International Research

International research, defined as research conducted at any location outside the U.S. (U.S., including U.S. territories), requires the researcher to provide the La Verne IRB with the following information:

1. Relevant documentation that provides a clear understanding regarding the local research context. This includes providing information about the cultural, political and socioeconomic factors that may potentially impact every aspect of the research. It also requires providing information regarding local authority structures which may influence the process of acquiring consent, the identification of research participants, or potential sources of coercion.
2. Any additional information, as deemed necessary by the La Verne IRB, before a final approval of protocols for the foreign site may be granted. This may include information about local laws and customs, local IRBs or similar organizations that might function as gatekeeper organizations, and any alternative means or forms related to obtaining informed consent.
3. When cooperative research is involved, note whether the study has domestic U.S. sites that are subject to single-IRB (sIRB) under 45 CFR 46.114 and NIH policy. Foreign sites typically retain local ethics review where required by law or policy.
4. Information necessary to ensure compliance with the General Data Protection Regulation (GDPR) for residents of the European Economic Area (EEA) and with the United Kingdom General Data Protection Regulation (UK GDPR) for residents of the United Kingdom (for the list of EEA countries, see Section 3, GDPR Compliance, below).

Researchers should refer to The International Compilation of Human Research Standards (https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) published by the Office of Human Research Protections (OHRP), which lists roughly 1,100 laws regulations or guidelines that govern research involving human participants in approximately 96 countries. It also includes a list of standards from several international and regional organizations. This compilation of standards was developed to familiarize IRBs/Research Ethics Committees, researchers, sponsors, and others involved with international research with local context laws, regulations, and guidelines to ensure compliance.

Note: For international researchers (e.g., international students), *who are physically located in their home countries at the time of data collection,* there is no need to check the "vulnerable

population" box on the IRB form unless their home country has different agreements and requirements. However, if such researchers collect data in a language other than English, supporting documentation in both English and the local language is still required.

General Requirements

Researchers engaging in international research must:

a. Provide detailed information (and possibly permission) about the geographic location, performance site, and other relevant information regarding where the study will be conducted.
b. Provide a statement showing review and comprehension of The International Compilation of Human Research Standards, and compliance with local context laws, regulations or guidelines that govern research involving human participants.
c. State whether review or permission from a local Institutional Review Board (IRB), Research Ethics Committee (REC), or other relevant ethics authority is required. If such review or permission is required, submit a copy of the local IRB/REC approval or its equivalent, where possible.
d. Provide information about the current social, economic and political conditions for the local context in which research will be conducted.
e. Provide information about any potential additional risks that participants might face as a result of participation.
f. Take into consideration factors relevant to obtaining informed consent from research participants including their literacy levels, confidentiality concerns and local context cultural climate.
g. Provide information regarding the study as it relates to the GDPR
h. Review and adhere to the La Verne IRB translation policy
i. Follow the personal data storage standards in Section 4 for international projects outside the EAA/UK
j. Complete CITI training modules covering GDPR/UK GDPR fundamentals and cross-border transfers (Question 8)

To what does this policy apply (§46.101)?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States." (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/)

GDPR and UK GDPR Compliance

The University of La Verne (La Verne) is identified as a controller of personal information and its vendors are processors. La Verne and the La Verne IRB take compliance with the General

Data Protection Regulation (GDPR) and the United Kingdom General Data Protection Regulation (UK GDPR) to be of the utmost importance. Thus, all researchers wishing to work with EEA residents (which include people living in Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Iceland, Liechtenstein, and Norway) must ensure their study is compliant with the GDPR, and all researchers wishing to work with United Kingdom residents must ensure their study is compliant with the UK GDPR. Moreover, the La Verne IRB consents all EEA and UK residents who are investigators on a study, consultants, and faculty/students who disclose personal information that is collected by the La Verne IRB while abroad.

A. These procedures apply to studies targeting EEA residents or United Kingdom residents, or others identified in B below. Our consent forms have been updated to be compliant with the tenets of the General Data Protection Regulation (GDPR) and the United Kingdom General Data Protection Regulation (UK GDPR). GDPR- or UK GDPR-compliant consent forms are required for all studies where EEA or United Kingdom residents may participate. The consent template must be completed in full, with no omissions, and address all required areas in order to be approved.
B. In addition to research participants who are EEA and UK residents, the following individuals must also be consented:
    a. EEA and UK residents who are investigators on a study.
    b. EEA and UK residents who are consultants.
    c. Faculty/staff/administration/students who disclose personal information that is collected by the La Verne IRB while abroad.
    d. La Verne researchers and external researchers are responsible for identifying EEA and UK residents on their research team, as well as any consultants used.
    e. Research team members (investigators and non-investigators named in the IRBManager application) must be consented through IRBManager and using the templates online (https://laverne.edu/irb/irb-forms-and- examples/informed-consent-forms-templates/)
    f. Faculty/staff/administration/students are responsible for disclosing they are in the EEA and UK.
        i. Faculty/staff/administration/students who are in the EEA and UK at the time of application to the IRB will disclose this on their application and the IRB will consent them within their application for processing their personal data.
C. At this time, storage of personal data for EEA and UK residents is only allowed in the following areas:
    a. Paper forms: locked in a University of La Verne filing cabinet, also locked in a University of La Verne office
    b. Paper forms: locked in a stationary cabinet in researcher's non-University of La Verne office
    c. A password-protected computer stored in a locked University of La Verne office
    d. A password-protected computer that only the researcher can access, stored in a locked non-University of La Verne Office

e. A password-protected drive or similar storage device locked in a University of La Verne filing cabinet, also locked in a University of La Verne office
f. The applicant's University of La Verne email (Google Gmail for students, Outlook for faculty/staff/administration)
g. The University of La Verne's provided OneDrive (other One Drives are not accepted)
h. The University of La Verne's provided Qualtrics
i. The University of La Verne's provided Google Drive (other Google Drives are not accepted unless they fall under (i) below)
j. Dropbox Education or Dropbox Business (evidence of such a subscription is required to be provided during application review)
k. Any other cloud storage that is demonstrated to be FERPA, GDPR and UK GDPR compliant (e.g., a signed contract and evidence of purchase of the appropriate cloud storage package, a signed contract with the data provider showing the desktop requirements have been met, etc.) or non-electronic equivalent with proper documentation of its adequate protections

D. At this time, retain at least 3 years after study closure (per 45 CFR 46.115(b)) and only as long as necessary for the research purpose. Longer retention is permissible under GDPR/UK GDPR research exemptions (Art. 5(1)(e), Art. 89) with safeguards documented in the IRB file.
E. Personal data should be assessed for pseudonymization, encryption of data, only the necessary personal data collected, and other measures of protection for each study in order to implement appropriate security procedures (Articles 25, 32, and 89).
    a. As per the GDPR (Article 25), "that obligation applies to the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility. In particular, such measures shall ensure that by default personal data are not made accessible without the individual's intervention to an indefinite number of natural persons."
F. For transfers of personal data from the EEA or the United Kingdom to the United States, an appropriate data transfer mechanism must be in place.
    a. EEA to U.S.: Use the Standard Contractual Clauses (SCCs, 2021 modular set) or rely on the EU–U.S. Data Privacy Framework (DPF) where the U.S. recipient is DPF-certified. Conduct any required transfer risk assessment and implement supplementary measures as necessary.
    b. UK to U.S.: Use the International Data Transfer Agreement (IDTA) or the UK Addendum to the EU SCCs, and ensure compliance with applicable UK transfer risk assessment and documentation requirements.
G. Personal data that will be collected as part of the study must be disclosed in an informed consent, including personal data collected by third party vendors (or processors), such as Qualtrics. These data can include:
    a. Cookies, IP Addresses, Geotags, etc.
    b. See the informed consent templates for more information (https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/)
H. Special categories of personal data require a signed (written or electronic) informed consent to process and retain these data (although the purpose of scientific research is

allowable under the GDPR (Article 9)). These data include: "racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation" (GDPR, Article 9).

I. The La Verne IRB will field all requests from EEA and UK residents for deletion of their data (pursuant to Article 17 of the GDPR).
    a. If an EEA or UK resident contacts the researcher for such a request, they will forward the request and contact information to the IRB (irb@laverne.edu) immediately as the GDPR requires an **immediate** response to all requests to be forgotten (as their right to object).
    b. Researchers are required to complete a Request to be Forgotten form in Word immediately upon being instructed by the IRB to do so.
        i. All correspondence regarding the personal data of an EEA or UK resident must be provided.
        ii. Researchers must follow the findings of the IRB as it relates to deletion of data.
    c. These requests will be responded to following the provisions in the GDPR and as outlined in the Requests to be Forgotten form in Word by the La Verne IRB.
    d. The La Verne IRB may elect to complete themselves the Request to be Forgotten form in Word.
        i. In this case, the researcher is expected to provide all information to the La Verne IRB necessary to process the document, including all correspondence with the EEA and UK resident, and other necessary information.
    e. If there is no legal basis for retention of the data, the researcher will delete all data, emails (sent and received), and other correspondence with the individual. The greater institution will do so as well.
    f. The La Verne IRB will document this request anonymously in a central repository for the university.

J. The La Verne IRB will field all requests for access to information about the processing of the personal data by EEA and UK residents (and will process these requests pursuant to Article 12 of the GDPR).
    a. If an EEA or UK resident contacts the researcher for such a request, they will forward the request and contact information to the IRB (irb@laverne.edu) as soon as possible, as the GDPR requires a response within one month to all Right to Access requests.
    b. Researchers are required to complete a Right to Access form in IRBManager immediately upon being instructed by the IRB to do so.
        i. All correspondence regarding the personal data of an EEA or UK resident must be uploaded to the form. If the La Verne IRB is completing the form on your behalf, you must provide all correspondence to the IRB immediately.
    c. These requests will be responded to by providing another copy of the informed consent (approved May 25, 2018 or later by the IRB) as all information required by the GDPR will have been verified to be included in the consent at the time of

the initial approval of the application.

d. The University of La Verne may charge a reasonable fee pursuant to the GDPR (Article 12) if the requests are unusually repetitive.
e. If the identity of the EEA or UK resident is reasonably doubted, additional information may be requested to verify their identity (Article 12, GDPR).

K. All questions regarding rights as it relates to personal data by EEA and UK residents should be sent to the La Verne IRB immediately.
   a. For written and electronic questions, send the original documents and/or emails to the La Verne IRB (irb@laverne.edu, or drop off original documents at our office **after** notifying us of email you will be dropping them off)
   b. For verbal questions, collect and email the EEA or UK resident's name and contact information so the La Verne IRB can respond.
   c. The La Verne IRB will document these situations on the study in IRBManager, which includes all correspondence on the matter, a list of actions taken and when, and a note on the final resolution. The La Verne IRB will answer all questions posed by the EEA or UK resident.

L. Data rectification will be facilitated by the La Verne IRB following the provisions in Article 16 of the GDPR.
   a. For written and electronic data rectifications sent to the researcher, the researcher will send the original documents and/or emails to the La Verne IRB (irb@laverne.edu, or drop off original documents at our office **after** notifying us of email you will be dropping them off)
   b. The researcher will be contacted by the La Verne IRB if data collected by the researcher needs to be rectified or additional information added to complete the personal information stored about a particular EEA resident
      i. The researcher must immediately comply with these requests
   c. The La Verne IRB will document these situations on the study in IRBManager, which includes all correspondence on the matter (with necessary redactions), a list of actions taken and when, and a note on the final resolution.

M. All requests for data restriction should be sent to the La Verne IRB. Data restriction requests can be submitted by EEA and UK residents for the reasons listed in Article 18 of the GDPR.
   a. If an EEA or UK resident contacts the researcher for such a request, they will forward the request and contact information to the La Verne IRB immediately as the GDPR requires an **immediate** response to all requests for restriction of personal data.
      i. For written and electronic data rectifications sent to the researcher, the researcher will send the original documents and/or emails to the La Verne IRB (irb@laverne.edu, or drop off original documents at our office **after** notifying us of email you will be dropping them off)
   b. The researcher will be contacted by the La Verne IRB if data collected by the researcher needs to be restricted for an EEA or UK resident
      i. The researcher must immediately comply with these requests
   c. The La Verne IRB will process all data restriction requests in compliance with Article 18 of the GDPR.
   d. The La Verne IRB will document these situations on the study in IRBManager,

which includes all correspondence on the matter (with necessary redactions), a list of actions taken and when, and a note on the final resolution.

N. Research data breach notifications to EEA and UK residents must be completed within 72 hours of notification of the breach to a representative at University of La Verne (e.g., the researcher, the IRB, etc.), unless not required by the GDPR in Articles 33 and 34. It is
required if it is "likely to result in a high risk to the rights and freedoms of natural persons" (Article 33).
    a. If someone contacts the researcher to notify them of the breach, they will forward the notification and contact information of the notifier to the La Verne IRB (irb@laverne.edu) immediately (within 8 hours) as the GDPR requires an **immediate** response to notify of particular data breaches.
        i. For written and electronic data rectifications sent to the researcher, the researcher will send the original documents and/or emails to the La Verne IRB (irb@laverne.edu, or drop off original documents at our office **after** notifying us of email you will be dropping them off)
    b. Researchers are required to complete a Personal Data Breach form in IRBManager immediately upon being instructed by the IRB to do so.
        i. All correspondence regarding the breach must be uploaded to the form. If the IRB is completing the form on your behalf, you must provide all correspondence to the IRB immediately.
    c. In consultation with the Provost's Office and their designee, a breach notification will be sent to the participants within 72 hours of the initial notification to a representative of the University of La Verne.
        i. Notifications will contain the required information in Article 33 of the GDPR.
O. EEA and UK residents who are also children have special regulations; contact the IRB Office (irb@laverne.edu) if you are designing a study that will involve child EEA residents.

Personal Data Storage Standards for Non-EAA/UK Residents

A. Store only on ULV-approved platforms. Choose a storage region that complies with the host country's laws. If a country requires localization, keep identifiable data in-country until a lawful transfer path is in place.
B. Enforce encryption in transit and at rest, MFA, least-privilege access, and university device management. Separate the code-key from study data when using pseudonyms. Keep direct identifiers in a separate, access-restricted store.
C. Collect/store only what is necessary. Classify data sensitivity and apply heightened controls to sensitive categories (e.g., health, precise location, financial, minors). Avoid storing direct identifiers unless unavoidable.
D. Maintain encrypted backups. If a country requires localization, keep backups in the same jurisdiction. Periodically test restore.
E. Retain access and administrative audit logs for at least the IRB record-keeping period; review on request.
F. Retain records ≥ 3 years after study closure (45 CFR 46.115(b)) or longer only as

necessary for research, then delete or irreversibly de-identify.

G. Report suspected breaches to ULV IRB/Privacy immediately. Follow host-country breach-notification rules if applicable.
H. Use vendors that provide independent security attestations (e.g., SOC 2/ISO 27001) and transparent sub-processor listings. Document the selected data center region(s).
I. No personal cloud accounts, personal email, or unencrypted removable media. No local storage on unmanaged devices.