National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

SAMPLE PRO-FORMA FOR NON-APPROVED PROTOCOLS

Background

In the **NCCP Oncology Medication Safety Review Report 2014** under section 3.9 'Chemotherapy Protocols' it was recommended that all requests to use a non-approved protocol should follow a locally standardized procedure which is to include the completion and submission of a pro-forma request to the hospital pharmacy. In addition a record should be kept of all such requests and an annual audit conducted to examine the reasons for such off-protocol treatments. For full text of recommendations see **Recommendations 44 & 45** below.

Recommendations

Chemo Protocols	Rec. 44	Each unit should have a **written policy for preventing regular use of protocols not on the accepted list**. The policy should state: • The exceptional circumstances under which such a regimen could be used. • The procedure which is then required to authorise it.

Chemo Protocols	Rec. 45	**Requests to use a non-approved protocol** should be made to hospital pharmacy by a medical consultant and accompanied by supporting references and a completed pro-forma request. A record should be kept of all such requests which result in off-protocol treatment. Annual audits should be conducted to examine the reasons why such off-protocol treatments were necessary.

The following sample pro-forma for non-approved protocols has been developed as a template and is based on University Hospital Limerick's pro-forma. This may be used as it stands or adjusted to suit local policy.

SAMPLE PRO-FORMA FOR NON-APPROVED PROTOCOLS

Protocol:	
Indication:	
Eligibility:	
Cycle Frequency:	**Total No. of cycles:**
Requested by:	**Name:** **Signature**: **Date:**
Completed by:	**Name:** **Signature**: **Date:**
Planned Treatment Date :	

Cycle Schedule

Drug	Dose (mg/m^2)	Route of administration	Frequency

Dose Modification / Treatment Delay:	*(e.g. delay if neutrophils < 1.5 x $10^{9/}$L or platelets < 100 x $10^{9/}$L for one week or decrease dose by x%, etc.)*

Administration and Safety

Anti-emetic Group:	*(Low, medium, high emetogenicity)*

Pre-medications / Ancillary Medications:	
Rounding Information:	
Toxicities:	
Drug Interactions:	

Investigations

Pre-treatment

Specify particular tests:	

Prior to each cycle

Specify particular tests:	

History:	
Examination:	

Performance score:		**Weight (kg):**		**Height (cm):**	

Post Treatment

Reviewed in:

Name of Clinic:		**No. of weeks after last cycle:**	

References

Please detail reference used to support non-protocol request. Please supply hard copy if available.

Version	Date	Amendment	Approved By
1	15/02/2016		Patricia Heckman

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.