASEC study number: (after the application to the ethics committee)	
Study title:	Identification of local sleep markers in wake EEG
Responsible institution: (Project management with full address)	University Children's Hospital of Zurich
Study location:	University Children's Hospital of Zurich
Study coordinator at the study location: (last name and name in block letters)	Huber, Reto
Participant: (last name and name in block letters) Date of birth:	☐ female ☐ male

- I have been informed orally and in writing by the investigator about the purpose, the conduct of the study, the disadvantages and the advantages as well as any risks.
- I participate voluntarily in the study and accept the contents of the written information document provided in relation to the above-mentioned study. I had enough time to make my decision.
- I received full answers to my questions regarding participation in this study. I can keep the written information document about the study and receive a copy of my written consent statement.
- I agree that the project management and the ethics committee responsible for this project may inspect my unencrypted data for audit and control purposes, but in strict compliance with confidentiality.
- I will be personally informed in case of new developments or incidental findings, which could have direct repercussions on the state of my health or willingness to participate.
- I can withdraw my consent at any time and without giving any reasons. I agree that my data and the data collected up to that point will still be evaluated.
- The civil liability of the hospital will respond to any damages.
- I am aware of the need to respect the obligations mentioned in the information document during the study.

s

Location and date	Signature of the study participant

Investigator statement: I declare that I have explained to the participant in question the nature, importance and scope of the study. I guarantee to fulfil the obligations inherent to this study according to the current law. If at any time during the study I become aware of aspects that could influence the patient's willingness to participate in the study, I will inform him / her immediately.

Location and date	First name and surname in capital letters of the informing experimenter Signature of the informing experimenter

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Declaration of consent for the re-use of data in coded form

Participant: (last name and first name in block letters)	
Date of birth:	☐ female ☐ male

I authorize my data from this project to be reused for research. This means that the coded data is kept in an online, publicly and freely available database for an indefinite period for further research projects that are not yet defined. This consent has an indefinite validity.

I understand that the data are coded and that the decoding code is kept in a safe place. All data protection guidelines are followed.

If the results deriving from data are marketed, I have no claim to participate in commercial use.

Location and date	Participant's signature

Declaration of the informing investigator: I declare that I have explained to the participant in question the nature, meaning and scope of the reuse of their data.

Location and date	First name and surname in capital letters of the informing experimenter Signature of the informing experimenter

Optional: Declaration of consent for being contacted for ongoing and future studies

Participant: (last name and first name in block letters)	
Date of birth:	☐ female ☐ male

I authorize the investigators of this study to inform me and contact me for participation in ongoing and/or future studies.

Location and date	Participant's signature

Declaration of the informing investigator: I declare that I will only contact the participant for additional participation in experimental research, and will not use their contact information to be used for any other purpose. This information will remain only in the hands of research management and the current project coordinator, and will not be shared with third parties.

Location and date	First name and surname in capital letters of the informing experimenter Signature of the informing experimenter