

Date	
Consultant	

LSMU BIOETHICS CENTRE: EEF-SR*

1. ALL THE REQUIRED DOCUMENTS SUBMITTED (researchers' data, ESA questions 1, 2, 5 and annexes are evaluated)
<input type="checkbox"/> Yes. <input type="checkbox"/> Not applicable. <input type="checkbox"/> No (please comment). Comment
2. CAN THE RESEARCH BE CLASSIFIED AS BIOMEDICAL RESEARCH (BMR)? (ESA questions 2,3,4,6,7)
Please check the appropriate option. <input type="checkbox"/> Yes. Attributes of a BMR are evident. Recommended to apply to the RBREC. <input type="checkbox"/> No. No attributes of a BMR present. <input type="checkbox"/> Not applicable. <input type="checkbox"/> Research classification is unclear. Recommended to consult with the RBREC (please comment). Comment
3. IS THE RESEARCH SAFE FOR THE SUBJECTS (i.e. IS THE POTENTIAL RISK TO THE SUBJECTS MINIMAL)? (Research instruments, SIS, ICF, and ESA questions 7,8,9,10,13,14,15,16,17,18 are evaluated)
<input type="checkbox"/> Yes. <input type="checkbox"/> Not applicable. <input type="checkbox"/> Potential risk to the physical or mental safety of the research subjects (please comment). Comment
4. ARE THE METHODS and/or PROCEDURES APPLIED WITHIN THE BOUNDARIES OF THE STUDENT'S COMPETENCE? (ESA questions 2,11,12,13,14,15,16,17,18 are evaluated)
<input type="checkbox"/> Yes. They are within the boundaries of the student's competence. <input type="checkbox"/> Not applicable. <input type="checkbox"/> No. They may potentially exceed the boundaries of the student's competence (please comment) Comment
5. QUALITY OF THE SUBJECT INFORMATION SHEET (SIS) AND INFORMED CONSENT FORM (ICF) (FOR SURVEYS – INFORMATION FOR THE SUBJECTS) (SIS and ICF, survey information section, and ESA questions 18,19, 20, 21 are evaluated)
Please check the appropriate option. <input type="checkbox"/> The SIS and ICF are appropriate and contain all mandatory sections. <input type="checkbox"/> Not applicable <input type="checkbox"/> The SIS and ICF require revision, amendment, or correction of wording (please comment) Comment
6. ARE VOLUNTARY INCLUSION AND (NON-)PARTICIPATION OF THE SUBJECTS ASSURED IN THE RESEARCH? (SIS and ICF, survey information section, and ESA questions 17,18, 19, 21 are evaluated)
<input type="checkbox"/> Assured in general. <input type="checkbox"/> Not applicable. <input type="checkbox"/> Better assurance could be provided; subject inclusion conditions could be revised (please comment). Comment
7. ARE SUBJECT CONFIDENTIALITY and/or PRIVACY ASSURED? (Research instruments (RIs) and ESA questions 15,19, 20, 22, 23 are evaluated)
<input type="checkbox"/> Yes. <input type="checkbox"/> Not applicable. <input type="checkbox"/> No (please comment). Comment
8. ARE PERSONAL DATA COLLECTED / ARE THERE ANY POTENTIAL RISKS RELATED TO PERSONAL DATA SAFETY? (RIs and ESA questions 22, 23, 24 are evaluated)
<input type="checkbox"/> Yes. <input type="checkbox"/> Not applicable. <input type="checkbox"/> No (please comment). Comment
9. QUALITY OF THE RESEARCH INSTRUMENTS (RI) (VOLUME, CORRESPONDENCE TO THE RESEARCH AIM, SENSITIVE QUESTIONS, WORDING OF THE QUESTIONS, ETC.)? (RIs and ESA questions 8, 11, 12 are evaluated)
<input type="checkbox"/> RIs are correct and will not compromise the subjects' dignity. <input type="checkbox"/> Not applicable. <input type="checkbox"/> RIs raise concerns about compliance with the ethical requirements (please comment). Comment
10. REASONED CONCLUSION
<input type="checkbox"/> Recommended to endorse. <input type="checkbox"/> Recommended to revise the research project (please comment). Comment

* - ethical evaluation form for student research.