Guidelines for Multi-centre studies:

For Multi-centre studies a summary including the following is required:

1. Abstract: This should be a one page or less digest of the proposal outlining the major points with an emphasis on local subjects. References to the main proposal can and should be made in the abstract with the appropriate page number. This needs to the done by the local primary investigator and not copied from the abstract supplied by the sponsor.
2. Local work plan: a work plan needs to be included which specifies the following:
    i) Timeline: the proposed timeline of the local portion of the study including the onset of subject selection, term of subject accrual with anticipated quarterly accrual rate, follow up period, and anticipated end of the study.
    ii) Role of investigators: who will be responsible for local subject recruitment, data collection, and reports to the RAC; each local investigator listed on the study should be noted as to their role in the aforementioned activities.
    iii) Subject recruitment: it should be clearly delineated as to how subjects will come into the study, from what source and how they will be processed.
3. Rationale: A rationale for local participation should be included. This should describe the following:
    i) Expected local impact: the investigator(s) should describe the projected impact on the local population at issue in the study as to how they will be affected through study outcome(s) and what benefit will accrue to local medical practice.
    ii) Recruitment of subjects: the investigator(s) should describe how subjects will be selected, whether the same inclusion/exclusion criteria will apply as in the main proposal and if not, how it will differ.
    iii) Justification for number of anticipated subjects: the investigator(s) should describe the justification for the number of subjects to be accrued locally based on previous experience, database information, other local studies, etc.
4. Registration: it should be stated whether or not the proposal has been registered in one of the 5 existing registries e.g. ClinicalTrail.gov or in any of the primary registries that participate in the World Health Organization's International Clinical Trial Registry Platforms as is required by the International Committee of Medical Journal Editors (ECMJE) for trials that begin enrollment on or after 1 July 2008.