1.0 POLICY

1.1 Background

1.1.1 Information about investigator conflict of interest (COI) will be contained within the research applications and the minutes. Investigators’ disclosure forms (Statement of Financial Interest) are kept in separate system files within the Office for Research.

1.2 Policy Statement

1.2.1 The Office for Research Compliance (ORC) will oversee and manage all documentation relative to research applications submitted for IRB review in accordance with federal regulations 45 CFR §46.115 and 21 CFR §56.115.

1.2.2 IRB Protocol Records

IRB records document determinations required by laws, regulations, codes, and guidance, including documentation the criteria for approval are met, and other required determinations, including whether non-compliance is serious or continuing, and whether a reported event is an unanticipated problem involving risks to participants or others.

The ORC will maintain a complete record of all research applications submitted for IRB review; and all material and documents submitted with each protocol, including, but not limited to:

1.2.2.1 Full Review Protocol

A. Initial IRB application;

B. External scientific evaluations of the validity of the proposed research by consultants or grantors such as NIH, if any;

C. For drugs, the investigator’s brochure;

D. For devices, a report of prior investigations;

E. Data Safety and Monitoring Board reports, if any;

F. Results of routine post-approval monitoring of protocols for quality Improvement, if any;

G. Signed Signature Assurance Sheet;
H. IRB-approved informed consent document and assent document, if applicable, with the approval date stamp;

I. Documentation of all IRB review and approval actions, modifications and all correspondence to and from the investigator, including initial and, if applicable, IRB continuation review and modification, deviation, exception review;

J. Documentation of type of review;

K. Documentation of study closure;

L. Specific findings (federal and institutional requirements);

M. Continuation/final review materials;

N. Significant new findings provided to human subjects;

O. Reports of unanticipated problems/adverse events involving risks to subjects or others;

P. Reports of protocol deviations;

Q. All relevant correspondence to and from investigator and any other correspondence related to the protocol either hard copy or email;

R. IRB Authorization Agreements, such as deferral to another IRB (rare)

S. Any existing contractual agreements for off-site research;

T. Applications for funding/sponsorship, if applicable;

U. Advertising or recruiting materials, if applicable;

V. Protocol amendments or modifications;

W. Instrument to be used for data collection, if applicable;

X. United States Department of Health and Human Services (DHHS) approved sample consent document and protocol, when they exist;

Y. Copy of the package insert or Food and Drug Administration (FDA) approved label (PDR reference) for drug or device studies using the FDA-approved medication/device for approved medical indication;

Z. Sponsor’s grant, contract, or device proposal if the protocol does not involve the administration of drugs, if applicable;

AA. Human subject protection training for principal investigators and study personnel;
BB. Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;

CC. Institutional Bio-safety Committee correspondence and approval letters, if applicable;

DD. Other committee approvals/correspondence, if applicable;

EE. Federally mandated reports, if applicable.

1.2.2.2 Expedited Review Protocol

A. All of the items listed above under full review protocol, as applicable to individual studies;

B. Description of the action taken by the expedited reviewer.

C. The justification for using expedited procedure.

D. Justification that the criteria are met.

E. Findings required by laws, regulations, codes, and guidance to be documented.

1.2.2.3 Exempt Review Protocol

A. All applications submitted for review exemption;

B. Signed Signature Assurance Sheet;

C. Justification for exempt determination

D. All items listed under full review protocol, if applicable to individual studies.

1.2.3 IRB Record Accessibility

IRB protocol records will be made available for inspection and copying within a reasonable time and manner upon the direct written request of the funding agency, regulatory/accrediting agencies, the principal investigator of the study, and/or institutional auditors.

1.2.4 IRB Record Retention

1.2.4.1 IRB Records

IRB records are to be retained in the Office for Research Compliance for a minimum of six years from the end of the fiscal year in which the protocol is closed. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least six years after cancellation.

1.2.4.2 Research Records
Records pertaining to the conduction of a research project remain the responsibility of the researcher. All materials generated from human subjects, such as consent forms, screening data, questionnaires, and all other materials generated from human subjects must be managed by the researcher as required by the IRB policy or federally established standards.

1.3 Objectives

1.3.1 Implementation of this policy will document all IRB activities relevant to all research proposal submissions, provide a history of IRB actions related to each protocol review, provide an assessable resource archive, and ensure UA compliance with all regulatory, sponsor, and accreditation requirements.

1.4 Responsibility.

1.4.1 The Vice President for Research is ultimately responsible for this policy. The enabling party is the Director of Research Compliance assisted by Research Compliance Specialists.

2.0 PROCEDURE

2.1 IRB Protocol Records

2.1.1 The Research Compliance Specialists (RCSs) enter documents into protocol file in reverse chronological order. This applies to submissions for both convened and expedited reviews. File documents include the following materials:

2.1.1.1 Original and revised IRB Human Subjects applications and any applicable special approvals (includes applications for initial and continuing review) undergoing convened or expedited review;

2.1.1.2 Applications for exemption or non-human use designation;

2.1.1.3 Sponsor’s protocol, if any;

2.1.1.4 DHHS/NIH approved sample informed consent document, if applicable;

2.1.1.5 Investigator’s Brochure or package inserts, if applicable;

2.1.1.6 Informed consent documents submitted by the investigator and final IRB-approved informed consent document(s);

2.1.1.7 Reports or serious adverse events or unanticipated problems, including risks to subjects or others;

2.1.1.8 Proposed amendments/revisions which may include significant new findings and revised informed consent document(s);

2.1.1.9 Applications for continuing review or modification of approved protocol;
2.1.1.10 All correspondence generated between IRB or ORC/OSP staff and the investigator or research staff (including the contact personnel);

2.1.1.11 All correspondence from sponsoring agencies;

2.1.1.12 Copies of IRB-issued approvals.

2.2 IRB Record Accessibility

2.2.1 The Director of Research Compliance:

2.2.1.1 Oversees and ensures the security of all ORC/IRB records and limits access to the funding agency, regulatory/accrediting agencies, the principal investigator of the study, or institutional auditors.

2.2.1.2 Makes provision for the access to records for inspection and copying at reasonable times and in a reasonable manner in response to request by authorized representatives.

2.2.1.3 Receives written requests to access and copy ORC/IRB records. All requests must be in writing and contain the following:
   - A. Name of the requestor,
   - B. Specific information being requested,
   - C. Reason for the request,
   - D. Assurance of confidentiality.

2.2.1.4 Consults, when necessary, with UA Legal Counsel on release of IRB records or documents.

2.2.1.5 Grants or denies access to IRB records per above procedures.

2.2.2 ORC Staff

2.2.2.1 ORC staff carry out the functions listed under the responsibility of the Director of Research Compliance at his/her direction.

2.3 Record Retention | Deposition

2.3.1 The ORC maintains protocol records for a minimum of six (6) years (as determined by the Director of Research Compliance) after the conclusion of a study. ORC staff destroys protocol records for studies that have been closed for six (6) years unless the Director of Research Compliance waives the requirement for a specific study.

2.3.2 Research Compliance Specialists maintain records indefinitely that are not part of specific protocol files, such as meeting minutes, agendas, standard operating procedures, membership rosters, or periodically destroy them, as determined by the Director of Research Compliance. The ORC has archival storage facilities.
2.3.3 The Research Compliance Specialists also maintain communications to and from the IRB in the ORC office and keeps any relevant communication related to a specific research protocol in the protocol record.

3.0 REFERENCES

- DHHS: 45 CFR §46.115 (a)-(b)
- OHRP Guidance on Written Institutional Review Board (IRB) Procedures
- FDA: 21 CFR 56.115(a)(b); FDA Information Sheets: Frequently Asked Questions about IRB Records

4.0 RELATED SECTIONS

4.1 GUIDANCE: IRB Application Guide