Analysis of Specimens and/or Data

You have been directed to this page because on the page "Description of The Research," you noted that your research includes either (1) Analysis of specimens and/or data collected for clinical (non-research) purposes. This would include retrospective records review; analysis of discarded tissues, etc.; OR (2) Analysis of specimens and/or data collected under a separately approved research protocol; OR (3) Core Laboratory.

Answer the responses below to determine if additional review is required:

1. Briefly describe why the proposed analysis is being done: purpose/significance of the proposed analysis.
2. Describe the data and/or specimens to be collected and analyzed.
3. Describe how data and/or specimens will be selected for analysis.
4. How will the material to be analyzed be collected and who will be responsible for collecting it?

This text box will be deleted and the questions above 1-4 are all required.

5. * Will CSMC investigators interact (i.e., communicate) or intervene (i.e., conduct research procedures) with subjects in order to collect data or specimens for the currently proposed research?
   - Yes
   - No
   - Clear

   Will the interaction or intervention occur as part of a separately approved repository that will forward specimens/data for this study's analysis?
   - Yes
   - No
   - Clear

   Are any of the investigators participating in this study also listed as investigators on the repository that will forward data/specimens to be analyzed?
   - Yes
   - No
   - Clear---This question already exists but didn't paste over

6. * Does the proposed analysis involve specimens?
   - Yes
   - No
   - Clear
to be analyzed during this research: (please see end of form for table)

   Will the analysis to be done on the samples and/or data possibly result in any genetic information related to the subject's (or his/her relatives') health or susceptibility to a disease or condition currently or in the future?
   - Yes
   - No
   - Clear

   Will any specimens for the proposed analysis be collected after the submission of the application?
   - Yes
   - No
   - Clear
How Many Specimens Will Be Analyzed:

Will specimens be used to evaluate a medical device?
- Yes
- No
- Clear

Will specimens be used to evaluate an in-vitro diagnostic or device?
- Yes
- No
- Clear

Will you record information that can be used to directly identify the individual whose specimens will be analyzed (e.g., name, address, social security number, etc.)?
- Yes
- No
- Clear

Will the specimens obtained include a code that is linked to the identity of the individuals?
- Yes
- No
- Clear

Will CSMC investigators be given access to the linking list/code to be able to ascertain the identity of the individual participants?
- Yes
- No
- Clear

4 * Does the proposed analysis involve data (e.g., information from medical records, data registries, etc.)?
- Yes
- No
- Clear

Will any data for the proposed analysis be generated after the submission of this application?
- Yes
- No
- Clear

How many records will be analyzed?

If a data abstraction tool will be used, upload it here:
None

Will you record information that can be used to directly identify the individual whose data will be analyzed (e.g., name, address, social security number, etc.)?
- Yes
- No
- Clear

Will the data obtained include a code that is linked to the identity of the individual?
- Yes
- No
- Clear

Will CSMC investigators have access to the code/linking list that would allow them to ascertain the identity of the individual participants?
- Yes
- No
- Clear

7. New Question: Briefly describe the nature of the information that will be generated and address any potential risks to the subject as a result of the generation of information related to the subject's health or susceptibility to a disease or condition.
Free text box here

58 * Are there plans to publish or present (e.g., at a professional conference) findings of the proposed analysis?
69 * Will this research require that you look at medical records or other sources of private patient information (e.g., appointment logs, surgery logs, pathology databases, etc)?

- Yes - No - Clear

710 * Will this research require that information from medical records or other sources of private patient information (e.g. appointment logs, surgery logs, pathology databases, etc.) be shared or used by others who are not involved in the subject's clinical care?

- Yes - No - Clear

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How to Define Who Is Involved in the subject's clinical care:

Any health care professional that intervenes, interacts, or who has access to the patient's information for the purpose of treatment, diagnosis or consultation is considered to have a role in the patient's clinical care. This would include any appropriate ancillary health professionals (Radiation, Pathology, Blood Bank, Infectious Disease, etc.) with whom the patient may not have a direct interaction.
<table>
<thead>
<tr>
<th>Specimens</th>
<th>Will the proposed analysis involve Specimens, Data, or both Specimens and Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will any of the proposed analysis be collected after the submission of the application?</td>
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<tr>
<td>How many samples will be analyzed</td>
<td></td>
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<tr>
<td>Will the analysis include a code that is linked to the identity of the individuals?</td>
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<tr>
<td>Will you record information that can be used to directly identify the individual whose data and/or specimen will be analyzed</td>
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<td></td>
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<tr>
<td>Could the analysis involved result in genetic information related the subject’s health?</td>
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</tbody>
</table>

**Comment [A1]:** if yes:
- Will specimens be used to evaluate a medical or in-vitro diagnostic or device? (Yes/No)

**Comment [A2]:** if yes:
- If a data abstraction tool will be used, upload it here: