



## Regulatory Changes August 2009

In response to new Food and Drug Administration guidelines for regulatory documentation, NCI's Division of Cancer Prevention (DCP) has revised its regulatory requirements. The goal is to provide a more complete and accurate record of all individuals involved in the administration of study agents and the implementation of all events within a clinical trial.

The changes described below take effect immediately. A revised CPN Regulatory Forms Packet with instructions and blank forms is available on the CPN website, "For Study Coordinators" page: <http://cancerpreventionnetwork.org/sc.shtml>

Note: It is not required to make these changes unless you are submitting new or revised forms. However, is recommended and would be appreciated.

### Summary of Changes:

1. Study Specific 1572: The site Principal Investigator should be listed in Field #1, and all investigators should be listed in Field #6. In addition, please list in Field #6 the names of all study team members who have (1) direct contact with the patients; (2) responsibilities for data entry, submission, or analysis; (3) Research Pharmacist; (4) pharmacy personnel with responsibilities for relabeling, repackaging, and/or formulating study agent; (5) responsibilities for performing study-specific procedures; and (6) other critical study implementation roles.
2. Delegation of Responsibilities (DOR): All of the individuals who are listed on the study-specific 1572 must be listed on the DOR. This form has been revised to combine the DOR and the Site Signature Sheet into one form, since the information required on each of the old documents was largely the same.

In addition to the individuals who play critical roles on the study (listed on the 1572), please also list back-up study coordinators, pharmacy assistants and technicians who are involved in the dispensing of study agent, and other ancillary personnel who have study responsibilities.

Note: It can be challenging to circulate a single form for signatures in an efficient manner. It is acceptable to have multiple forms and/or to have each individual listed on a separate DOR form. In these cases, make sure the information at the top of the form is identical and that the site PI signs and dates each form.

3. Documents for individuals added to the Study-Specific 1572: For every individual listed on the study-specific 1572, a complete regulatory packet is required. This includes the following documents:
  - o CPN Roster, Affirmation of Integrity, and Conflict of Interest Disclosure Forms (these were probably submitted previously unless there are new personnel, although they could be reviewed to make sure everything is current),
  - o Certificate or other documentation of Human Subjects Protections training,
  - o FDA form 3455,
  - o CV that is signed and dated (or Note-to-File if the individual does not have one),
  - o License or certification (or Note-to-File if the individual does not have one).

Please remember that any document with a signature must be submitted in its original signed form. All others can be submitted electronically.