## Appendix A: Examples of Considerations

Examples to consider in preparing a submission using existing human information (data) and/or biospecimens:

1. Chanel by which human information/biospecimens were obtained (IRB-approved research study, clinical discards, public health efforts, etc.)

    a. Was broad consent or informed consent obtained? (Provide a copy)
    b. If informed consent was obtained, what permissions for use were provided by the research subjects?
    c. What were the protocol allowances for this use?
    d. Does this use for the proposed project affect the rights and welfare of the subjects?

2. Current location and responsible steward. There can be complex issues of ownership of biospecimens and intellectual property considerations with regard to discoveries made using human information/biospecimens. How will the investigator handle future third-party access?

3. Sponsor requirements for the new or continued use should be gathered prior to submission.

4. Will research results be returned to subjects and if so, how and when? How will incidental findings be managed/reported?

5. Determination as to whether this project reasonably falls within the scope of the original research (as described in the objectives of the study or in the informed consent form, if one existed). What is the nature of the proposed secondary research?

6. Imposition of any new or significantly greater risks (including privacy risks) which were not described in the initial consent form.

    Special considerations might include, but are not limited to:

    a. Genetic studies where the findings might involve risks that could harm an individual, a family, a group or community. These risks could include psychological, social, or economic harm. Examples of this might include an employer or insurance company learning of a genetic predisposition for a particular disorder and refusing employment or coverage.

    b. Biospecimens from children who are now adults in secondary research

7. Cultural/religious acceptability. Known concerns of the study population(s) (from whom the biospecimens originated) about the proposed new use. Also understand:

    a. Role of community advisory boards
    b. Assessing community risk

8. Collaborating Institution's authorization requirements (human information/biospecimens origination). International partners may require import/export permits for use of the samples or data.

9. Know the requirements of the local IRB (or regulatory office) and how to gain approvals (determinations), or deferrals for new collaborators.

10. USAMRDC Office of Research Protection (ORP) Human Research Protections Office (HRPO) approval may also be needed, depending upon location of research, funding, vulnerable populations, and other considerations (refer to USAMRDC Command Policy 2018-75).

11. Understand business agreement (past and present) allowances, as well as those described in the protocol.