Human Research Protection Program
UNIVERSITY OF GEORGIA

Incoming Information Directed to the IRB

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-020-1	05/24/2021	HSO	HSO Director (HRPP Policy Committee notified)	Page **1** of **2**

1. PURPOSE

1.1. This ***policy*** establishes the process for Human Research Protection Program (HRPP) Staff to triage information submitted to the University of Georgia HRPP. The process begins when any communication is received by the HRPP and ends when a staff member determines the appropriate action for the received information.

2. POLICY

2.1. HRPP Staff carry out these procedures.

3. PROCEDURES: HRPP Staff

3.1. The process begins when the HRPP receives information or communication and ends when the appropriate action for the information has been determined.

3.2. If the information is a request for an approval or determination (approval of new research, response to modifications required to secure approval, ***continuing review*** of research, ***modification*** to previously approved research, request for study closure, or a determination if an activity is research involving human subjects or if the activity meets Developmental Review criteria), the *Policy and Procedures: Pre-Review* must be followed.

3.3. If the information is a prior notification of an ***emergency use of a test article*** in a life-threatening situation, the *Policy and Procedures: Emergency Use of a Test Article Review* must be followed.

3.4. If the information is a five-day notification after an emergency use of a test article in a life-threatening situation, the *Policy and Procedures: Emergency Use of a Test Article Review* must be followed.

3.5. If the information is a request from the ***Investigator*** to continue subjects in a study whose IRB approval has ***expired***, the *Policy and Procedures: Expiration of IRB Approval* must be followed.

3.6. If the information is a question, concern, or complaint:

3.6.1. The HRPP Staff documents the nature of the question, concern, or complaint and the name and contact information of the person contacting the IRB (unless the person would like to remain anonymous).

3.6.2. The HRPP Staff will respond to any questions or concerns that are basic or general in nature. For questions or concerns that are complicated or cannot be readily responded to, the HRPP Staff will let the person know that additional information will be obtained and communicated to him/her by phone or email as soon as this becomes available. The HSO Director, IRB Chair, and/or Office of Research Integrity and Safety Director must be consulted to identify the best course of action for the received information.

3.6.3.The HRPP Staff must follow the *Office of Research Integrity and Safety (ORIS) Policy and Procedures: Responding to Allegations of Research Non-Compliance.*

4. **MATERIALS**

4.1. None

5. REFERENCES

5.1. Policy and Procedures: Pre-Review of IRB Submissions

5.2. Policy and Procedures: Emergency Use of a Test Article Review

5.3. Policy and Procedures: Expiration of IRB Approval

5.4. ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance