To minimize the potential for complications resulting from needle muscle biopsies in research subjects, the protocol submitted for ethics review must meet the following conditions:

1. Name a licensed physician as a co-investigator or collaborator on the ethics protocol submission. This physician must accept responsibility for the muscle biopsy procedure and/or supervision of non-physicians performing the biopsies.

2. Exclusion criteria and the recruitment screening process must identify potential subjects with diagnosed and/or underlying pathology, or on any medication, that could increase the risk of excessive bleeding, allergic reaction, infection or other medical condition associated with the procedure. The Muscle Biopsy Screening Form must be completed for each subject prior to enrollment. This Screening form must be assessed by the physician or senior researcher doing the procedure.

3. Include, as part of the subject’s study participation, a formal post-biopsy appointment to attend to wound care and removal of stitches if required.

4. Identify clearly in the HSREB Submission Form Section 15.1, what health and safety procedures or protocols are in place to deal with emergencies that may arise during the procedure.

5. In addition to the usual Letter of Information, subjects must be given the Muscle Biopsy Information Sheet.

6. In addition to the usual required elements, the Letter of Information must identify:
   a. the purpose of the biopsy;
   b. the exclusion criteria and indicate that a Muscle Biopsy Screening Form will be completed and assessed before they can participate;
   c. indicate the source of responsibility for liability/compensation related to any complication of the study if study is sponsored by a commercial or industry sponsor;
   d. contain a reference to the Muscle Biopsy Information Sheet. (E.g. You will undergo a Muscle Biopsy - please refer to the Muscle Biopsy Information Sheet that is appended to this letter for complete details about the procedure and its risks.)
   e. The Consent form should also refer to the Muscle Biopsy Information Sheet. (E.g. I have read the Letter of Information and the Muscle Biopsy Information Sheet…)

“At rest” biopsies on normal healthy subjects

7. Biopsies that are not done in conjunction with exercise may be conducted by physicians or trained non-physicians who are under the supervision of a licensed physician. The supervising physician must be present in the general area when an ‘at rest’ biopsy is being done and be aware that a muscle biopsy is underway.

8. If the investigator carrying out the muscle biopsy is not a physician, s/he must be a senior, experienced researcher and demonstrate to the supervising physician documented experience in the appropriate sterile technique, use of local anaesthesia and adequate knowledge regarding potential complications during and following the procedure.

“Exercise” biopsies

9. Given the increased risk of excessive bleeding and difficulty in maintaining an acceptably sterile field, muscle biopsies associated with exercise may only be conducted by licensed physicians in an appropriate clinical setting.
Summary Chart

<table>
<thead>
<tr>
<th>Type of Muscle Biopsy</th>
<th>Participant characteristics</th>
<th>Biopsy may be conducted by</th>
<th>Review Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>At rest biopsy</td>
<td>Normal, healthy</td>
<td>Physician or Non-physician(^2)</td>
<td>Expedited(^1)</td>
</tr>
<tr>
<td>At rest biopsy</td>
<td>During or requiring surgery</td>
<td>Physician only</td>
<td>Expedited(^1)</td>
</tr>
</tbody>
</table>

\(^1\)This chart is merely a guide. Full REB Review may be required if the research protocol has other elements that are considered to be more than minimal risk or uses a population that could be considered as ‘at risk’

\(^2\)The UWO HSREB will consider approval for those non-MD but experienced senior investigators for limited biopsy settings as per these guidelines but does recommend an attritional phase-out of non MD's being approved for the procedure