**Not Human Subjects Research (NHSR) (Revised Common Rule)**

**The UH IRB has the determined the following to be NHSR**

**(\*Note – can publish and present as Evaluation data, etc…)**

* **Oral History**
* **Program Evaluation**
* **Assessment**
* **Quality Improvement**
* **Professional Development**
* **Curriculum Development**
* **Internal Investigations where the intention is to return the data to inform the source**
* **De-identified Secondary Data**
* **Information or biospecimens from deceased persons**
* **Publicly available information**

Additionally, the following activities are deemed **NHSR**:

* **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individual(s) about whom the information is collected.
* **Public health surveillance** activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
* Collection and analysis of information, biospecimens, or records by or for a **criminal justice** agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
* Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other **national security** missions.

**Background**: The Federal Policy for the Protection of Human Subjects—the Common Rule—was revised in 2017 to reduce administrative burdens for low-risk research while enhancing protections for human subjects enrolled in greater-than-minimal-risk trials.

Click here for more information: [The Revised Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)

Under some circumstances, research involving only unidentifiable / de-identified or coded private information or biological specimens is considered to be not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.

In order for your use of data and / or biological specimens to not meet the definition of a Human Subject, all of the following conditions must apply:

* The research is not FDA-regulated.
* The research team will not have access to identifiers or keys to link coded data (even temporarily).
* You are not conducting human stem cell research.

Note: If the project is NHSR, whether or not the information or specimens existed or are collected before the study is proposed does not matter. Source: <https://irb.ucsf.edu/research-needing-irb-review>