Subject: Revised IRB Forms and Policies - June 21, 2019

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) forms and policies, we are providing a summary of recent changes.

Main Changes (see below for all changes):

OHR-8: The OHR-8 has been reformatted to start with a brief summary of the general elements of consent, followed by the more detailed sections such as procedures, risks, cost, research-related injury, and HIPAA authorization. When completing the OHR-8, you should not include the same detailed information in both sections of the consent. The General Information Section should remain brief, and the Detailed Information Section should be comprehensive.

OHR-2 and GA 121: The IRB and Investigators must follow University Policy 102.39, Policy on Retention of University Records. Records must be destroyed as specified in the University policy. Shredding or locked confidential bins are acceptable methods. The destruction of records must be documented.

Note: Please remember to always access the most current forms and policies on the Office of Human Research website. Note: When opening documents, if prompted for user name and password, click cancel and the document should open. If you have any questions or comments about these policies, if you requested changes you do not see, or if you have any new suggestions, please contact Johanna.Yates@Jefferson.edu or Jacquie.Wright@Jefferson.edu. If you have any questions on your submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research

FORMS

Form Number	Title	Version Date

OHR-2	Summary of Interventional Human Subjects Research	6/21/2019
Changes: Clarified that the IRB and Investigators must follow University Policy 102.39, Policy on Retention of University Records. Records must be destroyed as specified in the University policy. Shredding or locked confidential bins are acceptable methods. The destruction of records must be documented.		

OHR-8	Informed Consent	6/21/2019
Changes: The OHR-8 has been reformatted to start with a brief summary of the general elements of consent followed by the more detailed sections.		

POLICIES

Policy Number	Title	Version Date
GA 109	**Roles and Responsibilities of Study Personnel and Department Chairs**	**6/21/2019**
Changes: The role of Principal Investigator has been clarified. Co-Investigator definition has been broadened.		
GA 121	**Documentation and Document Management**	**6/21/2019**
Changes: The IRB and Investigators must follow University Policy 102.39, Policy on Retention of University Records. Records must be destroyed as specified in the University policy. Shredding or locked confidential bins are acceptable methods. The destruction of records must be documented.		
GA 123	**Protection of the Confidentiality of Identifiable Data by the Investigator and the IRB**	**6/21/2019**
Changes: Moved document retention information to GA 121.		
GA 129	**Protection of Privacy Interests of Research Subjects and Confidentiality of Subject Data**	**6/21/2019**
Changes: Moved document retention information to GA 121.		
GA 131	**Research Device Acquisition, Use, and Tracking**	**6/21/2019**
Changes: Removed requirement for the PI to track devices using the OHR-21 as this form has been deactivated		
GA 133	**Human Research Training**	**6/21/2019**
Changes: Defined CITI training requirements for IRB Members.		
OP 201	**IRB Membership**	**6/21/2019**
Changes: Roster requirements and attendance expectations for IRB members were revised and clarified to include other Jefferson sites.		
OP 202	**Recruiting, Appointing and Performance Evaluation of IRB Members Chairs, and Vice Chairs**	**6/21/2019**

Changes: Revised requirement of reporting IRB membership changes to OHRP as per Revised Common Rule. Alternate members may now substitute for any primary member as long as membership requirements are met.

OP 204	IRB Review of Protocols	6/21/2019
Changes: Removed the requirement to have a PharmD on the IRB.		

OP 206	IRB Meeting Administration	6/21/2019
Changes: Revised requirement of reporting IRB membership changes to OHRP as per Revised Common Rule and that alternates do not have to be designated for specific members.		

QA 302	Quality Assurance/Quality Control Program, IRBs	6/21/2019
Changes: Revised requirement of reporting IRB membership changes to OHRP as per Revised Common Rule. Moved text regarding IRB Member CITI training to GA 133, Human Research Training.		

RR 404	Expedited Review of New and Continuing Research	6/21/2019
Changes: Under limited IRB review for exempt studies, the IRB makes an additional determination that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.		

RR 409	Study Completion	6/21/2019
Changes: Revised policy to indicate that the Co-Chair is responsible for reviewing Final Reports.		

G 603	Guidance on Lay Terminology: Informed Consent Glossary	6/21/2019
Changes: Removed from OHR Policy and Procedure Manual.		

GA 616	Independent Monitoring of Investigator-Initiated Clinical Trials	6/21/2019
Changes: Clarified monitoring for minimal risk studies.		

In addition, a number of administrative changes were made to other forms and policies.