



**University of La Verne Institutional Review Board Policy and Procedure
on Unengaged Investigators
Approved March 10, 2017**

The La Verne IRB relies on the guidance provided by the OHRP for engaged and unengaged institutions to determine whether a researcher is engaged or unengaged. The OHRP guidance can be found at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>. A good way to conceptualize the differences is to use the terminology from grants; key personnel are those who help facilitate the grant (who would be unengaged) vs. investigators (engaged).

Engaged

Unengaged

Performs activities that are engaged in human subjects research	Performs activities that would not be considered human subjects research when their role is examined alone without the context of the rest of the study (e.g., analysis of de-identified data) as long as proper permission have been obtained and external IRB has reviewed and approved, if applicable
Involved in recruitment, enrollment, obtaining informed consent, interventions, data collection (actually collecting the data), analysis of identified data, or long-term follow-up with participants	Facilitating data collection (e.g., providing access to a location, translating the researchers' statements, recording of data while the engaged researcher collects the data, translating recordings, etc.)
Role is to de-identify data for the researcher(s)	Acts as a consultant (e.g., translator, statistician of de-identified data, stenographer or court reporter)
	Manuscript preparation/editing

Procedure

A human subjects training certificate is not required for unengaged personnel.

- a. If the project will have unengaged personnel they do not need to be listed on the Initial IRB Application in IRBManager. However, if the unengaged personnel are known at the time of applying, they can be listed as a "Non Co-Investigator."
- b. If an applicant feels they have an unengaged investigator on the project that does not meeting the criteria in the table above, they may email the La Verne IRB Office for a final determination by the La Verne IRB Analyst or Chair.

- i. The La Verne IRB Analyst or Chair will email a determination to the applicant(s) and upload a copy of the email to the Initial IRB Application as an attachment in the Study area of the application in IRBManager.
- c. If a La Verne student, faculty, staff, and/or administrator is unengaged personnel in human subjects research at another institution, they do not need to apply to the La Verne IRB for approval
- d. If a La Verne student, faculty, staff, and/or administrator is engaged personnel in human subjects research at another institution, the La Verne IRB must approve the protocol using the procedures outlined in the Obtaining Site Permissions policy and procedure.