FWA Compliance	Department: Research	
Origination Date: 08/01/2022	**Effective Date:** 10/3/2022	**Next Review Date:** 10/3/2023
Policy contact: Research Director Barbara A. Konkle, M.D., Barbara.Konkle@WACBD.org	**Version:** # 1	

PURPOSE: Establish written procedures to ensure compliance with the Office for Human Research Protection (OHRP) and Federalwide Assurance (FWA). WIC is required to have written procedures for ensuring reporting unanticipated problems, serious or continuing noncompliance and suspension or termination of IRB approval as well as IRB reviews to which the FWA applies.

SCOPE: WIC conducts human subjects research under FWA00028301, therefore the scope of this policy applies to WIC and WIC's human research subjects.

POLICY STATEMENT: WIC is committed to maintaining an environment supportive of human subjects research which is compliant with OHRP policies and procedures to ensure the protection of human subjects in research. The responsibility for the conduct of human subjects research at WIC falls under the Research Director, including timely renewal of the FWA to ensure it is maintained. WIC does not have its own IRB but uses the University of Washington IRB or commercial IRBs which are registered under their own FWA.

DEFINITIONS:

Term	Definition
FWA	Federalwide Assurance
OHRP	Office for Human Research Protection
IRB	Institutional Review Board

PROCEDURES:

Procedure 1- WIC Responsibilities	
Ensuring prompt reporting of noncompliance	1. All research involving human subjects as defined by U.S. Health and Human Services 45CFR46 will be reviewed and approved by an accredited IRB prior to initiation of research. 2. Unanticipated problems involving risks to subjects or others will be promptly reported to the IRB to which the FWA applies for the study. 3. The Director of Research Administration under the direction of the Research Director will ensure that any serious or continuing noncompliance with the applicable U.S. Federal regulations or the requirements or determinations of the IRB are promptly reported to study sponsor, regulatory authorities, and others as required, and steps to prevent future noncompliance will be instituted. 4. The Director of Research Administration under the direction of the Research Director will ensure that suspension or termination of IRB approval will be promptly reported to study sponsor, regulatory authorities and others as

	required.
Ensuring IRB reviews of human subjects research	1. The Director of Research Administration under the direction of the Research Director will ensure that all studies involving human subjects will be conducted under an active IRB approval. 2. WIC will follow the requirements of the IRB for which the FWA applies in determining the frequency of project review and other aspects of required reporting to the IRB. 3. The Director of Research Administration under the direction of the Research Director will ensure prompt reporting to the IRB of proposed changes in a research activity, and ensure that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.
Ensuring human subjects protection requirements are met by external IRBs.	WIC will retain documentation of external IRB Authorization Agreements with statements of human subjects compliance.
Renewal or Update of the Assurance	1. WIC will renew its FWA every 5 years, even if no changes have occurred in order to maintain an active FWA 2. WIC will update its FWA within 90 days after changes occur regarding the legal name of the Institution, the Human Protections Administrator, or the Signatory Official. a. Any renewal or update that is submitted to, and accepted by, OHRP begins a new 5-year effective period

RELEVANT REFERENCES:

- https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

APPROVING PERSON:

- WIC Executive Director
- WIC Compliance Committee

REVISION HISTORY

	Final Approval by	Date	Brief description of change/revision
Revision			
Revision			

WIC Executive Director Signature

October 3, 2022
Date

This policy is signed as required by FWA