NOTE – This chart is not applicable to studies under FDA jurisdiction. In some instances, the entity supplying the data or specimens will require IRB approval despite a finding of exempt or NHSR. In these instances, you will need to conduct an expedited review.

Data/Specimen collected in previous research

- Is ICF silent or does it allow/prohibit future research?
  - Allows
  - Silent
  - Prohibits

- Does the original study have a COC?
  - Yes
  - No

- Is the PI part of the original research?
Are the new PI & research team part of the previous research?

Yes  No

Are the data/specimens identifiable when investigator receives it?

Yes  No

Cannot Approve

Does the new research record identifiers?

Yes  No

Exempt

Expedited