

**PROCEDURE FOR SEEKING EXCEPTION TO RESTRICTIONS
ON PRINCIPAL INVESTIGATORS
UNDER ASCO CONFLICTS OF INTEREST POLICY**

Due Date

Please refer to the due posted on the abstract submitter for the meeting which you are applying to and return completed exception request materials no later than this due date.

Please submit all materials using the web address made available to you in your Confirmation Email. If you did not save this email please contact the Associate Counsel (see contact information below).

Please direct all questions about the exception application process to Courtney Storm, Associate Counsel, Ethics and Compliance, at Courtney.storm@asco.org.

Criteria for Exceptions

Exceptions may be granted in the following circumstances:

1. The principal investigator is a widely acknowledged expert in a particular therapeutic area so that his or her exclusion from other activities on behalf of the trial sponsor would represent a potential impediment to education or research activities affecting cancer prevention, diagnosis or treatment.
2. The principal investigator is the inventor of a unique technology or treatment being evaluated in the clinical trial.
3. The principal investigator is involved in international clinical oncology research and has acted consistently with recognized international standards of ethics in the conduct of clinical research.
4. As otherwise approved by the Ethics Committee

These exceptions are not self-executing; rather they must be adjudicated by the Ethics Committee.

Request for Exception

Individuals seeking an exception for one or more of the reasons set forth above should forward a request for exception to the Chair of the Ethics Committee.

All requests should be accompanied by:

- a current curriculum vitae and any other information that the requester believes would be considered relevant in the deliberations of the Ethics Committee
- a list of open clinical trials for which the requester is presently serving as principal investigator, as well as any closed clinical trials that ceased accrual during the past two years
- a letter of request describing succinctly why the requester should be granted an exception from the restrictions on principal investigators set forth in the ASCO policy

Requests under the first criterion listed above should also include:

- a list of each major scientific meeting at which he or she has presented during the previous two-year period, including the subject matter of each such presentation
- full disclosure of all financial interests and consulting arrangements not just with the trial sponsor but with all commercial entities involved in oncology products; the scope of disclosure should be consistent with the disclosure requirements in the ASCO conflicts policy, and should include specific payments received for any service as an employee, consultant or adviser to each such commercial entity.
- a narrative statement demonstrating that “exclusion from other activities on behalf of the trial sponsor would represent a potential impediment to education or research activities affecting cancer prevention, diagnosis or treatment”

Requests under the second criterion listed above should also include:

- the requester’s curriculum vitae, as well as proof of his or her role as inventor of the technology or treatment in question
- a narrative statement justifying that the technology or treatment being evaluated in the clinical trial in question makes a “unique” contribution to the prevention, diagnosis or treatment of cancer

Requests under the third criterion listed above should also include:

- a curriculum vitae and a list of international scientific meetings at which the individual has presented during the previous two years, including the subject matter of each presentation
- reference to applicable international ethics standards that differ from the ASCO conflicts policy and a discussion of the sufficiency of those standards in the international environment in which the individual conducts clinical research

Requests under the fourth criterion listed above should also include:

- any relevant information to show the basis on which the requester believes an exception should be granted and relevant supporting documentation

Timing of Request and Response from Ethics Committee

Individuals believing that they may qualify for an exception from the restrictions imposed on principal investigators should submit the request at the earliest possible time to avoid delays that might affect eligibility for ASCO activities. Requesters will be notified as soon as a decision is made.

Recording and Reporting Exceptions

The Ethics Committee will retain a record of all requests for exception and all exceptions granted. A list of exceptions granted will be submitted to the ASCO Board on a quarterly basis. To the extent that exceptions are granted, there should be disclosure of the circumstances and rationale for each in connection with the relevant ASCO activity involving the clinical trial in question and the principal investigator receiving the exception.