

HAC Policies and Procedures

Waste or Extra Biological or Diagnostic Specimens

Research may involve the use of “waste” or “extra” biological or diagnostic specimens (human tissue or fluids). “Waste” materials would be those obtained during a clinical or diagnostic procedure but is no longer needed and would normally be discarded (e.g., left over blood or tissue samples). These types of studies may require an informed consent document but the HAC may also decide to waive the informed consent requirement. The decision to waive informed consent is determined by the HAC and not by the PI. This type of research must be approved by the HAC prior to its initiation.

“Extra” materials are those collected above and beyond what was needed for a clinical or diagnostic procedure. It is collected during the same procedure or process but solely for the purpose of the research (e.g., blood draw for lab value for clinical care and an extra tube for the research, or obtaining 2 more centimeters of tissue than is actually required for clinical care). This type of research must be approved by the HAC prior to its initiation and requires written informed consent.