Study can not be done without re-consent

NO

►Can you provide a compelling reason why performing the current study would not be a violation of subjects’ rights (see Waiver of Consent)?

NO

Submit for Expedited Review

YES

►Does the study involve genetic testing (not including tumor genetics), immortalized cell lines, stem cells, or samples/data from prisoners?

NO

Full Board Review required. No waiver of consent can be given; re-consent may be necessary

YES

►Do the investigators record all data from the sample analysis anonymously, without any links to subject identity?

IDENTIFIABLE

NO

May Submit for Exempt Review

YES

Non-human subject Research*

If submitted, IRB should consider whether secondary use of samples or data is appropriate

NON-HUMAN SUBJECT RESEARCH

NO

►Is the PI or any other member of the investigative team listed on the source protocol?

YES

Non-human subject Research*

IF SUBMITTED, IRB SHOULD CONSIDER WHETHER SECONDARY USE OF SAMPLES OR DATA IS APPROPRIATE

NO

►Are samples/data originating from a biobank that has an independent committee which determines appropriate use of samples?

YES

Non-human subject Research*

IRB review is not needed

NO

►Did subjects on the source protocol give consent for future unspecified use of samples/data? (provide copy of consent)

NO

►Did the source study consent adequately inform subjects that their samples/data could be used for the current study aim(s)?

YES

►Are samples identifiable (including coded without a coded use agreement, or with enough accompanying data to identify subjects) or are they anonymous?

BIOBANK DECISION TREE

For banked samples/data that are already in existence when the new study is proposed

* Testing of devices using stored samples may meet the FDA definition of human subject research. Please check with COMIRB to discuss