From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Friday, July 16, 2004 11:10 AM
To: **[Redacted]**
Subject: RE: IRB Rosters

Dear Mr. **[Redacted]** ,

The citation you are looking for is found at 21 CFR 56.115 which identifies what records an IRB must maintain. Specifically, 21 CFR 56.115(5) deals with the requirement for an IRB to maintain a list of members. The cite is quoted below:

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member`s chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

You can find this citation on our website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=56.115.

I hope this information is helpful.

Sincerely yours,

Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, July 13, 2004 4:56 PM
To: gcpquestions@oc.fda.gov
Subject: IRB Rosters

Is there an FDA regulatory requirement that requires or relates to an IRB maintain a roster of members? If so what is the regulatory citation? I would like to cross reference the citation in my policy and procedures. Thanks