



Policy

Title: Protocol Amendments

Control #	Version:	Written by:	Approved by:	Approval date:
P-004	v.1.0	Laura Kandziolka, ESCRO Administrator	ESCRO Committee	7/8/08 (effective immediately)

Any change to the conduct of an ESCRO protocol must be reviewed and approved by the ESCRO Committee prior to implementation of that change. These changes, called Amendments, can be either major or minor. A major amendment impacts the protocol in a significant way, while a minor amendment does not. Examples of both types of amendments include, but are not limited to:

Major Amendment	Minor Amendment
Change in principal investigator (PI) or change in or addition of co-principal investigator	Change in or addition of co-investigator or staff
Change in objectives of study	Change in title of protocol (assuming it does not imply a change in objectives)
Significant change in study design	
Addition of a new collaborative or study site	Addition of new hESC line not already listed on the protocol ¹
Total annual increase in the number of embryos, oocytes, skin biopsies, or other tissues of <i>more than 50%</i> of the number approved at the last annual review	Total annual increase in the number of embryos, oocytes, skin biopsies, or other tissues of <i>up to 50%</i> of the number approved at the last annual review

(Note: An amendment is not required for a decrease in numbers. This need only be reported on the Progress Report form during the annual review.)

Review Process

- Minor amendments are reviewed via expedited review.
- Major amendments to full-committee review (FCR) studies will undergo full-committee review.
- Major amendments to studies that previously qualified for expedited review will undergo expedited review as long as the study would still qualify for expedited review with the addition of the change. Otherwise the entire protocol with the amendment integrated will need to be reviewed by the full committee.

The approval of an amendment does not change the annual expiration date of the protocol, except in the case of a previously expedited study that must undergo full-committee review as described above. In this case, the expiration date is one year from the date of the full-committee review at which the protocol was approved or contingently approved.

¹ A non-NIH line derived outside of Harvard that has not already been accepted by the Harvard ESCRO must undergo full committee examination of provenance prior to the expedited review of the amendment.