

## **List of revisions for the Intramural Clinical Trial Template, Version 2.1, dated September 1, 2008:**

Note that no changes have been made to either template document (Blank or Sample Language) with this revision, only to the "Instructions Manual":

- **Statement of Compliance (Instructions Manual):** Added a new GCP Training resource.
- **Section 10.5 (Instructions Manual):** Added a reminder to also include local institutional reporting requirements if conducting studies in locations other than the NIH.
- **Section 14.2 (Instructions Manual):** An explanation that this section is optional and subject to the requirements of the in-Country EC if the protocol is to be conducted overseas.