



ANNOUNCEMENT: NEW ENGLAND IRB POLICY CHANGE

Effective September 13, 2009, New England IRB no longer requires submission of the following:

- 🌱 FDA Form 1572
- 🌱 Sub-investigator CVs
- 🌱 Sub-investigator licenses
- 🌱 CVs for individuals obtaining consent
- 🌱 Licenses for individuals obtaining consent

Effect of Policy Change on New Submissions

When submitting a new Site Submission to New England IRB, the submission does not have to be accompanied by the FDA Form 1572. In addition, CVs and licenses for sub-investigators and those obtaining consent are no longer required as part of the submission package. New England IRB will still review the qualifications of sub-investigators and research staff who will be obtaining consent. The qualifications of sub-investigators and research staff can be provided directly on the Site Submission Form (items B5 and E1) or in a CV. The CV and license of the Principal Investigator must still be submitted.

Effect of Policy Change for Ongoing Studies

New England IRB requires notification of the following:

- 🌱 Change of Principal Investigator
- 🌱 Addition or removal of a sub-investigator
- 🌱 Addition or removal of an individual who obtains informed consent
- 🌱 Change of site location
- 🌱 Addition or removal of an Additional Location

Changes made should be submitted using NEIRB's Notification of Change to Investigative Site or Research Staff form. The changes can also be submitted via a letter or memo, as long as the following information is provided: the specific change(s); the Principal Investigator at the site; and the study(s) for which the change(s) are being made. Additions to study staff or a change of Principal Investigator may not take effect until approved by NEIRB.

NEIRB does not require a copy of the revised FDA Form 1572. NEIRB does not need to be notified of changes to the FDA Form 1572 that do not affect the study location or study staff.