OFFICE OF RESEARCH AND DEVELOPMENT (ORD) VETERANS HEALTH ADMINISTRATION (VHA)

HUMAN BIOLOGICAL SPECIMENS USED FOR RESEARCH

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This guidance document describes human biological specimens in regards to their use in VA research.

1. Human biological specimens used for VA research

A human biological specimen is any material derived from a human such as blood, urine, tissues, organs, saliva, DNA/RNA, hair, nail clippings, or any other cells or fluids-whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures. Bacteria, fungi, or viruses obtained from human biological specimens are **not** considered human specimens as long as the human material has been removed. **Human biological specimens should be treated as a biohazard and potentially infectious at all times.**

a. Examples of human biological specimens

- Blood (including blood smears on slides)
- Plasma
- Serum
- Stool
- Urine
- Cells (red blood cells, white blood cells, lymphocytes, plasma cells, etc.)
- Tissue (including paraffin blocks)
- Fluids (pleural, synovial, CSF, etc.)
- DNA/RNA
- Hair
- Skin
- Nails
- Fixed or stained slides containing a human component

b. What would NOT be considered a human biological specimen

- Commercial reagent containing human components or cells
- Any specimen coming from a non-human (laboratory animal)
- Microbiological agents
- Viral agents
- Fungal agents
- 2. Autopsy Tissue- Research using human biological specimens removed at autopsy must be in conformity with VHA Handbook 1106.01. The use of specimens for research must be consistent with the permission given by the person authorized to grant permission for autopsy.

3. Embryonic Stem Cells- Federal requirements for embryonic stem cell research must be followed when conducting research involving embryonic stem cells. Refer to the National Institute of Health (NIH) website regarding stem cell use for additional information. http://stemcells.nih.gov/policy/Pages/Default.aspx