HARVARD LONGWOOD CAMPUS

HARVARD MEDICAL SCHOOL | HARVARD School of Dental Medicine | HARVARD SCHOOL OF PUBLIC HEALTH

ORARC
OFFICE OF REGULATORY AFFAIRS AND RESEARCH COMPLIANCE

Closing Time: What Researchers Departing HLC Schools Should Know

QIP Education Session
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Today's Agenda

During this education session, attendees will:

- Review **study closure policies** that impact both active Harvard researchers and departing researchers
- Learn the **criteria** for study closure eligibility, and how to close studies in ESTR
- Determine **study-specific next steps when leaving Harvard** (for both active and ceded studies)
- Establish action items needed to successfully **transition** studies from Harvard to a new institution
- Distinguish **PI-specific responsibilities** when research at Harvard is complete
- Identify other considerations that could impact study closure and/or study transition

Let's begin with two key items for everyone…

Two IRB policies applicable to both active Harvard researchers and those departing Harvard:

1. Studies must be closed with the IRB, once eligible

2. Researchers must follow record retention policies after study closure

Study Closure Criteria

Eligibility:

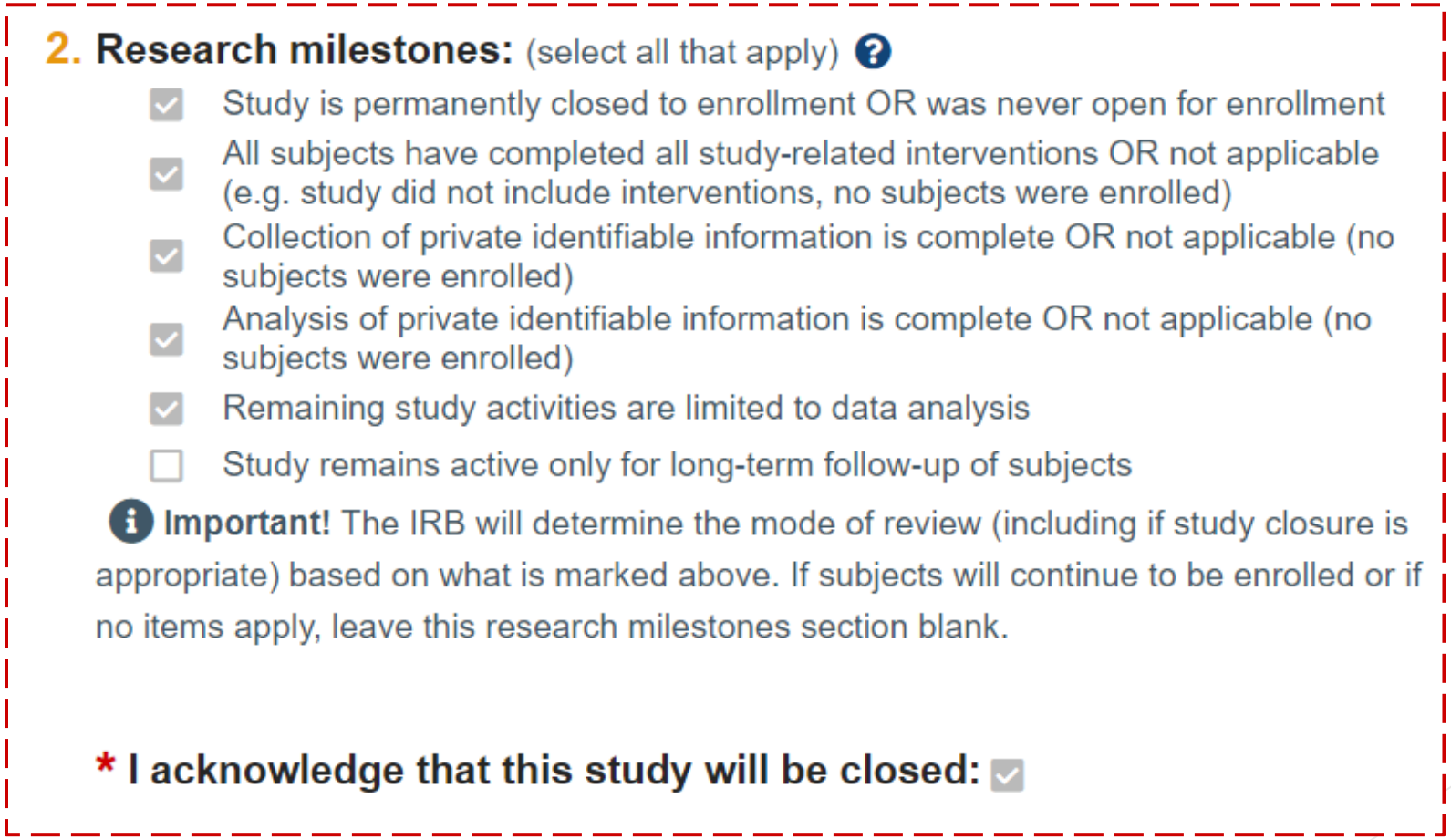
Study closure is appropriate when the following four research milestones have been met:

1. The research is permanently closed to enrollment;
2. All participants have completed all research-related interventions/interactions;
3. Collection of private identifiable information is completed, **and**
4. Analyses of private identifiable information is completed.

Under close-out status, de-identified data analysis and manuscript preparation can occur indefinitely.

Study Closure in ESTR

ESTR Study Closure Instructions: https://estrsupport.fss.harvard.edu/study-closure



Record Retention

- Investigators must maintain human research records and study documents, including signed and dated consent documents, according to ORARC policy: for at least **seven years after closing** the Human Research.

- Investigators must also retain research records according to their specific funder, sponsor, and/or other overseeing regulatory body policies (e.g. FDA, DoD, NIH).

- Investigators should retain research records according to the Harvard General Records Schedule (i.e. Human Subjects Protection Records (3550) (HarvardKey log in required)

Reference:

ORARC Investigator Manual, Record Retention Policy: https://cdn1.sph.harvard.edu/wp-content/uploads/sites/2352/2022/03/HRP-103-HLC-Investigator-Manual-1.pdf#page=23

Now, on to what researchers **departing** HSPH, HMS, or HSDM need to know - in three steps…

Step 1: Identify all active human research applications on file in ESTR in which the investigator serves as either PI or research staff.

This would include both:

- Active human subjects research studies reviewed by the HLC IRB
- Reliance agreements/external IRB records where the HLC IRB relies on another IRB of Record

Step 2: For active human subjects research studies reviewed by the HLC IRB…

Departing researchers have three options:

1. Continue the human research at new institution:
   - Contact the new institution's IRB office for instructions on how to secure review.
   - If any HLC School agents will collaborate on this human research, the HLC IRB should review their involvement and/or determine whether the study is eligible for reliance.
   - If/once the study is approved at the new institution, the PI should close their studies at Harvard.
2. Continue the human research at Harvard:
   - The PI should identify a new (HLC-affiliated) PI and submit a Modification in ESTR to change the PI on the project.
   - If the former PI will continue research activities, they should be added as a study team member on the current ESTR record, securing any required reliance agreements from their new institution.
3. Study closure

Step 3: For reliance agreements/external IRB records where the HLC IRB relies on another IRB of Record…

Departing researchers have two options:

1. PI will continue involvement in the ceded human research at new institution:
   - Contact the new institution's IRB office for instructions on how to secure a new review or establish a new reliance agreement.
   - The PI should close their studies via ESTR, unless HLC affiliates will continue to collaborate on this human research (see below).

2. Harvard agents to continue involvement in ceded human research:
   - The HLC IRB should review their involvement and confirm whether reliance is still appropriate.
   - If reliance is still appropriate, a new (HLC School-based) PI should be named in the ESTR record and reported to the reviewing institution/IRB.
   - If reliance is not appropriate, the PI should close their study/studies via ESTR.

Other Considerations

- **If the study has federal funding:** Ensure the PI's institution and contact information are updated with the sponsor.

- **If the study is a Clinical Trial:** Update the ClinicalTrials.gov record to ensure the PI's institution, contact information, and the listed responsible party are all accurate. Discuss with the HLC clinicaltrials.gov administrator to determine whether transfer of the clinicaltrials.gov record is appropriate.

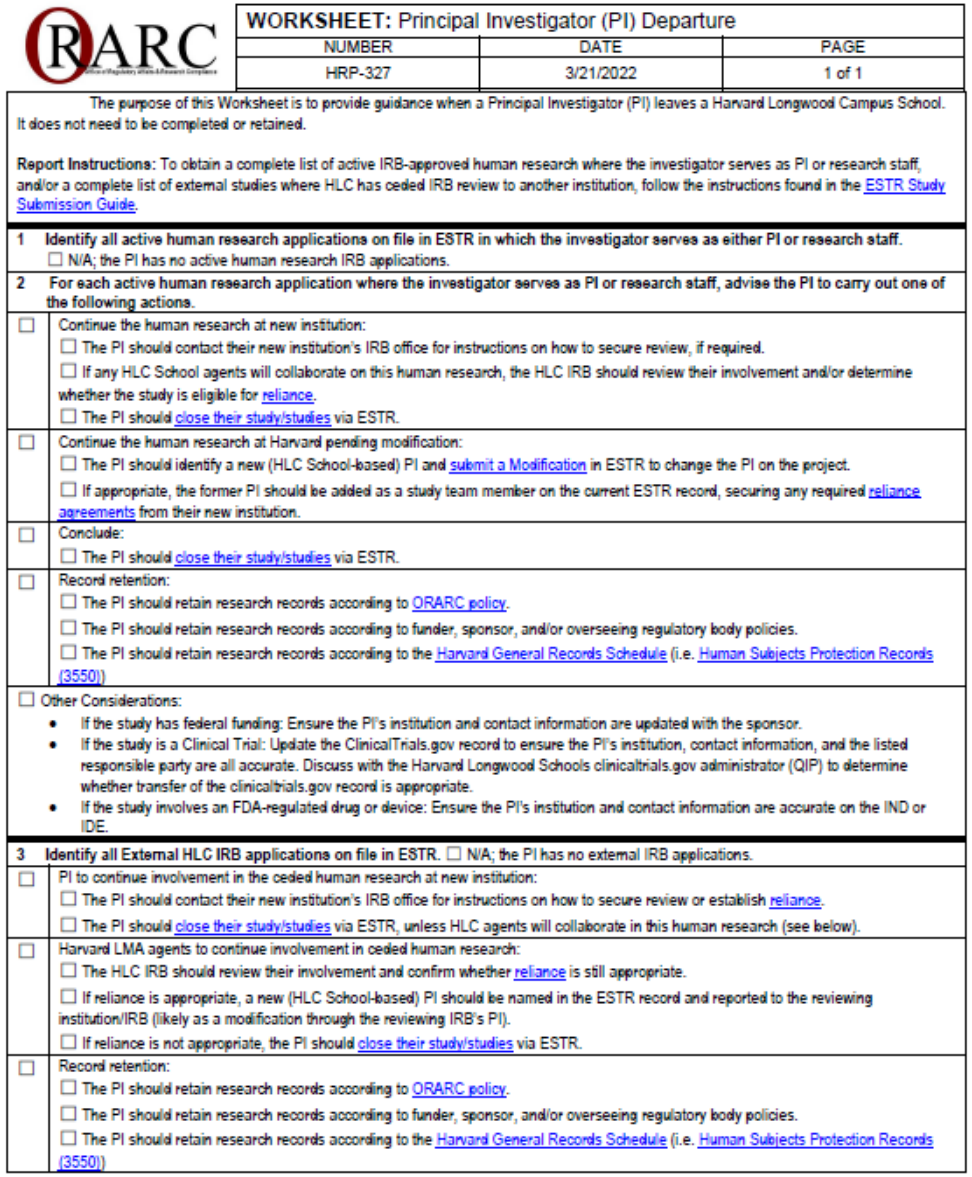
- **If the study is FDA-regulated:** Ensure the PI's institution and contact information are accurate on the IND or IDE. Ensure all activities, including de-identified data analysis, are complete (FDA regulated studies cannot be closed if any data analysis is ongoing).

Departure Tools & Resources: IRB

- Use the HLC PI Departure Worksheet (HRP-327) as guidance. Available in the ESTR Library.

- **Report Instructions:** To obtain a complete list of active IRB-approved human research where the investigator serves as PI or research staff, and/or a complete list of external studies where HLC has ceded IRB review to another institution, follow the instructions found in the ESTR Study Submission Guide.

- Your department-assigned IRB Review Specialist is available to assist at any time.



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WORKSHEET: Principal Investigator (PI) Departure

NUMBER	DATE	PAGE
HRP-327	3/21/2022	1 of 1

The purpose of this Worksheet is to provide guidance when a Principal Investigator (PI) leaves a Harvard Longwood Campus School. It does not need to be completed or retained.

Report Instructions: To obtain a complete list of active IRB-approved human research where the investigator serves as PI or research staff, and/or a complete list of external studies where HLC has ceded IRB review to another institution, follow the instructions found in the ESTR Study Submission Guide.

1 Identify all active human research applications on file in ESTR in which the investigator serves as either PI or research staff.
☐ N/A; the PI has no active human research IRB applications.

2 For each active human research application where the investigator serves as PI or research staff, advise the PI to carry out one of the following actions.

☐ Continue the human research at new institution:
- ☐ The PI should contact their new institution's IRB office for instructions on how to secure review, if required.
- ☐ If any HLC School agents will collaborate on this human research, the HLC IRB should review their involvement and/or determine whether the study is eligible for reliance.
- ☐ The PI should close their study/studies via ESTR.

☐ Continue the human research at Harvard pending modification:
- ☐ The PI should identify a new (HLC School-based) PI and submit a Modification in ESTR to change the PI on the project.
- ☐ If appropriate, the former PI should be added as a study team member on the current ESTR record, securing any required reliance agreements from their new institution.

☐ Conclude:
- ☐ The PI should close their study/studies via ESTR.

☐ Record retention:
- ☐ The PI should retain research records according to ORARC policy.
- ☐ The PI should retain research records according to funder, sponsor, and/or overseeing regulatory body policies.
- ☐ The PI should retain research records according to the Harvard General Records Schedule (i.e. Human Subjects Protection Records (3550))

☐ Other Considerations:
- If the study has federal funding: Ensure the PI's institution and contact information are updated with the sponsor.
- If the study is a Clinical Trial: Update the ClinicalTrials.gov record to ensure the PI's institution, contact information, and the listed responsible party are all accurate. Discuss with the Harvard Longwood Schools clinicaltrials.gov administrator (QIP) to determine whether transfer of the clinicaltrials.gov record is appropriate.
- If the study involves an FDA-regulated drug or device: Ensure the PI's institution and contact information are accurate on the IND or IDE.

3 Identify all External HLC IRB applications on file in ESTR. ☐ N/A; the PI has no external IRB applications.

☐ PI to continue involvement in the ceded human research at new institution:
- ☐ The PI should contact their new institution's IRB office for instructions on how to secure review or establish reliance.
- ☐ The PI should close their study/studies via ESTR, unless HLC agents will collaborate in this human research (see below).

☐ Harvard LMA agents to continue involvement in ceded human research:
- ☐ The HLC IRB should review their involvement and confirm whether reliance is still appropriate.
- ☐ If reliance is appropriate, a new (HLC School-based) PI should be named in the ESTR record and reported to the reviewing institution/IRB (likely as a modification through the reviewing IRB's PI).
- ☐ If reliance is not appropriate, the PI should close their study/studies via ESTR.

☐ Record retention:
- ☐ The PI should retain research records according to ORARC policy.
- ☐ The PI should retain research records according to funder, sponsor, and/or overseeing regulatory body policies.
- ☐ The PI should retain research records according to the Harvard General Records Schedule (i.e. Human Subjects Protection Records (3550))

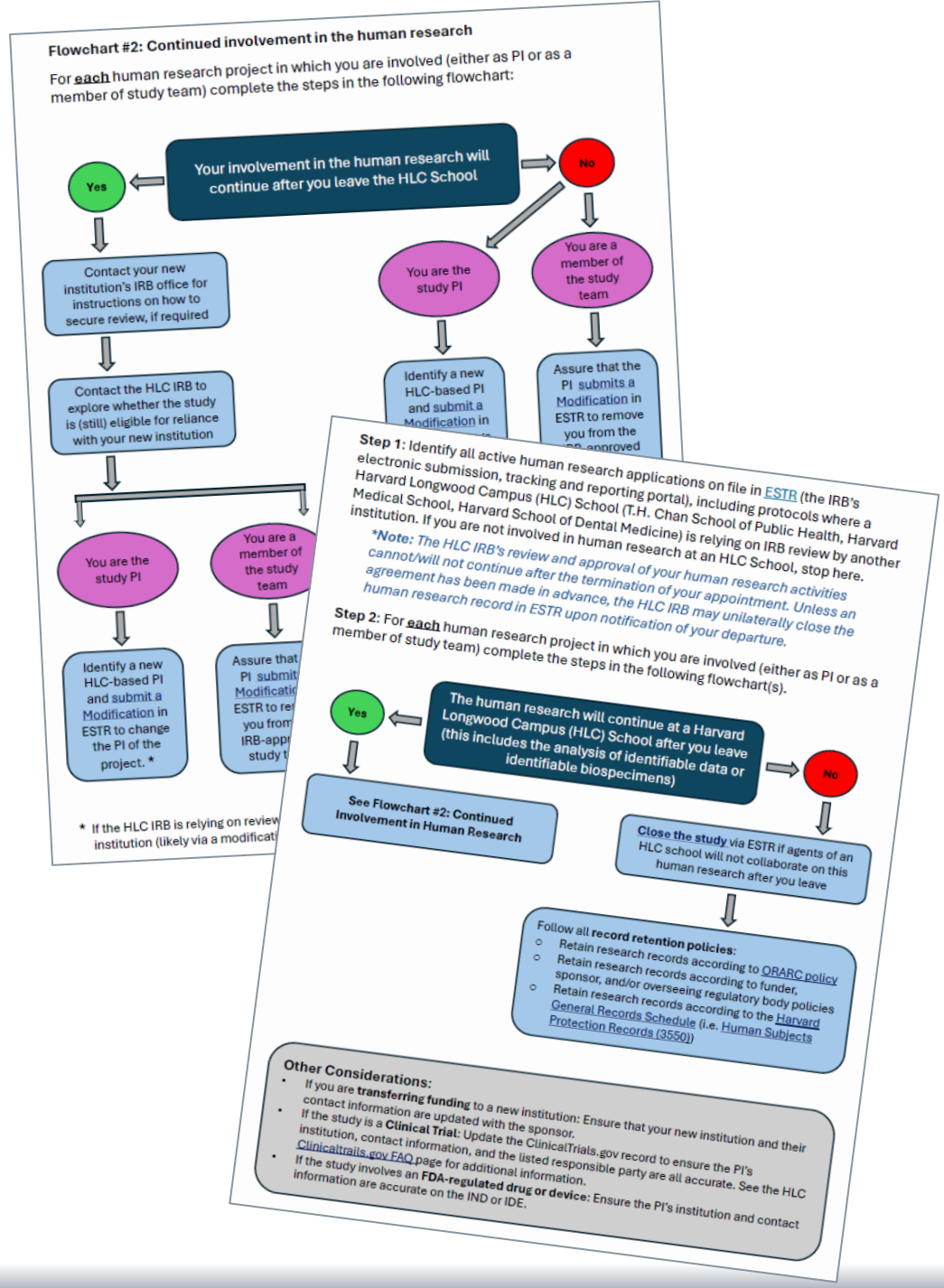
Departure Tools & Resources: QIP

Check out the Quality Improvement Program's

Departing Researcher Guide

This flow chart is for individuals leaving an HLC campus school; it can be used to determine appropriate next steps for transitioning human research.

- https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/study-management-tools/



Departure Tools & Resources:

Countway Library and LMA Research Data Management Group

The LMA Research Data Management Working Group (RDMWG) hosts a fantastic website about research data at all points within its lifecycle. This includes resources and tools for departing researchers, as well as templates to offboard PIs and tools to transfer critical knowledge between study team members.

Resources:

- **Knowledge Transfer File Template**: Tool to capture research project knowledge and document essential information related to projects and datasets. Ensures projects continue to be consistent and efficient following a researchers departure.
- **Knowledge Transfer File Template Webinar**: Watch a recording of the Spring 2024 RDM Webinar detailing the Knowledge Transfer File resource. Presentation slides and audio podcast from the session are available.
- **RDM Offboarding Checklists**: Checklists that outline steps for offboarding employees/trainees when they leave Harvard.

General Reference & Resources

- **ORARC Website:** https://www.hsph.harvard.edu/orarc
- **Department-Assigned IRB Review Specialists:** https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/department-assignments/
- **HLC IRB Investigator Manual:** https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/investigator-manual/
- **ESTR Support Site:** http://estrsupport.fss.harvard.edu

QUESTIONS?