Human Research Protection Office (HRPO)
Summary of Changes to Policies and Procedures
Release date: February 1, 2013

Section	Topic	Change	Rationale
I.H	Exempt Studies	A new exempt category, 2a, has been created for studies that are not federally funded.	Washington University has recently chosen to limit the scope of its Federal-wide Assurance with the Office of Human Research Protections (OHRP) allowing flexibility when determining policy for studies that are not federally funding. The addition of a new exempt category allows greater flexibility for studies that involve a benign intervention.
II.A	Activities Subject to IRB Jurisdiction	The following activities have been removed as subject to IRB jurisdiction: • Use of WU/BJH/SLCH resources, property or facility of the institution • Use of non public information maintained by WU/BJH/SLCH • Use of WU/BJH/SLCH Protected Health Information	This section has been revised to be in line with the OHRP's guidance on engagement. Whiles these activities have been removed as subject to IRB jurisdiction there may be other departmental, regulatory or institutional approvals required prior to conducting these activities.
II.A	Activities Subject to IRB Jurisdiction	Clarified that the WU IRB has jurisdiction over research conducted by or under the direction of any employee (including faculty or staff), agent, student, fellow, or post-doctoral appointee of WU/BJH/SLCH in connection with his/her institutional responsibilities, employment or academic status	This language was revised to clarify that research conducted in connection with an individual's employment or academic status is subject to IRB oversight.
II.F	Exempt Studies	A new exempt category, 2a, has been created for studies that are not federally funded.	Washington University has recently chosen to limit the scope of its Federal-wide Assurance with the OHRP allowing flexibility when determining policy for studies that are not federally funding. The addition of a new exempt category allows greater flexibility for studies that involve a benign intervention.

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II.F.4	Exempt Studies	A new exempt category, 2a, has been created for studies that are not federally funded.	Washington University has recently chosen to limit the scope of its Federal-wide Assurance with the Office of Human Research Protections (OHRP) allowing flexibility when determining policy for studies that are not federally funding. The addition of a new exempt category allows greater flexibility for studies that involve a benign intervention.
IV.B.	Committee Make-up	Removed reference to two to four voting staff members as part of the committee make-up.	This section was deleted because it is not necessary. While many of the HRPO staff are committee members it is not necessary to distinguish them from the other members.
VIII.G.1- 2	Research Involving an Investigational Drug or Device	Minor wording changes around the requirement for an IND or IDE	Revised for clarification purposes.
VIII.G.3	Research Involving an Investigational Drug or Device	The determination as to whether or not a study utilizing an investigational drug is exempt from FDA regulations can now be made by the Executive Chair or designee. If the exemption criteria are not met the Executive Chair or designee can require a formal IND determination from the FDA.	The regulations do not mandate who must determine if a drug under investigation is exempt from 21 CFR 312. Allowing the Executive Chair or designee to make this determination will improve consistency and efficiency of these determinations and the IRB review process.
VIII.G.4	Research Involving an Investigational Drug or Device	The determination as to whether or not a study utilizing an investigational device is exempt from FDA regulations can be made by the Executive Chair or designee. If the exemption criteria are not met the Executive Chair or designee can require a formal IDE determination from the FDA.	The regulations do not mandate who must determine if a device under investigation is considered exempt from 21 CFR 812. Allowing the Executive Chair or designee to make the exempt determination or to require the PI to obtain a determination from the FDA will improve consistency and efficiency of these determinations and the IRB review process.

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VIII.G.5	Research Involving an Investigational Drug or Device	Minor changes to the wording of this paragraph have been made.	This paragraph has been revised for clarity purposes.
VIII.G.7	Initial and continuing review of studies involving an IND or IDE	This section has been revised to apply to all investigational drugs and devices regardless of whether or not an IND or IDE is required. The requirement that at least one physician be present at the convened meeting has been removed.	This section has been revised to apply to all investigational drug and device studies, not just studies where an IND or IDE is required. It is not necessary that a physician always be present at the meeting when an investigational drug or device study is under review as long as the meeting has achieved quorum and individuals with the necessary expertise are present.
VIII.G.9. a-f	Emergency Treatment with an investigational drug or device	A follow up report of the use of an investigational drug or device for emergency treatment as defined in 21 CFR 56.102(d) must be submitted to the IRB within 5 working days of the actual use of the drug or device. This 5 day reporting requirement has replaced the submission for a 30 day follow up report.	FDA regulations require that a report be submitted 5 days after use of the investigational drug or device, even if the IRB was notified prior to the use.
VIII.G.10	Compassionate Use of an Investigational Device for a Serious Disease or Condition	New information about the compassionate use of investigational devices for a serious disease or condition has been added to the policies.	Similar to the emergency use of an investigational drug or device, the FDA allows for compassionate use of a device for a serious disease or condition. This section of the policies has been added to outline the requirements that must be met to allow this use.
IX.D	Financial Conflicts of Interest	Disclosure Review Committee (DRC) has been replaced with Conflict of Interest Review Committee (CIRC).	The name of the committee that reviews financial conflicts of interest has changed.
IX.P	Appeal Process	Language stating that the IRB will not disapprove a study without giving the investigator an opportunity to present to the committee has been removed.	This change has been made to allow the IRB to disapprove a study prior to giving the investigator the opportunity to respond. The right to appeal a decision by the IRB, as described earlier in this

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			section of the policies, has not changed.
X.B.3	Reporting Requirements for FDA Audits	HRPO should be notified within one working day of notice of an audit by the FDA. This applies to both routine and for-cause FDA audits. After the audit the investigator should provide follow up information to HRPO within one working day describing the outcome of the audit, even if there are no findings. If there are findings from the audit supporting documentation should be included, such as a 483 report, warning letter or any other correspondence from the FDA.	This section has been revised to provide more detailed information about the reporting requirements for FDA audits.
XI	Conflicts of Interest Review Committee	Disclosure Review Committee (DRC) has been replaced with Conflict of Interest Review Committee (CIRC).Details of the definition of a financial interest, as defined by CIRC policy, have been removed.	This section has been revised to reflect the new name of the conflicts of interest committee. CIRC policies should be referenced for the definition of a financial interest that requires management.
Glossary	Exempt Category 2a	The definition of Exempt Category 2a has been added.	A new exempt category has been created for studies that are not federally funded.