Standard Operating Procedure for the Development and Checking of SACT Protocols for Oncology and Haematology

1.0 Objective

The purpose of this standard operating procedure (SOP) is to set out the criteria used when developing and validating systemic anticancer therapy (SACT) protocols within the Kent and Medway Cancer Collaborative as requested by the Kent and Medway wide Non-surgical Oncology Sub-Groups (NOGs; the haematology equivalent group is known as the HOG).

2.0 Scope

This SOP will cover all oncology and haematology protocols, excluding clinical trials and paediatrics. This will encompass NHSE MHRA EAMs schemes, and complex supportive care regimens which require a protocol as identified by the Kent and Medway Chemotherapy Group. Algorithm deviations, one-off requests, and access schemes offered by manufacturers (for licensed drugs which have not been through the NICE process) should be considered within the context of the 'Policy for the Management of Algorithm Deviations and the use of Unfunded Medicines' and are outside the scope of this SOP.

Appendix 1 describes the authorisation of protocols.

NB: the criteria laid out in this checklist are not exhaustive and additional information may be required.

3.0 Responsibilities

Refer to Figure 3 of reference 1.

4.0 Method

	Check that:	**Prepared by**	**Checked by**
1	Correct KMCC template has been used.		
2	Name of protocol / regimen is clear to include brand name if required (due to pharmacokinetic, bioavailability or licensing issues). The brand name should be in the regimen title and in the administration details.		
3	The disease type has been stated.		
4	Indication correct.		
5	Therapeutic intent stated.		

6	Number of cycles to include maximum duration of therapy if required.		
7	Length of cycle included.		
8	Wording unambiguous (e.g. repeat 'every 3 weeks' not '3 weekly').		
9	Any mandatory tests prior to treatment are included and required parameters stated (e.g. DTPA/ ECG). Ensure consistency between drugs of the same therapeutic class where appropriate.		
10	Where routine monitoring is required during treatment (e.g. echo every 3 months) this should be included in the protocol.		
11	Where routine monitoring parameters are not met (e.g. CrCl, Hb, WBC etc.) and dose interruptions or modifications are required, guidance is provided or referenced.		
12	The most significant drug interactions are included.		
13	Significant adverse reaction including infusion related reactions (monitoring and management) are stated.		
14	Ensure reference to any patient alert/information cards is included if relevant.		
15	All the correct drugs are prescribed.		
16	Drug doses are correct.		
17	Correct form of drug is stated.		
18	Drug doses are stated for the correct number of doses or days.		
19	Order of drug administration is correct. e.g. The most vesicant drug is given first, drugs with high incidence of hypersensitivity reaction given first.		
20	Routes of administration are appropriate (IV administration <10mins is a bolus, >/=10mins is an infusion).		
21	Maximum doses are stated if applicable.		
22	The total daily dose is stated if applicable.		
23	Doses are in mg wherever possible.		
24	BSA is capped if appropriate. As ARIA is capped at BSA 2.0, for adjuvant or neo-adjuvant treatments, a statement should be included		

	on the protocol to advise the clinician to consider using actual BSA.		
25	Timings are correct where relevant.		
26	Diluents and concentrations are appropriate.		
27	If filters and/or specific disposables (e.g. non PVC bag and giving sets) are required, these are stated. NB For paclitaxel ensure non PVC bag and giving set is stated.		
28	If vinca alkaloids are listed, they are added to at least 50ml sodium chloride 0.9%.		
29	If pre-medication is required a reminder is given before chemotherapy.		
30	Appropriate anti-emetics are included and are in accordance with network anti-emetic guidelines.		
31	Supportive drugs are included if appropriate. (e.g. hydration, mesna etc.) N.B hydration should be prescribed as per network approved hydration schedule for cisplatin.		
32	TTO's are included where appropriate.		
33	BNF severe warnings included.		
34	Filgrastim listed where appropriate and in line with KMCC guidance (should be started at least 24 hours after chemotherapy).		
35	Intrathecal drugs are not included.		
36	If oral SACT is listed ensure that the following statement is included "For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet" Formulation and strengths are listed. Number of days treatment and day of treatment supply is stated.		
37	The use of steroids within immunotherapy protocols should be agreed by the NOG.		
38	"algorithm deviation" is included if appropriate.		
39	Approvals record is present and current to include: written by / check by, date, disclaimer, protocol number, version, superseded version,		

	authorising consultant.		
40	Page 1 of x is correct.		
41	References used for the protocol are listed and used for checking the protocol.		
42	Protocol to be PDF for electronic sign off.		n/a

References:

1) Organisational Structure and Governance Processes for a Central Collaborative Team Supportive the Maintenance of Oncological Treatment Guidelines (treatment algorithms) and Systemic Anti-Cancer Therapy (SACT) Protocols in Oncology and Haematology across the Kent and Medway Cancer Collaborative (including the maintenance of the SACT prescription on an electronic prescribing system) v9
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
2) Algorithm Deviation Policy Version 5
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
3) Cisplatin Hydration Guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
4) Guidance on capping of BSA for the purposes of calculating cytotoxic chemotherapy v1
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/network-chemotherapy-prescription-proformas-protocols-nhs-staff-use/
5) KMCC anti-emetic guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/sact-pathways-guidelines-for-the-management-of-sact-induced-adverse-reactions-and-nursing/
6) KMCC filgrastim guidelines
http://www.kmcc.nhs.uk/medicines-and-prescribing-incorporating-sact-pathways/sact-pathways-guidelines-for-the-management-of-sact-induced-adverse-reactions-and-nursing/

Appendix 1:

Authorisation of KMCC SACT Protocols

The table below indicates the responsible person authorised to make specific changes within a protocol. Re-circulation of the protocol to all checkers would then not be required. These would be classed as a minor amendment and the version number updated as described.

The sign off process for protocols will be electronic, using pdf 'sign and fill', to ensure a clear audit trail.

Version numbers
The introduction of a second decimal point will be used to differentiate a change made under a minor amendment.
For example:
v0.4 has been signed off by a clinician however there is a subsequent change requested which would be classified as a minor amendment as per the table above.
The protocol would then become v0.4.1
Within the approvals records we would then have v0.4 authorised by the clinician and v0.4.1 authorised by the pharmacist.

Protocol amendment	KMCC technician	Oncology / haematology pharmacist*	Consultant**
Formatting issues	√	√	√
Spelling errors	√	√	√
Page numbers	√	√	√
Protocol name		√	√
Regimen number		√	√
Indication - if in line with a new commissioning decision (e.g new CDF indication)		√	√
Administration instructions		√	√
Medication form (eg liquids / tablets)		√	√
Brand name (if applicable)		√	√
References		√	√
Indication – other than new commissioning decision			√
Frequency and number of cycles			√
Monitoring parameters			√
Treatment intent			√
Drug			√
Dose			√
Route			√
Order of administration			√
Infusion duration / rates		√(if within SPC)	√

* An oncology / haematology pharmacist who is trained and deemed competent to check SACT protocols by their Trust Chief Pharmacist

** A consultant may be a consultant oncologist or haematologist or a consultant Nurse or Consultant Pharmacist working within their area of clinical practice. A Consultant Pharmacist must be deemed competent by their Trust Chief Pharmacist and a Consultant Nurse deemed competent by the Chief Nurse.