

History of SOP Updates & Changes

Date	SOP/Section(s)	Brief Description of the Change
12/13/07	SOP 6F	<ul style="list-style-type: none"> ▪ Requirements for ClinicalTrials.gov registration have been revised and are reflected in this new policy <i>Required Registration with ClinicalTrials.gov</i>. The policy also provides rationale and specifies processes for registration and indicates that “all clinical trials required to register at www.ClinicalTrials.gov will not receive final approval until proof of registration is provided.” ▪ Please see the complete policy for details.
12/7/07	SOP 12C	<ul style="list-style-type: none"> ▪ This is a new policy <i>IRB Relation to the University of Maryland Greenebaum’s Cancer Center (UMGCC) Clinical Research Committee (CRC)</i>. “All research submissions which involve the diagnosis, treatment, imaging, or prevention of cancer must be reviewed by the University of Maryland Marlene and Stewart Greenebaum’s Cancer Center (UMGCC) Clinical Research Committee (CRC).” ▪ Please see the complete policy for details.
10/15/07	SOP 10H Policy I.A.2 & II.A; Procedure I.A.1	<ul style="list-style-type: none"> ▪ Updated to be consistent with the HRPO’s practice of requesting an FWA for international studies <i>regardless of funding</i>.
10/15/07	SOP 2C Procedures I.A & D; IV.B, C, & E; V.A	<ul style="list-style-type: none"> ▪ Updated to be consistent with the HRPO’s practice of sending the letter/incident report by or before thirty days of the IRB determination; other changes included updating titles & clarification of responsibilities
8/20/07	SOP 5B	<ul style="list-style-type: none"> ▪ The following language has been added to the Policy statement: “<i>Studies that receive less than \$10,000 from the Industry Sponsor are exempt from this policy.</i>”
5/23/07	Signature Page	<ul style="list-style-type: none"> ▪ Updated with the signature of the current Institutional Official.
4/6/07	Throughout SOPs as Indicated	<ul style="list-style-type: none"> ▪ Update to use appropriate title Vice Dean for Research and Academic Affairs and indicate that this individual is the Institutional Official (IO) ▪ Update to properly use the term Advisory Committee for Human Research Policy (ACHRP)
1/4/07	SOP 5B: Policy IV.A & B	<ul style="list-style-type: none"> ▪ Policy IV.A & B revised to reflect new sponsor’s fees that were effective October 1, 2006.

11/27/06	10A: Policy II.B.8.b & Policy III.A.2.b	<ul style="list-style-type: none"> ▪ Revised to reflect that the HIPAA document will reflect the fact that a plan is in place to "RETURN OR destroy identifiers."
11/13/06	10G: Policy V and Procedures I.B, II.E, & III.B	<ul style="list-style-type: none"> ▪ Revised to reflect new requirements for recruitment of veterans in research
4/24/06	7D: Policy IV.B & Procedure IV.A	<ul style="list-style-type: none"> ▪ Revised to indicate that Human Protections Administrator (HPA) and the Program Manager for Quality Improvement have the authority to review and approve amendments and renewals that are designated expedited according to the regulations and UMB IRB Policies and Procedures
3/29/06	3J: Policy I.B.4 and Procedure II.A.2.b	<ul style="list-style-type: none"> ▪ Changes made to clarify which types of protocols that were initially reviewed at the fully convened IRB meeting could be subsequently reviewed by expedited procedures
3/17/06	2C: Procedure I.B.9	<ul style="list-style-type: none"> ▪ Revised the list of additional reporting requirements (letter/incident report) for VAMHCS research following IRB determination following IRB determination
3/17/06	Master Glossary	<ul style="list-style-type: none"> ▪ The following terms and their respective definitions were added: Adverse Event (AE) for [VAMHCS Research], Imminent Threat of an AE in Research [for VAMHCS], Substantive Action [for VAMHCS], and Unexpected Death [for VAMHCS]
2/21/06	2F: Policy I and Procedure I.B	<ul style="list-style-type: none"> ▪ Reporting requirements for external Unanticipated Problems Involving Risks to Participants or Others was changed from two to five business days