Accrual/Data Submission Expectations

Ellis Levine, M.D., IPEC Committee Liaison
Roswell Park Cancer Institute

Group Meeting, June 2005

SO, WHAT ARE BEHIND THOSE ANNOYING IPEC LETTERS THAT INFORM YOU THAT YOUR AFFILATE(S) IS(ARE) BEING DROPPED FROM CALGB MEMBERSHIP?

Membership Requirements For Affiliates

Affiliates that do not meet their accrual obligation of 6 registrations per calendar year during any consecutive two year period will automatically have their CALGB membership terminated, as of January 1 of the year following the two year period. At the winter meeting the affiliate members likely to be affected by this policy will be informed of the action, which may not be appealed.

Date of Approval of Affiliate Application by the Membership Committee

Accrual†

Affiliate	July or Nov/2005-12/2005	1/2006-12/2006	1/2007-12/2007	1/2008-12/2008	1/2009-12/2009
A	1	4	4	-	-
B	2	3	8	5	3*
C	4	3	4	-	-
D	2	9	5	8	11
E	2	9	5	3	-

*Membership withdrawn on 1/2010

†Does not apply to CCOP affiliates

Membership Requirements For At-large Members

At-large members who do not fulfill their accrual requirement of 30 registrations per year for two consecutive calendar years would automatically be changed to an affiliate as of May 1 in the year following their two years of substandard accrual. They would be allowed 4 months to find a main member or at-large member with whom to affiliate. It is understood that any affiliates of the at-large member would also need to find a new main member or at-large institution with which to affiliate by May 1. If affiliation agreements cannot be executed in this time frame, the at-large member (and their affiliates) will be dropped from participation in the CALGB. At the winter meeting, the at-large members likely to be affected by this policy will be informed of the action and be give the opportunity to appeal the action to the Membership Committee before January 1.

Membership Requirements For At-large Members

The Membership Committee may recommend exceptions to the Chair for approval. If an exception is granted, the affected institution will be granted a grace period of 1 year. If the institution does not meet their accrual goal at the end of the grace period, their membership status will be changed to affiliate, without an opportunity to appeal. If the at-large member and/or their affiliates do not find another at-large or main member with which to affiliate by the end of the grace period, their CALGB membership will automatically be terminated, as of January 1 in the year following the grace period.

Membership Requirements For Main Members

Main members who do not meet their accrual of 50 registrations per year during two consecutive calendar years will automatically be changed to an at-large member, as of January 1 in the year following those two consecutive years of substandard accrual. At the winter meeting, the main members likely to be affected by this policy will be informed of the action and be given the opportunity to appeal the action to the Membership Committee before January 1.

Membership Requirements For Main Members

The Membership Committee may recommend exceptions to the Group Chair for approval. If an exception is granted, the affected institution will be granted a grace period of 1 year. If the institution does not meet their accrual goal at the end of the grace period, their membership status will automatically be changed to at-large, without an opportunity to appeal.

HOW DOES IPEC MAKE A DETERMINATION OF THE QUALITY WITH WHICH A MAIN MEMBER OR AT-LARGE MEMBER OR CCOP IS CONDUCTING COOPERATIVE GROUP RESEARCH?

Criteria Used By IPEC For Assessing Quality Of Performance By Networks

- Delinquency rates for the network* *(Sherry Breaux)*
- Audit reports* *(Ray Weiss)*
- I-008 Evaluations *(Sherry Breaux)*
- PET Quality Assurance Subcommittee report *(Tony Miller)*
- Quality Assurance Review Center/Radiation Oncology Quality Improvement Subcommittee report *(Jeff Bogart, Giulia Cicchetti, and Donna Wardle)*
- Surgical Quality Assurance Committee report *(Judy Smith)*
- Miscellaneous information brought before the Committee *(e.g., suspension of individual studies due to protocol non-compliance)*

** More heavily weighted than other criteria.*

Criteria Used By IPEC For Assessing Quality

The Pharmacology and Experimental Therapeutics Committee (PET-QASC) , the Radiation Oncology Quality Improvement Subcommittee (ROQIS), the Surgery Quality Assurance Committee (SQAC), and the Transplant Committee, each have criteria in place that mandate either suspension of registration to an individual study at an institution (PET - QASC), or the need for immediate treatment review (QARC and SQAC), or removal of an institution from participation in a category of studies (Transplant).

Criteria for recommendation of probation of main or at-large member networks to the Membership Committee by the Institutional Performance Evaluation Committee

(Draft)

The IPEC will recommend probation if a network meets one major criterion or $\geq$3 minor criteria.

Probationary Criteria *(Draft)*

- Major criteria
  1. Two successive audits (audit and re-audit) with unacceptable ratings in the same audit review category, or three successive audits with at least one unacceptable rating in any of the three audit categories. The categories are:
     - IRB and Informed Consent
     - Pharmacy
     - Patient Case Review (includes data quality)

Probationary Criteria *(Draft)*

- Major criteria
  2. Data delinquency in two or more of the four assessed variables of >10% for two consecutive IPEC evaluation periods. The four delinquency variables include total survival status, total clinical status, survival status in the last year reported, and clinical status in the last year reported. There must have been at least five separate delinquent cases over the 3.5-4 year reporting period for this criterion to be applicable.

Probationary Criteria *(Draft)*

- Minor Criteria
  1. Statistical Center assessment of institutional data quality finds deviation of more than 2 standard deviations from the mean in an unfavorable direction for two consecutive IPEC evaluation periods.
  2. Accrual to a study is suspended exclusively within a network during the most recent evaluation period because of an inability to meet PET quality assurance requirements, despite a prior warning.

Probationary Criteria (*Draft*)

- Minor Criteria
  3. There are substandard QARC ratings for either submission or performance for 2 consecutive evaluations, concurrent with receipt of two warning letters from ROQIS.
  4. There are substandard SQAC ratings for two consecutive evaluations, concurrent with receipt of two warning letters from SQAC.
  5. Study registration privileges for one or more studies were suspended exclusively within a network for poor data management or protocol non-compliance during the most recent evaluation period.

Probationary Criteria (*Draft*)

Isolated probation of selected affiliates within a network is preferable to probation of an entire network. However, if the network is underperforming in more than one area, IPEC considers the entire network to be underperforming and recommends probation for the entire network. Therefore, the IPEC may recommend probationary status for individual affiliates or the entire main/at-large member network.

Probationary Criteria *(Draft)*

Accrual over any 24-month period determines membership status changes. Therefore, IPEC does not consider accrual as a parameter used to determine a recommendation for probation.

CALGB