**SCRIPTS: Ethics Policy**

This policy refers to projects with activities involving work with human subjects that are not part of the staff of the participants (beneficiaries, affiliated entities, associated partners, subcontractors, etc). It covers research or study participants, persons concerned by the project activities, etc., regardless of its nature or topic.

The main ethics issues concern:

- the respect for persons and for human dignity

- fair distribution of benefits and burden

- the rights and interests of the participants

- the need to ensure participants' free informed consent (with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent, etc.)

- warn human subjects about any potential intervention, risks or harm that can be brought by the study and about the efforts to minimize such risks

The methodologies used should not result in discriminatory practices or unfair treatment. When a project involves studies using particular methodological tools (e.g. surveys, questionnaires, interviews, standardized tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions), the ethical implications of the chosen methodologies must be clarified.

Any project that presumes interacting with human subjects must verify with the principal investigators home institutions the necessity of ethics review and ethics committee approval. If at least one home institution with which principal investigators on the project are affiliated with requires an ethics review, researchers must seek ethics approval of their study, otherwise the project is exempted from the ethics review (See Fig.1).

In case of several co-principal investigators from multiple institutions, it is sufficient to have an ethical approval from one institution, unless otherwise specified in the ethical guidelines of principal investigators’ institutions.

SCRIPTS internal ethics committee report is ***only*** necessary if the researchers affiliated institutions mandate scholars to receive ethics approval of the study, but cannot provide such a review internally due to the lack of a designated committee that is eligible to review the extent to which project complies with the highest ethical standards (See Fig.1).

If principal investigators’ home institutions require an ethics review[[1]](#footnote-1), but such review cannot be obtained internally at any of the corresponding home institutions, scholars shall fill in the Ethics Report for the internal review inside the SCRIPTS (see Fig.1 and the Ethics Report Template in the Appendix).

**Figure 1. Schematic Description of the Ethics Review Process**



**SCRIPTS: Ethics Policy. Appendix**

**Ethics Report Template**

**Introduction**

***Important***: SCRIPTS internal ethics committee report is ***only*** necessary if the researchers affiliated institutions mandate scholars to receive ethics approval of the study, but cannot provide such a review internally due to the lack of a designated committee that is eligible to review the extent to which project complies with the highest ethical standards (See Fig.1 below).

This template aims to assist applicants and beneficiaries of the SCRIPTS excellence cluster to apply for the ethics committee approval that their research is conducted according to the existing ethics protocols and to the highest ethical standards. The template is meant to be an illustrative example of an ethics report at the project implementation phase and should be used alongside SCRIPTS Data Management Policy and adjusted to a specific project.

The template is based on and heavily draws on existing guidelines for data management, in particular on the Horizon Europe Programme Guide[[2]](#footnote-2) and the University of Rochester Research Subjects Review Board Protocols and Templates[[3]](#footnote-3). While preparing an ethics report please also refer to any existing discipline standards and subject-specific recommendations

***Note: You may delete sections that are not applicable to your research.***

**Study Title**

**Principal Investigator – Name**

**1.** **PURPOSE OF STUDY**

Describe the purpose, specific aims, or objectives (not more than one paragraph). State the hypothesis to be tested or the research questions that will guide the study.

* If the study has more than one phase, clearly map out the different phases.
* Indicate if this a pilot or feasibility study.

**2.** **BACKGROUND AND RATIONALE**

Briefly (1 paragraph) describe the following:

* The relevant current context of the study and gaps in current knowledge.
* Describe the significance of the research including potential benefit for individual subjects or society at large
* Include applicable references at the end of the protocol.

**3.** **ADMINISTRATIVE ORGANIZATION**

Describe the participating center/department/units as well as other participating *research locations*, participating *sites*(for multi-site research), data management center, and coordinating center, as applicable.

* A ***research location is*** defined as a location where the SCRIPTS faculty will collaborate with and conduct research at locations outside of their affiliated institution, such as: local schools, community centers, public venues, etc.
* A ***participating site*** is defined as an institution/organization/university which is not part of the PI’s affiliative institution and is engaged in the research.

*For the studies conducted outside the EU*

* Details on the countries and the institutions outside the EU involved
* Confirmation that a similar activity could have be proceeded in the EU
* If the study plans to use some local resources, provide descriptions of such resources (and their compliance with the EU)
* If some materials planned to be imported from the non-EU to the EU countries describe what countries were involved and the nature of such materials with the confirmation that such transfer is legally permitted.
* Provide descriptions of how the risk for all parties participating in the study is minimized.

For more information on non-EU studies refer to the EU Horizon Ethics self-assessment protocol Part 6 (<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf> )

**4.** **STUDY DESIGN**

Provide a description of the following:

* The design of the study, including indication whether subjects will be randomly assigned to study interventions or activities, as applicable.
* Study (anticipated) outcomes

**5.** **SUBJECT POPULATION**

Describe the study population (see Inclusion of Vulnerable Populations below), including total number of subjects to be enrolled and/or data records/samples to be accessed.

* If more than one site is involved, describe the total number of subjects at each site.
* Total to be enrolled should include the number of evaluable subjects (i.e., those who meet eligibility criteria), as well as the number of anticipated screen failures necessary to obtain the enrollment goal. A subject is considered in the total count once informed consent has been obtained (as applicable). If evaluable subjects who withdraw from the study will be replaced to meet the enrollment goal, this should also be stated here.
* Are the human participants volunteers?
* Are the human participants a vulnerable population? Provide details on the vulnerability and details on the recruitment procedure.

*Inclusion of Vulnerable Populations:*

* **Students/Employees:** If the research involves individuals who are vulnerable or susceptible to coercion or undue influence, describe additional safeguards included to protect rights and welfare of these individuals.
* **Children/Minors:** If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), describe in detail the age range, consent procedures including parental/legal guardian consent, procedures to secure the welfare of children, and justification of including children/minor subjects. Attach the informed consent form to this ethics report.
* **Decisionally Impaired Adults:** If the research involves adults with decisional impairments, describe in detail the age range, consent procedures including parental/legal guardian consent, procedures to ensure that participants are not subjects to any form of coercion or undue inducement, briefly describe justification of including decisionally impaired adults in the study. Attach the informed consent form to this ethics report.

For more information on background documents and protocols please refer to the EU Horizon documentation:

* Research Ethics in Ethnography/Anthropology (<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/research-ethics-in-ethnography-anthropology_he_en.pdf>)
* Ethics in Social Science and Humanities (<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-in-social-science-and-humanities_he_en.pdf>)
* Guidance note — Research on refugees, asylum seekers and migrants (<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidance-note-research-on-refugees-asylum-seekers-migrants_he_en.pdf>)

**6.** **INCLUSION AND EXCLUSION CRITERIA**

List the criteria (such as age range, gender, race, diagnoses, lab values, language, etc.) that define who will be eligible to participate. Ensure criteria addresses if the subject must be able to consent for themselves, and whether non-German and non-English speaking individuals will be included.

**7.** **RECRUITMENT METHODS**

Describe how potential subjects will be identified, as well as when/where/how potential subjects will be recruited (include the types of strategies and materials that will be used for recruitment.

For Mturk (or a similar online survey platform) users include the following information:

* Be clear about compensation and bonuses. How long it will take for researchers to approve a HIT (i.e., how long it takes for Mturk users to receive payment).
* Clearly and accurately state the time required to complete the task.
* Consider participantion confidentiality.
* If the subject will complete a screener in order to qualify for study, include if they will be paid for the time it takes to complete the screener or not. Include if the screener data will be kept/linked to study data or destroyed.
* If any outside software is required to complete the task, this should be stated in the description (e.g. this task requires Qualtrics or other programmed platforms).
* Describe a process of reviewing responses (i.e., whether responses will be accepted or rejected and whether unapproved responses will be included in the study dataset).

**8.** **CONSENT PROCESS**

Describe the consent process, including the following, as applicable:

* Where and when will consent be obtained?
* Who will obtain consent?
* How will investigators ensure the potential subject comprehends the information presented?
* How will coercion or undue influence be minimized?
* Will the potential subject be provided sufficient time to consider their participation?
* Will the subject be provided a signed copy of the consent form?
* If a witness signature line is included on the consent form, describe whether a witness to the consent process is mandatory or optional (and if optional, under what circumstances should they be used). Identify who may act as a witness.
* If a parental/legal guardian/proxy consent is needed, include such line in a consent form and identify who may act as such an actor.
* How will investigators ensure ongoing consent, if appropriate? This may include re-consent for longitudinal studies or if there are multiple stages to a study over time.

*Consent Process for Minors/Children (under 18 years of age):*

* Describe how parental permission will be obtained
* If applicable, describe the process for obtaining assent of the subjects

*Consent Process for Adults with Decisional Impairment:*

* Describe the process to determine whether an individual is capable of consent.
  + If the individual is not capable of giving consent to participate, indicate who will be authorized to give consent (e.g., power of attorney for health care, court appointed guardian for health care decisions, spouse, adult child.)
  + If subjects may lose decision-making ability during the study, describe the process for the subject to identify the Research Proxy, when this will be done, how the Research Proxy will be notified, and how the Research Proxy will be involved in the study. Also describe how decision-making ability will be monitored over the course of the study.

*Consent Process for Foreign Language Speaking Subjects*:

* If there are foreign language speaking subjects who will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in the language understandable to those potential subjects. Indicate the language that will be used by those obtaining consent. If a translator will be used during recruitment, consent, data collection, or data analysis, specify how an appropriate translator will be identified and what the provisions will be for protecting the confidentiality of subjects.

*Consent Process through On-line Platforms (e.g., surveys):*

* The first page of the on-line platform should contain the consent form that the respondents have to agree on.

*Consent Process for Deception Research:*

* Explain the process for providing consent to procedures that will be used to explain the study and the consent to data use debriefing form that will be used by researchers.

*Certificate of Confidentiality:*

* If the study involves the use of a Certificate of Confidentiality, describe here.

**9.** **STUDY PROCEDURES**

Provide a description of all research procedures and activities. When developing study procedures, consider minimizing or eliminating the collection of identifying information where possible and, when applicable, provide justification as to why identifiers need to be retained.

* Screening procedures
  + Which screening tests/procedures are used?
  + What happens with screen failures (including any data gathered during screening)?
* Source of records, measures, stimuli, or experiments that will be used for data collection
* Describe randomization procedures, if applicable.
* Duration of individual’s participation in the study and overall anticipated duration of the study.
* Briefly describe what data will be collected at each participation event; include approximate duration of time to complete each task.
* Describe plans for return of research results, if applicable
  + Indicate research results that will be provided back to the subject if applicable
  + When they will be provided (e.g., not until the study is completed, at the time the Investigator receives the result, etc.)

*Studies involving deception:*

Deception occurs when subjects are not given information about the real purpose or the nature of the research.

* Describe what information will be withheld from subjects and provide justification for the deception.
* Explain the process to debrief subjects (i.e., when subjects will be debriefed, who will debrief them, and how they will be debriefed)

*Note: For online studies, the debriefing process should occur as soon as a participant has completed the research activity. As an added measure, it may be necessary to send an email out to all participants after the study is completed to ensure that all participants (those that completed and those that may have stopped mid-way) receive a debriefing form.*

* Indicate whether use of deception is likely to cause the subject psychological discomfort (e.g., stress, loss of self-esteem due to manipulations, embarrassment at being deceived or guilty at having been induced to commit regretted acts) while the deception takes place. Explain how this risk will be minimized during the experiment and after the experiment is completed (i.e., full debriefing).

*Use of AI technologies in the study (if applicable):*

* If the study presumes developing AI technologies, describe in what capacity they will be used and in what way participants will interact with them, provide a justification of using such technologies in the study
* Describe in what way such AI algorithms can create the discriminatory conditions, and what is done to minimize such a possibility; what measures are set to avoid biases, discrimination, stigmatization.
* Can such AI algorithms impact human’s behavior, and if yes, in what way; describe how humans still have a meaningful control over the important decision-making process
* Describe the procedures to minimize risk and harm from such technologies for all the participants involved in the study and for society in general and environment; explain any potential ethical concerns and how they were addressed.

For further guidance refer to the EU Horizon Ethics self-assessment protocol Part 8 (<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf>).

**10.** **AUDIO/VIDEO RECORDINGS**

Describe the type of recording or device being utilized and the purpose of the recordings as applied to the research (e.g., data analysis, verification, teaching tool for educational purpose). Describe how and where the recordings are stored, who has access to them, and if/when they will be destroyed. If recordings are done with a personal device (e.g., cell phone or iPad), indicate how long it will take before the recordings are transferred to a secure server and how the original recordings will be managed (i.e., destroyed, stored, shared).

**11.** **RISKS TO SUBJECTS**

* Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the subjects’ participation in the research.
* For each risk identified, describe the probability, magnitude, duration, and methods of mitigating the risk.
* Potential risks and discomforts must be minimized to the greatest extent possible by using procedures such as appropriate training of personnel, withdrawal of the subject upon evidence of difficulty or adverse event; and referral for treatment, counseling or another necessary follow-up.
* Consider physical, psychological, social, legal, and economic risks as well as community or group harms (e.g., breach of confidentiality is a common risk in social and behavioral research). If applicable, describe risks to others who are not participants (e.g., group harms, harms to society).
* Provide a description of alternative courses of action which are available in case the subject elect not to participate in the study. If there are no alternatives available to the subject, this should be stated.

**12.** **POTENTIAL BENEFITS TO SUBJECTS**

Describe the potential benefits that individual subjects *might* experience from taking part in the research. If there are no anticipated benefits, this should be stated. **Do not include** subject payments or benefits to society or others.

**13.** **COSTS FOR PARTICIPATION**

Describe and justify **any costs** that participants may be responsible for because of participation in the research.

**14.** **PAYMENT FOR PARTICIPATION**

* Describe the payment method (gift card, lottery, cash, check) and include how much money or what gifts will be provided and for what activities, as well as when (timing) compensation will be provided (including the repeated studies and any reimbursement).

**15.** **SUBJECT WITHDRAWALS**

* Describe anticipated circumstances under which participants will be withdrawn by the principal investigator(-s) from the research without their consent (e.g., non-compliance, termination of funding).
* Describe procedures that will be followed if subjects withdraw from the research, if applicable
* Describe the use of data after withdrawal
* Indicate whether subjects withdrawn from the study will be replaced.

**16.** **PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA**

* Describe the steps that will be taken to protect subjects’ privacy. “Privacy” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information.
* Indicate how the research team has access to the sources of information about subjects.
* If subjects will be re-contacted for any reason, describe this process and explain why subjects might need to be re-contacted. If subjects will be re-contacted, this must be disclosed in the consent form.
* Briefly describe the steps that will be taken to maintain the confidentiality of the data and information collected during the study
* Describe any data/sample sharing and storage (which data and samples and who will have access to them), if applicable

1. The SCRIPTS scholars are recommended to seek an approval from the ethics committees of their affiliated institutions. For Freie Universität Berlin refer to the Central Ethics Committee (<https://www.fu-berlin.de/en/forschung/service/ethik/index.html>) and the corresponding form (: <https://www.fu-berlin.de/en/forschung/service/ethik/_media/zEA_Antragsformular_v3_EN.pdf>). For Humboldt Universität zu Berlin refer to the Faculty of Humanities and Social Sciences Ethics Commission (<https://fakultaeten.hu-berlin.de/de/ksb/die-fakultaet/rat_kommissionen/ethikkommission>) and the corresponding form (<https://fakultaeten.hu-berlin.de/de/ksb/die-fakultaet/rat_kommissionen/ethikkommission/hu-ksbf-ek_antragsformular_2018_03_28.pdf>). For WZB Berlin Social Science center refer to the ethics committee (<https://www.wzb.eu/en/node/47682/subpage/44282>). ZOIS Centre for East European and International studies refer to the open access policy (: <https://en.zois-berlin.de/research/principles-of-research-ethics>). [↑](#footnote-ref-1)
2. Horizon Europe (2021), “[Programme Guide](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf)”. [↑](#footnote-ref-2)
3. University of Rochester Research Subject Review Board <https://www.rochester.edu/ohsp/rsrb/> and the corresponding Protocol Templates <https://www.rochester.edu/ohsp/rsrb/docTemplates/protocolTemplates.html> [↑](#footnote-ref-3)