Disease Site Group Clinical Trial Assessment & Approval Form

Clinical Trials Unit – Adult Trials

Study Title:

Local PI:

Study Sponsor:

Co-Investigators – list all physicians who will be involved in this study (eg. Rad Onc, Gyne Onc, Med Onc, Surg Onc, Hematologist):
(*Those listed will be asked to sign a form agreeing to actively screen for study participants and to provide back up coverage in the case of investigator absence.)*

Pathologist (if tissue submission required; as per DSM, the PI must speak to the pathologist identified below and get their approval prior to adding their name to the study):

Sites of Local Activation:

Number of patients seen per year with this diagnosis: _____

Number of patients you expect to enroll per year based on numbers above: _____

Recruitment Plan – Please outline how potentially eligible patients will be identified:

Do any trials currently open conflict with this trial or compete for the same patient population? ☐ No ☐ Yes If yes, please justify:

Discussed and approved by applicable DSG(s) and sub-specialties (if applicable)?

☐ Yes - list DSG's:_____ ☐ No - reason why not: _____

What is the standard treatment for this patient population?

☐ Chemotherapy, drugs:_____ cycles:_____ or ☐ until progression; average number of cycles: _____

☐ Radiation therapy, schedule:_____

☐ Surgery, describe: _____

☐ Best Supportive Care

☐ Other: _____ (please provide drug names, average number of cycles)

For budgeting purposes:
How long would you estimate that the average patient would remain on active protocol treatment (i.e. number of weeks or cycles): _____ and on follow-up (once off treatment): _____.

Please attach the Schedule of Assessment from the protocol. Please indicate directly on the schedule which assessment and/or timepoints are ABOVE STANDARD OF CARE (ASOC). The CTU will be charged for all above-standard assessments.

Signature of DSG Chair **(or delegate, if Chair is also PI)**	**Date**	**Printed name**