

# Human Development EEG and Psychophysiology (HEP) Laboratory IRB Templates

**This document contains two helpful templates which we encourage you to use for your Institutional Review Board (IRB) Initial Request for Approval. They have been explicitly reviewed by the IRB, and deemed appropriate for all relevant proposals.**

## Contents

- I. HEP Lab Informed Consent form template.....pp. 2 – 4**
- II. HEP Lab IRB Initial Request for Approval template.....p. 5**

**I.** The first is a HEP Lab template of the IRB Informed Consent form, which you are required to submit with your IRB request form (a generic template can be found by clicking here: <http://www.irb.cornell.edu/forms/>). The HEP Lab template includes language for each measurement modality, so please remove the sub-sections (indicated with brackets, e.g. *[Eye-tracking module]*) that do not apply to your research request. Please fill in where there are blanks; however, it is in your best interest to leave the pertinent language in this template as it is, because the IRB administration has explicitly deemed it appropriate for psychophysiology research. Changing this standard language may cause a delay in the processing of your application.

**II.** The second form is a HEP Lab template of Part 4 of the IRB Initial Request for Approval form itself, pertaining to the Risks and Benefits of the proposed research. You can paste the response (highlighted in yellow) to each question directly into the appropriate field in the IRB Initial Request for Approval submission form (which can be found by clicking here: <http://www.irb.cornell.edu/forms/>). For Question 1 under Part 4, there are two check-boxes to check, as well. Similarly as with the afore-mentioned template, leave this language as it is, unless you have an explicit need to modify it (which, again, may delay the processing of your application to the IRB).

## HEP Lab Consent Form Template

I am asking you to participate in a research study. This form is designed to give you information about this study. I will describe this study to you and answer any of your questions.

**Project Title:** *Provide the title of the study*

**Principal Investigator:** *Name*  
*Department*  
*Contact Information*

**Faculty Advisor** *(if PI is a student): Name*  
*Department*  
*Contact Information*

**What the study is about** You are being asked to participate in a research study conducted by \_\_\_\_\_ of Cornell University.

*[EEG module]* The purpose of this research is to use a special technique called electroencephalography (EEG) to measure electrical signals produced by your brain. Your participation will help us gain knowledge about...

*[Eye-tracking module]* The purpose of this research is to use a special technique called eye-tracking to measure your eye movements. Your participation will help us gain knowledge about...

*[Electrodermal activity (EDA) module]* The purpose of this research is to use a special device to measure the electrical activity of your skin. Your participation will help us gain knowledge about...

**What we will ask you to do** I will ask you to come to the Human Development EEG and Psychophysiology Laboratory in Room 256 of the Human Ecology Building.

*[EEG module]* There you will be fitted with a cap of electrodes that will measure the small electrical signals produced by your brain, in a completely non-invasive manner. You will be asked to *[describe experiment task]*. Your participation is expected to take a total of \_\_\_\_ hour(s), and involve \_\_\_\_ visit(s).

*[Eye-tracking module]* There you will be asked to *[describe experiment task]*. You will be asked to place your head in a padded head-rest, while your eye-movements are recorded. Your participation is expected to take a total of \_\_\_\_ hour(s), and involve \_\_\_\_ visit(s).

*[Electrodermal activity (EDA) module]* There you will be fitted with a comfortable, non-invasive, sensor fitted to your wrist like a watch, or in your palm. You will be asked to *[describe experiment task]*, during which time the sensor will measure the electrical activity of your skin. Your participation is expected to take a total of \_\_\_\_ hour(s), and involve \_\_\_\_ visit(s).

***Optional Enrollment Criteria:***

*[For Example: Because of the effects of medication and mental illness on the brain, you will be asked a series of questions about whether you are presently taking or have ever taken medication for depression, anxiety, and other forms of mental condition (e.g., schizophrenia). You will be asked about your history of neurological and*

*psychiatric illness. If you have previously taken such medications or are currently taking any you should not participate in this study. If you feel uncomfortable in discussing such information, you should not participate. You do not need to tell us why you have chosen not to participate.]*

**Risks and discomforts** The rare and minor physical risks associated with participating in this research are: a) possible skin irritation from the electrolyte paste or the adhesive discs we use to place the electrodes on your skin; b) discomfort associated from sitting still in one position for \_\_\_ minutes; c) discomfort due to having electrolyte gel in your hair; d) the possibility for you to receive unperceivable electrical signals from the equipment. The likelihood of you experiencing electric discharge from the EEG equipment, or damaging infrared radiation from the eye-tracking equipment, is extremely small, as is the potential amount of electricity/radiation that you could receive. Finally, despite careful precautions, there is a risk that your personally identifying information, including measurements we make and the log of our participation in this study, could become available to an unauthorized third party.

**Benefits** There are no direct benefits associated with participating in research that involve measurements of EEG, eye movements, or skin electrical activity.

Information from this study may help us learn more about \_\_\_\_\_ .

**Compensation** *[Indicate whether the participant will receive compensation or payment for being in the study. If participants will not receive any compensation, state that there is no payment for taking part in the study.]*

**Audio/Video Recording** *[Eye-tracking]* A video will be recorded of your eye-movements, in order to determine where your eye movements fall on the screen, and will not be associated with your personal information. The records of your eye-movements will be kept for \_\_\_ year(s), after which point, considering research-related factors, it may be destroyed.

**Confidentiality** Your participation in this study will remain confidential, and your identifying information will not be stored with your data or images. Servers and computers where the data and images are stored are password protected. Any paper surveys will be kept in locked rooms. Your images and data will be assigned a code number, which will be used in place of your name to allow linkage of data if follow up is necessary. The list connecting your name with this number will be kept in a locked room. We will review our data storage requirements periodically to determine if data need to be discarded. Only people authorized by the Principal Investigator will be granted access to the data. We may also need to collect some identifying information for administrative purposes (i.e., for study compensation, Cornell parking services, and/or an unexpected finding report), but this will not be linked to the research records. In the unlikely event of an emergency, we will also need to provide your information to medical and/or emergency assistance personnel. The data will be used for research and educational purposes, such as teaching, publications, and/or presentations and may be viewed by students, other trainees, and professional colleagues. In any sort of report we make public, we will not include any information that will make it reasonably possible to identify you.

*[If the activities involve an online survey, include the following:]*

Please note that the survey(s) *[is/are]* being conducted with the help of [company name], a company not affiliated with Cornell and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet. Please

also note that email and Internet communication may not be private or secure. Though we take precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

**Taking part is voluntary:** Taking part in this study is completely voluntary. If you have no objection to a question, then please answer every question. It is better to answer than to leave it blank (even if you are unsure). If you decide not to take part or not to complete the study, it will not affect your current or future relationship with Cornell University. If you decide to take part, you are free to withdraw at any time.

**If you are injured by this research.** Emergency medical care is not available on-site. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Cornell University. If you think that you have suffered a research-related injury, contact *[principal investigator's name]* right away at *[insert phone number]*.

**Withdrawal by investigator, physician, or sponsor:** The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**If you have questions** The main researcher conducting this study is *[principal investigator's name]*, a *[professor, graduate/undergraduate student, etc.]* at Cornell University. Please ask any questions you have now. If you have questions later, you may contact the research assistant *[research assistant's name]* at *[email address]* or at *[phone number]*, and the principal investigator *[principal investigator's name]* at *[email address]* or at *[phone number]*. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-5138 or access their website at <http://www.irb.cornell.edu>. You may also report your concerns or complaints anonymously through Ethicspoint online at [www.hotline.cornell.edu](http://www.hotline.cornell.edu) or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

**Statement of Consent** I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature \_\_\_\_\_ Date \_\_\_\_\_

Your Name (printed) \_\_\_\_\_

Researcher Signature \_\_\_\_\_ Date \_\_\_\_\_

Researcher Name (Printed): \_\_\_\_\_

*This consent form will be kept by the researcher for at least \_\_\_\_\_ year(s) beyond the end of the study and was approved by the IRB on \_\_\_\_\_ (IRB # \_\_\_\_\_).*

Template for HEP Lab:  
IRB Initial Request for Approval [relevant excerpt]

**Part 4: Risks and Benefits**

1. From the list below, please select ALL of the potential risks that are involved in your study.
  - ✓ Risk of injury or bodily harm
  - ✓ Other risks (please specify)
    - i. “Risk of mild skin irritation; risk of breached confidentiality; risk of discomfort; risk of eye damage from infra-red eye-tracking sensor; risk of exposure to imperceptible electric discharge from EEG equipment.”
  
2. Describe the nature and degree of the risks or harms selected above. All of the risks harms must be disclosed in the consent form.
  - ✓ “Participants involved in an EEG, EMG or EDA study may experience skin irritation from the use of electrodes, a mild electrolyte gel, and/or adhesive discs. Participants may also experience discomfort as a result of sitting still and minimizing self-adjustments, during experiments lasting up to 1 hour. They may also experience discomfort from having the aforementioned electrolyte gel in their hair; however, it is water-soluble and easily rinsed out of one’s hair. The potential for eye-damage due to the use of an infra-red eye-tracking sensor is extremely unlikely, due to the limited power and wavelength of the sensor, its distance from the participant, the short duration of the experiment, and the natural protective abilities of the eye. The potential to experience perceptible electric discharge from the EEG equipment is extremely small, as there is only one electrode (out of 136) that carries a return current to the participant, and that electrical current is inherently limited to 50 microAmps (lower thresholds of perceptible electric discharge are 1 milliAmp). Finally, despite careful precautions, the on-site storage of personally identifying information, including names, and recorded psychophysiological data, pose a small risk that participant confidentiality could be breached.”
  
3. Explain what steps will be taken to minimize risks or harms and to protect subjects’ welfare. If the study will include protected populations, please identify each group and provide an explanatory paragraph for each group.
  - ✓ “Participants will be notified verbally, and in the informed consent document, that there are small risks of skin irritation, discomfort, and breaches of confidentiality. Participants will be asked to self-determine their susceptibility to skin irritation and discomfort arising from sitting still for up to 1 hour. The use of an eye-tracking camera with an infrared sensor poses minimal risk to participants due to the limited power and wavelength of the sensor, its distance from the participant, the short duration of the experiment, and the natural protective abilities of the eye. The potential to experience perceptible electric discharge from the EEG equipment is extremely small, as there is only one electrode (out of 136) that carries a return current to the participant, and that electrical current is inherently limited to 50 microAmps (lower thresholds of perceptible electric discharge are 1 milliAmp). Regarding confidentiality, personally identifying data will be stored in locked cabinets inside approved-card-access-only rooms, and digital copies of data will be stripped of personally identifying information, to prevent any data from being associated with names or other personal identifiers.”