**Checklist Light track for master thesis**

The light track procedure is an ethical assessment intended for low-risk research of master theses students. The procedure is a lighter version of the ethical assessment and contains a checklist covering all relevant ethical and GDPR criteria. The main principles here are the Code of ethics for research in the social and behavioural sciences involving human participants, the Code of Conduct for Research Integrity and the GDPR. This checklist also calls on the researcher's own scientific integrity. There are various binding advice and guidelines imbedded in the checklist.

**How to apply a light track assessment?**

Students can complete the checklist together with their supervisors, starting with a check of the conditions for low and high-risk research. Research that is classified as higher-risk research, has to be applied as a fast or full track procedure in the cETO app. It is essential that the checklist must be answered fully and truthfully. A fully completed checklist can be signed by the student and their supervisor. Signed checklists can be sent to cETO by email as attachment together with the materials for data collection and the approved assessment form of master thesis.

**Ethical assessment**

When a light track checklist is submitted, a light track reviewer will assess the light track checklist. This will take about 5 working days.

* ***Approval***: Low-risk master thesis research that complies to all ethical and GDPR criteria as indicated in the checklist, can be considered as ethically approved. Approved light track checklists are signed by the light track reviewer and sent to the student and supervisor by email. When the research is ethically approved, the student can start the recruitment of participants.
* **Rejection**: It is also possible that the light track reviewer rejects the light track proposal. He or she provides a clear motivation to the student and their supervisor why the light track approval is not granted. Then the student has to apply a fast or full track application for ethical approval by the cETO.

***Please note that if a checklist is not filled in truthfully or some binding advice or guideline was not taken in account afterwards, the ethical approval will not be valid. It is the shared responsibility of the student and his/her supervisor to take good care of this.***

**How to apply an amendment?**

Students can apply for an amendment in case substantial changes are needed to an application previously approved as light track. The original approved checklist can be sent with track changes and/or comments to the cETO for approval by email.

***Do you need ethical approval or not?***

Not all research is admissible for ethical assessment as light, fast or full track. Please check the following conditions:

* Research that falls under the scope of the WMO is not admissible for ethical review by the cETO ([WMO - Open Universiteit - Open Universiteit](https://www.ou.nl/ceto-wmo) ). This type of research must be assessed by an accredited Medical Research Ethical Committee (MREC). If you are unsure whether your research is in the scope of WMO, you can ask the cETO for a WMO check before the start of the research. You can submit an online full track application, which includes a WMO check. If the cETO concludes that the research falls under the scope of the WMO, you still need to go to a MREC.
* Research that is already ethically assessed by another research ethics committee (in the Netherlands) and carried out under the responsibility of an institute other than the OU, requires no second ethical assessment. ***Please note*** that research given a no-WMO advice by a MREC is not yet ethically approved.
* Research that involves only fully anonymous secondary data and no new data collection is taken place, requires no ethical assessment. Make sure that you document some clear agreements about the sharing, storage, publishing and responsibilities concerning the data, to avoid conflict or discussion afterwards. The advice is to ask the data steward for consultation.
* Research that already started or finished the recruitment, can no longer be ethically assessed. If the recruitment has only just started, please contact cETO as soon as possible to discuss possible solutions.
* Research that is performed to evaluate and improve the quality of the education at the Open Universiteit.

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| In case your research is admissible for the ethical review by the Open University, you can continue to check the conditions for the light track procedure. |

**Part 1: Personal information:**

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| --- | --- |
| Name student: |  |
| Name supervisor: |  |
| Faculty: |  |
| Title of the research: |  |
| Research question(s): |  |

**Part 2: High/low risk conditions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Vulnerable participants*** | | | | | |
| **1** |  | | | | |
| Please describe the participants of your research. | | | | | |
| [open field] | | | | | |
| **2** |  | | | | |
| Traditionally, research including participants who belong to a *vulnerable group* was considered as high risk research. However, recent ethical views[[1]](#footnote-2) simply belonging to a vulnerable group, does not always imply that a person is indeed vulnerable in the context of the research that needs to be conducted. A woman early in her pregnancy is for example not vulnerable in the context of research that aims to examine attitudes towards prenatal vitamins, but can be considered vulnerable in the context of research studying the psychological effects of prenatal screening, as this can be a very stressful research context.  Participants are vulnerable and therefore at higher risk, when there is an intrinsic or situational condition present that puts them at greater risk of being used in ethically inappropriate ways of research (= contextual vulnerability)1. There are several categories of contextual vulnerability. Carefully consider each type of vulnerability in your research. Look at who your participants are, what your research context is, and how this possibly influences their vulnerability. Please estimate each type of vulnerability on a scale of 1 to 5 (1= not vulnerable; 2= little vulnerable; 3= vulnerable; 4=very vulnerable) | | | | | |
| * ***Cognitive or communicative vulnerability***:   People who have difficulty comprehending information and making decisions about participation. *Examples: children under the age of 16 years, adults with cognitive impairments, people with linguistic barriers*. | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| * ***Institutional vulnerability:***   Persons who are under formal authority of others, who might have different values, goals, and priorities than those of the potential participant. *Examples: prisoners, military, and any person whose relationship with a superior might make it difficult to say ‘no', such as managers and their employees matched in the research, students in the researcher's own course or classroom.* | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| * ***Deferential vulnerability:***   Persons who are under informal authority based on gender, race, class, inequalities or inequalities of power and knowledge. Feelings of fear of offending the authority and incurring retribution or a genuine sense to please the respected other. *Examples*: *patient-doctor relationship* | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| * **Medical vulnerability**:   People with serious health conditions for which no satisfactory standard treatment options are available. | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| * **Economic vulnerability**:   People who are disadvantages in distribution of social goods and services as income, housing or healthcare. *Examples: impoverished mother trying to feed her children receives 20 euro for a 30-minute survey, making it difficult for her to say no.* | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| * **Social vulnerability**:   People who belong to undervalued social groups, which includes stereotyping and can lead to discrimination. *Examples: ethnic minorities, transgenders*. | | | | | |
| * 1 | | * 2 | * 3 | * 4 |  |
| Looking at your indicated scores on each of the six types of vulnerability, do you consider the participants in your research to be vulnerable (any indication of scale 3 or 4 will be considered as vulnerable and requires a fast track procedure)?  In case of doubt, please contact the cETO for advice. | | | | | |
| * Yes. You cannot continue with the light track. * No | | | | | |
| ***Burden*** | | | | | |
| **3** |  | | | | |
| Will the research be conducted in Belgium **and** does it concern medical research or clinical psychology, psychotherapy or an invasive intervention? | | | | | |
| * Yes. You cannot continue with the light track. Apply for local ethical assessment in Belgium and do not forget to obtain a No-Fault insurance at the OU. * No | | | | | |
| **4** |  | | | | |
| Do you employ deception in your research? | | | | | |
| * Yes. You cannot continue with the light track. * No | | | | | |
| **5** |  | | | | |
| Do you collect sensitive/risky data (such as questions depression, sexual arousal, bullying or suicide), that can be invasive and/or provoke negative emotions? | | | | | |
| * Yes. You cannot continue with the light track. * No | | | | | |
| **6** |  | | | | |
| Do you collect sensitive information about third persons, who are not participating in the research? | | | | | |
| * Yes. You cannot continue with the light track. * No | | | | | |
| **7** |  | | | | |
| In case you collect personal data, will you anonymize or pseudonymize the personal data?  *Personal data means that data is traceable to a individual person. Data can be direct identifiers like name and email address, but can also be indirectly identifying. For example: zip code and date of birth are in itself not directly traceable, but can identify a person when they are combined.*  *Factors such as available (supplementary) information, user and access, and technology also determine whether identification is possible. In an environment where other datasets are available, the combination of different data can enhance traceability. Who has access to the data is important. A random person may not be able to do any deduction, while an organization with access to additional data can. New analytical techniques and data aggregation methods may change the reducibility of previously non-reducible data.*  *Examples:*   * *An anonymous survey on job satisfaction may not seem traceable, but if the answers contain unique details about the job or team, an employer can still identify the person.* * *An IP address on its own is not always directly traceable, but when combined with login details at a website, it can be.* * *In a small town, a combination of gender, age and occupation may be enough to trace someone, while the same combination in a big city may not be traceable.*   *Thus, whether data is traceable depends not only on the data itself, but also on the context in which it is used. You should always take into account the possibilities of deduction and take appropriate measures to protect privacy.* | | | | | |
| * Yes. * Not applicable * No. You cannot continue with the light track. | | | | | |
| **8** |  | | | | |
| Will new data to be collected linked to other already existing data? | | | | | |
| * Yes, You cannot continue with the light track * No | | | | | |
| When you answered one of the questions 2-6 and 8 with YES or question 7 with NO, your research is considered as a higher risk. You cannot continue with the light track. Please adjust the research accordingly to low risk research if you want to continue with the light track or submit your application online for a full or fast ethical review by the cETO.  When you answered all questions 2-6 and 8 with NO **and** question 7 with YES/NOT APPLICABLE, your research is considered as low-risk research. You can continue with the light track. | | | | | |

**Part 3 Participants:**

|  |  |
| --- | --- |
| **9** |  |
| How large is the sample size? | |
| [open field] | |
| **10** |  |
| Was the sample size supported by evidence-based research, power calculation or rules of thumbs? | |
| * Yes * No. Please estimate your sample size by evidence-based research, power calculation or rules of thumbs before you continue with the light track checklist | |

**Part 4 Recruitment:**

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| Please note that it is not allowed by the OU to recruit all student or employees of the OU. It is possible to recruit these target groups on a smaller scale, such as OU students of a specific course or OU employees of a faculty. | |
| **11** |  |
| Do you use social media platforms (e.g., Facebook, Instagram, Twitter, LinkedIn, Whatsapp) to recruit the participants?  *The OU has a policy on the use of social media: The OU advises strongly against the use of social media for the recruitment of study participants. Posting a call for recruiting participants on social media platforms can lead to an unnoticed collection of data. This can mean that personal data is being processed. It is even possible that special personal data is collected, for instance, when someone clicks on a link to participate in research about depression. Unfortunately, there are no agreements with the social media platforms about the processing of these data. In case a social media platform collects, sells or leaks (personal) data of participants, the researcher and the university could at least be held partly responsible and accountable for this. Therefore, the data protection officer advises against the recruitment of participants by use of social media. If you still decide to use social media for the recruitment, then you should at least inform the potential participants what can happen with their data. You can use the following passage:*  *[Door gebruik te maken van dit media platform heeft u eerder ingestemd met de verwerking van uw persoonsgegevens door dit platform. Bent u zich ervan bewust dat er informatie verzameld wordt over mensen, pagina's en groepen waarmee u verbonden bent, alsook welke inhoud u bekijkt of benadert, welke functies u gebruikt en welke acties u uitvoert]*  ***Important note****: placing an active link to a survey is not allowed. You can, however, mention an OU email address. In case participants sign in, they can receive a link to the survey by e-mail. Alternatives for e-mail address on social media:*   * *Use an inactive copy-paste link* * *Provide a link to the O4U platform (O4U is only available for the faculties Psychology and Educational Sciences)*   *If you use* ***Whatsapp****, please, use only your personal contacts for recruitment and no group chats.* | |
| * Yes (please comply to the OU policy on social media explained above) * No | |
| **12** |  |
| Do you use any other platform, panel, software, website or tool to recruit the participants? | |
| * Yes * No *(continue with question 14)* | |
| **13** |  |
| Only OU accredited software can be used in research. Is the recruitment platform, panel, software, website or tool approved by the OU? More information: [software list](https://mijn.ou.nl/group/mdw/-/onderzoek-verzameling-gegevens) | |
| * Yes * No or unsure. Please, contact the Data steward for advice ([datasteward@ou.nl](mailto:datasteward@ou.nl)). | |
| **14** |  |
| Do you approach an organization/institute/association to recruit the participants? | |
| * No *(continue with question 17)* * Yes, an organization with a hierarchical structure and/or dependent position for the participants. For example, students at university (also including OU students), or managers and their employees at a specific company. * Yes, a network/organization without a hierarchical structure or dependent position of the participants. For example, a patient organization, sport club or church community. (*continue with question 16*) | |
| **15** |  |
| Do you declare that you will collect written consent from a mandated person within the organization/institute/association before you start the recruitment procedure? | |
| I recruit a group of participants at one or more organizations/institutes/associations (for example teachers at university or students at a faculty)   * Yes, I will collect written consent of each organization/ institute/association individually. *In case you recruit students of employees of the OU, please follow OU (1) if you recruit students from a specific faculty, you need to obtain permission from the Dean of that faculty; (2) if you recruit students from one or more specific courses, you need to obtain permission from the coordinator of each course you intend to include; (3) if you recruit student in your own course or supervisor's course, please ask consent of all other course coordinators/examinators of the specific course*.   I recruit only a few individual participants at one or more organizations/institutes /associations (for example, two HR managers from all different companies)   * Yes, I will collect written consent via the participants, by adding an extra bullet to the consent form, for instance 'I declare that my management/board consents with my participation in the research'. | |
| **16** |  |
| How do you recruit participants in the organization/institute/association? | |
| * In person, on location. * A mandated person will approach participants and inform the researcher if someone is interested. * By using publicly available contact information of participants. * By email, and a mandated person of the organization disseminates the message. * By email, and you receive an e-mail list from the mandated person of the organization. * By their platform, and a mandated person of the organization posts the message. * By disseminating flyers or posters, on location. * None of the above, but   .......................................... [open field]  (Note: ensure that everything is within ethical guidelines and GDPR regulations) | |
| **17** |  |
| Do you use only OU contact information or your own professional contact information (of the organization where the research takes place) for recruitment and communication?  *Whatsapp is allowed, if Whatsapp is used for personal networking. Please, use only your personal contacts for recruitment and no group chats.* | |
| * Yes. You can only use your own professional contact information in case this is logical, such as teachers approaching students or care professionals approaching patients via their professional email address. * No. Please, note that only OU phone number and email address can be used for research communication (if necessary, the supervisor can request a ‘research’ email address at [servicedesk@ou.nl](mailto:servicedesk@ou.nl)). | |
| **18** |  |
| Do you collect contact information (not as research data) of the participants during the recruitment? | |
| * Yes. Collected contact information must be stored on a secure folder on Research drive and must be deleted when they are no longer needed. * No | |
| **19** |  |
| Do you use incentives to boost the recruitment?  *It is not obligatory to offer compensation for participation, but it could motivate potential participants to take part in the research. Please make sure that the value of the incentive is in proportion with the research burden, i.e. the incentive should be an extra motivation but should not be the main motivation to participate. And there is no conflict of interest.* *Examples:*   * *Do's: Children filling in a survey for 20 minutes, receive an apple. Reimbursement of (travel) expenses. Students receive course credits for participating in research.* * *Don'ts: 50-euro voucher for a survey of 30 minutes. Free samples of books for which you receive royalties*   *Given financial rewards could mean that you require personal data of participants. We advise to contact an OU accountant for more information about given financial rewards.* | |
| * Yes and in proportion to the burden/risk of participants. Ensure that participants are informed in the information letter. * Yes but I am not sure if this is in proportion to the burden/risk of participants. Please adjust or contact the cETO to discuss alternatives. * No | |
| **20** |  |
| Do you declare that there is no conflict of interest in relation to the incentives? | |
| * Yes * N/A * No. Please adjust or contact the cETO to discuss alternatives. | |

**Part 5: The information letter(s)**

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| **21** |  |
| Is the information comprehensible for the participants, taking factors into account like age, cultural differences, economic and linguistic barriers, and levels of education and literacy? | |
| * Yes * No. To continue with the light track, please adjust the information letter in such a manner that it is comprehensible for the participants. | |
| **22** |  |
| Did you offer sufficient time for participants to consider participation? | |
| * Yes * No. To continue with the light track, please adjust the consideration time. The duration dependents on the nature of the research. General rule: higher impact or burden requires more time. | |
| **23** |  |
| The following topics are **mandatory** in the information letter. Check every box once you have included them in the information letter (***note: the boxes including ‘if applicable’ are optional and not mandatory***): | |
| * + Title of the research   + Purpose of the research (also including, that it concerns a master thesis)   + What is expected of the participants   + Costs and benefits for the participants   + Contact information in case of negative emotions (if applicable)   + Voluntariness   + Right to withdraw from the research without giving a reason   + Summary of all personal or person-related data to be collected and an explanation why you need to collect them (*in accordance with answers on question 35*)   + Information about anonymization and pseudonymization   + Reference to the OU privacy disclaimer: <http://www.ou.nl/privacy>   + Where, how and for how long the data will be stored, and who has access to the data   + Availability of the data for open science (if applicable)   + Right to remove data from the dataset, unless the removal of the data is damaging for the achievement of the research purpose(s). Please, add at what point removal is no longer possible.   + Opportunity to ask questions at any time before, during and after the study   + Contact information (OU or professional contact information as explained earlier)   + Name and contact information of the supervisor   + How to provide consent | |
| **24** |  |
| * + I declare that I can provide the information letter(s) if someone, such as the cETO or a visitation committee, requests it. | |

**Part 6 Consent procedure:**

|  |  |
| --- | --- |
| **25** |  |
| Do you ask for active consent from the participants? | |
| * Yes * No. Please, contact the cETO | |
| **26** |  |
| How will active consent be collected from the participants? | |
| * Paper consent will be collected in person or in sealed drop-box. * Paper consent will be collected by post using answer envelopes. * Paper consent will be collected by a third person using sealed envelopes. * Online consent will be collected by imbedding the consent form in an online tool (continue with question 28). * Online consent will be collected by sending a scanned consent form through SURFfilesender. * None of the above, but   .......................................... [open field]  *(Note: ensure that everything is within ethical guidelines and GDPR regulations)* | |
| **27** |  |
| How will the signed consent form be stored during the study? | |
| * Paper consent will be stored in a closed closet or room during the study and later archived at Oasis. * Paper consent will be scanned and stored on a secure OU T-drive or OU Research drive, separately from the data (and the originals will be destroyed) * Online consent sent through SURFfilesender will be stored in a password-secured folder on OU T-drive or OU Research drive, separately from the data. * Other, please explain:   .......................................... [open field]  *(Note: ensure that everything is within ethical guidelines and GDPR regulations)* | |
| **28** |  |
| The following topics are **mandatory** in the consent form. Check every box once you have included them in the consent form (***note: the boxes including ‘if applicable’ are optional and not mandatory***). | |
| * Being informed about the study * Opportunity to ask questions * Time to consider participation * Voluntariness * Right to withdraw from the research without giving a reason * Agreement to the collection of the data. * Agreement to the collection of personal data (example: “Ik geef hierbij toestemming voor het verzamelen van mijn persoonsgegevens en/of video/audio-opnames) (if applicable) * Agreement to the collection of special personal data (example: “Ik geef hierbij toestemming voor het verzamelen van mijn etniciteit en geaardheid”) (if applicable) * Use of the collected data for research purposes. * Agreement that data will be collected or processed anonymously and as such is not traceable to the individual. * Availability of data for open science (if applicable) * Data storage of 10 years at the secured server of the OU | |
| **29** |  |
| * I declare that I can provide consent form(s) if someone, such as the cETO or a visitation committee requests it | |

**Part 7 Data collection**

|  |  |  |
| --- | --- | --- |
| Please indicate how data will be collected (*you can click more than one*):   * Questionnaire * Interview * Observations * Eye-tracking * Activity trackers * Document analyses * Other: …………..   Please, upload your questionnaire, observation list, interview protocol or other materials used for data collection. | | |
| **30** |  | |
| Will data be collected on paper/in written? | | |
| * + Yes, the researcher collects the data in person or picks up a sealed drop-box.   + Yes, the participants sent the data by post using answer envelopes.   + Yes, a third person collects the data from the participants in sealed envelopes and hands them over to the researcher.   + Not applicable | | |
| **31** |  | |
| Will data be collected online? | | |
| * + Yes, researchers fills in an online document or form, like observation or interview notes.   + Yes, participants receive a link by e-mail, online platform or scan a QR code.   + Yes, participants sent a scanned version of the questionnaire through SURFfilesender.   + Not applicable | | |
| **32** |  | |
| Will data be collected as audio/video-recordings (in compliance with OU policy on audio/video-recordings presented below)?  *The OU has a policy on audio/video recording: The use of your own video/audio recorders is allowed (please note that smartphones are not allowed). These recorders should contain a memory card to safely store the data. It is under no circumstances allowed to transfer the data via Wifi. Microsoft Teams can be used for online recordings. The audio or video data can be stored in a password secured folder in Research drive. Students should delete the original data on the memory card as soon as possible. The data in Research drive can be used to transcribe the audio or video data in such a manner that people are no longer traceable to a specific person. The supervisor can transfer the audio/video data and the transcripts from Research Drive to the secured T-drive. It is not allowed to store audio/video data or anonymous transcripts on a personal computer, and they must be deleted. The advice is to start the recording after collecting the personal data during the introduction. Please also make sure that no personal information about third persons (such as names) is collected and recorded.* | | |
| * + Physical meeting using a voice recorder or MS Teams (account provided by the OU).   + Online meeting using MS Teams (account provided by the OU).   + Eye-tracking recordings using OU accredited tools.   + Not applicable | | |
| **33** |  | |
| Do you collect any additional data besides paper, online, or audio/video recordings? | | |
| * + Lifedata / Reallifetm Exp (note: use of fictitious email addresses, location mobile device switched off & not personal data in open text fields).   + Data from activity trackers   + Prompting output AI tools (like ChatGPT)   + Data from other apps/devices:   .............................................. [open field]   * + Not applicable | | |
| **34** |  | |
| Do you use software/devices that is allowed and/or accredited by the OU? | | |
| * + Yes   + No (check the software list for accredited tools by the OU or contact the Data steward: datasteward@ou.nl).   + Not applicable | | |
| **35** |  | |
| Which of the following data do you collect from the participants for the analysis (not for recruitment)? | | |
| * Name * Address * Age / date of birth * Gender * Education * Work experience * Living situation * Marital status * Nationality * Birthplace * Birth country * Number of identification (such as student number) | | **Special data**   * Audio * Video/ facial * Race/ethnicity * Religious beliefs * Sex life or orientation * Political beliefs * Union membership * Health data * Genetic data * Biometric data |
| **36** |  | |
| Do you consider the data traceable to an individual person (based on the target group, recruitment method and data collection process)? | | |
| * Yes, and data will be anonymized or pseudonymized (see question 7) * No | | |
| **38** |  | |
| Do you collect no more data than strictly necessary to answer the research question, and will you use all data in the analysis? | | |
| * Yes * No. Go back to the list at question 33 and check off the data that you don’t really need | | |
| **39** |  | |
| Do you store personal data in a password-secured folder according to the current OU policies and delete them when no longer needed? | | |
| * Yes * No. Please check the data management matrix ([link](https://mijn.ou.nl/group/mdw/-/onderzoek-verzameling-gegevens)) and comply with that before you continue. * Not applicable | | |

**Part 8 Datamanagement checklist**

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| Please check the following. I certify that I understand and will comply to the statements formulated below. |
| * During the research project, store all digital data and documents regarding the research project on Research drive and/or the T-drive as provided by the Open Universiteit. Store all paper data and documents in closed cabinets or rooms during the research. * Raw data (with personal data) should be stored separately from the analyzed data on a password protected server. * Personal data should be anonymized or pseudonymized. Store the codification in a secure folder on Research drive or T-drive, separate from the research data. * After finishing the research project, the online data should be stored on the T-drive and the data on paper at OASIS. * Make sure that the supervisor(s) has access to the data after finishing the research project. * Not save any data or documents on personal devices such as your laptop, tablet or phone. If so, make sure that the personal device is password protected, and that the data will be deleted after finishing the research project. |

|  |  |
| --- | --- |
| I hereby declare that the information provided is true and correct. I also understand that any willful dishonesty may be rendered for refusal of ethical approval.  Obligatory attachments uploaded:   * Approval document of the research protocol * Data collection material(s) | |
| Signature student  Date: | Signature supervisor  Date: |

|  |  |
| --- | --- |
| **The board gives a positive decision on the research proposal which is in line with the Ethical Code for Research with Human Subjects** | |
| Additional binding advice from the Light track reviewer: | |
| Registration number: |  |
| Signature by the light track reviewer: | Date: |

1. B. Gordon, 2020. Vulnerability in research: basic ethical concepts and general approach to review. Ochsner Journal, 20, p. 34-38. [↑](#footnote-ref-2)