# Working with Human Samples at CSU – Quick Reference for CSU Researchers

Analysis of de-identified samples that are “on the shelf” (secondary; **not** collected for you or your research) would most likely not be considered human subjects\* research.

* No IRB review would be required.

Some research involving human subjects may still be exempt (45CFR46.101) or may be eligible for expedited review procedures (45CFR46.110).

* An IRB coordinator will work with you to determine if your project must be reviewed by the IRB, if it requires full review, or is eligible for expedited review.
* If the receipt and use of the specimens is determined to be “not human subjects,” or “human subjects exempt research” the coordinator will prepare the relevant memo documenting the exemption status for you and Sponsored Programs (if applicable).

Please contact an IRB coordinator.
In order to be consistent with OSHA guidelines and best practices for Biomedical research in Biological laboratories\*\* all research using human biological samples shall include IBC protocol approval (regardless of IRB status)

* Visit the CSU IBC website to initiate the IBC approval process

Please contact the IBC Coordinator, with any questions regarding these IBC requirements.

## Notes/References:

*\*The regulatory definition of a “human subject” means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information” (45CFR46.102(f).*[*The NIH has flow charts to help researchers to answer questions about research with human specimens*](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1)*.

\*\*Please refer to the*[*BMBL Appendix H*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixH.pdf)*regarding research using human cell lines and*[*OSHA’s Bloodborne Pathogens Standard*](https://www.osha.gov/SLTC/bloodbornepathogens/gen_guidance.html)*for reference material regarding the risk and practices when working with human samples.*