**BUas Research Ethics Review Application Form**

v1.1

N.B. The assessment by the BUas Research Ethics Review Board will be conducted in compliance with the Standards for Good Research Practices, from: Netherlands Code of Conduct for Research Integrity (2018). An overview of these standards is included to this form as an appendix, for the applicant’s convenient reference.

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| **A - GENERAL INFORMATION** | | |
| REVIEW APPLICATION FORM – registration code: | **N.B. WILL BE ENTERED BY REVIEW BOARD**  *REGISTRATION CODE: < Project # (YY/MM + order of receipt)-REV (review application form)-serial# in document sequence-IP (in progress) or CC (case closed) 🡪 e.g. 2101-01-REV-01-IP>* | |
| REQUEST FOR: | (NON-BINDING) ADVICE  *<mark bold / underlined if selected>* | CRITICAL REVIEW / ASSESSMENT  *<mark bold / underlined if selected>* |
| Date of Review Application Submission: |  | |

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| **B – APPLICATION PACKAGE** | |
| List of documents included with the application (i.e. the input for the committee’s advice / assessment) |  |

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| **C - PERSONAL INFORMATION APPLICANT** | |
| Name of applicant (lead researcher): | *<last name, first name>* |
| e-Mail address: |  |
| BUas Department (Research Group): |  |
| External parties involved (individuals or groups from other universities, organizations): |  |
| Application approved by professor or research group leader (if applicant does not have this role him-/herself): | *<name, date>* |

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| **D - RESEARCH PROJECT DESCRIPTION** | |
| Name of Research Project: |  |
| Projected Project Duration: |  |
| Research Project Rationale  (i.e. what is the intended goal, the ‘point’ of the research project? This brief description helps to establish the interpretation frame for the review board) |  |
| Brief Overview of Methods  (i.e. what will be done with/to research project participants / respondents / informants): |  |

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| **E - ADVICE AND ASSESSMENT ELEMENTS** |
| (Approval by the Research Ethics Review Board is conditional on the accuracy of the information presented below. The overarching assessment framework of values and standards is in compliance with the 2018 *Netherlands Code of Conduct for Research Integrity* – see appendix for the core standards) |

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| **E0 – Preliminary Risk Assessment** |
| (this preliminary check of elements E0.1, E0.2a and E0.2b. matches the questions (1), (2a) and (2b) of the RESEARCH ETHICS SELF-ASSESSMENT FORM. These elements E0.1, E0.2a and E0.2b establish a first risk assessment of the proposed research project, to help classify the application in a LOW, MEDIUM or HIGH risk category. After the Preliminary Risk Assessment, assessment elements E1-E4 below will address the four main research ethics assessment criteria) |

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| **E0.1 – Preliminary Risk Assessment: Special Rules Regarding Medical Research** | | | |
| **E0.1a** - Does your research involve *medical scientific research? [[1]](#footnote-1)* | YES  NO | If E0.1a = YES, explain: How? | |
| **E0.1b** - Does your research involve *medicinal products?* | YES  NO | If E0.1b = YES, explain: How? | |
| **E0.1c** - Does your research involve *collecting tissue samples, blood, etc.?* | YES  NO | If E0.1c = YES, explain: How? | |
| **E0.1d** - Does your research involve *situations in which participants are subject to specific procedures or are required to follow rules of behaviour? [[2]](#footnote-2)* | YES  NO | If E0.1d = YES, explain: How? | |
|  | **YES at least once in E0.1** 🡪 Research proposals subject to the WMO [[3]](#footnote-3) (Dutch *Medical Research Involving Human Subjects Act*) require assessment by a specially accredited medical ethics review board. If you wish to conduct this kind of research and seek medical ethics approval, please contact the BUas Research Ethics Review Board via <...@...>. | | |
|  | **NO on all questions in E0.1** 🡪 continue with **E0.2** | | |
| **E0.2 – Preliminary Risk Assessment: Participants** | | | |
| **E0.2a – Participant Consent Capacity [[4]](#footnote-4)** | | | |
| **E0.2a1** - Does your research involve individuals lacking capacity or agency to consent, namely *children under 12? [[5]](#footnote-5)* | YES  NO | | If E0.2a1 = YES, explain: How? And: Why? |
| **E0.2a2** - Does your research involve individuals lacking capacity or agency to consent, namely *children aged 12-16? [[6]](#footnote-6)* | YES  NO | | If E0.2a2 = YES, explain: How? And: Why? |
| **E0.2a3** - Does your research involve individuals lacking capacity or agency to consent, namely *participants unable to give consent, e.g. in case of mental or legal incapacity?* | YES  NO | | If E0.2a3 = YES, explain: How? And: Why? |
| **E0.2b – Treatment of Participants** | | | |
| **E0.2b1** - Does your research involve *situations in which participants might experience physical or psychological stress?* Physical stress might include, but is not limited to, pain or discomfort. Psychological stress might include, but is not limited to, interview or survey questions about painful or traumatic experiences. | YES  NO | | If E0.2b1 = YES, explain: How? And: Why? |
| **E0.2b2** - Does your research involve *the collection of sensitive data which can endanger the participant’s privacy?* This might include but is not limited to data about the participant’s religion, political affiliation, criminal history or sex life. | YES  NO | | If E0.2b2 = YES, explain: How? And: Why? |
| **E0.2b3** - Does your research involve *procedures or situations which might raise doubt in any other way whether proper rules of research conduct are followed?* Answer ‘YES’ if any of the following are in doubt: implementation of a secure research protocol detailing who / what / when / where / why; only necessary data is collected in a legal/rightful way; a careful informed consent procedure; proper safeguards against illegitimate access to and/or modification of the data, defined in a secure data management policy. | YES  NO | | If E0.2b3 = YES, explain: How? And: Why? |
|  | **YES at least once in E0.2a,b** 🡪 your research probably requires approval from the BUas Research Ethics Review Board. Please do the following ***two*** things:  🡪 ***first***, under ‘E0 – Preliminary Risk Assessment - OUTCOME’, indicate which category you believe your research project to belong. N.B. based on the information provided in this review application form, the research ethics review board will also categorize the project; this categorization might be different from yours. In the follow-up process, addressing this assessment and any potential divergent analyses can be part of a constructive, solution-focused dialogue.  🡪 ***second***, continue with assessment elements ***E1-4*** below, to add more detailed information for the formal research ethics approval process. | | |
|  | **NO on all questions** 🡪 your research probably does not require approval from the BUas Research Ethics Review Board. If you are still in doubt and/or wish to request advice from the BUas Research Ethics Review Board, please contact the board via <...@...>. | | |

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| **E0 – Preliminary Risk Assessment - OUTCOME** | | | |
| Risk Assessment:  (based primarily on the following risk categories, as specified in the Review Application Form: involvement of vulnerable and/or underage participants; presence of privacy safeguards; negative effects of test design on participants, environment and/or property) | LOW  *<mark bold / underlined if selected>* | MEDIUM  *<mark bold / underlined if selected>* | HIGH  *<mark bold / underlined if selected>* |

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| **E1 - Informed Consent of Participants** | | |
| (e.g. does this study involve minors or other vulnerable groups? Are participants instructed properly?) | | |
| **E1.1** – Will the participants, or (in case of one or more times YES on questions **E0.2a1,2,3**) their legal parents / guardians / representatives, be informed about the reason for and nature of the research and the manner in which their data is used, *in advance and in full*? | YES  NO | If E1.1 = NO, explain: Why not? And: What information will be presented, and at what time during the research? If E1.1 = YES, explain: How? |
| **E1.2** – Will the participants give actively informed / explicit consent to their participation in the research, *and* the manner in which their data is used? E.g. by signing a clear, truthful and complete consent form, without being placed under duress to comply.  N.B. this applies if participant is over 16 and able to give legal consent. If between 12 and 16: consent by participants PLUS their legal parents / guardians / representatives. If under 12 or unable to give consent due to mental or legal incapacity: consent by their legal parents / guardians / representatives. | YES  NO | If E1.2 = NO, explain: Why not? If E1.2 = YES, explain: How? |
| **E1.3** – Will it be clear to participants that they can terminate their participation in the research at all times? | YES  NO | If E1.3 = NO, explain: Why not? |
| **E1.4** – Outside of this research project, are the participants in a subordinate relationship to the researcher? E.g. lecturer vs. students, or manager vs. employees. | YES  NO | If E1.4 = YES, explain: How? |

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| **E2 - Safeguards to Avoid Negative Consequences** | | |
| (e.g. is there sufficient focus on participant wellbeing, environmental sustainability in methodological design? If there are to be negative consequences, is there a convincing reason for this?) | | |
| **E2.1** – Will participants be under any risk of harm, damage, danger or stress during the research? Include your answer to question **E0.2b1**: Does your research involve situations in which participants might experience physical or psychological stress? | ☐ YES ☐ NO | If E2.1 = YES, explain: How? And: also answer **E2.4** and **E2.5**.  If E2.1, E2.2 *and* E2.3 = NO, mark **E2.4** and **E2.5** as N/A (not applicable) and continue with **E2.6**. |
| **E2.2** – Will your research create any risk of harm, damage, danger or stress for any non-participants, animals, the environment, public or private property, or in any other way? | YES  NO | If E2.2 = YES, explain: How? And: also answer **E2.4** and **E2.5**.  If E2.1, E2.2 *and* E2.3 = NO, mark **E2.4** and **E2.5** as N/A (not applicable) and continue with **E2.6**. |
| **E.2.3** – Will your research create any risk of harm, damage, danger or stress for the researcher or any member of the research team, of for the reputation or property of Breda University of Applied Sciences? | YES  NO | If E2.3 = YES, explain: How? And: also answer **E2.4** and **E2.5**.  If E2.1, E2.2 *and* E2.3 = NO, mark **E2.4** and **E2.5** as N/A (not applicable) and continue with **E2.6**. |
| **If E2.1, E2.2 and/or E2.3 = YES:**  **E2.4** – If there is any risk of harm, damage, danger or stress, is the importance of the research sufficiently great to offset that risk? (proportionality) | YES  NO  N/A | If E2.4 = either YES or NO, explain: How and Why? |
| **If E2.1, E2.2 and/or E2.3 = YES:**  **E2.5** – If there is any risk of harm, damage, danger or stress, can the research design be modified in such a way that said risk is lowered? (subsidiarity) | YES  NO  N/A | If E2.5 = either YES or NO, explain: How and Why? |
| **E2.6** – Will participants be rewarded for their participation? | YES  NO | If E2.6 = YES, explain: How and Why? |
| **E2.7** – Are there any other (potential) benefits to participating in this research for the participants, other than the reward as specified in E2.6? | YES  NO | If E2.7 = YES, explain: How and Why? |

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| **E3 - Integrity in Research Project Management** | | |
| (e.g. are there conflicts of interest involving participants, researchers and/or financiers?) | | |
| **E3.1** – Who / what is the source of funding for the research? |  | Explain: |
| **E3.2** – Will the funding organization have any control over the methods, execution and/or reporting of the research? | YES  NO | If 3.2 = YES, explain: How? |
| **E3.3** – Are there any researchers involved with the research who have connections to any organization or company, in such a way that a conflict of interests (or the impression thereof) might arise? | YES  NO | If 3.3 = YES, explain: How? And: What will be done to mitigate that risk? |

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| **E4 - Privacy and Data Management** | | |
| (e.g. availability of sound data management plan) | | |
| **E4.1** – Is there a Data Management Plan? | YES  NO | If E4.1 = YES, please include the file in the application package (listed under **B**). If E4.1 = NO, explain which other safeguards of secure data management have been established. |
| **E4.2** – Will it be possible to link any data to specific participants? E.g. will any of the data NOT be anonymous? | YES  NO | If E4.2 = YES, explain: Why? And: also answer **E4.3**. If **E4.2** = NO, mark **E4.3** as N/A (not applicable) and continue with **E4.4**. |
| **If E4.2 = YES:**  **E4.3** – Will any personal information (name, address, phone number, etc.) be stored? | YES  NO  N/A | If E4.3 = YES, explain: Why? |
| **E4.4** – How will the data be stored? Who will have access to any private and/or non-anonymized data (including but not limited to the raw data)? |  | Explain: |

* APPENDIX: Standards for Good Research Practices, from: *Netherlands Code of Conduct for Research Integrity* (2018).

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1. “Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.” (from: <https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not>) [↑](#footnote-ref-1)
2. “In general, research with human subjects is only subject to the WMO if there is an infringement of the physical and/or psychological integrity of the subject. The subject himself/herself must be physically involved in the research for the research to be subject to the WMO. Therefore retrospective research/file research is not subject to the WMO. In that case the data are already available and not collected specifically for a medical-scientific research. The subject does not have to do or abstain from something on behalf of the research.

   A blood sample being taken from the participant for the purpose of scientific research: this is always subject to the WMO as the participant is subjected to a procedure. If additional blood is taken for the research as part of a planned vene puncture or from an existing line, then the research is also subject to the WMO.

   Research during which a participant must provide one urine sample once, generally is not subject to the WMO. However, research during which urine samples must be provided over the course of a three-week period does.”

   (from: <https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not>) [↑](#footnote-ref-2)
3. For more information on whether your research might be subject to the WMO (the Dutch **Medical Research Involving Human Subjects Act)**, see:

   <https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not> [↑](#footnote-ref-3)
4. From 16 years of age, for all mentally and legally competent participants, consent for approved research is only obtained from the participant. For some types of research it may nevertheless be good practice to inform the parents or legal guardian/representatives. IF ANY OF THE CASES AS SPECIFIED ABOVE APPLY, make special note of the consent requirements for when you enter the formal approval process, particularly for ADVICE AND ASSESSMENT ELEMENT E1 - Informed Consent of Participants. [↑](#footnote-ref-4)
5. In case of minors under 12 years of age, informed consent is obtained from the parent(s) or legal guardian/ representative(s). It is good practice to also ask the child where possible. N.B. This is all IF the research is deemed appropriate, because in principle, scientific research for this group is severely restricted, and is generally subject to a ‘no, unless’-policy. See also <https://english.ccmo.nl/investigators/additional-requirements-for-certain-types-of-research/research-with-subjects-under-the-age-of-16-years> [↑](#footnote-ref-5)
6. In case of minors between 12 and 16 years of age, informed consent is obtained from both the minor and the parent(s) or legal guardian/representative(s). N.B. This is all IF the research is deemed appropriate, because in principle, scientific research for this group is severely restricted, and is generally subject to a ‘no, unless’-policy. See also <https://english.ccmo.nl/investigators/additional-requirements-for-certain-types-of-research/research-with-subjects-under-the-age-of-16-years> [↑](#footnote-ref-6)