STEP-BY-STEP: ADDING NON-UK STUDY PERSONNEL

Non-UK individuals assisting an investigator with their research may need to be added as non-UK study personnel on the research protocol. The following step-by-step guide is intended to walk the investigator through the process of adding non-UK study personnel to a research protocol.

Checklist for Non-UK Study Personnel	
	Step One: Assess the role of the non-UK individual to determine if they will be engaged in research.
	Step Two: Attach an Individual Investigator Agreement (IIA) signed by the non-UK individual and the Vice President of Research (VPR) to the draft protocol
	Step Three: Enter the non-UK individual into the E-IRB system and add the individual to the draft protocol as non-UK study personnel.
	Step Four: Email Human Subject Protection (HSP) Training documentation (e.g., certificate of completion) to hsptrainingsupport@uky.edu

STEP ONE - Determine Whether Individuals Will Be Engaged in Research: The first step in establishing whether an individual needs to be added as non-UK study personnel is to **determine whether individuals will be engaged in research**. Study personnel that engage in research are individuals who:

- Interact or intervene with research participants.
- Access Personally Identifiable Information (PII) of participants or research data collected from participants.
- Take part in the informed consent process.

Non-UK individuals that meet any or all criteria for being engaged in research will need to be added to the study protocol as non-UK study personnel. *The one exception would be if an IRB Authorization Agreement (IAA) is in place and the other institution (reviewing) is the responsible party agreeing to confirm training for study personnel from their institution.*

STEP TWO - Individual Investigator Agreement (IIA): An **Individual Investigator Agreement** (IIA) is an agreement the non-UK study personnel signs agreeing to follow relevant institutional policies and procedures for the protection of human subjects. An IIA requires the signature of the non-UK individual and the Vice President of Research (VPR) before it is attached to a protocol draft.

The investigator can fill out the protocol information section of the IIA before giving it to the non-UK individual to sign. The non-UK individual must sign the IIA in Adobe Digital Signature or in ink and return it to the investigator. The investigator will need to email the signed IIA to IRBReliance@uky.edu. The ORI Reliance Team will obtain the signature of the Vice President for Research (VPR) and return the IIA to the investigator. The entire process takes about a week so steps two, three, and four may be done concurrently.

STEP THREE - Add Non-UK Study Personnel to E-IRB Draft Application: An investigator must enter the individual into the E-IRB system before they **add non-UK study personnel to an E-IRB draft application**. An E-IRB video tutorial How to Add and Remove UK and Non-UK Study Personnel provides instructions for entering the individual into the E-IRB system. Instructions for entering a non-UK individual into the E-IRB system start at minute 7:43. Or refer to the quick reference guide here:

- From the main E-IRB dashboard, click “Manage Study Personnel” and choose the “Non-UK Personnel” option.
- Check to make sure the individual is not already in the system. Use different filters, do multiple searches, and be sure to use the correct spelling.
- If there is no record, click “Insert New.”
- Complete the record fields as fully and as accurately as possible before submitting.

Once the individual is entered into the E-IRB system, the investigator can add the individual to the protocol in the Study Personnel section of the draft application.

STEP FOUR - Human Subjects Protection (HSP) Training: All study personnel, whether UK or non-UK, must complete **Human Subjects Protection (HSP) Training.** The IRB does not mandate the type or completion date of HSP Training for individuals who are not UK employees or students. If external study personnel have completed an equivalent HSP Training outside of UK, please email the document to hsptrainingsupport@uky.edu for review to confirm equivalency. If study personnel have not completed previous HSP training, ORI provides several publicly available HSP training courses for Non-UK Research Personnel.

PUBLICLY AVAILABLE NON-UK STUDY PERSONNEL HSP TRAINING OPTIONS	
Title/Description	**Weblink**
University of Kentucky (UK) Office of Research Integrity (ORI) Non-UK Human Subject Protection (HSP) Course *You MUST have a Coggno account to receive a certificate.	*See instructions for creating an account* [HTML]
Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) Human Research Protection Training	[HTML]
The **Association of Clinical Research Professionals (ACRP) online Ethics and Human Subject Protection** training without Contact Hours is available to the public at no cost.	[HTML]

In addition, HSP Training courses are available for non-research individuals from the community who assist with or partner with researchers to provide input to community needs or engage participants via their role in the community.

COMMUNITY-BASED NON-UK STUDY PERSONNEL HSP TRAINING OPTIONS	
Title/Description	**Weblink**
CIRTification: Community Involvement in Research (CIRT) Developed by the University of Illinois at Chicago	CIRT
K-12 Teacher & Support Staff Human Subject Protection (HSP) Training For non-UK teachers and support staff helping with research in a K-12 classroom.	K-12 Teacher & Support Staff HSP Training
Research Ethics for All (RE4ALL) Research ethics training for Community Research Partners with developmental disabilities.	RE4ALL
Johns Hopkins University Human Subjects Research Ethics Field Training Guide Training document available multiple language translations; useful for international research study personnel	International Field Training Guide
Research Ethics Training Curriculum for Community Representatives (RETC-CR) designed for international research.	RETC-CR
Building Research Integrity and Capacity (BRIC) Program created by Research Optimal Digital Ethics Health (ReCODE) designed for community partners with emphasis on research design and research ethics.	BRIC

Investigators will need to email the HSP Training certificate or equivalent documentation to hsptrainingsupport@uky.edu . Include the non-UK individual's name and email used to add as study personnel in E-IRB. The Office of Research Integrity (ORI) will manually update the individuals training record in E-IRB. HSP Training for non-UK study personnel has no expiration date.