# Does the activity require IRB submission?

* The term *"investigator"* is used generally here and includes any co-investigators or study team members (STM) of the research.

** To make the appropriate selections under ECOS Section D to correctly reflect the type of research and how data is accessed and recorded for the research.

\# A person who is not a STM shall not access any databases to extract required information.

**HBM:** Human Biological Material

**Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?**

A **systematic investigation** involves a system, method, or plan to search and inquire for facts; detailed or by careful examination. **Generalizable knowledge** means the information can be widely applicable or universal.

No → **IRB submission is NOT required**

Subject to PPDA, cluster and institution policies

Yes – Activity is research

**Is this a restricted Human Biomedical Research under the HBRA 4th schedule?**

E.g. Use of human gametes or human embryos; cytoplasmic hybrid embryos; etc.

Yes → **IRB submission is required****

Applicable local regulations (e.g. Health Products Act, Medicines Act, Human Biomedical Research Act), cluster and institution policies shall be complied with.

No

**Is the research on a living individual whom an investigator* obtains information or HBM through intervention or interaction with the individual to study these information or HBM?**

**Intervention**: Physical procedures or manipulations of those individuals or their environment.
**Interaction**: Communication or interpersonal contact with the individuals.

Yes → **IRB submission is required****

No, there is no intervention or interaction with the individual

**For research on individuals (*including deceased persons*), is the data or HBM obtained by the investigator* viewing individually identifiable private information from databases for the data or HBM?#**

This includes retrieval of existing clinical data for the research.

Yes → **IRB submission is required****

No

**For the research activity conducted, is the investigator* able to ascertain the identity of the participant (*either directly or by linkages to the participant code*)?**

Yes → **IRB submission is required****

No, the investigator* is not able to ascertain the identity of the participant

**Is an effective barrier in place to prohibit the release of the linkage key to the investigator*?**

Examples of effective barriers include de-identification of data through an institution-appointed TTP or through cluster approved processes prohibiting the release of the key.

No → **IRB submission is required****

Yes → **IRB submission is NOT required**

*The investigator* is not obtaining either data through intervention or interaction with living individuals or obtaining identifiable private information or HBM.*

Subject to PPDA, cluster and institution policies