

SERVICE AGREEMENT and GENERAL CONDITIONS for NETHICS REVIEW

BETWEEN

- 1) **[name]**, a legal entity established under the laws of the Netherlands and governed by public law under section 1.8 of the Higher Education and Research Act (Wet op het hoger onderwijs en wetenschappelijk onderzoek) and having its registered offices at **[address]** the Netherlands, for the benefit of the [department/faculty of] in this matter duly represented by **[name]**, **[function]**, hereinafter also referred to as **"Reviewing Institute"**

AND

- 2) **[>>>]**, as the external party requesting ethical review of their research, hereinafter also referred to as **"Requesting Party"**;

together also referred to as **"Parties"** or each separately a **"Party"**;

WHEREAS:

- A. The faculties that are member of Nethics have installed an Ethics Review Board hereinafter also referred to as **"ERB"** (in Dutch ETC);
- B. The ERB of the Reviewing Institute that is part of the Nethics alliance aims to contribute to the integrity of empirical human-related scientific research in the Social and Behavioural sciences by reviewing intended studies with human subjects for criteria regarding informed consent, acceptable load and risks for subjects, and adequate data management procedures, according to the Nethics Ethical Code:
<https://www.nethics.nl/Gedragcode-Ethical-Code/>;
- C. The Requesting Party wishes to enable the ERB to review its research proposal subject to the conditions laid down in this Service Agreement and the General Conditions.

THE PARTIES HEREBY AGREE AS FOLLOWS:

Article 1. Research review

- 1.1 The Requesting Party requests that the **ERB** assesses the research protocol of the Requesting Party's investigator named **[insert name proposal]**, subject to this Service Agreement and the conditions laid down in Annex I: General Conditions for external review, hereinafter "General Conditions".

Article 2. Financial conditions

- 2.1 The Reviewing Institute will charge an amount of €750,- (sevenhundredandfifty Euros) excluding VAT per study to be assessed. This amount shall cover a maximum of three (3) revision rounds. If more rounds of review are necessary, then an additional fee of €250,- (twohundredandfifty Euros) per revision round shall be charged. In case a research protocol is submitted that cannot be accepted as eligible for review as defined in Clause 2.5 of the General Conditions (Annex I), an administrative fee of at most €50,- (fifty Euros) will be charged.
- 2.2 If an additional assessment of a Data Privacy Officer is needed, such is possible for an additional fee to be determined. The services shall not include a Data Privacy Impact Assessment.
- 2.3 The Reviewing Institute will send invoices to the Requesting Party for the submitted application. VAT will be charged on the total amount.
- 2.4 The Requesting Party will pay the amounts of the invoices within 30 days from the date of invoicing.

Article 3. Contact persons

The Parties appoint the following contact persons for any matters related to this Service Agreement and the performance thereof.

Requesting Party / Applicant	[name]
Reviewing Institute	[name]

As agreed in twofold:

Reviewing Institute,

Requesting Party,

(signature)

Name:

Title:

Date:

(signature)

Name:

Title:

Date:

Annexes:

Annex I General Conditions for external review

Annex II Requesting Party's application

Annex I: General Conditions for external review

These General Conditions for external review apply to the Service Agreement between the Reviewing Institute and The Requesting Party.

Clause 1. Definitions:

"Service Agreement"	The agreement for the provision of services of the ERB of the Reviewing Institute for external review;
"Confidential Information"	All information, correspondence, including business-sensitive information, knowledge, intellectual property rights, data and materials that the Parties provide to each other in writing, orally, on a data carrier or in another manner within the context of performing the service under the Service Agreement.

Clause 2. Implementation and scope of the Service Agreement

- 2.1 The Parties have entered into a Service Agreement for the review by the Reviewing Institute of the ethical aspects of human-related non-WMO-required research that The Requesting Party wishes to carry out. It is the sole responsibility of the Requesting Party to verify that the research is non-WMO.
The Reviewing Institute will perform its review according to the criteria of the Nethics Ethical Code, <https://www.nethics.nl/Gedragscode-Ethical-Code/>.
- 2.2 The Reviewing Institute will not be involved in any conduct of The Requesting Party's research.
- 2.3 The review procedure will be as follows.
- 2.3.1. The Reviewing Institute will provide the Requesting Party with the application form for review.
- 2.3.i The Requesting Party will ensure that the ERB receives in a timely manner all information, as requested by it, with regard to the investigation to be assessed and will ensure that the information it provides is as accurate as possible. The (secretary of the) ERB will be available for (procedural) questions but cannot be responsible for (choices made in regard to) the text of the application.
- 2.3.ii The Reviewing Institute will carry out the review with professional care, based on the information in the documents required for review (the application form, the participant information and consent form, and other information the ERB may request, such as description of the measurements, questionnaires, Data Management Plan aspects). The Reviewing Institute will provide the remarks to the protocol in writing and in a timely manner but at the latest within a month, after which the Requesting Party can respond to the ERB by revising the application and resubmitting it.
- 2.3.iii The Reviewing Institute aims to respond to a request for review within two weeks and to complete the review within one (1) month after having received all requested information.

- 2.4 The Requesting Party shall deliver their request for review in accordance with the form as provided by the Reviewing Institute and as complete as possible.
- 2.5 The Reviewing Institute reserves the right to reject a request in case the research falls outside of the scope of the Social and Behavioural Sciences domain that is covered by Nethics, is executed outside of the Netherlands, is commercial or otherwise non-scientific or for ethical reasons (including considerations regarding feasibility and liability).
- 2.6 The Reviewing Institute also reserves the right to terminate a review in case of (continued) incompleteness of the information provided by the Requesting Party and/or the need of more rounds of review than reasonably foreseen. In case of such rejection or termination, the Reviewing Institute shall inform the Requesting Party thereof in writing (including e-mail) and the Requesting Party shall be invoiced for the work already performed.
- 2.7 In the event that the Requesting Party does not agree with the outcome of the ethical review, it will report this in writing and substantiated to the contact person mentioned in the Service Agreement within three weeks. If further consultation does not lead to a solution, the Requesting Party can submit its objection to Nethics within six weeks via the e-mail address [secretaris Nethics]. In such a case, the Nethics board (chair and secretary) will review the content and procedure of the application process for omissions and/or errors and, if deemed necessary by the board shall consult another ERB affiliated with Nethics that was not originally involved in the review procedure, and will communicate its final decision to both parties within 8 weeks of receiving the fully documented objection.
- 2.8 Each Party shall promptly inform the other Party(s) of important information, facts, problems or delays that may affect the review of an investigation.
- 2.9 A positive advice after review is valid for the project duration as specified in the application. The review will be performed according to the criteria of the Nethics Ethical Code at the moment of review. After the final outcome of the review has been shared, it is the sole responsibility of the Requesting Party to verify if any criteria have changed.
- 2.8 An amendment on a previously reviewed protocol shall be handled by the same Reviewing Institute.

Clause 3. Confidential Information

- 3.1 All Confidential Information that the Parties provide each other during the Cooperation will be treated as such by the receiving Party and will not be copied, reproduced, disclosed or provided to third parties without the prior written permission of the issuing Party. The receiving Party will use the Confidential Information only for the purpose of the Service Agreement.
- 3.2 The Parties will make the Confidential Information as referred to in this Clause available only to those persons within their respective organisations for whom that Confidential Information is necessary in order to carry out the obligations arising from the services under the Service Agreement properly.

- 3.3 The obligation of confidentiality regarding Confidential Information does not apply or is no longer applicable if:
- i. the Confidential Information is generally known through no action of the receiving Party and this does not breach any obligation of confidentiality;
 - ii. at the time of receipt, the Confidential Information is already in the possession of the receiving Party and no other obligation of confidentiality rests on it, which must be demonstrated by means of written documentation should the issuing Party so demand;
 - iii. the receiving Party also receives the Confidential Information from an independent source of information and no other obligation of confidentiality rests on it, which must be demonstrated by means of written documentation should the issuing Party so demand;
 - iv. the Confidential Information has been developed independently by the receiving Party, which must be demonstrated by means of written documentation should the issuing Party so demand;
 - v. the receiving Party is obliged to disclose the Confidential Information under laws or regulations applicable to that Party or a judgment by a competent authority.
- 3.4 If the receiving Party is obliged to disclose the Confidential information under laws or regulations applicable to that Party or a judgment by a competent authority, the receiving Party will immediately inform the issuing Party of that obligation so that the issuing Party, in consultation with the receiving Party, can limit the level of disclosure as far as possible.
- 3.5 The confidentiality provisions of this Clause remain in force for a period of 3 years after termination of the Service Agreement.
- 3.6 Each Party will comply with the General Data Protection Regulation (if applicable) when processing personal data in the context of the service under the Service Agreement. Each Party that processes data is responsible and liable for this and will indemnify the other Party against all claims of third parties, damage, fines or costs arising from any claim relating to a breach of the General Data Protection Regulation by the first Party.

Clause 4. Sharing ERB reports

- 4.1 The Requesting Party is permitted to make public or to have made public, the final outcome of the review only, excluding any correspondence, under the following conditions:
- The publication is not for marketing or commercial purposes
 - Nethics and/or the Reviewing Institute may be listed as a reviewing institution, but The Requesting Party is not permitted to use the logo of Nethics and/or the Reviewing Institute, the faculty concerned and/or names of staff and;
 - The Requesting Party will explicitly state in any publications that mention Nethics and/or the Reviewing Institute as reviewer of the research that Nethics and/or the Reviewing Institute is not involved in

the planning and execution of research and that Nethics and/or the Reviewing Institute does not take any responsibility for the conduct of the research.

- 4.2 If the publication of the review leads to media coverage, Nethics and/or the Reviewing Institute are at all times entitled to explain and defend their role, position and the conclusions reached.

Clause 5. Liability and Indemnification

- 5.1 The services and review delivered under the Service Agreement are performed to a professional standard, but are made available WITHOUT ANY REPRESENTATION OR WARRANTY, express or implied, including any implied warranty of fitness for any particular purpose or a positive outcome of the review, or any warranty that the use of the same will not infringe or violate any rights of any third party.
- 5.2 A positive review does not warrant that the performance of the research by the Requesting Institute will not infringe any applicable laws and regulations. In no event shall the Reviewing Institute, its personnel and/or its subsidiaries be liable for any use of the review by the Requesting Party, and the Requesting Party hereby agrees to defend, indemnify and hold the Reviewing Institute, its personnel and its subsidiaries harmless from any loss, claim, damage, expense, or liability, which may arise from Partner's use of the review, except to the extent such loss, damage or liability is the direct result of the Reviewing Institute's gross negligence or omissions.
- 5.3 Neither Party shall be liable to the other Party for any indirect damages arising out of or in connection with these General Conditions and the Service Agreement. For the sake of these General Conditions: indirect damages meaning: loss of profit, loss of revenue and loss of business opportunities.

Clause 6. Duration

- 6.1 The Service Agreement shall be effective as of the date of last signature and shall end after the review is completed or the Reviewing Institute has terminated the Service Agreement according to Clause 2.4 of the General Conditions and all payments have been made.
- 6.2 The termination of the Service Agreement for any reason, shall not affect the obligations of the Parties incurred before termination. Any articles intended to apply after termination, including Clauses 3, 4, 5 and 7 of these General Conditions, shall continue to apply for the period mentioned therein.

Clause 7. Governing Law

- 7.1 The Service Agreement and General Conditions shall be governed by and construed in accordance with the laws of the Netherlands.
- 7.2 For all disputes that might arise as a result of the performance of the services under the Service Agreement, the Parties shall first try to resolve such disputes amicably and in good faith out of court. If Parties subsequently fail to resolve their dispute out of court, then such dispute will be submitted to the adjudication by the competent court of Midden-Nederland (Utrecht), the Netherlands.