**Not Engaged in Human Subject Research**

Certain types of projects meet the DHHS definition of "Not Engaged in Human Subject Research". A common example of this type of project is described below. For the full OHRP guidance see <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

*You are collaborating with a colleague from another institution and your colleague is sending you data or specimens without any HIPAA identifiers (see below). The data/specimens will be/were collected for the same research project on which you are collaborating. Your colleague may keep a key to the code which could identify the subject from whom the data or specimen was collected- but will never share the subjects' identity or HIPAA identifiers with you.*

If your project meets the criteria of Not Engaged in Human Subject Research an alternate submission process is required.

**IRB-HSR Submission Process**

Proceed to Protocol Builder and answer the question "**Does this study meet the criteria of "not engaged" in human subject research" YES.** Protocol Builder will then provide you with the appropriate documents to complete. *NOTE: This is a DHHS definition. Therefore this alternate application process does not apply if the protocol involves FDA oversight.*