March 24, 2015

Subject: Revised IRB Policies – Mar 24, 2015

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) policies and forms, a summary of recent changes is being provided. Please remember to always access the most current policies and forms on the Division of Human Subjects Protection page of the OHR website.

Thank you

The Office of Human Research

Policies

Number	Title	Version
GA 116	**Use of Students and Employees as Key Personnel and Subjects in Clinical Trials**	**03/24/15**
Changes: Policy modified to include employees.		

Number	Title	Version
GA 130	**Definition of Key Personnel in Research**	**05/15/14**
Changes: This policy was deleted because it is a duplicate of Policy G 601.		

Number	Title	Version
OP 201	**IRB Membership**	**03/24/15**
Changes: IRB membership clarified.		

Number	Title	Version
OP 202	**Recruiting and Appointing IRB Members, Chairs and Vice Chairs**	**03/24/15**
Changes: Recruitment, appointment and evaluation of IRB members clarified.		

Number	Title	Version
RR 401	**Initial Review - Criteria for IRB Review and Approval**	**03/24/15**
Changes: Typographical error fixed.		

Number	Title	Version
RR 402	**Continuing Review and Amendments**	**03/24/15**
Changes: Process to be followed for expired studies clarified.		

Number	Title	Version

RR 403	Review of Exempt Studies	03/24/15
Changes: Clarify who in the IRB can review exempt studies.		

Number	Title	Version
RR 404	Expedited Review of New and Continuing Research	03/24/15
Changes: Title changed.		

Number	Title	Version
SC 501	Determining Whether a Device Study Involves a Significant Risk or Nonsignificant Risk	03/24/15
Changes: Grammatical changes.		

Number	Title	Version
SC 502	Review of Cancer Trials Approved Under NCI Central IRB Independent Review Model	03/24/15
Changes: Grammatical changes.		

Number	Title	Version
SC 503	Review and Approval of an Humanitarian Device Exemption	03/24/15
Changes: The policy for HUDs was clarified and consolidated.		

Number	Title	Version
IC 702	Documentation, Waiver and Alteration of Informed Consent	03/24/15
Changes: At the discretion of the IRB, for some minimal risks studies, the signature of an investigator will not be required on consent forms.		

Number	Title	Version
IC 705	Informed Consent – Illiterate and Non-English Speaking Subjects and Subjects Physically Unable to Sign	03/24/15
Changes: Clarify who may serve as a witness to informed consent. The witness cannot be study personnel.		

If you have any questions or comments about these changes, please contact patrick.herbison@jefferson.edu .