GCIG Harmonization Committee

Site Selection Checklist

Participating Group:_____

Site Name:_____

Site City and Country:_____

Please confirm that your site meets the following criteria by initialling your response in the appropriate column:

	Yes	No
1. The site will regularly undertake the care of gynaecologic patients [SPECIFY site ovary, endometrium, cervix, etc] and will have gynaecologist and oncologists as part of multidisciplinary team experienced in the care of patients receiving [surgery, systemic or localized therapies, radiation therapy] for gynaecologic cancers.		
2. The investigator will have appropriate experience of conducting trials according to good clinical practice (GCP).		
3. The site will have an adequate number of qualified clinical staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.		
4. All staff assisting with the trial will be adequately informed about the protocol, the investigational product and procedures, and their trial related duties.		
5. The trial will be conducted in accordance with the [STUDY NAME] protocol, to GCP standards and applicable regulatory requirements..		
6. Standard local practice guidelines will be in place at the site to deal with acute medical or surgical complications of treatment		
7. The trial will be conducted in accordance with the current protocol and changes will only be made when necessary to protect the safety, rights and welfare of patients		
8. The site will maintain an Investigator Site File which will contain essential documents for the conduct of the trial.		
9. All trial data will be submitted in a timely manner, and as described in the [STUDY NAME]protocol.		
10. All Serious Adverse Events (SAE) will be reported within one working day to the LEAD GROUP, except for those that the protocol identifies as not requiring immediate reporting.		

11. The site agrees to participate in the monitoring and audit plans for STUDY NAME giving access to representatives of their GCIG Participating group and the LEAD GROUP, to all relevant trial documents including site files, patient records, reports and data. In addition sites may also be required to allow access to trial documents to regulatory authorities should the trial be audited.		
12. [Add specific criteria according to trial type, may include pathology, radiology, laboratory, pharmacy requirements]		
How many patients do you typically see with (specify diagnosis or condition) _____ per year?		
How many of those patients are likely to be eligible for Study Name?		
How many gynecologic cancer trials have been opened at your site in the last year?		
Will there be a dedicated research nurse / data manager and/or clinical research associate working on study name at your site? (please specify which)		

Name of Principal Investigator: _____
(Print name in capitals letters)

Signature: _____ **Date**: _____