**GUIDANCE 32**

**TISSUE COLLECTION, PRIVATE IDENTIFIABLE INFORMATION AND DATA BANK GUIDANCE**

CLEAR DESCRIPTION OF THE GUIDANCE IS PROVIDED IN ARTICLE 11 OF RU GUIDANCE BOOK (<https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html>.)

The guidance listed below serves as a resource for investigators who wish to develop: (a) standard operating procedures to establish a research tissue bank or a research data bank; (b) a consent document to collect tissue for future research; and (c) an addendum consent document to collect tissue for future research secondary to a main study. This guidance applies to activities that include the collection and storage of blood, tissue or other biological materials (excluding embryos\* or embryonic stem cells\*) and/or health data that will be used by a single investigator or shared with multiple investigators for future research not yet defined, including genetic (but not stem cell\*) research. This guidance does not apply to the collection and storage of specimens or data as part of a single IRB-approved protocol for defined research purposes. \*Contact your IRB Office for guidance on embryo or stem cell research.

11.2 Human Tissue for Research

11.3 Data and Specimen Repositories

11.3.1 IRB Oversight

11.3.2 Consent for obtaining Private identifiable Information or Identifiable Biospecimens

11.3.3 Privacy Rule

11.3.4 Constructing and Managing Repositories

11.3.5 Outside Repositories

11.3.6 Tissue Procurement

11.4 Research on human tissue that DOES NOT require IRB review (require IBC registration)

11.5 Research on human tissue that DOES require IRB review

11.5.1. Research on samples obtained prospectively, explicitly, and solely for research

11.5.2. Research on excess clinical samples obtained from tissue procurement center

11.6 Research on autopsy specimens and donated cadavers

11.7 Tissue or specimens obtained from collaborators

11.8 Secondary use of previously collected research samples

11.9 Special Samples

11.10 Labeling Human Samples

11.11 Transfer of samples to research collaborators outside of the Institution

11.12 Requirements for a tissue repository within the Institution