

Use of Human Samples for Research Involving COVID-19

The increased research interest in COVID-19 and handling of human and viral samples has caused concerns with research safety compliance. The Office of Occupational Health and Safety

(<u>http://www.uams.edu/campusop/depts/ohs/</u>) enforces rules and regulations regarding research involving biohazards. The Institutional Biosafety Committee (IBC; <u>http://www.uams.edu/campusop/depts/ohs/BioSafety_Cmte.aspx</u>) reviews and evaluates investigator-initiated protocols for the proposed use of biohazardous agents, including, but not limited to, recombinant DNA, use of hazardous chemicals in animals, human cells/cell lines and samples, and infectious agents at biosafety level-2 (BSL-2) or higher, including bacteria, viruses, mycotic agents, parasites, prions, and virus-shedding tumor cells. The IBC approves or disapproves safety protocols and makes recommendations to the Safety Coordinating Committee regarding biohazards that may exist or arise on the UAMS campus.

Please contact James Bishop, Biosafety Officer, at 501-603-1288 with any questions.

Requirements

- Research involving human subjects using viral and/or human samples must obtain both IRB <u>and</u> IBC approval prior to starting the project.
- Research determined to not meet the definition of human subjects research but involving viral and/or human samples <u>must obtain IBC approval</u> prior to starting the project.
- Work with confirmed or suspected SARS-CoV-2 samples requires BSL-2+ or BSL-3 measures. Special laboratory capabilities are required.
- Researchers proposing the use of samples containing confirmed or suspected SARS-CoV-2 or SARS-CoV-2 products must formulate safety protocols detailing laboratory-specific procedures for the safe handling, storage, and disposal of the agent. The principal investigator must ensure that all personnel are informed.
- Any change in biohazard research must be reported to the IBC.
- Investigators must maintain an inventory of all potentially COVID-19/SARS-CoV-2-positive samples. It is likely that COVID-19/SARS-CoV-2 may be classified by the Centers for Disease Control (CDC) as a Select Agent in the future. If this occurs, the institution will need to account for all COVID-19/SARS-CoV-2 research materials.
- Investigators must sign the COVID-19/SARS-CoV-2 assurance statement and return it to the IBC. Some of the requirements noted above are also reiterated in the assurance.
- All work must meet requirements of applicable regulations and the UAMS Biosafety Manual.
- Additional requirements may be required based on biosafety level of procedures and applicable regulations.