Biomedical Laboratory R&D (BLRD) versus Clinical Science R&D (CSRD) Purview for Observational Studies Decision Tool

BLRD funds preclinical biomedical and behavioral studies of disorders and diseases prevalent in the Veteran population. BLRD purview includes in vitro and in vivo studies using tissue cultures, animal models or human biological samples, collected using minimally invasive procedures (blood, urine, buccal swabs) or invasive human tissue materials or health record data acquired from other sources (e.g., from tissue banks, pathology material, EHR or MVP databases) without investigators directly contacting subjects.

CSRD funds clinical, behavioral, and epidemiological research on disorders and diseases prevalent in the Veteran population. CSRD purview includes studies that involve administering survey instruments or questionnaires, collecting medical histories from research subjects, performing medical procedures (including imaging studies or surgical biopsies), or treatment regimens in any of the specific aims.

Determining whether an observational study falls under BLRD or CSRD purview can be difficult. This decision tool is intended to help make that determination. The outcomes being measured or whether the study is prospective or retrospective are not determinative factors when considering BLRD versus CSRD purview. Purview depends on the methods utilized, how the study materials are obtained, and how the researchers interact with patients. If any part of the study falls under CSRD purview, the whole study will be considered a CSRD study, and the application can be submitted to an appropriate CSRD RFA.

The purview will be BLRD if:

- Biospecimens are collected using minimally invasive methods (e.g., urine collection, blood draw, buccal swab), utilize specimens that would be collected during standard clinical care (e.g., excess pathology materials), or utilize biobanked or other previously collected materials.
- Experimental data is collected through chart reviews, the Central Data Warehouse (CDW), Million Veteran Program (MVP), data that would be collected during standard clinical care, or utilizes previously collected experimental data.

The purview will be CSRD if:

- Any biospecimens from human subjects are collected for research purposes, using non-minimally invasive methods (e.g., biopsy, bronchoalveolar lavage).
- Any medical procedures are performed (including imaging studies) on human subjects.
- Any experimental data is collected from human subjects through surveys instruments or questionnaires.

Procedures performed, and data and specimens collected during standard clinical care that are subsequently utilized for research do not count towards CSRD purview.

Any questions concerning BLCRD versus CSRD purview can be directed to the BLCS Review Mailbox: vhacoblcsrdrev@va.gov. **Investigators are strongly encouraged** to contact their Scientific Program Manager to discuss purview of any observational studies they want to submit to BLRD or CSRD. Applications submitted to RFAs outside of purview may be withdrawn from review.