

RECENTLY POSTED HSPP DOCUMENTS - 11/09/09

INFORMED CONSENT SUITE

- **REVISED TEMPLATES**

Title: *Biomedical Research Consent form template*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/bio_consent.doc

Version, date: NA, 10/08/09

Revision Log: Minor change in the "What are my rights as a research subject" section.

Title: *Biomedical Research Consent form template – SPANISH VERSION*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/bio_consent_spanish.doc

Version, date: NA, 10/08/09

Revision Log: Minor change in the "What are my rights as a research subject" section.

Title: *Behavioral Research Consent form template*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/beh_consent.doc

Version, date: NA, 10/08/09

Revision Log: Minor change in the "What are my rights as a research subject" section.

Title: *Behavioral Research Consent form template – SPANISH VERSION*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/beh_consent_spanish.doc

Version, date: NA, 10/08/09

Revision Log: Minor change in the "What are my rights as a research subject" section.

- **NEW TIP SHEET**

Title: *TIP SHEET - Glossary of Lay Terms*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0918.pdf>

Version, date: 1.0, 10/19/2009

NEWLY POSTED TIP SHEET

Title: *Investigator Responsibilities Poster*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf>

Version, date: Version: 1.1, Date: 12/15/2008

POLICY REVISIONS

- **SIGNIFICANT POLICY REVISION**

Title: *Study Closure, Lapse in IRB Approval and Withdrawal of Research*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0284.pdf>

Version, date: Version: 2.0, Date: 10/05/2009

Revision Log: Significant changes to the time period and general procedures for closing research for lapses in IRB approval. Re-structuring and redrafting of the procedure portion.

- **MINOR POLICY REVISIONS**

Title: *Scientific and Scholarly Review of Research*

Version, Date: Version: 1.1, Date: 8/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0867.pdf>

Revision Log: Added information as to Policy section III about Department of Defense requirements for scientific review.

Title: *Institutional Authorization for Determining whether Research or Other Activities Represent Human Subjects Research*

Version, Date: Version: 2.2, Date: 09/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0273.pdf>

Revision Log: Policy revised to include Department of Defense sponsored survey research requirements. Created a more detailed "procedures" section that outlined the process.

Title: OPRS Quality Improvement/ Quality Assurance Program

Version, Date: Version: 2.1, Date: 09/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0865.pdf>

Revision Log: Revised entire document, previously named IRB Chair, IRB Staff, and IRB Coordinator Compliance Monitoring and Auditing.

Title: *Expedited Review for Initial Review, Continuing Review, and Amendments*

Version, Date: Version: 1.4, Date: 9/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0294.pdf>

Revision Log: Added language as to the process by which IRB members with a conflict of interest are identified. Described to whom IRB members report a conflict of interest when they are assigned to review a protocol in which they have a conflict of interest.

Title: *IRB Review Process*

Version, Date: Version: 1.2, Date: 09/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0285.pdf>

Revision Log: Included a description of the quorum requirements, a description of the calculation period, the list of items reviewed by the primary reviewer and other IRB members, the list of items reviewed by the primary reviewer and other IRB members for continuing review.

Title: *Investigator Essential Documents*

Version, Date: Version: 1.2, Date: 8/25/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0899.pdf>

Revision Log: Deleted several citations in Section IV.

Title: *UIC IRB Review of Domestic Research Involving Non-UIC Sites, Agencies, Organizations, or Institutions*

Version, Date: Version: 3.3, Date: 8/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0857.pdf>

Revision Log: Added requirement for DOD sponsored research that when conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.

Title: *International Research*

Version, Date: 1.2, 8/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0888.pdf>

Revision Log: Added a Policy section that establishes requirements for a formal agreement between institutions that specifies the roles and responsibilities of each party when conducting multi-site research.

Title: *Continuing Review*

Version, Date: 1.1, 09/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0289.pdf>

Revision Log: Revised policy to include policy statement II, which further refines the explanation of the duration of continuing review.

Title: *Approval Criteria: Recruitment, Advertising, and Subject Payment*

Version, Date: 1.2, 08/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0890.pdf>

Revision Log: Added section VI, which provides Department of Defense sponsored research requirements as to recruitment.

Title: Institutional Oversight and Assurance

Version, Date: 1.1, 9/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0891.pdf>

Revision Log: Clarified that only the IRBs may approve the research.

Title: *Approval Criteria: Data and Safety Monitoring*

Version, Date: 1.1, 08/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0900.pdf>

Revision Log: Added relevant DOD sponsored research requirements (policy section II).

Title: *IRB Member, Ad Hoc Consultant, and OPRS Staff Conflicting Interest Policy*

Version, Date: 1.2, 8/12/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0271.pdf>

Revision Log: Included a statement that IRB members with a conflicting interest will not be counted towards quorum.

Title: *Approval Criteria: Decisionally Impaired and Cognitively Impaired Subjects*

Version, Date: 1.1, 09/21/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0854.pdf>

Revision Log: Specified the responsibilities of the investigator when research is being conducted in another state.

Title: *Informed Consent Process and Documentation*

Version, Date: 1.1, 7/17/09

Web link: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0916.pdf>

Revision Log: Added information related to Department of Defense sponsored research in the "Waiver or Alteration of Consent" section.

IRB REVIEW SUITE

The tools (review guides & tip sheets) that the IRB uses to review protocols are now posted on the OPRS web site. **PLEASE NOTE:** these documents are for internal use only; investigators are not required to complete or submit these forms. These are posted for informational and educational purposes only.

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/review_guide/index.shtml

RECENTLY POSTED HSPP DOCUMENTS - 08/03/09

FDA-REGULATED RESEARCH SUITE

- **NEW POLICIES**

Title: *Humanitarian Use Devices (HUD)*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0922.pdf>

Version, date: Version: 1.0 Date: 06/23/2009

Title: *Research Involving the Use of Drugs, Biologics or Medical Devices*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0919.pdf>

Version, date: Version: 1.0, Date: 06/23/2009

Title: *Sponsor-Investigator Holding an IND*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0920.pdf>

Version, date: Version: 1.0, Date: 06/23/2009

Title: *Sponsor-Investigator Holding an IDE*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0921.pdf>

Version, date: Version: 1.0, Date: 06/23/2009

- **NEW CONSENT TEMPLATE**

Title: *Consent for Use of a Humanitarian Use Device (HUD) template*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/hud_consent.doc

Version, date: 6/29/09

- **NEW FORM**

Title: *FORM Humanitarian Use Device Application*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/0953.doc>

Version, date: Version: 2.0, Date: 06/23/2009

RECENTLY POSTED HSPP DOCUMENTS - 07/22/09

INFORMED CONSENT SUITE

- **NEW POLICY**

Title: *Informed Consent Process and Documentation*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0916.pdf>

Version, date: Version: 1.0, Date: 06/23/2009

- **REVISED CONSENT TEMPLATES**

Title: *Biomedical Research Consent form template*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/bio_consent.doc

Version, date: NA, 06/16/09

Note: the Spanish version of this template will be available August 1, 2009

Title: *Behavioral Research Consent form template*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/beh_consent.doc

Version, date: NA, 06/29/09

Note: the Spanish version of this template will be available August 1, 2009

Title: *VA RESEARCH CONSENT FORM*

Web address:

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/va_consent.doc

Version, date: NA, Master Version 06/22/09

- **NEW TIP SHEETS**

Title: *Tip Sheet for the Informed Consent Template*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0923.pdf>

Version, date: Version: 1.0, Date: 07/01/2009

Title: *TIP SHEET Certificate of Confidentiality Language for Informed Consent*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0914.pdf>

Version, date: Version: 1.0, Date: 06/25/2009

POLICY REVISIONS

- **SIGNIFICANT POLICY REVISIONS**

Title: *Engaged or Not Engaged in Research*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0912.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Expanded policy title to include individuals as well as institutions. Linked this policy to the educational policy and tip sheet. Clarified information for non-federally funded research.

Title: *UIC IRB Review of Domestic Research Involving Non-UIC Sites, Agencies, Organizations, or Institutions*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0857.pdf>

Version, date: Version: 3.2, Date: 06/18/2009

Revision Log: Removed local research context section and moved it to stand alone policy

Title: *Local Research Context*

Web address:

<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/index.shtml#sec8>

Version, date: 1.0, 06/25/09

Note: New stand alone policy; used to be part of *UIC IRB Review of Domestic Research Involving Non-UIC Sites, Agencies, Organizations, or Institutions*

Title: *IRB Review Process*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0285.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Revised policy to be more inclusive of both convened and expedited review. Changed title to reflect this from "Convened Review Process" to "IRB Review Process."

Title: *Exempt Review of Research*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0282.pdf>

Version, date: Version: 1.2, Date: 06/18/2009

Revision Log: Revised Section IV to permit amendments, rather than modifications, with respect to exempt research.

Title: *Amendments*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0288.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Included language that prevents the research team from implementing amendments to research without IRB approval and clarified alternate IRB member language.

Title: *IRB Record Retention*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0286.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Added credentials and FDA IND and IDE letters to documentation required by policy.

Title: *Investigator and Research Personnel Education Program and Training Requirements*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0895.pdf>

Version, date: Version: 1.2, Date: 06/18/2009

Revision Log: Clarified that individuals who engage UIC in human subjects research must complete the required training.

Title: *OPRS Quality Improvement/ Quality Assurance Program*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0865.pdf>

Version, date: Version: 2.0, Date: 06/18/2009

Revision Log: Revised entire document, previously named *IRB Chair, IRB Staff, and IRB Coordinator Compliance Monitoring and Auditing*.

Title: *Documentation of IRB and OPRS Activities*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0283.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Included greater detail as to meeting minutes throughout the policy and procedure based on meeting minute audit findings.

- **MINOR POLICY REVISIONS**

Title: *Institutional Biosafety Committee (IBC)/Institutional Review Board (IRB) Coordination*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0883.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Edited to reflect appointment of HPA and deletion of the term "UPIRSO," as it is not used any longer by UIC OPRS.

Title: *Undue Influence of IRB Members and OPRS Staff*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0860.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Small correction of reference and clarification of progress report time table in Section XI.

Title: *The Institutional Official*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0863.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Clarified IO responsibilities

Title: *University of Illinois at Chicago Human Subjects Protection Program Plan*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0862.pdf>

Version, date: Version: 1.2, Date: 6/18/2009

Revision Log: Addition of educational program and Assistant Director of Quality Assurance/ Quality Improvement position.

Title: *Investigator Essential Documents*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0899.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Clarified record retention time periods and procedure for re-requesting documents.

Title: *Approval Criteria: Recruitment, Advertising, and Subject Payment*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0890.pdf>

Version, date: Version: 1.1, Date: 06/19/2009

Revision Log: Policy revised to clarify difference between recruitment process and recruitment materials.

Title: *Complaints or Concerns Received from Subjects or Others*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0290.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Added Assistant Director of Quality Assurance/ Quality Improvement title.

Title: *Clinical Research Center/ Institutional Review Board Coordination*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0898.pdf>

Version, date: Version: 1.1, Date: 06/18/2009

Revision Log: Deleted reference to SAC since disbanded; clarified that institutional reporting includes but is not limited to the examples listed.

Title: *Unanticipated Problems and Other Events Requiring Prompt Reporting*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0279.pdf>

Version, date: Version: 2.1, Date: 06/18/2009

Revision Log: Corrected small error to the number of VA Form 10-0420.

Title: *Research Involving Children (Including Wards of the State)*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0910.pdf>

Version, date: Version: 1.2, Date: 06/18/2009

Revision Log: Removed citation to ILCS from definition of child.

Title: *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0262.pdf>

Version, date: Version: 6.2, Date: 06/18/2009

Revision Log: Added Assistant Director of Quality Assurance/ Quality Improvement title.

Title: *IRB: Evaluation of Resources and Workload*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0864.pdf>

Version, date: Version: 1.2, Date: 06/18/2009

Revision Log: Added Assistant Director of Quality Assurance/ Quality Improvement title.

Title: *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0270.pdf>

Version, date: Version: 2.1, Date: 06/18/2009

Revision Log: Added Assistant Director of Quality Improvement/ Quality Assurance title.

Title: *IRB Approval Criteria: Confidentiality*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0889.pdf>

Version, date: Version 1.1, 06/26/2009

Revision Log: Expanded agencies issuing certificates of confidentiality and inserted updated certificate of confidentiality language.

TIP SHEET REVISIONS

Title: *TIP SHEET - Recruitment Materials*

Web address: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0233.pdf>

Version, date Version: 2.2, Date: 5/1/2009