NHS
Surrey Downs
Clinical Commissioning Group

Policy and Operating Procedures for Individual Funding Requests

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Equality Impact Assessment

To be completed and attached to any procedural document as part of main document sited between version control sheet and contents page

		Yes/No	Comments
1.	**Does the document/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?**	N/A	
4.	**Is the impact of the document/guidance likely to be negative?**	No	
5.	**If so, can the impact be avoided?**	N/A	
6.	**What alternative is there to achieving the document/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

For advice in respect of answering the above questions, please contact Justin Dix, Head of Corporate Services and Governing Body Secretary at justin.dix@surreydownsccg.nhs.uk.

If you have identified a potential discriminatory impact of this procedural document, please contact Justin Dix as above.

Version control

Version	Date	Author	Status	Comment
1	March 2013	Amended from NHS Surrey policy version 7 April 2012.	Draft	Adapted for Executive Committee and Governing Body April 2013
1.2	April 2013	Legal advice (from Weightmans)	Draft	For Executive Committee approval
1.3	July 2013	To adopt former NHS Surrey policy	Final	For Governing Body approval
1.4	July 2013	To adopt former NHS Surrey policy	Final	Final version approved by Governing Body 19 July 2013

Contents

Equality statement

Surrey Downs Clinical Commissioning Group (Surrey Downs CCG) aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the Human Rights Act 1998 and promotes equal opportunities for all. This document has been assessed to ensure that no-one receives less favourable treatment on grounds of their gender, sexual orientation, marital status, race, religion, age, ethnic origin, nationality, or disability.

Members of staff, volunteers or members of the public may request assistance with this policy if they have particular needs. If the person requesting has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

Surrey Downs CCG embraces the four staff pledges in the NHS Constitution. This policy is consistent with these pledges.

1 Introduction

The South East Coast (SEC) Health Policy Support Unit (HPSU), acting on behalf of the CCG Alliance, produced the following documents in 2009:

- The South East Coast Primary Care Trusts Principles and Guidance for dealing with Individual Funding Requests
- South East Coast Primary Care Trusts Model Policy and Operating Procedures for dealing with Individual Funding requests

These documents were designed to help CCGs develop systems in relation to individual funding requests (IFRs) which will facilitate the adoption of area-wide standards and procedures operating in accordance with the requirements of current national guidance (NHS Constitution for England Jan 09, Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatments March 09 Department of Health, Defining guiding principles for processes supporting local decision-making about medicines Jan 09 Department of Health / National Prescribing Centre, Handbook of good practice for local decision-making March 09 National Prescribing Centre). These documents have been utilised to assist with producing this policy.

From April 2013 the NHS England (NHSE) Single Operating Model for directly commissioned services has been implemented. The NHSE will be responsible for the consideration of IFRs for NHSE Prescribed Services. Prescribed Services are defined in the Manual of Prescribed Services and the associated Identification Rules and include specialised services (NHS Commissioning Board. Specialised Commissioning Resources. Available from: http://www.commissioningboard.nhs.uk/resources/spec-comm-resources). This policy therefore does not apply to the services which are the responsibility of the

NHSE and Surrey Downs CCG will not accept any IFRs for the services it is not responsible for commissioning.

IFRs for mental health placements will be considered by a separate placement panel and are not within the scope of this policy.

Surrey Downs CCG has also ratified a number of the South East Coast policy recommendations:

- **PR 2010-02** in relation to NHS pick up of trial funding. Surrey Downs CCG will not pick up the ongoing funding of treatments for patients who have completed clinical trials unless either:
- The CCG has agreed through normal commissioning processes prior to the trial commencing with the trial funder that the CCG will provide funding for the trial participants' on-going treatment once they have left the trial. This agreement will be documented through normal commissioning processes and according to the Trust's governance procedures. In that event, the NHS organisation hosting the clinical trial is required to document the agreed exit strategy in the trial protocol and state the CCG will provide funding for the trial participants' on-going treatment once they have left the trial and provide detail as is appropriate to each individual study; or

- The CCG has agreed to fund the treatment as a service development for all patients in the clinical category of those patients leaving the clinical trial; or

- The CCG's IFR Panel has considered and approved a request to provide individual funding for a patient. However, if such a request is made the fact that the patient has been involved in a clinical trial shall not amount to an exceptional clinical circumstance or be used by the IFR Panel to justify a finding of exceptionality. It is the consenting clinician's responsibility to ensure that patients are fully informed of and agree to their management plan at the end of the trial. This includes making patients aware of this commissioning policy and, where relevant, any successful or unsuccessful request for post-trial funding. Their consent should be documented.

i. **PR 2011-01** in relation to patients changing responsible commissioner which recommends:

- Where the commissioner has assumed responsibility for exercising the Secretary of State's functions under the NHS Act 2006 in respect of a patient where (a) the patient has been previously provided with one or more particular treatments by another NHS commissioning body and wishes the CCG to continue to commission those treatments for the patient, and (b) a patient in the same clinical circumstances would not routinely have been provided with those particular treatments by the commissioner, the policy of the commissioner is that it will operate a presumption in favour of continuing to provide the particular treatments to the individual patient.

- The commissioner reserves the right not to continue funding for all or any of the treatments if, in the individual circumstances of the case, the commissioner has

a good reason for refusing to commission a particular treatment for the patient. A good reason could include where the commissioner considers that:

- The particular treatment is likely not to be clinically effective; or
- The particular treatment is likely not to be cost effective for the patient; or
- That the commissioner had a concern a patient had arranged or may have arranged to change their responsible commissioner wholly or partly in order to obtain the requested treatment; or
- Where the continuation of the funding for this particular treatment may create a level of inequity with other local patients so that the commissioner considers that the particular treatment should not be funded.

- The commissioner reserves the right to seek a formal clinical review of the patient's future healthcare needs and to consider whether the decision to provide the patient with any further courses of treatment of the type previously provided, and of any other nature, are equitable and appropriate.

- The patients future healthcare needs, including consideration of whether to provide the patient with any further courses of treatment of the type previously provided will be determined through the commissioners usual local decision making mechanisms.

2 IFR Process

2.1 Submission Process

Who can make a submission?

IFRs may be submitted by an NHS consultant, a GP or an equivalent autonomous practitioner provided s/he will be responsible for administering the treatment ("the requesting clinician"). Patients may not make submissions directly.

Responsibilities of the requesting clinician

- The requesting clinician is required to affirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the submission is made for funding on his/her behalf.

- The requesting clinician is required to affirm that s/he has made the patient aware of the implications of embarking on the IFR process, the fact that it may take some time before a decision can be made and that if the patient is considering privately funding the requested treatment while the IFR is being considered, retrospective funding will not be available even if the IFR is subsequently approved.

- It is the responsibility of the requesting clinician to ensure that all the information required in support of a submission is submitted.

- If the IFR submission is considered eligible for panel and it is considered further information is required to enable the panel members to make an informed decision then the requesting clinician may be asked to submit additional information. This can be through a written request or as a request to attend the IFR panel (in person or via a teleconference) to present their funding request to the panel members

Submission Form

All funding requests should be submitted on this form (see Appendix 1).

Prior approval is required for ALL individual funding requests. Surrey Downs CCG does not fund retrospectively and the onus is on the requesting clinician to ensure that IFRs are submitted and funding approved before treatment is initiated.

Submissions

Submissions for drug IFRs must be sent electronically as an attachment to highcost.drugs@nhs.net & intervention IFRs to tnrf@nhs.net. The IFR team at Surrey & Sussex Commissioning Support Unit (S & S CSU) will check the account daily.

Requesting clinicians are advised that failure to use the correct paperwork, to follow the above process or submit the form in the required format may result in a delay in Surrey Downs CCG considering IFRs. Incomplete submissions will not be considered.

All drug submissions will be processed as follows:

1. Form to be completed by requesting clinician (in combination with specialist nurse if appropriate)

2. Completed form to be sent to the Provider Trust's pharmacy department for authorisation. The S & S CSU and the Provider Trusts need to work with clinicians to ensure that only IFRs which can meet the criteria of 'exceptionality' or 'rarity' are submitted to the IFR process.

3. Authorised form to be sent electronically as an attachment to highcost.drugs@nhs.net by the Provider Trust's designated contact(s)

IFRs must be received by the IFR Team at S&S CSU, on behalf of Surrey Downs CCG, a minimum of 6 working days before the next IFR panel in order for the request to be considered at that panel.

2.2 Receipt of IFR Submission and Triages for Eligibility

- Only submissions using the standardised submission form (Appendix 1) with the required supporting information will be considered by an IFR panel.

- All eligible IFRs will be considered by a Surrey wide IFR panel.

2.3 On Receipt of IFR Submission

On receipt of an IFR submission each form will be checked by the S&S CSU IFR team to ensure that:

- The CCG is the Responsible Commissioner for that patient
- All contact details have been provided
- Relevant parts of the form have been fully completed
- All supplementary documentation referred to is attached
- The submission has been approved by a suitable representative of the Trust providing the treatment (as appropriate)

2.4 Check for Eligibility for Consideration by the IFR Panel

If the submission is not sufficiently complete, the form and any accompanying material will be returned to the requesting clinician within 5 working days of receipt of the form by the S&S CSU IFR team.

Completed forms will be reviewed at triage to check that the IFR is eligible for consideration by the IFR panel by reference to the following questions – whether the treatment requested:

- Is funded within an existing commissioning policy?
- Is covered by another CCG policy or process?
- Amounts to a service development? **

within 10 working days of receipt of the completed form.

If the answers to the above three questions are all negative, then the submission meets the criteria for consideration as an IFR on the grounds that either:

- The patient is suffering from a medical condition or clinical presentation which is considered rare **and** for which the CCG has no policy because the low probability of the condition occurring among the CCG's population means that an explicit policy is not warranted ("A rarity request"), or

- The patient is suffering from a presenting medical condition for which the CCG has a policy but where the requested treatment has not been agreed to be funded under the policy ("An exceptionality request") and the patient's clinical circumstances are considered by the requesting clinician to be exceptional.

** Whether or not a request should be considered as an IFR or as a request for an in-year service development will depend on whether there are one or more other patients within the population served by the CCG who are, or are likely to be, in the same or similar clinical circumstances as the requesting patient in the same financial

year, and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment.

If it is foreseeable that there will be other than one similar patient, then the request should properly be considered as a request for a service development, except in the circumstances where all the anticipated patients are expected to be from the same family group; a situation which may arise in the context of a rare genetic disease. If all anticipated patients are expected to be from the same family group then the request should be considered as an IFR.

A bi-weekly triage meeting will be held to determine if an IFR is eligible for consideration by the IFR panel (see Appendix 2 for TOR of the triage meeting).

2.5 Redirection of Requests that are Ineligible for Consideration by the IFR Panel

If an IFR submission is ineligible for consideration by the IFR panel the reason why will be determined and appropriate action taken. The submission will be returned to the requesting clinician by the S&S CSU IFR team within 10 working days of the triage meeting decision being made. Where applicable the requesting clinician will either be directed to a more appropriate contact or advised that the request is considered a service development and requires a business case to be submitted to Surrey Downs CCG for consideration.

However, if there is a clear clinical reason why the patient's health will be significantly compromised by waiting until a service development decision has been made then the submission will be processed and taken to the IFR panel and be considered by the IFR panel in the second part of the meeting.

All ineligible IFRs received will be entered onto the IFR database by the S&S CSU IFR team noting:

- the date received, the date scrutinised, and the date returned
- the reason why the submission is ineligible
- the nature of the redirection or transfer
- if a service development whether the submission is to be considered by the IFR panel in part 2 of the meeting

The requesting clinician or patient does not have the right to appeal if an IFR submission is ineligible for consideration by the IFR panel and they will be advised if they wish to take the matter further this must be through the NHS Complaints process.

2.6 Dealing with an Eligible Request

2.6.1 Anonymity and IFR Tracking Record

A file for each eligible IFR submission will be created on the IFR database by the S&S CSU IFR team. A unique identifier will be assigned to the submission.

The first part of the form (parts 1 and 2), containing the identity of the patient and requesting clinician will be separated. From this point in the process forward the submission form (and all copies) will be annonymised and distinguished only by the identifier, in keeping with Caldicott principles.

All the actions, decisions and reasons for decisions relating to the IFR will be summarised on the IFR database.

2.6.2 Acknowledgement

The S&S CSU IFR team will inform the requesting clinician that the submission has been accepted for consideration at the next panel and inform them of the date of the next panel.

All IFRs will be considered within 25 working days of receipt of a fully completed IFR form.

Where there is likely to be a delay the S&S CSU IFR team will inform the requesting clinician.

2.6.3 Identification of time limits and potential cost pressures

In respect of each submission received, it is the responsibility of the applying clinician to establish and notify the S&S CSU IFR team if any time-limited procedures, such as the 18-week rule, apply to each submission and whether any special circumstances exist which may interact with the timing and progress of the IFR process.

Additionally, the CCG finance directorate will be notified by the S&S CSU IFR team of any submissions received which, if approved, are likely to lead to substantial cost pressures. Such notification is not to be taken as an indicator that the submission will be approved.

2.6.4 Call for more information/evidence review/specialist advice

Submissions for Drug IFRs

Each individual IFR drug submission will be allocated to a pharmacy member of the S&S CSU IFR team for processing. The onus is on the applying Trust clinician, as the experts in the area, to submit all relevant clinical information with the submission.

The S&S CSU IFR team will following receipt of the submission routinely perform a literature search (see Appendix 3 for relevant standard operating procedure) to identify relevant clinical information.

It is the responsibility of the member of the S&S CSU IFR team processing the drug IFR to decide what further information, specialist advice, and/or review of evidence is required to enable the IFR panel to consider the submission.

Each case is likely to be different and so will be handled on a case by case basis. When requesting more information the S&S CSU IFR team member will make it clear what further information is required and the timeframe within which it should be received.

The member of the S&S CSU IFR team processing the IFR will make a note of any further information, specialist advice and/or evidence review requested in respect of each submission on the IFR database and will take any steps necessary to ensure that the submission is fully complete and all supplementary information has been received prior to circulation of the IFR submission to the IFR panel.

Submissions for Intervention IFRs

If the IFR is for treatment that is new or unusual, the S&S CSU IFR team will ask Public Health to provide an evidence briefing for the requested treatment.

If an evidence briefing on a new or unusual treatment is required from the Public Health this may take up to 10 working days to enable members of that team to access information from diverse sources including published research and expert opinion. Public Health will endeavour to obtain this information prior to the scheduled IFR panel meeting date.

Where the information requested is not available for the next IFR panel meeting date and / or information is sought from external organisations and the view is that insufficient information is available for a decision to be made, consideration of the intervention IFR may be deferred so as to enable an informed Panel decision to be made**.**

Clinical advice may be sought from CCG clinicians, local consultants and specialist commissioning services. Where a delay may occur this will be conveyed to the requesting clinician by the S&S CSU IFR team.

2.7 Fast-tracking Urgent IFRs

IFRs should only be fast-tracked where there is a clear clinical reason that the patient's health will be significantly compromised by waiting until the next scheduled IFR panel meeting for a decision to be made.

It is expected that only a small minority of IFRs will be fast tracked and these will usually involve life-threatening conditions.

IFRs will not be fast-tracked on grounds that waiting until the next IFR panel is inconvenient or problematic for the patient or requesting clinician.

Before assigning IFRs to the fast-track procedure careful consideration will be given as to whether sufficient information is available for the IFR Panel to make a decision without compromising any of the principles upon which decisions should be made.

If a clinician is requesting that an IFR is fast-tracked on clinical grounds then S&S CSU IFR team will contact Surrey Downs CCG for a decision to be made as to the appropriateness of the request to fast-track.

A fast-tracked IFR will be considered by a specially convened group ("the group") acting as a sub-committee of the next scheduled IFR panel under delegated powers.

The group will be comprised of at least three (3) members of the IFR panel membership group, and must include one lay member, one person qualified to chair and one member who is clinically-qualified (at least one of which must be a member of Surrey Downs CCG). The group will usually confer either by telephone conference or in person however in special circumstances when this is not possible this will be done via email. Where possible the requesting clinician will be asked to present their funding request to the group via the telephone conference or in person.

A fast-track decision will be made by reference to the SEC Ethical Framework and the consensus method for decision-making, as would be the case for regular IFRs and the decisions of the group will be ratified by the IFR panel during its next scheduled meeting.

The decisions available to a group are:

- the request will be funded **without conditions**
- the request will be **funded with conditions** attached
- the request will **not** be **funded**
- a decision cannot be made because more evidence / information is required and the decision is therefore **deferred.**

If the group defer the decision the evidence / information required will be obtained as soon as possible at which point the submission will be re-considered by the group.

S&S CSU IFR team are responsible for managing the fast-track process and the distribution of information/evidence among the group for fast tracked IFRs.

S&S CSU IFR team are also responsible for communicating the fast-track decision to the requesting clinician (and the patient if appropriate) and for documenting the decision, the reasons behind the decision and the consensus reached.

All information relating to the fast-tracked IFRs (the processed IFR submission form, emails and the decision made) must then be included in the papers for the next scheduled IFR panel meeting for ratification, and for inclusion and updating of the IFR database.

2.8 Agenda and Supporting Papers

The IFR panel agenda will list general business, the submissions requiring consideration, submissions withdrawn, fast-tracked submissions and any other business including part 2 submissions for consideration pre service development.

For each submission requiring a decision, the agenda should set out:

- the unique identifier
- status (i.e. new submission, second/third consideration of deferred submission, ratification of sub-committee decision, interim report on patient condition following conditional approval, consideration pre service development)
- a list of documents relating to each submission: e.g. submission form, reviews of evidence, statement of specialist advice, statement by patient or others, published articles, second consultant opinion, interim report on patient condition following conditional approval, etc.

IFR Panel members will receive the agenda and supporting papers no less than 3 working days before each scheduled panel meeting. The requesting clinician attending the IFR panel will also receive the paperwork relevant to their funding request no less than 3 working days before the panel meeting.

If an IFR panel member requests further information or raises a question about the papers in advance of the meeting, both the request/question and the response should be circulated to all IFR panel members as soon as possible.

The S&S CSU IFR team are responsible for all the logistical and administration arrangements for IFR panel meetings. The S&S CSU IFR team will prepare the agenda and papers for each panel meeting.

2.9 The Panel Meeting

All IFRs will be considered by a Surrey wide IFR Panel including those considered via the fast-track procedure.

The IFR panel reports to the Clinical Governance, Clinical Quality and Patient Safety Committee.

The Chair is responsible for the conduct of the meeting, determining whether the meeting is quorate, and ensuring that the agenda is completed.

The requesting clinician may be asked to attend the IFR panel to present their funding request to the panel members (in person or via a teleconference) – see section 2.1. The clinician will only be asked to attend the IFR panel for their submission; they will be expected to present their funding request and answer any queries but will not be present when the funding decision is made by the panel members (the clinician will be informed that the decision will be communicated to them as detailed in section 2.16).

Patients will not be invited to make representations in person. The Panel may ask specialists to attend the meeting and advise members during their deliberations.

During the meeting the Panel members will consider:

- new submissions
- submissions deferred from an earlier meeting pending the availability of evidence/information
- follow-up information relating to earlier conditional approvals
- ratification of decisions made using the fast-track procedure

The Panel will also note submissions that have been withdrawn and in respect of which no action or decision is required.

In the second part of the IFR Panel Meeting (Part 2) the IFR Panel will consider new submissions for which a service development is required but which requires early consideration due to a clear clinical reason having been identified which would significantly compromise the patient's health if the patient had to wait until a service development decision was made.

The IFR panel meets monthly, but the frequency may be subject to variation over time. Dates will be set quarterly in advance (see Appendix 4 for TOR).

2.10 Principles to be applied by the IFR Panels

Each IFR will be considered on its own merits. Decisions will be taken using the agreed Consensus Decision-making Process (see Appendix 5) and IFR panel members will have received training on this as part of their induction training.

The SEC Ethical Framework (see Appendix 6) will be used to support the decision-making process and will help to promote consistency across the SEC Strategic Health Authority (SHA). In keeping with the principles of the SEC Ethical Framework, the IFR panel will need to take an objective view of the submission, and maintain an open mind about the information and factors to be considered.

The IFR panel shall be entitled to approve requests for funding for treatment for a named patient where all four of the following conditions are met:

- Either (a) a rarity request for funding for treatment in connection with a presenting medical condition for which the CCG has no policy or (b) an exceptionality request for funding for treatment in connection with a medical condition for which the CCG has a policy and where the patient has demonstrated exceptional clinical circumstances;

- There is sufficient evidence to show that, for the named patient, the proposed treatment is likely to be clinically effective

- Applying the approach that the CCG takes to the assessments of costs for other treatments outside this policy, the cost to the CCG of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the named patient by the requested treatment.
- The request for this patient is not a request for a service development (and therefore not one to be considered in part 2 of the meeting).

The IFR panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances.

Whether a patient can demonstrate "exceptional clinical circumstances" will depend on the precise and particular clinical facts of the individual case and whether those can genuinely be described as exceptional.

For instance, evidence which is identified as showing that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case put by the requesting clinician to say that the patient's clinical circumstances are exceptional. However in order to determine whether a patient is able to demonstrate exceptional clinical circumstances the IFR panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

When considering exceptionality the IFR panel will consider that a named patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient could show that their clinical circumstances were sufficiently unusual that they could properly be described as being exceptional. Whether or not a named patient demonstrates "exceptional clinical circumstances" however is a matter for determination by the IFR panel dependent on the precise and particular clinical facts of the individual case.

The IFR panel should take care to avoid adopting "the rule of rescue" approach. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at the same stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

2.11 Decisions Available to the Panel

When considering a new submission, the panel may decide as follows:

- the request will be **funded without conditions**
- the request will be **funded with conditions** attached
- the request will **not** be **funded**

- the submission cannot be decided at this meeting because more evidence/information is required and is therefore **deferred**

2.12 Deferred Submissions

The IFR Panel may decide to defer a decision because information called for before the meeting is not yet available, or because the panel members decide at the meeting that they need more information. If a decision is deferred the Chair of the panel must make a decision on whether the deferred IFR should be fast-tracked (see section 2.7) or whether the deferred decision can be re-considered at the next panel providing the information is available.

The status and progress of deferred submissions must be reviewed within one month of the decision to defer. If the required information is still not available the panel may decide to defer for a second time.

The minutes of the meeting at which the second deferral is made must record in detail the reasons why a decision cannot be made (for example, information has been requested from a specialist in a very rare disease who is located outside the UK, and a response has not yet been received). The IFR panel may ask for alternative sources of information to be used.

All submissions must be considered and a decision made in respect of each within two months of the date of the first decision to defer. The aim is to ensure that submissions which have been deferred, and for which information is not forthcoming, are not allowed to languish without a decision for an unacceptable period of time.

Once the IFR panel is in a position to make a decision, it may decide:

- the request will be funded without conditions
- the request will be **funded with conditions** attached
- the request will **not** be **funded**

2.13 Conditional Approval

IFRs may be approved for funding subject to conditions.

In some cases the IFR panel will need to be advised of the patient's status at an interim point in order to approve a second phase of treatment. For example, a requesting clinician may request 6 cycles of a treatment but advise that a response may be observed within 3 cycles. The IFR panel may agree to fund 3 cycles, but decide that funding for a further 3 cycles will be conditional upon the patient's response and the submission to the panel of a report detailing the response observed after the first 3 cycles will be required for further consideration to be given to the submission.

2.14 IFRs can be withdrawn

IFRs can be withdrawn at any time by written notice / email from the requesting clinician and /or from the patient. The IFR panel will note that a submission has been withdrawn at the next available meeting.

For example, it may be necessary to withdraw if the patient opts for an alternative course of treatment, or opts to fund treatment privately, or has in the interim passed away.

2.15 Record of Panel Meetings and Confidentiality

All discussion during a meeting of the IFR panel will be confidential.

At the end of the meeting all the copies of the papers from panel members will be collected.

Members of the fast-track group will be instructed to forward relevant emails and faxes, and then to destroy their own copies. All details are entered onto the patient's records on the IFR database as appropriate by the S&S CSU IFR team.

The panel's decision, including the rationale for the decision will be clearly recorded in the minutes (taken by the S&S CSU IFR team) will be sent to the Panel Chair for sign off. The minutes for each individual case will then be entered onto the patient's records on the IFR database (by S&S CSU IFR team).

The wording used to convey the panel's decisions, conditions and rationales in the minutes will be transcribed **exactly** into the decision letters by the S&S CSU IFR team which will be signed off by the Panel Chair before being sent. The letter needs to adequately explain the reason for the decision and must be intelligible. The following points should be included:

- for applications submitted on the basis of exceptional clinical circumstances the letter should state whether the panel reached the view that the patient did or did not demonstrate exceptional clinical circumstances. If the decision was made that exceptional clinical circumstances were not demonstrated then the letter should explain why the specific factors in the application were not considered as amounting to exceptional clinical circumstances.
- for applications submitted that the panel considered demonstrated either exceptional clinical circumstances or fulfilled the rarity criteria the letter should state whether the panel considered if the requested treatment was likely to be clinically effective for the patient. If the panel reached the view that the requested treatment was not likely to be clinically effective, then the letter should explain why the decision was reached.
- for applications submitted that the panel considered demonstrated either exceptional clinical circumstances or fulfilled the rarity criteria the letter should state whether the panel considered if the requested treatment was likely to be cost effective use of NHS resources. If the panel reached the view that the requested treatment was not likely to be cost effective for the individual patient, then the letter should explain why the decision was reached.

Any error or ambiguity in this wording is the responsibility of the Panel Chair signing of the minutes and / or letter.

When preparing minutes, both the S&S CSU IFR team member and the Panel Chair should bear in mind that these are documents which could be discloseable and use language accordingly. The decisions of an IFR panel are attributable to the panel as a whole. The minuting of discussion about specific concerns raised by individual submissions should avoid personalities.

The items of general business in the minutes should include:

- The date, time and place the meeting was held
- The name and organisation of all members present, including a note of any member arriving late or leaving early and the items for which they were present
- The name and organisation of the Chair
- The name and organisation of any member submitting apologies for non-attendance
- The name and organisation of any observer / expert adviser who attended and the items for which they were present

For each individual submission considered by the panel the minutes should record:

- The unique reference number of the submission
- The status of the submission (i.e. new submission, second consideration of deferred submission, ratification of sub-committee decision, interim report on patient condition following conditional approval)
- Confirmation of the patient's CCG
- The name of any member who declared an interest in or association with the submission, and the nature of the declaration (the chair to determine whether they should leave the meeting during discussion of that item)
- All the items of information considered with regard to the submission
- Note of the written comments on the submission made by any IFR panel member not present
- A summary of the opinion given by any special advisors attending the meeting
- Specific concerns raised by this submission and the panel's response to them
- The decision reached and the degree of consensus (shown as X out of Y, where Y is the maximum, depending on the number of panel members)
- Any conditions attached to the decision (exact wording to be advised by the chair) including if and when a follow-up report is required
- The rationale for the decision (exact wording to be advised by the chair)
- The form of words to be used in communicating a negative decision and rationale to the patient (exact wording to be advised by Chair)
- Further information required and/or actions in the case of a deferred decision

Copies of the minutes will not be distributed to panel members for their retention and will not be placed in the public domain. This is in the interests of preserving patient confidentiality. Although patients' names have been removed, the IFR process is by definition dealing with rare conditions. The singularity of these may be enough to identify an individual.

Notes for submissions considered by the IFR panel will be taken by a member of the S&S CSU IFR team and will be written up as formal minutes within 2 working days and approved by the Chair within 5 working days of the meeting.

For IFR submissions one complete set of original records submitted and papers considered by the IFR panel will be retained electronically on the IFR database. This information is retained indefinitely.

2.16 Communicating the Panel's Decision

The IFR panel's decision will be communicated by letter or email to the individual or requesting clinician who submitted the IFR. The letters communicating the decision are signed by or on behalf of the Panel Chair.

Once the minutes and letters are signed off and approved then within 5 working days of the IFR panel meeting the S&S CSU IFR team will:

- Write / e-mail the individual or requesting clinician who submitted the IFR to convey the panel's decision, any conditions attached to funding agreed and whether the conditions require any interim report on the patient's status
- Write to the patient (or his/her representative) to convey the panel's decision, provided the patient has indicated they wish to receive such communication using appropriate language
- Update the IFR Database
- Produce a summary report for the Clinical Governance, Clinical Quality and Patient Safety Committee which is collated on a quarterly basis

2.17 Time Periods for IFR Process

Surrey Downs CCG in conjunction with S&S CSU IFR team will work to the standard that funding decisions will be provided within 25 working days. Achievement of this standard is dependent upon receiving complete requests together with the relevant references to support the submission. This standard applies from the point at which full information from the requesting clinician is received.

3 The IFR Appeal Process

The IFR Appeal process enables patients and their clinicians to appeal against a decision made by an IFR panel. The Appeal process is independent of the IFR process.

An IFR Appeal panel will not consider new evidence. If new evidence becomes available after a decision not to fund has been made by an IFR panel, then the correct procedure is for the requesting clinician to submit a new IFR submission form supported by the new evidence, not to appeal the existing decision.

The numbers of appeals that may be received are difficult to predict and therefore arrangements for Appeal panel meetings are to be flexible and will be made in response to demand. The Appeal panel will aim to meet within 20 working days of an Appeal being received by Surrey Downs CCG but this may not always be possible.

3.1 Grounds for Appeal

The decision of an IFR panel can be appealed on the grounds of:

- That there was procedural irregularity in the original decision making process
- There is evidence to suggest that the IFR Panel failed to consider and take into account relevant information, or apply appropriate weighting to that information when reaching its decision.

3.2 Remit of the IFR Appeal Panel

The IFR Appeal panel will review all the documents relating to the appeal, the original IFR submission and the IFR panel's decision. The Appeal panel will consider whether they are satisfied that:

- The IFR panel acted in accordance with the CCG's approved procedures
- The decision was consistent with the SEC Ethical Framework for decision-making and the principles set out in the Policy and Operating Procedures for dealing with IFRs
- The IFR panel properly considered the scope and nature of evidence
- In reaching its decision the IFR panel took into account and weighed all relevant factors.

If the IFR Appeal Panel concludes following such a review that the decision cannot be supported on any one of the above grounds, the case must be sent back for re-consideration by the relevant IFR panel.

3.3 Lodging an Appeal

The appeal should be lodged within one calendar month of the date of the letter to the requesting clinician and/or patient notifying them of the decision of the IFR panel. The appeal can be lodged by:

- The requesting clinician who submitted the original IFR
- The patient
- The legal guardian where the patient is a child under 18 years of age
- A person appointed with lasting power of attorney if the patient lacks the mental capacity to lodge an appeal themselves
- A third party (e.g. friend or relative) with the documented consent of the patient.

If the requesting clinician lodges the appeal s/he is required to confirm that s/he has discussed the appeal process fully with the patient and is acting with his/her consent. If the patient or his/her representative lodges the appeal the representative should have the support of the clinician who originally requested the IFR.
The person lodging the appeal should write to Surrey Downs CCG stating that they wish to appeal and the grounds on which the appeal is being made, confirming that they have the consent of the patient.

The appeal will be acknowledged in writing to the requesting clinician and/ or the patient or his/her representative within three (3) working days of receipt of the appeal. Appellants will then have 20 working days in which to provide as much information/ evidence as possible in support of their appeal.

3.4 Information Provided by the Clinician or Patient

The Appeal Panel will meet in private and the patient or his/her clinician will not be invited to attend. The appellant will have been given the opportunity to make written representation and/or provide such literature and material as they consider appropriate in support of the Appeal. This may be provided by the clinician and/or the patient and on behalf of the patient by guardians, representatives, family members, carers etc. Information provided by the clinician should be in English and in writing or a conventional clinical medium such as x-ray or scan results provided these are accompanied by a report with interpretation from the appropriate specialist and/or consultant. If the information submitted is considered to be new evidence this will not be considered by the IFR Appeal panel, the correct procedure is for the requesting clinician to submit a new IFR submission form supported by the new evidence, not to appeal the existing decision.

3.5 Actions in Advance of the Meeting

As soon as the date of the Appeal panel meeting is confirmed the appellant will be informed of that date.
Appeal Panel members will receive the Agenda and papers in support of an Appeal no less than 3 working days before the meeting. For each appeal the members will receive copies of:

- All papers considered by the original IFR panel, including the original submission form, supplementary information and evidence review
- The minutes of the IFR meeting(s) at which the submission was considered and decided
- A written statement summarising any advice given verbally by specialists attending the meeting
- The decision letter
- The letter lodging the appeal
- The further information provided by the patient, his/her representative, and the clinician in support of the appeal (not considered to be new evidence)

If a Panel member requests further information or raises a question about the panel papers, both the request/question and the response will be circulated to all members as soon as possible. The Appeal panel may, in appropriate cases, seek external advice.

3.6 Appeal Panel Meeting and Decision

All discussion during the Appeal panel meeting will be confidential. Decisions will be taken using the Consensus Decision-Making Process (Appendix 5). The SEC Ethical Framework for decision making (Appendix 6) will be applied throughout the Appeal process.

The Appeal panel may uphold or overturn the decision of the original IFR panel. Reasons for the Appeal panel decision must be clear. A decision to overturn does not mean that the request will be funded: it means that the request will be considered again by the appropriate IFR panel. The Appeal panel may not defer the making of a decision.

3.7 Minutes

Notes of an Appeal panel meeting will be taken and written up as formal minutes within 2 working days by the S&S CSU IFR team. The minutes will record:

- The decision taken
- The reasons for the panel's decision
- The consensus reached

The minutes will be written up and verified and approved by the Chair within five (5) working days of the meeting. The text of the minutes will be used in communicating the panel's decision to the appellant. Copies of the minutes will not be distributed to panel members for their retention and will not be placed in the public domain. This is in the interests of preserving patient confidentiality.

3.8 Communicating the Decision

The decision of the Appeal panel will be notified in writing and sent by secure means to the appellant within ten (10) working days of the meeting by the S&S CSU IFR team.

3.9 Next Steps

If the Appeal panel upholds the original IFR panel's decision, the appellant will be advised that if they wish to take the matter further this must be done through the NHS Complaints process. If the Appeal panel overturn the original IFR panel's decision the appellant will be advised that the original IFR submission will be reconsidered by the next available IFR panel, with that Panel taking account of any

additional evidence which has become available in the interim. Surrey Downs CCG will ensure the IFR submission is reconsidered at the earliest possible opportunity. If the IFR panel who reconsider the submission upholds the original IFR panel's decision, the appellant will be advised that if they wish to take the matter further this must be done through the NHS Complaints process.

4 Approval, ratification and review process

This policy will be subject to review after one year and at any stage at the request of management or following a change in legislation or national guidance.

5 Dissemination and implementation

Dissemination of this document will be organised centrally and disseminated and implemented as follows:

- A copy of the policy will be held on the Surrey Downs CCG website
- A copy of the policy will be sent to all GPs in Surrey Downs CCG
- Managers will convey the contents of the policy to members of staff and ensure they have read and understood the document and abide by its contents
- The policy will be shared with all relevant stakeholders.
- This policy will be brought to the attention of all staff and monitored in line with normal assurance processes.

6 Glossary

- Surrey Downs CCG:	Surrey Downs Clinical Commissioning Group
- S&S CSU:	Surrey & Sussex Commissioning Support Unit
- SEC:	South East Coast
- IFR(s):	Individual Funding Request(s)
- HPSU:	Health Policy Support Unit
- MPOP:	Model Policy and Operating Procedures
- TOR:	Terms of Reference

Individual Funding Request Form

(Effective April 2013)

Please read the guidance notes on the back page before completing this form.
Incomplete application forms received will be returned to the requesting clinician.

Unique Patient Identifier (IFR team use only):

PART 1: DETAILS OF CLINICIAN SUBMITTING REQUEST AND PATIENT

1. Details of clinician submitting the request	Name	
	Designation:	
	NHS Trust or GP practice:	
	Correspondence address:	
	Tel:	
	Email:	

2. Patient details	Surname:			
	First name:			
	Address (including Postcode):			
	NHS Number:			
	Date of Birth:		Gender	
	Registered Consultant (if different from the submitting clinician):			
	Registered GP name:			
	Registered GP practice and postcode:			
	Hospital id no: (if applicable)			
3. Instructions for	Does the patient or his/her representative wish to receive letters regarding this request? ☐ yes ☐ no			

communicating with the patient	If YES are the letters to be sent to the patient at the address above? ☐ yes ☐ no	
	If letters are to be sent to anyone other than the patient, please provide the following information, and obtain the patient's written agreement:	
	Name	
	Relationship to patient	
	Address (including Postcode)	

PART 2: INFORMED CONSENT AND PROVIDER TRUST APPROVAL

4. Clinician's affirmation of patient's consent	I affirm that I have discussed this Individual Funding Request with my patient. The patient has given consent for personal information to be passed to the Clinical Commissioning Group for the purpose of processing this Individual Funding Request. The instructions for communicating with the patient at Q3 are his/her expressed wishes.	
	Signature	
	Name:	
	Designation:	

5. Which organisation will be providing the treatment requested?	☐ NHS Trust ☐ GP practice ☐ Private sector ☐ Other
	Name of NHS Trust/GP:
	If provider is outside the NHS, please give details of name and location

6. Approved by representative of NHS Trust (for drugs this should be the Chief or Directorate Lead Pharmacist)	Name of representative:	
	Designation:	
	Signature or email confirmation:	
	If this funding request is approved, the NHS provider will be notified. Please give details for the person who should be notified:	
	Name:	
	Designation:	
	Contact details:	

CCG/CSU use only:

Date received:	
Identifier:	
Identifier assignment checked by:	

Please note, pages containing confidential details of patient's name, etc. will be removed before the remainder of the form is copied and seen by IFR panel members.

PART 3: STATEMENT TO CONFIRM APPROPRIATENESS FOR CONSIDERATION BY IFR PANEL

If it is foreseeable that there are one or more other patients within the CCG population who are or are likely to be in the same or similar clinical circumstances as the requesting patient in the same financial year, and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment then the request should properly be considered as a request for a service development and inappropriate for consideration by an IFR Panel except in the circumstances where all the similar patients are expected to be from the same family group, a situation which may arise in the context of a rare genetic disease.	
I confirm that it is not expected that there will be more than one patient from within the CCG population who is or is likely to be in the same or similar clinical circumstances as the requesting patient in the same financial year and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment unless similar patients are expected to be from the same family group.	☐ NO ☐ YES

PART 4: DIAGNOSIS AND PATIENT'S CURRENT CONDITION

7. Diagnosis (for which the intervention is requested)			
8. Has a second consultant opinion been obtained?	If YES, please give details		
9. Current status of the patient: (a) Intervention for **cancer**:	What is disease status? (e.g. at presentation,1st,2nd or 3rd relapse)		
	What is the WHO performance status?		
	How advanced is the cancer? (stage)		
	Describe any metastases:		
(b) Intervention for **non-cancer**	What is the patient's clinical severity? (Where possible use standard scoring systems e.g. WHO, PASI, DAS scores, walk test, cardiac index etc.)		
10. Please summarise the current status of the patient in terms of quality of life, symptoms etc.			
11. Summary of previous interventions for this condition *Reasons for stopping may include: - course completed - no or poor response - disease progression - adverse effects / poorly tolerated	Dates	Nature of intervention	Reason for stopping*/ response achieved

PART 5: INTERVENTION FOR WHICH FUNDING IS REQUESTED

12. Nature of the intervention If combination, tick all that apply and complete 6A and 6B	□ Surgical procedure □ Medical device □ Therapy □ Other (give details)
13. Name of intervention	
14. Where will intervention be provided?	Indicate whether in-patient, out-patient, day case
15. Is the requested intervention a continuation of existing treatment funded via another route?	□ NO □ YES - give details of existing funding arrangement and why ceased
16. Is the intervention experimental, part of a trial or research?	□ NO □ YES - give details

PART 6A: INTERVENTIONS INVOLVING DRUGS

17. Full name of drug and manufacturer		
18. Planned dose and frequency		
19. Planned duration of intervention		
20. Route of administration		
21. Optimal start date		
22. If the intervention forms part of a regimen, please document in full	(e.g. Drug X as part of regimen Y (consisting of drug V, drug W, drug X and drug Z).	
23. Drug licensed for requested indication in the UK?	□ YES □ NO	
24. Has the Trust Drugs & Therapeutics Committee or equivalent Committee approved the requested drug for use?	□ YES □ NO	
25. Drug listed as a PBR exclusion?	□ YES □ NO	
26. Estimated costs Please consult Pharmacy team for current contract prices as these may differ from those stated in BNF or other sources.	Anticipated cost (inc VAT)	
	Are there any offset costs?	□ YES □ NO
	Describe the type and value of offset costs	
	Funding difference being applied for	

PART 6B: INTERVENTIONS INVOLVING SURGICAL PROCEDURES, THERAPIES, DEVICES

27. Describe the intervention as it applies to this patient		
28. Is this intervention listed in the CCGs Treatments Not Routinely Funded (TNRF) or Procedures with Restrictions or Thresholds Policies (PWRT)?	□ YES □ NO	
29. Photographic evidence is required (with patient consent) to support applications for all external procedures(i.e. breast surgery, facial procedures, body contouring, skin lesions etc)		
30. Patients Body Mass Index (BMI)		
31. Specify any devices, prostheses, etc. and the manufacturer		
32. Estimated costs	Anticipated cost (inc VAT)	
	Are there any offset costs?	□ YES □ NO
	Describe the type and value of offset costs	
	Funding difference being applied for	

PART 7: PROJECTED OUTCOMES

33. Is there a standard intervention for this patient at this stage of their condition?	If so, please describe the standard intervention
34. What would be the expected outcome from the standard intervention?	
35. Why is the standard intervention inappropriate for this patient?	
36. What would you consider to be a successful outcome for the requested intervention in this patient?	This may include likely OS, TTP or improvement in QOL. Please relate to measures describing patient's condition in Part 3.

PART 7: PROJECTED OUTCOMES (continued)

37. Please outline any anticipated or likely adverse effects of the requested treatment for this patient, including the toxicity of any drug?	
38. How would you monitor the effectiveness of the requested intervention?	Please refer to the measures used to describe the patient's condition in Part 3
39. What is the minimum timeframe/course of treatment after which a clinical response can be assessed?	
40. What are the likely consequences for the patient if this request is not approved?	

PART 8: STATEMENT OF EXCEPTIONALITY OR RARITY

41. On which basis are you making this request?	□ Exceptional clinical circumstances OR □ Rarity of condition or presentation
42. For exception to existing policy, please describe as clearly as possible why the patient's clinical circumstances are exceptional. You must give specific information to indicate how this patient is significantly different to the population considered in the existing policy	
43. For rare condition or presentation, please describe as clearly as possible why this patient's condition or clinical presentation is so unusual that there is no relevant commissioning arrangement.	

PART 9: EVIDENCE OF CLINICAL EFFECTIVENESS

44. Give details of published data supporting the use of the requested intervention for this condition. Please provide references or attach articles.

PART 10: URGENCY

45. Only a small minority of requests can be decided using the CCG's fast-track procedure. If there are compelling clinical reasons why this patient's request should be fast-tracked, please state them here.	

Thank you for completing this form; please send an electronic attachment to tnrf@nhs.net for intervention IFRs and highcost.drugs@nhs.net for drug IFRs

Alternatively, post to:

IFR Panel Service Team
Surrey Downs Clinical Commissioning Group
Cedar Court
Guildford Road
Leatherhead
Surrey
KT22 9AE

GUIDANCE NOTES FOR CLINICIANS COMPLETING THIS IFR FORM

IFR Policy and further information

Before submitting an IFR, please check you are using the correct process. IFRs can be submitted by an NHS consultant a GP or an equivalent autonomous practitioner where s/he will be responsible for administering the treatment. The requesting clinician is responsible for providing all supporting information and evidence.

If treatment is to be provided at an NHS Trust, the IFR must be approved, and this form signed, by the appropriate representative of that NHS organisation. This will usually be the chief pharmacist or a business manager (or their nominated deputy). This approval ensures that capacity issues have been considered.

Uncertain? We WANT to help you!

All IFRs for our CCG are managed by the S&S CSU IFR Team. The team would much rather answer your questions than send the form back to you because it is not properly completed. If you would like help to complete this form, please don't hesitate to contact us via email at tnrf@nhs.net for intervention IFRs and highcost.drugs@nhs.net for drug IFRs

Why all these questions?

Please be assured there is good reason for all the questions on this form. Not every question need be answered for every case; but please signify 'not applicable' rather than leaving a blank.

Part 1: Details of patient and clinician submitting the request

We need to contact you – so full details every time please. We must be able to identify the patient. Please ask your patient to choose whether s/he wishes to receive correspondence about the progress of his/her IFR: if YES please indicate where letters should be directed.

Part 2: Informed consent and provider approval

Your signature at this point validates the whole request. Details of the provider (and approval, where appropriate) are essential. An unsigned form cannot be accepted.

Part 2A: Equality and diversity monitoring form

This information is optional and the panel will not view this information. This information will be used to enable audit to take place to identify if particular sections of the community are being disadvantaged through the IFR process.

Part 3: Statement to confirm appropriateness for consideration by IFR panel

Affirmation of the statement confirms that, to the best of your knowledge, the request is an appropriate IFR. Where you are unable to confirm the statement, your request for funding will need to be considered via another mechanism.

Part 4: Diagnosis and the patient's condition

The fullest possible information will help the panel make a decision. Q8 will not be relevant to every case. At Q9 complete either (a) or (b). Q11 may not be relevant to every case.

Part 5: Intervention for which funding is requested

Please name the intervention clearly, and describe the detail if necessary. If the answer to either Q15 or Q16 is YES, please provide the details separately if the space on the form is insufficient.

Part 6A: Interventions involving drugs / Part 6B: Interventions involving surgical procedures, etc.

In most cases it will only be necessary to complete either A or B. It is likely that this information will be required before the NHS provider can approve the form. Information on likely costs helps the CCG to be aware of potential cost pressures.

Part 7: Projected outcomes
Again, the fullest possible information will help the panel come to their decision.

Part 8: Statement of exceptionality or rarity
At Q38 you must choose either exception or rarity - otherwise the form will be returned. At Q39 please state as clearly as possible, and with reference to the existing policy, why your patient should be treated as an exception; OR at Q40 provide clear information about the rarity of your patient's condition or presentation.

Part 9: Evidence of clinical effectiveness
Comprehensive information and accurate references will help to get your IFR through the process quickly.

Part 10: Urgency
We aim to deal with all IFRs as quickly as possible. Each IFR can only be decided when sufficient information is available to inform the decision. Urgency will be evaluated on the basis of clinical need.

For help in filling this form out please email your query to the IFR team at tnrf@nhs.net for intervention IFRs and highcost.drugs@nhs.net for drug IFRs.

Appendix 2 – Individual Funding Request (IFR) Triage Meeting Terms of Reference

1.0 PURPOSE / REMIT

On receipt of an IFR the S&S CSU IFR team will check for completeness before the triage meeting to ensure:

- The CCG is the Responsible Commissioner for that patient
- All contact details have been provided
- The appropriate form has been submitted and all parts of the form are fully completed
- All supplementary documentation referred to is attached
- The submission has been approved by a suitable representative of the Trust providing treatment (as appropriate)

Providing the IFR fulfils the above the IFR will then be submitted to the next IFR Triage Meeting. The purpose of the IFR Triage Meeting is to assess all IFR submissions for their eligibility for consideration by the IFR Panel, in accordance with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs.

The purpose of the IFR Triage Meeting is therefore to determine eligible and ineligible submissions to the IFR Panel and to consider whether the treatment requested:

- Is funded within existing commissioning policy?
- Is covered by another CCG policy or process?
- Amounts to service development and thus requires a CCG policy decision?

The IFR Triage Team will ensure that submissions that do not go forward to the IFR Panel are sign-posted to the most appropriate route, in accordance with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs.

The IFR Triage Team will then assess each individual submission against the definitions of **a "rarity request"** or an **"exceptionality request"** as set out in the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs.

Eligible IFRs will be forwarded for consideration at the next IFR Panel, providing sufficient information is available, in accordance with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs.

2.0 ACCOUNTABILITY

The IFR Triage Team is accountable to the IFR Panel, and to the Clinical Executive Committee on behalf of Surrey Downs CCG.

3.0 MEMBERSHIP

The IFR Triage Team shall comprise:

- Surrey Downs CCG IFR Clinical Lead (clinician – a pool of clinicians will be identified)
- Head of Medicines Management, Surrey Downs CCG
- IFR Team Lead, S&S CSU
- Public Health Consultant, Surrey County Council

The IFR Triage process is carried out on a Surrey wide basis to help ensure consistency in decision making across a wider geography. The triage team will therefore also include members from the other Surrey CCGs. However decisions in relation to IFRs for Surrey Downs CCG patients cannot be made unless there is a Surrey Downs CCG representative present at the Triage Meeting.

The Team reserves the right to request the ad hoc attendance of any other member of staff as it requires.

4.0 QUORUM

The Meeting will be considered quorate if the Surrey Downs CCG IFR Clinical Lead and the IFR Team Lead (S&S CSU) are present.

5.0 FREQUENCY

The Team shall meet bi-weekly, unless no submissions are received, in which case the meeting shall be cancelled.

6.0 REPORTING

The minutes of the meetings shall be recorded by the S&S CSU IFR team.

The S&S CSU IFR team will maintain a record of ineligible submissions, noting the reasons why considered ineligible, in accordance with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs.

7.0 REVIEW

The terms of reference will be reviewed at least annually

Appendix 3A – Standard Operating Procedure for Processing IFRs

Background

IFRs are processed by the S & S CSU IFR team and presented to the IFR panel who make a decision on the funding request.
Complete enquiry documentation is an audit standard and allows collation of correct statistical information relating to the handling of IFR requests.

Objective/ aim of procedure

To ensure full and complete documentation is achieved for all IFRs processed by the S & S CSU IFR team.

Risk Management Notes

Clear and comprehensive documentation is necessary for legal and ethical reasons, in order to ascertain exactly what information was provided, by whom and what resources were used.

This also ensures that an enquiry can be located at a later date, to save time in dealing with future enquiries.

Procedure

1. All IFRs for Surrey Downs CCG should be submitted as an electronic attachment to highcost.drugs@nhs.net for drug IFRs and tnrf@nhs.net for intervention IFRs. It is the responsibility of the S & S CSU IFR team to check the account daily

2. Where IFR submission forms are hand written, these must be sent back to the requesting applicant with a request that it resubmits the form as an electronic attachment to the S & S CSU IFR team.

3. When an IFR is received the submission is to be checked to ensure that the patient is registered with a Surrey Downs CCG GP.

4. The submission form must then be checked for completeness and if from an Acute Trust ensure that it has been approved by a suitable representative of the Trust. The requesting clinician should be contacted for clarification where any information is missing.

5. A decision about appropriateness for consideration by the IFR panel must then be made at the Triage Meeting. The rest of this procedure only applies if the IFR is considered eligible for consideration by the IFR panel. If the IFR is not considered eligible for consideration by the IFR panel the reason will be communicated directly with the requesting clinician.

6. Before processing an IFR check “Question 42” on the IFR Request Form to see if a decision is required urgently. Where a case has been identified as urgent the processor needs to confirm this with the requesting clinician and then follow the process set out in the fast-tracking urgent IFRs section of Surrey Downs CCGs Policy and Operating Procedures for dealing with IFRs (section 2.7). See also (section 2.6.3 regarding 18 week rule)

7. It is the responsibility of the processor to email the requesting clinician / Trust and acknowledge receipt of the IFR Form and to inform them of the next available panel date

8. Check on the IFR database to see if a previous funding submission has been received for the same patient.

9. The processor must then ensure that the IFR request is saved onto database following the relevant procedure (see database SOP).

10. Ensure that all information from the Trust or parties related to the funding submission (letters, pictures etc) are anonymised and uploaded on to the IFR database.

11. Process the CCG version of the form as per SOP for processing IFRs

12. The processor should ensure that all relevant information is included. If there are any gaps or whilst reading the form the processor has questions or knows what the members of the panel will ask, contact the requesting clinician to seek clarification.

13. When editing the form ensure that the words ‘S & S CSU comments’ are annotated into the relevant boxes (so that it is clear which information was from the Trust / applying clinician and which came from the S & S CSU)

14. Published data section (question 41): This section is where the evidence for the intervention is reviewed. The following headings/information should be provided:

    - **Trust Identified Information** for all information submitted by the Trust. Where links to a journal have been provided these should be replaced with the journal, title, author and dates. Where the full document can be obtained a critical appraisal of the paper must be done by the processor. If the full paper cannot be found then the Trust should be contacted and asked whether they can forward this. Alternatively contact Guys and St Thomas’s Medicines Information department as they can sometimes send the full paper or critically appraise the paper. Where it is not possible to get access to the whole paper from the Trust or Guys and St Thomas’s Hospital then the abstract must be included. Any comments from the Trust about the evidence they have submitted will be preceded with the words ‘**Trust Comment**’ so that there is no misunderstanding where the comments have come from.

- **S & S CSU Identified Information** for all information identified by the processor whilst conducting a search or review.

The processor must ensure that clinical trials are summarised and a S & S CSU comment made which makes reference to the relevance of the particular trial/information to the particular patient. Also make reference in the S & S CSU comment to the trial and its robustness.

15. **For DRUG IFRs only:** Check the wording of the license on summary of product characteristics (SPC) (http://emc.medicines.org.uk/).

16. **For DRUG IFRs only:** Document the search in the order the resources have been searched. A list of search terms used must be documented and the date the resources were accessed. Where nothing has been found, "Nil found" should be recorded. The following resources should be used:

    - Medical Information Departments/ specialist doctors/ pharmacists.
    - Other electronic resources e.g. websites: specify name and/or full address of website(s) used, the date accessed and search terms used. NB. Full address is not necessary for those websites used regularly or those listed in the minimum resources list (e.g. eMC etc.).
    - The National Electronic Library for Medicine accessed via www.nelm.nhs.uk. Type the name of the drug in the search box. Hits found will be grouped under the following headings:
      View results in Evidence (IFR reviews done by Guys MI unit will be under this heading)
      View results in Community Area
      View results in other areas
      View results in communities
      UK QA Info Zone
    - NHS Evidence (developed by NICE and incorporates some of the key components from the former National Library for Health, cochrane systematic reviews etc) accessed via www.evidence.nhs.uk. Enter your search term into the search box to reveal all hits found. A more refined search can then be conducted by selecting any of the following headings (found on the left hand side of the page):
      Areas of interest (clinical, commissioning, education & training)
      Types of information (eg care pathways, evidence summaries)
      Clinical queries
      Sources
      Medicines and devices
      Published date
      - National Electronic Library accessed via www.library.nhs.uk. This should be used to conduct an EMBASE and MEDLINE search. (see SOP for using EMBASE and MEDLINE).
      - Summary of Product Characteristics accessed via www.medicines.org.uk

- National Institute for Health and Clinical Excellence accessed via www.nice.org.uk. Information can be found by entering the search term into the search function on the top right side of the search page or by searching under the "Find guidance" or other tabs
- Scottish Intercollegiate Guidelines Network accessed via www.sign.ac.uk
- Scottish Medicines Compendium accessed via www.scottishmedicines.org.uk
- All Wales Medicines Strategy Group accessed via http://www.wales.nhs.uk/sites3/home.cfm?OrgID=371
- Kent, Surrey & Sussex Health Policy Support Unit accessed via www.ksshealthpolicysupportunit.nhs.uk
- Relevant Professional Bodies e.g.:
    - British Society of Rheumatology www.rheumatology.org.uk
    - British Association of Dermatology www.bad.org.uk
    - Royal College of Ophthalmologists www.rcophth.ac.uk
    - American Society of Haematology http://bloodjournal.hematologylibrary.org/misc/ASH_Meeting_Abstracts_Info.dtl
    - British Society of Haematology www.bcshguidelines.com

It may also be relevant to contact drug company's Medical Information department especially when published information is lacking.

17. **For INTERVENTION IFRs only:** if at the triage meeting it was agreed that the IFR is for a treatment that is new or unusual and a Public Health evidence briefing is required this should be included with the IFR and uploaded onto the IFR database.

18. The processor must also ensure that prevalence data is incorporated in the request. The following websites can be used to obtain details but it might also be useful to contact the requesting clinician for prevalence data if in doubt. The National Statistics website www.statistics.gov.uk are useful tools for this purpose.

19. Clearly state the names of all resources used, with additional information as follows:

    - Books: specify edition number and page number(s).
    - Journals: specify year, volume and page number(s).
    - Databases: specify dates searched/accessed and state search terms used.
    - People: include full name and title of people you speak to where possible e.g. company be included.

19. For rare IFR submissions check on the Kent, Surrey & Sussex HPSU website which contains details of IFRs received by all the CCGs across the region (you will need to register to view this list). If a request is listed for the same indication the relevant CCG should be contacted directly for

more information to assist processing the IFR submission. (www.ksshealthpolicysupportunit.nhs.uk)

20. Annotate the search with the date and identity of the processor. This must be repeated if the processor changes part way during the enquiry process.

21. IFR submissions must always be processed in sufficient detail to allow a panel member to reach a decision without further contact with the enquirer. If in doubt about any aspect of the IFR clarify this with the Trust before submitting to the panel.

22. Once processed summarise at the end of the submission form 'points for discussion'. The following is a list of minimum points to be included in this section:
    - Reason for request – no CCG policy due to rarity or patient has demonstrated exceptional clinical circumstances
    - Comment on efficacy & safety (e.g. strength of evidence, applicability of trials etc)
    - Comment on licensed status (**for drug IFRs only)**
    - Comment on alternative treatments (if applicable)
    - Comment on cost effectiveness
    - Any other relevant information
    - IFR case prepared by

23. The date of the IFR panel meeting should be included in the document.

24. Panel members and persons in attendance names and titles should also be included within the document

25. Where a case has been declined and resubmitted with new clinical information this case should be reconsidered at the next IFR panel. All new information should be processed at the end of the document under the title **Review based on new information submitted by . . . . . .** Under this section should be included the following minimum information:

    - Date new information received
    - Record of any communication post panel
    - New information provided (this should be processed in a similar way to the section on published data question 41 if relevant/applicable)
    - Minutes from the previous discussion at IFR
    - The name of the person preparing the review document
    - The date of panel
    - Panel members and attendants

27. Appealed IFR submissions with no new information should be considered by the Appeals panel if they meet the appeal criteria (see section 3).

Appendix 4A – Individual Funding Requests (IFR) Panel - Terms of Reference

Purpose

- Consider Individual Funding Requests for high cost drugs and other interventions (the panel will not consider IFRs for the services which are the responsibility of the NHS CB).
- Review complex follow up cases where the decision to approve long term funding is not straightforward
- Review decisions made for individual funding request submissions where new information is available
- Consider in part 2 of the meeting funding requests for submissions which are not appropriate for the IFR process but there is a clear clinical reason why the patient's health will be significantly compromised by waiting until a service development decision has been made.

Chairman

The panel can be chaired by any of the members provided that s/he has sat as an IFR panel member at least two times. The Chair must be identified in advance of the meeting, and must be available to approve the minutes / letters and fulfil any other obligations within the specified time frame.

Membership, delegation and probity

The IFR panel will be held Surrey wide and will include members from all 5 CCGs (North West Surrey, Surrey Heath, Surrey Downs, Guildford & Waverley and East Surrey)

The membership of this committee is as follows:
Core (voting) members

- GP from each of the 5 Surrey CCGs
- Head of Medicines Management, Surrey Downs CCG or nominated deputy
- Public Health representative from Surrey County Council
- Lay member

Members are expected to send suitable representation for the meetings they are unable to attend. A register of attendance at the committee will be maintained and reviewed by the committee on a 6 monthly basis.

All individuals attending a meeting, whether as a member or in attendance, must declare any potential conflicts of interest. It will be for the chair of the meeting to decide how this is managed, including asking the individual to withdraw from the meeting in some cases where issues are discussed or decisions taken.

Frequency of meetings and quorum arrangements

- The IFR panel will meet monthly, but the frequency may be subject to variation over time
- The venue will usually be Pascal Place unless notified otherwise
- Four core members should be present to make a decision on an IFR, one of whom must be a clinician from Surrey Downs CCG (legal advice in relation to this needed)

Accountability / dependencies with other committees and group (formal and informal)

- The IFR Panel reports to the Clinical Executive Committee on behalf of Surrey Downs CCG. The IFR Panel will provide reports quarterly to the Clinical Executive Committee. The report will include; number of submissions with decisions, associated financial expenditure, number of appeals and related outcomes, trends, policy requirements for service developments and any other relevant issues.

List of dependent sub committees / groups / functions / programmes

The IFR Panel will link with the following committees/groups providing reports on the activity of the Panel as relevant to the particular committee.

- Clinical Governance, Clinical Quality and Patient Safety Committee and CCG Governing Body (as required)
- Surrey Prescribing Clinical Network

Process for Monitoring Effectiveness of the Committee in relation to expectations set out in the terms of Reference.

Members must have attended training, and ensure that they are fully familiar with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs and process before sitting on a panel. Members should attend a training session at least once every two years and partake in a panel at least once a year in order to retain their qualification to serve.

The agenda and minutes of the meeting will be audited annually to ensure there is evidence the committee executed its duties as stipulated in its terms of reference and met the minimum data set of the NHSLA standard 1.1.3.

NHSLA standard	Method of review of effectiveness	Lead	Frequency of review
Duties of the committee	Review of TOR	Chair	Annually
Reporting arrangements into high level committees(if appropriate) and Board	Review of TOR	Chair	Annually
Membership including nominated deputy	Review of TOR	Chair	Annually
Required frequency of attendance.	Attendance figures	Chair	6 monthly
Quoracy of meeting	Review of minutes	Chair	Per meeting

Date and Review

The terms of reference will be reviewed at least annually.

Appendix 4B – Individual Funding Requests (IFR) Appeals Panel - Terms of Reference

Purpose

Consider Appeals against decisions made by the IFR Panel on the grounds that:

- There was procedural irregularity in the original decision making process
- There is evidence to suggest that the IFR Panel failed to consider and take into account relevant information, or apply appropriate weighting to that information when reaching its decision.

The IFR Appeal panel will review all the documents relating to the appeal, the original IFR submission and the original IFR panel's decision, and will consider whether they are satisfied that:

- The original IFR panel acted in accordance with the CCG's approved procedures
- The decision was consistent with the SEC Ethical Framework for decision-making and the principles set out in the Policy and Operating Procedures for dealing with IFRs
- The original IFR panel properly considered the scope and nature of evidence
- In reaching its decision the original IFR panel took into account and appropriately weighed all relevant factors.

An IFR Appeal panel will not consider new evidence.

If the IFR Appeal panel decides to uphold the IFR panel's decision, the patient and his/her clinician will be advised that no further considerations can be made by Surrey Downs CCG through the IFR process and their next recourse must be to the NHS Complaints process.

If the Appeal panel decides to overturn the original IFR panel's decision the patient and his/her clinician will be advised that their IFR submission will be reconsidered by the IFR panel, which will take account of any additional evidence which has become available in the meantime

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Chairman

The panel can be chaired by any of the members, provided that s/he has received appropriate training. The Chair must be identified in advance of the meeting, and must be available to approve the minutes / letters and fulfil any other obligations within the specified time frame.

Membership, delegation and probity

The membership of this committee is as follows:

Core (voting) members

- Chair
- Chief Officer
- Independent member
- Lay member
- GP from the governing body

During their membership of the IFR Appeal panel the above members may not also sit as members of the IFR panel.

A register of attendance at the committee will be maintained and reviewed by the committee on a 6 monthly basis.

All individuals attending a meeting, whether as a member or in attendance, must declare any potential conflicts of interest. It will be for the chair of the meeting to decide how this is managed, including asking the individual to withdraw from the meeting in some cases where issues are discussed or decisions taken."

Frequency of meetings and quorum arrangements

- The numbers of appeals received are difficult to predict and therefore arrangements for the IFR Appeal panel meetings are worked on a flexible basis in response to demand. The IFR Appeal panel will usually meet within 20 working days of an appeal being received by Surrey Downs CCG.
- The venue will usually be Surrey Downs CCG Headquarters unless notified otherwise
- The IFR Appeal Panel must be comprised of a minimum of three members including a clinician

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Accountability / dependencies with other committees and group (formal and informal)

- Clinical Governance, Clinical Quality and Patient Safety Committee

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List of dependent sub committees / groups / functions / programmes

The IFR Appeals Panel will link with the following committees/groups providing quarterly reports on the activity of the Panel as relevant to the particular committee.

- Clinical Governance, Clinical Quality and Patient Safety Committee

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Process for Monitoring Effectiveness of the Committee in relation to expectations set out in the terms of Reference.

Members must have attended training, and ensure that they are fully familiar with the Surrey Downs CCG Policy and Operating Procedures for dealing with IFRs before sitting on a panel. Members should attend a training session at least once every two years in order to retain their qualification to serve.

The agenda and minutes of the meeting will be audited annually to ensure there is evidence the committee executed its duties as stipulated in its terms of reference and met the minimum data set of the NHSLA standard 1.1.3.

NHSLA standard	Method of review of effectiveness	Lead	Frequency of review
Duties of the committee	Review of TOR	Chair	Annually
Reporting arrangements into high level committees(if appropriate) and Board	Review of TOR	Chair	Annually
Membership including nominated deputy	Review of TOR	Chair	Annually
Required frequency of attendance.	Attendance figures	Chair	6 monthly
Quoracy of meeting	Review of minutes	Chair	Per meeting

Date and Review

The terms of reference will be reviewed at least annually.

APPENDIX 5 – Consensus Decision Making

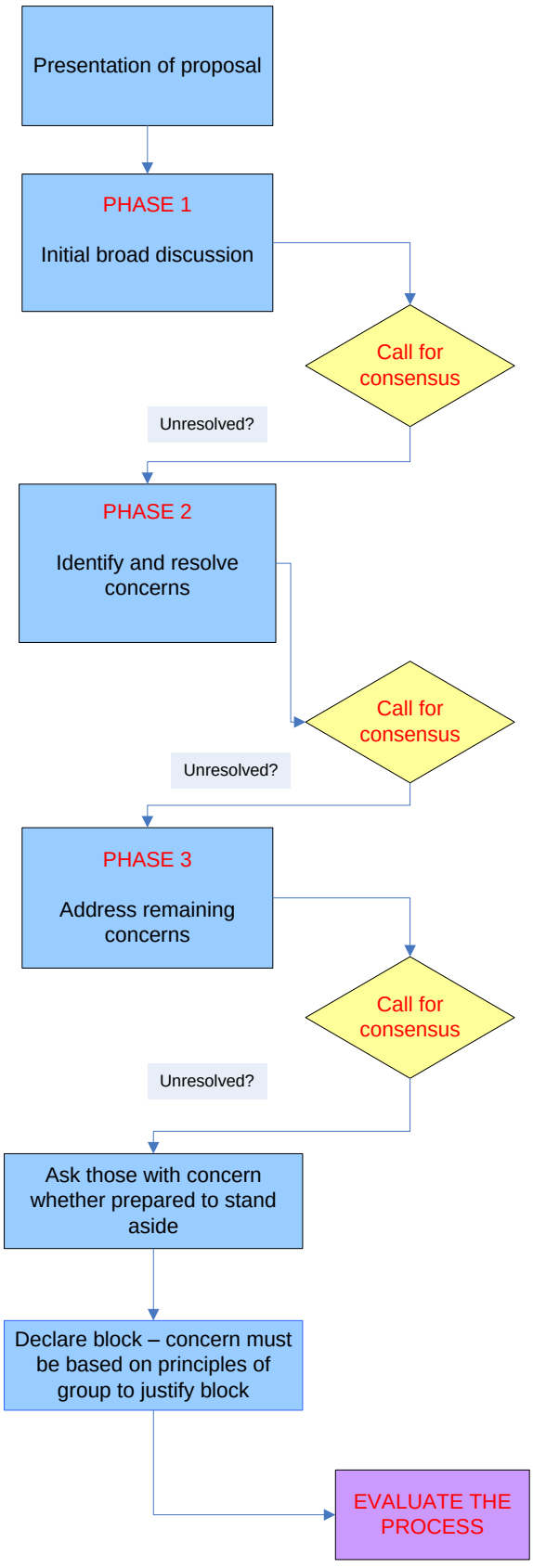
5 fingers:	I strongly support this decision.
4 fingers:	I support this decision.
3 fingers:	This decision is acceptable to me but my support for it isn't particularly strong.
2 fingers:	I am uncomfortable with this decision, but I can live with it.
1 finger:	I personally do not support this decision but I promise not to sabotage it.
Closed fist:	I cannot live with this decision. I need an alternative I can live with.

From Dane County COMP Plan
Consensus Document
http://www.daneplan.org/pdf/documents/consensusdocument.pdf

1 A proposal is accepted if more than 75 percent of the potential votes are cast (i.e. fingers), and there are no fists.

Number of Panel Members Present	Number of Fingers required for 75%
7	26
6	22
5	18
4	15
3	11

FORMAL CONSENSUS



- Proposal ciriculated in writing in advance
- Proposer presents proposal at meeting, provides background information, states clearly the benefits and reasons for adoptions.
- Questions for clarification only – no comments or concerns at this stage

- Encourage comments which take whole proposal into account
- Discussion often philosophical and principled, focussing on long-term benefits, what precedents it creates etc.

Facilitator asks "Are there any unresolved concerns?"

- Brainstorm all concerns: no comments, no attempts to resolve or establish validity
- Group related concerns
- Resolve groups of related concerns

- Re-state remaining concerns
- Questions for clarification
- Address concerns one by one

Options:
1. Turn proposal down.
2. Agree to return to phase 3 and continue discussion.
3. Agree to discuss at another meeting, to allow time for reflection.
4. Send proposal back to committee to look at again in a new, creative way.

From "On Conflict and Consensus. A handbook of Formal Consensus Decision Making." CT Butler, Amy Rothstein, 1991

Appendix 6 - SEC Ethical Framework for Decision-Making (updated November 2010)

Purpose

Surrey Downs CCG has adopted the former South East Coast Ethical Framework for decision-making.

As a publicly accountable body, it is important that a CCG can demonstrate that the way it makes decisions is consistent across all levels of commissioning including strategic planning, funding of new technologies, and funding individual treatment requests. It is also important that decision-making is consistent with the requirements of the NHS Constitution, national best practice policy / guidance, and legislation.

The public will want to know that the CCG takes account of the values of the wider healthcare community when making its decisions, and to be able to recognise and understand processes for prioritisation and resource allocation.

Context

Each CCG has the responsibility for commissioning healthcare services on behalf of its population and receives a fixed budget from central government with which to do this.

Commissioned services include those provided through primary, secondary and tertiary care providers, the independent sector, voluntary and community agencies and independent contractors.

A CCG will also commission services jointly with others including other CCGs and the local council. Decisions made within these partnership relationships have to take into account the impact of decisions on broader populations.

The mechanism through which investment and disinvestment decisions are taken is the Local Operating Plan (LOP) process, which occurs annually. In undertaking this process of prioritisation, one of the challenges for CCGs is how to strike the right balance between providing services that meet the needs of the population, whilst balancing this with the differing needs of individuals. It is an unavoidable feature of state-funded healthcare systems, such as the NHS, that CCGs have insufficient resources to fund all types of healthcare that might be requested for their populations.

CCGs will always had to make difficult and sensitive decisions about what will be funded and what will not. The way in which decisions are made is fundamental to their democratic acceptability and contributes to whether a decision is judged to be fair or not. A key requirement is for CCGs to

demonstrate that decision-making is consistent, takes account of all relevant factors and is underpinned by locally established principles.

The need for commissioning decisions to ensure high quality outcomes and efficient use of NHS resources is unlikely to change. The NHS Constitution requirements will still apply as the rights within the constitution are supported through legislation (i.e. these will apply until there is a change to the legislation).

The principles framework establishes the values based principles that underpin how commissioning decisions are made. The principles can be used to determine the approach to decision-making and the development and application of specific tools and/or criteria to be used in decision-making processes.

It is important to remember the framework of principles is a guide to inform the way commissioners think about decision-making. It establishes the conditions necessary for fair decision-making. The framework of principles is not a decision-making tool. It should not be viewed as an algorithm or the process for decision-making. The values based principles which form the framework should not be used as a checklist or criteria to be satisfied before a decision can be made.

Establishing the principles

SEC CCGs determined that a single framework of values based principles should be established to underpin the approach and application of processes for local decision-making at all levels including decisions for their population and decisions for individuals.

The values based principles were established though a series of focus groups, held in November and December 2009, involving health colleagues, clinicians, and lay members.70 people participated in total and between them generated 580 statements defining the key attributes of decision-making that would assure them decision-making was consistent and fair.

The statements generated were analysed by an independent researcher and grouped according to theme, and then sorted by the number of statements coded under each theme. No attempt was made to rank or weight themes in the form of criteria as this is not their purpose.

A review of the research literature, bioethical literature and current practice among English CCGs was undertaken at the same time. The following conclusions were made:

- The SEC approach is theoretically sound and consistent with the requirements of the NHS Constitution, relevant national guidance and Directions.

- Approximately 80 CCGs in England have established frameworks for decision-making.
- An emerging finding is that a number of frameworks start to distinguish principles from criteria (the principles/ethical framework set out the values based principles that underpin the approach to how commissioning decisions are made; criteria and/or decision-making tools, when applied, give the principles practical effect.)
- No single set of established principles exist that can be adopted nationally.
- There is greater agreement on specific criteria/tools for decision-making than on the principles that underpin the approach to decision-making.
- Weighting or ranking criteria is problematic. There is greater preference for facilitating consistent and coherent process which allows for consideration of the relevant factors and requires judgment.

Six principles for decision-making

Six principles for decision-making have been identified. Key principles are the need for decisions to be rational, socially inclusive, clear and open to scrutiny and take account of economic factors. A further principle is the requirement to allocate health care resources according to health needs, taking care to balance the needs of the individual with the needs of the wider community. The sixth principle is that a wide range of factors and perspectives should be considered when deliberating a decision.

Principle: Rational

Decision-making is rational based upon a process of reasoning;

- Ensuring that the decision is based on thoughtful consideration of the available evidence.
- Making a realistic appraisal of the likely benefit to patients.
- Weighing up all the relevant factors, including risks and costs.
- Taking account of the wider political, legal and policy context.
- Ensuring individuals involved in decision-making are appropriately skilled and trained.

Decisions should be made on the basis of a reasonable evaluation of the available evidence, including evidence of efficacy, safety and clinical effectiveness.

A process of inquiry is required to gather the available relevant evidence. The approach to assessing the validity and credibility of evidence should be broad but maintain high standards of critical appraisal. Both qualitative and quantitative evidence will be taken into consideration, with evidence from sources other than large-scale randomised clinical trials given appropriate weight. Expert opinion should be sought.

Decisions should be based on careful consideration of the trade-offs between costs and benefits, both in the short and longer term, but also recognise that complex trade-offs cannot necessarily be reduced to simple cost-benefit calculations.

Rational decisions will weigh up likely outcomes, the wider contexts in which treatments can be provided, the implications for service delivery, clinical pathways, and benefits, costs and risks.

Existing national policy and guidelines must be considered. Decisions should be taken within the political and legal context.

Consideration needs to be given to the people who are responsible for decision-making. The position, qualifications and skills of decision makers should be appropriate to ensure due deliberation of all the relevant factors and to ensure that appropriate specialist clinical and technical knowledge is available.

Principle: Inclusive

Decisions about the allocation of health care resources should be arrived at through a fair and non-discriminatory process:

- Reinforcing the concept of equal opportunity of access to health care.
- Ensuring patient and public engagement in decision-making.
- Balancing the rights of individuals with the rights of the wider community.

Effort should be made to ensure broad based participation in decision-making groups and committees. Decision-making should be non-partisan and individuals will need to be able to take an objective view of the topic, and maintain an open mind about the evidence. As far as possible consensus decision-making will be used.

Decision-making should not discriminate on characteristics which are irrelevant to health conditions and the efficacy of treatment. Consideration of factors such as age and ethnicity will only be considered where this is clinically relevant.

Decisions should take account of local and societal sensitivities. There should be an active attempt to engage patients, carers and the wider public in the decision-making process to ensure that the perspectives of both health care providers and consumers are fully taken into account.

The aim is to achieve consistent and equitable opportunity of access to health care, between individuals and groups in society, and to promote equity of health outcome.

Principle: Clear and open to scrutiny

The process of making decisions about the allocation of health resources should be transparent and easily understood. Patients and the public should have easy access to the processes of decision-making and these processes should be consistently applied.

Both the decisions themselves, and the way they are determined, should be clearly specified, including roles and responsibilities of individuals involved, accountabilities and governance arrangements, and the right of appeal. Decision-makers will need to provide the rationale for their decisions, any particular factor that has influenced a decision should be clearly stated including, for example, insufficient evidence of effectiveness, or insufficient capacity or resources.

The information provided to decisions-makers should be fully documented. The process of decision-taking should also be documented, to show that it has conformed to the principles agreed by South East Coast Primary Care Trusts (and adopted by Surrey Downs CCG), and to record the degree of consensus.

Communication throughout a decision-making process is required to be clear and effective, and communication about decisions need to be unambiguous and articulate.

Principle: Investment and disinvestment decision within available finite resources.

Resources are finite and must be managed responsibly. Decisions need to be made within the context of available resources. Investment in one area of health care will divert resources away from other areas of potential investment, or existing services. Factors such as current areas of spend, and the existing care provision must therefore be considered.

Ensuring efficacy and effectiveness of spend are key considerations and a clear understanding of costs and opportunity cost is called for. There is a need to balance cost impact against other factors such as health impact for the population. Impacts need to be considered both in the short and longer term.

Principle: Allocation of health care resources according to health needs

Each CCG is required to identify priorities for its population, decide how healthcare resources are to be allocated, and determine the priority to be assigned to a service or a particular health care intervention.
Decisions about the allocation of health care resources should be based on a clear understanding of the health needs of the population whom decisions will affect, and the scale and nature of benefits.

There is requirement to balance the needs of the individual with the needs of the wider community. There may be times when it is appropriate to target

some demographic groups or health issues in order to reduce inequalities and promote the well-being of the community as a whole.

Policies which promote health and avoid people becoming ill are considered alongside curative treatments and other interventions.

Principle: Promote consideration of a wide range of factors

Decision-making should embrace the concept of ‘broad thinking’, being secular, open to new ways of working and thinking as well as new technologies, and taking account of biological and psychological health outcomes.

The combination of individuals involved in decision-making should provide scope for a good range of perspectives in respect of the detail of the topic and its wider contribution to health care in the area.