

## Select a Roster

New rosters are issued when membership changes or at the beginning of the year. Rosters are posted only for the prior three years.

## IRC's policy about our Roster

We are occasionally asked about the lack of names on our rosters. IRC does not include member names on the roster in order to protect the privacy of members. Our roster does indicate that the membership requirements are satisfied and are sufficient to give some idea of the areas of interest. We note that no regulation requires names to be listed publicly and, of course, FDA inspectors review not only the names but also the qualifications.

## Membership

IRB membership is assessed by each and every FDA investigator. We have had five audits and only one question was raised. The IRB and CDRH disputed whether one of the members' "primary concern was non-scientific" or whether this person is a scientist. Although still unresolved, another member was added who is "unambiguously non-scientific." The regulations speak of a member whose "primary concerns are non-scientific." The guidance speaks of "unambiguously non-scientific." The person FDA investigator's challenged had been a scientist in a previous life but had followed other interests for the prior 18 years.

