Attachment 3 - Establishment of a Research Biorepository Checklist

Self-Audit/Review Assistance

- Review privacy and confidentiality SOPs and informed consent criteria.
- Identify what action is taken if a sample is received without the proper informed consent documentation.
- Identify how the research biorepository ensures that the proposed use of human tissue is consistent with the informed consent.
- Select a biospecimen in storage and review that the proper informed consent documentation is complete.

1. **Informed Consent Criteria** Y/N/NA

   Mechanisms are in place to ensure that the proposed uses of human tissue with or without data shared for research purposes are consistent with the informed consent and scope of services, when applicable.

   There are some instances when informed consent and/or waiver of consent are not applicable (e.g. non-human biospecimens).

   Evidence of Compliance:

   ✓ Document outlining the mechanism

2. **Required Approval(s) Documentation** Y/N/NA

   When human biospecimens are to be collected, all of the required approvals (e.g. Metro South Health Research Biorepository Strategic Oversight Committee or other Human Research Ethics Committee) have been documented and appropriate patient/participant consent processes are complete.

   The only exception to this is when there has been a waiver of consent.

3. **Informed Consent Documentation** Y/N/NA

   Informed consent documentation is obtained for the collection, storage, distribution, and use of identifiable biospecimens and data.

   The only exception to this is when there has been a waiver of consent.

4. **Waiver of Consent** Y/N/NA

   A waiver of consent, in accordance with applicable laws and/or requirement and approved by the Metro South Health HREC, is obtained when informed consent documentation is not obtained/required.

5. **Biospecimen/Data Usage** Y/N/NA

Processes are in place to ensure that the proposed use of the biospecimen/data is within the guidelines of the research project and of the informed consent, when applicable.

6. **Privacy/Confidentiality** Y/N/NA

SOPs are in place to ensure the privacy and confidentiality of the patient/participant.

7. **Procedures Available for Review** Y/N/NA

The research biorepository's SOPs for human biospecimen collection, processing, storage, and dissemination are available for Metro South Health Research Biorepository Strategic Oversight Committee or other Human Research Ethics Committee review, as needed.

Completed By:_____

Date: _____

Adapted from National Cancer Institute *NCI Best Practices for Biospecimen Resources 2016* *Biorepository Checklist: CAP Accreditation Program (2014).*