# IRB INTERACTION WITH COMPLIANCE OFFICES

**11/20/2023**

The DUHS IRB relies upon and works cooperatively with the Office of Audit, Risk and Compliance (OARC) to investigate complaints, allegations of non-compliance, and allegations of misconduct in human subject research. As defined in 42 CFR Part 93.103, *research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

The DUHS IRB may suggest or request OARC review of a particular study for any credible reason, including on the basis of a complaint from a research participant (or family member) or an individual internal or external to DUHS. Both the IRB and OARC have the authority to interview relevant research personnel in response to an allegation of research misconduct.

The DUHS IRB, working through its relationship with OARC, investigates instances of failure to adhere to an IRB-approved protocol, instances of research misconduct, and allegations of non-compliance with federal regulations, state and local laws, and IRB and institutional policies and procedures. The IRB also relies on OARC to evaluate concerns about clinical trials billing and program procedures for all Duke entities involved in clinical trials.

OARC has the authority to review both IRB records and IRB conduct.

## Exchange of Information between DUHS IRB and OARC

The IRB Office receives copies of all final review summaries conducted by OARC related to human subject research. All findings and allegations of non-compliance discovered on study review are promptly reported to the IRB for further review. Upon review by the IRB Executive Director, OARC summaries are maintained electronically in a secure location by the Executive Director. If OARC has reported a finding or allegation of non-compliance, or the IRB Executive Director concludes from the review of the OARC summary that an assessment for non-compliance is needed, the policy titled “Non-Compliance with the Requirements of the Human Research Protection Program” will be followed.

In cooperation with the IRB, OARC staff members monitor all corrective actions required of the research team to ensure that all such actions have been adequately addressed. After all corrective actions have been resolved by the investigator, OARC issues a closeout letter, a copy of which is sent to all individuals or entities that received the final summary.

An OARC staff member may attend any convened IRB meeting as a non-voting observer and representative of OARC, and may answer questions about an OARC investigation. When this occurs, the OARC representative is granted the same access to the agenda items as the attending IRB members.

The Executive Director of the IRB, OARC personnel, the Chief Compliance Officer and the Vice Dean for Clinical Research meet bi-monthly to review summaries of OARC review results and discuss concerns regarding the conduct of research involving human subjects within DUHS. In addition, the IRB Office provides OARC with quarterly reports concerning IRB compliance monitoring efforts. These reports are based on mutually agreed-upon parameters consistent with institutional risks, such as compliance with federal human subject protection regulations, serious and/ or continuing non-compliance events, drug and device regulatory issues, and emerging risk areas.

**Monitoring/Observation of the Informed Consent Process**
The IRB has the authority to observe or appoint a designee to observe the informed consent process in IRB approved research. OARC has the expertise and the authority to conduct this activity on behalf of the IRB. Monitoring the actual informed consent process may be particularly applicable to protocols involving vulnerable populations such as fetuses, pregnant individuals, imprisoned people, children, or the cognitively impaired.

**Monitoring of Protocols at External Sites**
Directed audits and routine periodic compliance reviews may also be conducted by OARC at non-Duke University Medical Center (DUMC) and non-DUHS sites, especially those sites for which the DUHS IRB serves as the IRB of Record; and/or a Duke PI holds an IND and is shipping drug to external sites.

Previous Version Date(s): 7/18/2008, 6/10/2011, 2/19/2016, 4/4/2021