

## IRB Policies on Conflict of Interest (COI)

The Washington Drug Letter, published an article in the April 9, 2007 issue titled “Many IRBs Lack Policies on Conflicts of Interest.” According to the publication, “one-quarter of IRBs that oversee research at medical schools have no written policy on conflicts of interest among members and only one in five systematically collects information about members’ potential conflicts of interest..”

Written policies on conflicts of interest may address financial interests, personal and professional relationships as well as personal beliefs. Of particular interest are those conflicts which are financially based. US Public Health Service regulations stipulate that “significant financial interests” are payments or equity from the trial sponsor of more than \$10,000.

According to a survey published in the *New England Journal of Medicine* in 2006 stated that “approximately one in seven IRB members reviewed at least one protocol...that would be considered a conflict of interest”.

## Anemia Drug Safety Data Request

The FDA has requested additional safety data for anemia drugs which have raised safety concerns in recent months. Recent studies have show that the injectable anemia drugs may increase risk of death or tumor growth when prescribed outside of the approved guidelines. The FDA has already added additional warnings to these drugs about the risks of death, stroke and heart attacks when used at higher-than-recommended levels. Europe’s drug agency has announced a safety review of anemia drugs as studies suggested an increased risk of serious cardiovascular complications in patients with chronic renal failure. A panel of outside experts will decide if companies should be required to add additional warnings to their drugs or conduct safety studies.

### INSIDE THIS ISSUE

IRB Documents Available Online!	1
Anemia Drug Safety Request	1
IRB Documents Available Online	1

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