October 2, 2017

Subject: Revised IRB Forms and Policies – October 2, 2017

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) forms and policies, a summary of recent changes is being provided. 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 already filled out the previous version of a form for a submission, you do not have to start over with the new form indicated below. But if you just started filling out the previous version, please start over with the new form indicated below. If you have already filled out a form for a submission you are planning and are interested in including the new changes, please use the contact email below to request the new changes.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
NA	**Overview of IRB Submissions for New Studies**	**10/2/2017**
Changes: Administrative change.		
OHR-1	**Proposal Transmittal and Approval Form**	**10/2/2017**
Changes: The information for the reviews needed before IRB submission has been updated. The COI section has been simplified.		
OHR-2 Guidelines	**Submission Guidelines**	**10/2/2017**
Changes: The references to OHR-2A have been removed. OHR-2A is no longer in use.		
OHR-2	**Summary of Interventional Human Subjects Research**	**10/2/2017**
Changes: Administrative changes. Information has been added about non-English speaking and decisionally impaired subjects. New locations (Abington, Aria, Kennedy) have been added to the list of locations where the research will be conducted.		
OHR-2B	**Summary of Non-Interventional Human Subjects Research**	**10/2/2017**
Changes: Administrative changes. Information has been added about non-English speaking and decisionally impaired subjects.		

OHR-8	Informed Consent Document for Human Subjects Research	10/2/2017
Changes: A description of phase I/II research has been added. The pregnancy section has been clarified.		

OHR-8S	Informed Consent – Short Form	10/2/2017
Changes: The OHR-8S – Short Form has been completely revised to improve readability. The new translated short forms will also be posted.		

OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	10/2/2017
Changes: Some unneeded questions have been removed. The form now asks for more detailed information about withdrawals, subjects lost to follow-up and deaths. The table used to summarize study personnel who have been added/removed has been simplified. The COI section has been simplified. The IRB Use Only section for documenting the type of review has been moved to the OHR-12.		

OHR-12	Amendment to Research Protocol	10/2/2017
Changes: Administrative changes. The form now asks for more detailed information about the changes to the study. The IRB Use Only section for documenting the type of review has been moved from the OHR-9 to this form.		

OHR-12B	Adding Study Personnel	10/2/2017
Changes: Commercial IRB have been added. Information has been added to clarify the adding and removing of study personnel. The COI section has been simplified. The signature section has been revised.		

OHR-34	Research Not Requiring IRB Review: A Checklist	10/2/2017
Changes: Remove reference to OHR-23.		

Please note that the versioning options in the form headers are recommended but optional. You are encouraged to use version date, version number or both.

Policies

Policy Number	Title	Version Date

GA 109	Roles and Responsibilities of Study Personnel and Department Chairs	10/2/2017
Changes: Since the OHR-12C (removing study personnel) was eliminated, this policy describes how to remove study personnel by entering a stop date in JeffTrial.		

GA 120	Reporting and Reviewing Unanticipated Problems Involving Risks to Subjects or Others	10/2/2017
Changes: This policy has been completely revised and simplified. This includes simplified definitions of the different types of events and a simplified table for reporting timelines (5 Days). Please see the new		

policy for details.

GA 133	**Human Research Training**	**10/2/2017**
Changes: This policy has been simplified to describe CITI training requirements.		

QA 301	**Quality Assurance/Quality Improvement Program**	**10/2/2017**
Changes: Change to approval needed for IRB audit reports.		

QA 302	**Quality Assurance/Quality Control Program, IRBs**	**10/2/2017**
Changes: IRB Member CITI training requirements have been clarified.		

RR 401	**Initial Review – Criteria for IRB Review and Approval**	**10/2/2017**
Changes: A minor change was made to reflect that the FDA allows consent waiver/alteration in some circumstances.		

SC 501	**Determining Whether a Device Study Involves a Significant Risk or Nonsignificant Risk**	**10/2/2017**
Changes: A minor change was made to indicate that OHR-25 is not required if a drug and a device (e.g. a drug and its delivery system) are under the same IND.		

IC 701	**Informed Consent and HIPAA Authorization: General Requirements**	**10/2/2017**
Changes: Reference to new consent guidance document was added. This guidance document is helpful for determining consent requirements in different consent scenarios. It can be found under IRB Reference Document on the IRB Webpage. Also added to this policy is guidance on ensuring that the most current, IRB approved consent document is used.		

IC 702	**Documentation, Waiver and Alteration of Informed Consent**	**10/2/2017**
Changes: Reference to new consent guidance document added. Information on re-consent added. Information on illiterate subjects and subjects physically unable to sign has been moved from policy IC705 to this policy. This will allow IC 705 to just address translations.		

IC 705	**Informed Consent – Non-English Speaking Subjects and Translations**	**10/2/2017**
Changes: This policy has been simplified and now just addresses translations.		

IC 706	**Waiver of Informed Consent and HIPAA Authorization**	**10/2/2017**
Changes: A minor change was made to reflect that the FDA allows consent waiver/alteration in some circumstances.		

If you have any questions or comments about these changes, if you requested changes you do not see or if you have any new suggestions, please contact patrick.herbison@jefferson.edu .