

	POAT-REVIEW NOTIFICATIONS			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	3.04	02.07.2020	4.3, 4.4	03.25.2019

Notification of Investigators Following Review

The IRB office notifies each investigator in written memo form of the review of their submission. The memo will outline the necessary actions, and upon receipt of that memo the PI makes the required corrections and modifications, or re-submits a new application. If a response is not received within the time-frame noted on the letter, the application will be rescinded. This would require that a complete new application package be submitted for consideration by the Board at a future meeting if the PI wishes to pursue the study.

Investigator Assurance and Notice to the Institutional Official

Upon IRB initial approval or approval after MRSA, the IRB office generates an assurance notice, which is addressed to the Vice-Chancellor for Academic Affairs (the Institutional Official). Two copies of this notice are prepared and sent to the PI, who must sign both and return them to the IRB office. The Chair or Vice-Chair signs both copies of the notice; this signature date is the approval date of the protocol.

The approval period is also stated on the assurance and is determined by the IRB based on the merit of the study and the level of risk to the subject. The approval period will not exceed one year. The initial approval period will begin on the date of the meeting at which the application was approved or determined MRSA. If the determination that a period of less than one year is required, the IRB may set any time-period as the appropriate interval and may change that interval at any time. The IRB may require progress reports from the principal investigator. The IRB has the authority to suspend, terminate or require changes at any time. If the Board requires any restrictions in the protocol, e.g., a limitation on the initial number of subjects allowed before a report is provided to the IRB, this information is included in the written documentation. The duration of the approval period is tracked through a computer database to generate protocol continuing review notices.

One original of the signed assurance is returned to the investigator for their files, and the other is kept in the protocol file for that project. A copy is forwarded to the Vice-Chancellor for Academic Affairs. The IRB office also forwards to the investigator a signed, stamped copy of the first page of the approved consent form and any other approved study documents. No research activities can commence until the assurance is signed by the Chair.