RESEARCH REVIEW COMMITTEE

APPENDIX 1: COLLECTION OF BIOLOGICAL SPECIMEN(S) FOR A RESEARCH STUDY
REQUIRED IF “YES” WAS RESPONDED FOR QUESTION #13 IN THE STUDY APPLICATION

1. Biological Specimen Collection

<table>
<thead>
<tr>
<th>Please check all that apply:</th>
<th>Mandatory for Research Study</th>
<th>Optional for Research Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic Testing</td>
<td></td>
<td></td>
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<tr>
<td>Biomarker testing</td>
<td></td>
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<tr>
<td>Future Research</td>
<td></td>
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<tr>
<td>Biobanking</td>
<td></td>
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<tr>
<td>Other, please specify:</td>
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</tbody>
</table>

2. Informed Consent Form(s)

Please Note:
A separate and optional Informed Consent Form is required if biological specimens (tissue, serum, plasma, bodily fluids, etc.) are to be collected for future research/genetic studies/biobanking not related to the current research application.

Separate and Optional Informed Consent Form(s) attached: □ Yes □ No

3. Use and Storage of Biological Specimen(s)

i. Description

<table>
<thead>
<tr>
<th>Type of Specimen</th>
<th>Number of specimen(s)</th>
<th>Method of sample collection</th>
<th>Purpose of collection</th>
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</table>

ii. Are any of the specimens being sent off-site (i.e. to a sponsor, repository, biobank, registry, another investigator, central laboratory, etc.)? □ Yes □ No

iii. If yes, will a material transfer agreement (MTA) or contract be signed to ensure safe and secure transfer, storage of specimen(s) and related health information? □ Yes □ No

If No, please explain:

4. Personal Health Information

i. Will any personal Health Information (PHI) be linked to the collected biological specimen (i.e. patient name, initials, date of birth, unit number, etc.)? □ Yes □ No

If yes, please specify and justify:
ii. Please explain who will have access to this information and how confidentiality will be preserved:

iii. Please explain how the biological specimens will be stored:

iv. Please explain how long biological specimens will be retained and how they will be destroyed:

v. Please explain what will happen to the biological specimens and data collected if the participant withdraws consent after the sample has been collected and stored?

5. Disclosure of Results:
   i. Participants’ sample results will be disclosed to the following:
      ☐ Participant ☐ Participant’s Family Members
      ☐ Principal Investigator ☐ Participant’s Family Physician
      ☐ None of the above ☐ Not currently known. The RRC will be notified as soon as this information is made available.

   ii. If results will be disclosed to any of the above, please explain the type of result (i.e. all findings, only findings of clinical relevance, etc.)

   iii. If results may be disclosed to the participant, please indicate whether the participant will have the option of refusing to receive this information: ☐ Yes ☐ No
      If yes, please ensure there is written documentation (e.g. in the ICF or patient clinical trial chart) of this refusal.

   iv. For genetic results, will genetic counseling be provided to the participant?