Section 400:	**REVIEW OF RESEARCH**		
Standard Operating Procedure (SOP):	**402 DELEGATED REVIEW**		
This SOP pertains to:	All Research submitted to the REBs		
Responsibility for executing this SOP:	Director, Research Ethics, Research Ethics Staff, the Chairs of the U of S Research Ethics Boards		
Approval Authority	The Vice-President Research		
Effective Date:	January 1, 2013	**Supersedes documents dated:**	July 1, 2012

1. PURPOSE This SOP outlines the process to determine if the proposed research meets the criteria for delegated review.	
2. POLICY A delegated review procedure consists of a review of research involving human participants by the REB Chair or by one or more experienced reviewers designated by the Chair from among members of the REB. Full review by an REB should be the default requirement for all research involving human participants. The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research. The REB delegates research ethics review to an individual or individuals. Delegates shall be selected from among the REB membership. An exception arises in the ethics review of student course based research which can be delegated to the department, faculty or equivalent level as indicated below.	Proportionate approach – see TCPS2, Article 2.9 and Article 6.12

Research that may be reviewed by the REB through a delegated review procedure shall include activities that present no more than minimal risk to human participants, and minor changes in approved research. One exception is in the case of above minimal risk research taking place at more than one site. At the discretion of the REB, subsequent sites of above-minimal risk multi-site studies will be reviewed by delegated review provided the initial review has been conducted at a full board meeting and the documentation submitted by the secondary site(s) is a duplication of the documentation approved by the REB for the initial site (with site specific customization only). This SOP pertains to both initial and continuing REB review of the items included in this policy.	
3. SPECIFIC POLICIES **3.1 Definition of Minimal Risk** Minimal risk research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research. For studies that are funded or supported by the US federal government or regulated by the US FDA, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. **3.1.1 Definition of Minor Change** Minor changes are changes that neither increase the risk, nor materially change the risk-benefit ratio of the research study and do not substantially change the specific aims or design of the study.	Minimal Risk – see TCPS2, page 23 45 CFR 46 102(i) 21 CFR 56 102(i)
3.2 Authority of the Reviewer The REB Chair or designate may exercise all of the authorities of the REB except that she/he may not disapprove the research. A research proposal may be disapproved only after review by the full REB. A delegated reviewer may refer a study to the full Board at his/her discretion.	TCPS2 Article 6.12
3.3 Notification of the Board When the delegated review process is used, all regular members shall be informed of actions taken by the REB Chair or designate at the next convened meeting.	
3.4 Documentation • Applications reviewed by delegated review will be reported to	

the full REB in the summary report of REB activities which will include a listing of the studies that were reviewed via delegated review. • The delegated reviewer will receive the full application and all documentation for review. • If a study qualifies for review via delegated review, the delegated reviewer will provide his/her determination concerning the study in writing.	
3.5 Examples of Minimal Risk Studies qualifying for Delegated Review at Initial Review Examples of minimal risk studies qualifying for delegated review of research are detailed in the guidance notes accompanying the biomedical and behavioral ethics applications. Studies that are funded or supported by the U.S. federal government or regulated by the U S Food and Drug Administration are eligible for delegated (expedited) review if listed in the OHRP and FDA guidances and are no more than minimal risk or include only, minor changes in previously approved research as defined by the applicable regulations and in the U of S SOPs. When determining if initial review of research or modification to previously approved research are eligible for delegated REB review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, knowledge and training of the research staff.	45 CFR 46.110 21 CFR 56.110 FDA Guidance November 9, 1998 OHRP Guidance August 11, 2003 U of S SOP 405 TCPS2 Article 6.12
3.6 Additional Items that may be Reviewed through Delegated Procedures **3.6.1. Responses to Provisos (Studies rated B in current BioREB system)** • REB required revisions to consent forms and documents and responses submitted by the investigator as a result of full REB review and as a condition of final approval may be reviewed by the REB Chair or designee and/or the member(s) designated by the REB. • **This does not apply to applications that were deferred or that require substantive clarifications or modifications, including but not limited to any of the criteria for REB approval listed in 45CFR46.111**. **3.6.2 Amendments** The REB Chair or designate may use the delegated review procedures to review minor changes in previously approved research during the period for which approval is authorized.	45CFR46.111

Any protocol revision that entails more than minimal risk to the participant as determined by the Chair or designate will be forwarded to Research Ethics administration for inclusion on the agenda at the next available meeting of the full Board. Changes to informed consent documents that do not involve increased risk or significant changes in study procedures may be reviewed by the REB Chair or her/his designee.	
Changes to US federally funded studies that entail either increased risk or that materially change the risk/benefit ratio of the study are not eligible for delegated review.	45 CFR 46.101(i) 45 CFR 46.110 21 CFR 56.101(i) 21 CFR 56.110
3.6.3 Continuing Review / Renewals Delegated review procedures may be used for annual renewals of approved minimal risk research;	
For U.S. federally funded studies and studies subject to the US FDA regulations, any research study that was reviewed and received initial approval at a convened REB meeting will be reviewed by the convened REB at annual renewal, unless the study meets the criteria outlined in SOP 406 Article 3.6.1 or one of the conditions described in the FDA or DHHS guidances as applicable. •annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis.	OHRP Guidance August 11, 2003 FDA Guidance November 9, 1998 (Federal Register Vol. 63) SOP 406
3.6.4. Unanticipated Problems including Serious Adverse Event Reports and Safety Updates Unanticipated problems, including serious adverse event reports, protocol deviations, and safety updates such as reports from Data Safety Monitoring Committees may be reviewed by the Chair or his/her designee, in accordance with SOP405 “on-going review”. If the REB Chair or designee considers that action is needed to protect the safety of research participants, she/he may take such action immediately and/or request a review of the report at a convened REB meeting or by a designated sub-committee to determine what further action, if any, is required.	See SOP 405 ICH_GCP 3.3.9 (a) (b)
3.6.5 Advertisements: The REB Chair or designate, may approve new or revised recruitment advertisements or scripts.	
3.6.6 Translations: Translated consent documents submitted pursuant to REB requests may be reviewed by the REB Chair or her/his designate.	

3.6.7 Additional Items: The REB Chair or designee may use delegated review procedures for the review of miscellaneous items such as correspondence from the investigator.	
3.7 Decisions Arising from Delegated Review All Certificates of Approval for studies approved by Delegated review will denote that the review was delegated. 3.7.1 The outcome of the first review of the application through delegated review will be one of the following three decisions: **Approval, Proviso or, Deferral** (as detailed in SOP 404) or referral to the Full Board as provided in 3.2 above. The Principal Investigator and the primary contact will receive an email notification of the Board decision followed by the original sent through the mail.	See SOP 404 SOP 001 for definitions