Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #15	Closures and Transfers	
Approved by IRB Chair	R. Andrew Shanely	Date: 04/23/2025
Approved by RP Director	Shante' Mathes	Date: 04/24/2025

I. PURPOSE

This document details Appalachian State University's IRB's unit standard for research with human participants regarding approved protocol transfers and closures. The requirements in this document apply to studies qualifying for exemptions and studies deemed non-exempt.

II. AUTHORITY

In accordance with 45 CFR 46, the HHS Policy for the Protection of Human Research Subjects, compliance with pertinent federal and State laws or applicable regulations that provide additional protections for human participants must be followed.

III. RESPONSIBILITY

1. Research personnel are responsible for designing and implementing research with human participants that complies with 45 CFR 46, University Policy 209, all IRB unit standards, and reasonable requests from the IRB office or IRB Full Board. Researchers must ensure that the Appalachian State University IRB office is updated with a study's status, including study transfers and study closures.

2. Research protections (RP) staff are responsible for ensuring researcher compliance with 45 CFR 46, University Policy 209, and all IRB unit standards. This is accomplished through protocol review and approval.

IV. DEFINITIONS

1. Protocol Closures
   A protocol is closed when all research procedures with humans and the analysis of their identifiable data or identifiable biospecimens is completed.

2. Protocol Transfer
   Whenever any of the following occur, the principal investigator (PI) must transfer their research responsibilities to an Appalachian State researcher in order for the protocol to remain open – a process referred to as protocol bequeathal:
   a. The PI will depart from Appalachian State University, but Appalachian State University will remain engaged in the research after the PI's departure;
   b. The PI will no longer be involved as a research team member, but the research will continue under the direction of another agent of Appalachian State;
   c. The PI will remain engaged in the research, but wishes to transfer the PI responsibility to another Appalachian State University researcher.

V. PROCEDURES

All human subjects research studies, regardless of review level, must seek IRB approval for transfer of an approved protocol to another PI and to "close out" an approved IRB protocol.

A. Study Closure

1. Process
    a. Protocols should be closed when:
        i. all related study activities will no longer involve research with human participants, and the link between identifiers and data or biospecimens has been destroyed: OR
        ii. the investigator(s) are no longer under the purview of Appalachian State's IRB and no other Appalachian State researcher will remain engaged in the research.

    b. Protocols do not need to be closed if the researcher engages in cooperative research and Appalachian State University is not the IRB of record.

    c. Once a protocol is closed, IRB approval ceases and no research activities with human participants are permitted to occur.

2. Required Information to be Submitted to the IRB
    a. A statement that the study is permanently closed to enrollment.
    b. A statement that all participants have completed all study-related interventions.
    c. A statement that collection of private identifiable information and/or identifiable biospecimens is complete.
    d. A statement that analysis of private identifiable information and/or identifiable biospecimens is complete.
    e. A statement that the data, specimens, and recordings have been managed in accordance with the IRB protocol, including sharing, storage or disposition.
    f. A statement regarding the final number of participants who completed all study related procedures.
    g. A statement about any unanticipated problems, adverse events, participant complaints, and participant withdrawals that occurred during the research and any relevant resolutions.
    h. If the study is closing before completion, provide a statement as to why the study is closing before completion and provide the relevant information in bullet points a-g above.

B. Study Transfer, PI Leaving App State

1. Process
    a. Protocol transfer is initiated through an amendment to the protocol that is submitted to the Appalachian State IRB Office.

    b. The new investigator for whom the protocol is transferred must have access to all procedures, documentation, and data once the bequeathal process is complete after the protocol amendment is approved or determined to be exempt by the Appalachian State IRB or IRB Office.

    c. In rare circumstances where a lead investigator has left the university without updating a protocol, the PIs' department head can work with the IRB staff to address transferring the protocol.

2. Required Information to be Submitted to the IRB
    a. The amendment(s) to transfer a protocol must include the following:
        i. Documentation of which PI is being removed from the protocol;
        ii. Documentation of which researcher is assuming the leaving PI's responsibilities;
        iii. Provision of proof of completion of human subject training requirements for all new personnel on the research team; and
        iv. Updates to any documents that provide the name or contact information of the PI.

b. Any necessary updates to the IRB application and supporting documentation as a result of this personnel change.

3. IRB Review and Approval Considerations
    a. The expertise of the researcher assuming the role of the PI.
    b. If the required human subjects training has been completed.
    c. If all appropriate documentation and relevant sections of the IRB protocol have been updated.
    d. Any real or perceived conflicts of interest related to the new researcher and the study's participants or design.

C. Study Transfer, to App State

1. Process
    a. When a researcher becomes an agent of Appalachian State University and they want to continue research from a protocol that was already approved by a non-Appalachian State IRB that is registered with an FWA number, they must apply to transfer their protocol to Appalachian State.

    b. Researchers should transfer all studies reviewed at any IRB level (i.e., exempt, exempt with a limited review, expedited, and convened full board) if they plan to continue the research as an agent of Appalachian State and the research is not cooperative.

    c. To transfer a study to Appalachian State University, a researcher will complete the relevant IRB application processes for either an exempt or non-exempt research protocol.

    d. Cooperative research that will continue may not need to be transferred to Appalachian State unless an Appalachian State University PI remains engaged in the research.

2. Required Information to be Submitted to the IRB
    a. Transferring a study involves submitting a new study protocol for review and approval to the Appalachian State University IRB Office.

    b. Investigators wanting to transfer a study to Appalachian State University must provide the IRB Office with the following information:
        i. If appropriate, a request for a reliance agreement; OR
        ii. A protocol submission that includes:
            1. A completed IRB application;
            2. All materials that must continue to be implemented;
            3. Proof of human subjects training completion in accordance with Appalachian State University IRB standards for all Appalachian State University affiliates (faculty, staff, students, and any individual investigators) on the research team;
            4. Approval letter or exemption determination letter for the previously approved protocol from the previous IRB.

3. IRB Review and Approval Considerations
    a. The IRB will review the project in its entirety to determine if the study continues to meet the criteria for approval.

    b. The IRB will review the project in its entirety to determine if the study accounts for applicable laws in North Carolina, and policies and procedures at Appalachian State University.

    c. All appropriate documentation and relevant sections of the IRB protocol must be updated with Appalachian State University information.

d. The application must disclose all real or perceived conflicts of interest related to the researcher's new role at Appalachian State University as related to the study's participants, design, or sponsorship.