Below are pertinent considerations for reviewers for all international studies. If not addressed by the protocol, comments should be included in either the “List of Concerns that Must be Addressed Before Approval” section (for deal-breaker concerns) or “Suggestions” section (for minor concerns) and brought to the attention of the investigator(s). **The primary concern is to require that each PI connect with the UCSF Global Cancer Program (www.globalcancer.ucsf.edu).** If they have not already done so, add a comment to connect with the Global Cancer Program in the “List of Concerns that Must be Addressed Before Approval” section of your Site Committee review form.

* **Is Funding Adequate?**
	+ - Is it standard practice to compensate/provide stipends to co-investigators? What are the standard rates?
		- Is it standard practice to provide “tokens” or small compensation to study participants (ex. transportation vouchers, airtime cards, etc.)? What is the study site standard? If so, are study participant “tokens”/compensation to study participants included?
		- Have the in-country team members budgeted for the appropriate amount of UCSF guest accounts required to use UCSF applications (ex. OnCore) ($11/month)?
		- Are all required IRB/ethical review board fees included?
		- Are all IRB/ethical review board renewal and/or amendment fees included?
		- Are administrative fees/indirect costs for subrecipients incorporated?
		- Are co-investigators compensation and/or are stipends included?
		- Are fees/stipends included for procedures (ex. biopsies, pathology, etc.)
		- If planning to collect data electronically, but laptops/tablets are not currently available, are tablets/laptops included in the budget?
		- Are printing costs included for study tools, flyers, materials, etc.?
* **Data Management Resources Adequate/Available?**
	+ - How will the data be collected?
		- If via paper tools, who will be responsible for entering the data into a database? What data collection platform/database will be used?
		- If electronically, are tablets/laptops available? What data collection platform/database will be used?
		- Is the timeline for collecting data feasible *(ex. based on estimates from patient load)?*
		- How will data be shared between investigators/institutions? Will material transfer agreements and/or data transfer agreements need to be executed to share data, biospecimens, etc.?
		- If this is an interventional study, who will be responsible for entering data into OnCore?
		- Does this person have access to OnCore and appropriate training?
		- If international team member(s) will be entering data, do they members have a sufficient number of UCSF guest accounts required to use UCSF applications? (REDCap, OnCore, etc.).
		- Will the study team at the International sites have access to Wi-Fi in order to complete the OnCore training and ensure ability to complete OnCore entry requirements?
* **Study Design**
	+ - Will there be a local, in-country leader for this study?
* **Potential for UCSF Publication**
	+ - Have authorship expectations been openly discussed with international collaborators?
		- What is the role of the in-country leader in developing this study?
		- What is the role of the UCSF investigator team?
		- Where will data analysis be performed?
* **Accrual/Feasibility**
	+ **Accrual**
		- Have the in-country team members provided their accrual estimates?
		- Are accrual estimates based on tumor registry data or prior accrual in similar populations? If not, what justification was used to determine the estimates?
	+ **General Feasibility**
		- Does the study have in-country support to coordinate activities, collect data, etc.?
		- Does the in-country study team have reliable access to internet?
		- Does the in-country team have reliable access to the UCSF VPN/DuoMobile?
		- If expecting the in-country team to conduct data analysis, do they have the required software license (ex. STATA, SPSS, MAXQDA, etc.)?
	+ **Data Monitoring**
		- Is a data and safety monitoring board required? If so, who will be the data and safety monitoring board for the trial?
		- Will auditing/monitoring be required? If so, is there adequate funding to support the hiring of a Clinical Research Organization (CRO) to complete this auditing/monitoring? How will the source documents be provided to the monitoring entity?
	+ **Ethical Considerations**
		- Is the timeline for obtaining IRB/ethical approvals sufficient *(recommended minimum of 3 months)?*
		- What in-country IRBs and/or review committees will need to review this study?
		- Are additional approvals needed to initiate this research at the study site (ex. letter of approval from hospital director)?