Guidelines for Applications Involving the Use of Existing Specimens

- Specify source of the specimens.
- Provide documentation of the source institution’s IRB approval or acceptable alternative.
- Describe conditions under which specimens were obtained. If obtained with informed consent, include a copy of the approved consent document.
- Provide information adequate to demonstrate that the proposed use is appropriate.
- If specimens have identifiers that would enable them to be linked back to the individual subjects by anyone, discuss in depth how the results of the research will be used; such as
  - whether the results of the research will be made available to the subjects or subjects’ physicians and if so, under what circumstances,
  - discuss potential risks to subjects.