**Supplement M**

**RESEARCH INVOLVING STORED DATA/SPECIMENS FOR FUTURE USE**

Indicate your responses below and explain your selections in the protocol. Do not provide details in this document.

# Access

## Who is expected to use the data/specimens? Check all that apply:

\_\_ Study investigators associated with this protocol for this protocol

\_\_ Study investigators associated with this protocol for another protocol/purpose

\_\_ Other researchers at other NIH ICs

\_\_ Researchers at other institutions

\_\_ Future use is unknown at this time

**Note:**  New uses of these data/specimens by the Principal Investigator or Study investigators will require an amendment submission or new protocol submission to the IRB for approval.

## If the data/specimens are to be released to other researchers, outside the NIH, please provide the FWA# for the other institution(s). Contact the Office of Technology Transfer/Development for your IC before sharing any data/specimens.

# Storage

## Describe how the data/specimens are to be stored, including location.

## Describe protections in place, if any, to restrict access to authorized persons.

## Will the stored data be identifiable [i.e. retains Personally Identifiable Information (PII)]?

\_\_ Yes

If yes, explain why this is necessary, provide justification

\_\_ No

If no, explain how the data will be de-identified.

## Will the data/specimens be coded? \_\_ Yes \_\_ No

### If yes, explain how the data will be coded and how the key will be secured.

# Consent

# The consent must include permission to have the data/specimens stored for future use.

## Will results of future use data/specimens be shared with participants?

## \_\_ Yes \_\_ No

## If yes, explain in the protocol/consent.