

Human Subjects Research (HSR) Training Compliance Review Process

Purpose: To ensure administrative oversight and monitoring of PIs and co-investigators' adherence to the institutions' human subject training requirements.

The faculty, staff, and doctoral student populations who are involved in research or are teaching about research need to have un-expired CITI Group 2 - Biomedical Human Subjects Researchers or Group 1 - Social Behavioral and Educational Human Subjects Researchers training.

The WP undergraduate and master's student population who are involved in research need to have un-expired CITI Group 3 - Student Human Subject Researchers training.

On-Going Review Compliance with CITI HSR training:

OSP System-wide monitoring and automated reminders

The Cayuse System will monitor and provide system wide reminders to keep the general William Paterson University population body informed of whose Human Subjects' research training is going to expire within the next 30 days. The automated reminders by the system will notify those with expiring protocols via email and will follow a general Human Subjects' research training expiring format.

IRB Protocol specific Human Subjects Research Training Monitoring

The expiration date of CITI HSR training is checked by the IRB Analyst at the time of initial protocol submission against the project period to ensure that the HSR training is current and will not expire during the first year of the project.

If the training record is found to be incomplete, the IRB analyst will notify the investigator that they must complete this required training. IRB analyst will track completion of training. IRB Review notices will not be issued until training is completed by the PI and all investigators listed on the protocol.

Additionally, on a quarterly basis, the IRB Analyst will conduct a review of training records to monitor compliance with Human Subjects Research training requirements.

This audit will include monitoring the following reports available through CITI "Set to Expire List" and the "Overdue List"

Monitor the **Set to Expire List in CITI:**

1. On a quarterly basis, WP CITI Administrator (or IRB Administrator) will export from CITI the “**Set to Expire list**” covering the next 120 days. This list will include people whose HSR training will expire in the next **120 days** and will be saved in the appropriate IRB SharePoint folder for the IRB Analyst to access.
2. The IRB Analyst will run the IRB PI's report and Co-PI Report (Reporting> Classic Reporting> Customer Reports. On Cayuse named ‘Soon to expire list.’ From Cayuse HE to generate the list of current Investigators with active Human Ethics protocols.
3. The IRB Analyst will compare the Investigator list with the Set to Expire list.
4. The IRB Analyst will notify the expiring PIs that they need to complete training within 30 days.
5. The IRB Analyst will report investigators who do not complete the required training within 30 days and the impacted protocols to the IRB at the next board meeting.
6. The Board will assess the risk of non-compliance with these training requirements and direct IRB Analyst on the next steps.

Monitor the **Overdue List in CITI**

1. The WP CITI Administrator (or IRB Administrator) will run the export from CITI the “**Completion Reports That Are Now Overdue,**” and will save it in the appropriate IRB SharePoint folder for the IRB Analyst to access.
2. The IRB Analyst will run the IRB PI report and CO-PI (Investigator List) from Cayuse HE (Reporting> Classic Reporting> Customer Reports from Cayuse HE to generate the list of current Investigators with active Human Ethics protocols.
3. The IRB Analyst will compare the Investigator List to ensure that CITI HSR training to identify the investigators whose training has expired.
4. The IRB Analyst will notify each expired investigator that their training has expired. Investigators will not be permitted to perform any human subjects until completed training is reviewed by the IRB. Investigators who fail to meet these training requirements within 14 days of the initial notification may receive further sanctions by the Board.

5. The IRB Analyst will report to the IRB Board all investigators with expired training and the protocols that are impacted by this noncompliance. Continued failure to comply with training requirements will also be reported to the Board.
6. The Board will review the risks of non-compliance with these training requirements and will determine if the research should be terminated. The board may also opt to issue further sanctions, if appropriate. The Board will direct the IRB Analyst to the next steps.

To ensure continued compliance with CITI HSR training completion:

The IRB will audit Human Subjects Research training compliance audit on a bi-annual basis using the following process:

1. The IRB Administrator will be responsible for conducting an audit of the current active IRB protocols. A sample of 20% of the current active protocols will be identified to review compliance with WP IRB's Human Subjects Research training requirements.
2. The IRB Administrator will review the training completed by the investigators listed on these protocols.
3. Investigators who do not currently comply with the training requirements will be contacted and required to complete this training within 14 days. Human Subjects Research activities must cease until training is completed and reviewed by the IRB Administrator.
4. The results of this audit will be presented to the Board.