GCIG Harmonization Committee

Criteria for joining [Trial name] as a GCIG group

Participating Group: _____

Please confirm that you meet the following criteria by deleting as appropriate:

**These documents are not required if the GCIG group is a previous collaborator (within the previous 5 years)*

1.	The Participating Group must have a trials office with dedicated personnel and adequate resourcing, who abide by their own SOPs (for safety, monitoring, site initiation and closure).	List of SOPs provided to GCIG LEAD GROUP CTU?* Yes / No	Organisational Structure provided to GCIG LEAD GROUP?* Yes / No
2.	Named Principal Investigator for the Participating Group (must be Gynecological or Medical oncologist) who will undertake responsibilities of the sponsor.	CV provided for review? Yes / No	
3.	The Participating Group must work from the same protocol version as the Lead Group.. Group Specific Appendix (GSA) may be individualized for each PCC.	GSA required? Yes / No	
4.	Participating Group procedures must be consistent with [insert relevant regulations, e.g. EU Clinical trials Directive 2001, safety reporting]	SAEs reported within 24hours. Yes / No	SUSARs 7 and 15 day rule Yes / No
5.	Portfolio of trials to be supplied to determine extent of prior experience (must have experience of Phase II/III trials and use of IMPs). List of GCIG trials which Participating Group have participated with must be supplied.	Portfolio of trials Yes / No	GCIG Trials List Yes / No
6.	Compliance with principles of ICH GCP	Yes / No	
7.	Regulatory/National ethics information must be supplied to GCIG LEAD GROUP prior to collaboration, with details of reports required.	Regulators and any reports* Yes / No	National Ethics and any reports* Yes / No
8.	Guarantee that participants in [STUDY NAME]will be followed up at Participating group sites (unless an emergency).	Yes / No	
9.	Participating Group will ensure that each participating site will sign the [STUDY NAME] checklist and an Investigator's agreement.	Agree Yes / No	
10.	Archiving facilities available (records to be kept at end of trial for [7] years).	Yes / No	
11.	Laboratory GCP (accreditation)	Yes / No	
12.	Translation of the protocol, clinical guidelines and GSA may be performed.	Necessary? Yes / No	
13.	GCIG LEAD GROUP to be provided with estimated total number of potential participants as well as number of sites that will be opened in Participating Group.	No. of participants (total for PCC)	No. of sites

Name of Prinicipal Investigator in Participating Group:

_____

(Print name in capitals letters)

Signature: _____ Date: _____

The ultimate decision regarding collaboration is decided by the GCIG LEAD GROUP