Operating process for dealing with Individual Funding Requests (IFR’S)

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<td>Ratified by:</td>
<td>CCG Governing Body</td>
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<tr>
<td>Name of originator/author:</td>
<td>Andrea Golding</td>
</tr>
<tr>
<td>Name of responsible committee/individual:</td>
<td>Surrey Priorities Committee</td>
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<td>NHSLA Standard (if applicable):</td>
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<td>Last review date:</td>
<td>June 2018</td>
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## Version History

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**Equality Statement**

The Clinical Commissioning Group (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.

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

**Equality Analysis**

This policy has been subject to an Equality Analysis, the outcome of which is recorded below.

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<tr>
<td>1.</td>
<td>Does the document/guidance affect one group less or more favourably than another on the basis of:</td>
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<td><strong>Age</strong>&lt;br&gt;Where this is referred to, it refers to a person belonging to a particular age (e.g. 32 years olds) or range of ages (e.g. 18-30 year olds)</td>
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<td><strong>Disability</strong>&lt;br&gt;A person has a disability if s/he has a physical or mental impairment which as a substantial and long-term adverse effect on that persons ability to carry out normal day-to-day activities</td>
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<td><strong>Gender reassignment</strong>&lt;br&gt;The process of transitioning from one gender to another</td>
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<td><strong>Marriage and civil partnership</strong>&lt;br&gt;In England and Wales marriage is no longer restricted to a union between a man and a woman but now includes a marriage between a same-sex couple. Same-sex</td>
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couples can also have their relationships legally recognized as ‘civil partnerships’. Civil partners must not be treated less favourably than married couples (except where permitted by the Equality Act)

| 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? | N/A |
| 5. | If so, can the impact be avoided? | N/A |

- **Pregnancy and maternity**
  Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period of birth, and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treated a woman unfavourably because she is breastfeeding.

- **Race**
  Refers to the protected characteristic of Race. It refers to a group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.

- **Religion and belief**
  Religion has the meaning usually given to it but belief includes religious and philosophical beliefs including lack of belief (e.g. atheism). Generally, a belief should affect your life choices or the way you live for it to be included in the definition.

- **Sexual orientation**
  Whether a person’s sexual attraction is towards their own sex, the opposite sex or both sexes.
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 the corporate office, Surrey Downs CCG. If you have identified a potential discriminatory impact of this procedural document, please contact as above.

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<tr>
<td>Justin Dix, Governing Body Secretary/Clare Johns, Medicines Management</td>
<td>April 2016</td>
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1. **Introduction**

The South East Coast (SEC) Health Policy Support Unit (HPSU), acting on behalf of the Primary Care Trust (PCT) 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

And the following Policy Recommendations in 2010 & 2011

- PR 2010-02 NHS pick up of trial funding
- PR 2011-01 Patients changing responsible commissioner

The above SEC documents were designed to help PCTs develop systems in relation to individual funding requests (IFRs) which would facilitate the adoption of area-wide standards and procedures operating in accordance with the requirements of National guidance;

- NHS Constitution for England, Jan 2009
- Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments, March 2009
- Department of Health: Defining guiding principles for processes supporting local decision-making about medicines, Jan 2009
- Department of Health / National Prescribing Centre: Handbook of good practice for local decision-making, March 2009

These documents have been utilised to assist with producing this policy. In April 2013 the NHS England (NHSE) Single Operating Model for directly commissioned services was implemented. NHSE is 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 Available from: [https://www.england.nhs.uk/commissioning/spec-services/key-docs/](https://www.england.nhs.uk/commissioning/spec-services/key-docs/).

This policy therefore does not apply to the services which are the responsibility of NHSE and the CCG’s will not accept any IFRs for services it is not responsible for commissioning.

IFRs for Mental Health placements will be considered by Surrey and Borders Partnership NHS Foundation Trust and are not within the scope of this policy.

i. **NHS pick up of trial funding**

- The CCG’s will not pick up the ongoing funding of treatments for patients who have completed clinical trials or treatments initiated on free compassionate supplies unless either:
The CCG’s have agreed through normal commissioning processes prior to the trial commencing with the trial funder that the CCG’s 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’s 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’s have 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 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.

ii. Patients changing responsible commissioner

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’s 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 commissioner’s usual local decision making mechanisms.

**Funding Validity**

Where funding approval has been granted by the CCG, individuals must initiate treatment within six months of the approval letter.

2. Ethical Framework

2.1 Introduction

2.1.1 A primary responsibility of the commissioners of NHS health care in England is to make decisions about which treatments and services should be funded for their designated populations. This includes making decisions about the continued funding of currently commissioned treatments and services, as well as the introduction of new treatments and approaches to the delivery of care.

2.1.2 Commissioners are subject to a statutory duty not to exceed their annual financial allocation. Further, despite an incremental increase in funding, the NHS needs to make substantial financial savings in order to continue to meet increasing demands for care and treatment. As the demand for NHS health care exceeds the financial resources available, commissioners are faced with difficult choices about which services to provide for their local populations.

2.1.3 The Priorities Committee has representatives of the NHS organisations across five Surrey Clinical Commissioning Groups (CCGs):

- NHS East Surrey CCG
- NHS Guildford and Waverley CCG
- NHS North West Surrey CCG
- NHS Surrey Downs CCG
- NHS Surrey Heath CCG

The Committee also includes lay members as well as clinicians and managers.

2.1.4 The purpose of the Priorities Committee is to make recommendations, in the form of policies, to the local CCGs as to the services and health care interventions that should or should not be funded.

2.1.5 The Priorities Committee is supported by Surrey Public Health, who will
provide evidence reviews to support prioritisation and decision making and support for agenda setting and work plan development.

2.1.6 The Surrey Priorities Committee is established to support the due process behind decision making across the CCG population. Decisions regarding individual patients (Individual Funding Requests) are outside the remit of this process and are considered by a separate process.

2.2 Purpose of the Ethnical Framework

2.2.1 Ethical Frameworks were originally developed by the NHS public health organisation Priorities Support Unit and the Berkshire PCTs in 2004 and for South Central NHS PCTs in 2008. Since then, the Framework has been revised to take account of policy developments in the NHS and changes in the law, and has been adopted more widely.

2.2.2 The purpose of the ethical framework is to support and underpin the decision making processes of constituent organisations and the Priorities Committee to facilitate fairness and transparency in the priority-setting process and support consistent commissioning policy through:

2.2.3 Providing a coherent structure for the consideration of health care treatments and services to ensure that all important aspects are discussed.

2.2.4 Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity. Ensuring that the principles and legal requirements of the NHS Constitution and the Public Sector Equality Duty are adhered to.

2.2.5 Providing a transparent means of expressing the reasons behind the decisions made to patients, families, carers, clinicians and the public.

2.2.6 Supporting and integrating with the development of CCG Commissioning Plans.

2.2.7 Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committee.

Although there is no objective measure by which such decisions can be based, the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

2.2.8 The following Ethical Framework consists of 8 principles that will be taken into account in the development of each recommendation. It does not preclude the weight that any one principle is given nor does it require that all should be given equal weight.
2.3 Principle 1: Equity

2.3.1 The Committee believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community.

However, the Committee will not discriminate, or limit access to NHS care, on grounds of personal characteristics including: age, race, religion, gender or gender identity, sex or sexual orientation, lifestyle, social position, family or financial status, pregnancy, intelligence, disability, physical or cognitive functioning.

However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

2.3.2 The Committee abides by the Equality Act (2010) which protects people from being discriminated against because of: race, sex, sexual orientation, disability, age, caring responsibilities, religion or belief, being transsexual, being pregnant or just having had a baby, or being married or in a civil partnership.

2.3.3 The Committee values mental health equally with physical health in line with the NHS “parity of Esteem”.

2.4 Principle 2: Health Care Need and Capacity to Benefit

2.4.1 Health care should be allocated justly and fairly according to need and capacity to benefit.

2.4.2 The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. As far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

2.4.3 This approach leads to three important principles:

2.4.4 In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.

2.4.5 A treatment of little benefit will not be provided simply because it is the only treatment available.

2.4.6 Treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.
2.5 Principle 3: Evidence of clinical effectiveness

2.5.1 The Committee will seek to obtain the best available evidence of clinical effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committee. Choice of appropriate clinically and patient-defined outcomes need to be given careful consideration, and where possible quality of life measures should be considered.

2.5.2 The Committee will promote treatments and services for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment and services that cannot be shown to be effective.

For example, is the product likely to save lives or significantly improve quality of life? How many patients are likely to benefit? How robust is the clinical evidence that the treatment or service is effective?

2.5.3 When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients’ health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients’ evidence of significant clinical benefit is relevant.

2.5.4 The Committee will also take particular account of patient safety. It will consider the reported adverse impacts of treatments and the license status of medicines and the authorisation of medical devices and diagnostic technologies for NHS use.

2.6 Principle 4: Evidence of cost effectiveness

2.6.1 The Committee will seek information about cost effectiveness in order to assess whether interventions represent value for money for the NHS. The Committee will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. The Committee will consider studies that synthesize costs and effectiveness in the form of economic evaluations (e.g. quality adjusted life years, cost-utility, cost-benefit) as they enable the relationship between costs and outcomes of alternative healthcare interventions to be compared, however, these will not by themselves be decisive.

2.6.2 Evidence of cost effectiveness assists understanding whether the NHS can afford to pay for the treatment or service and includes evidence of the costs a new treatment or service may release.
2.7 Principle 5: Cost of treatment and opportunity costs

2.7.1 Because each CCG is duty-bound not to exceed its budget, the cost of a treatment must be considered. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high. This is important because of the overall proportion of the total budget: funds invested in these areas will not be available for other health care interventions.

2.7.2 The Committee will compare the cost of a new treatment to the existing care provided, and consider the cost of the treatment against its overall health benefit, both to the individual and the community. As well as cost information, the Committee will consider the numbers of people in their designation populations who might be treated.

2.8 Principle 6: Needs of the community

2.8.1 Public health is an important concern of the Committee and they will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and Health and Social Care Outcomes Framework). Others are produced locally. The Committee also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

2.8.2 Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient’s doctor may still seek to persuade the CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

2.9 Principle 7: National policy directives and guidance

2.9.1 The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual CCGs. The Committee operates with these factors in mind and recognise that their discretion may be affected by Health and Social Care Outcomes Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

2.9.2 Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG and these will be described in their Local Delivery Plan.
2.10 Principle 8: Exceptional Need

2.10.1 There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Individual cases are considered by each respective CCG. Each case will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases through their Individual Funding Request Process.

2.11 Principle 9: Personal responsibility

2.11.1 Individual patients have a personal responsibility for improving their health outcomes. By doing so they give themselves the best chance of a successful outcome prior to and during medical interventions (prevention).

2.12 Bibliography

- Commissioning Policy: Ethical framework for priority setting and resource, NHSCB (2013)
- Ethical Framework, Thames Valley Priorities Committee (2014)
  http://www.windsorascotmaidenheadccg.nhs.uk/download/windsor_ascot_and_maidenhead_public_governing_body_meetings/5th_march_2014/10.6%20Thames%20Valley%20CCGs%20-%20Ethical%20Framework%20for%20priority%20setting%20FINAL%202014%20(2).pdf
- Health and social care outcomes frameworks (2013)
  - The NHS Belongs to the People – A Call to Action. NHS England (2013)
  - The NHS Constitution (2013)
    http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx
  - The Public Sector Equality Duty (2011)
  - The Spending Review settlement for healthcare: Health Select Committee (2010)
    http://www.publications.parliament.uk/pa/cm201011/cmselect/cmhealth/512/51208.htm
3 IFR Process

3.1 Application process

Who can submit an application?

IFRs must only be submitted, for an NHS patient, by an NHS consultant, GP or an equivalent NHS autonomous practitioner provided s/he will be responsible for administering the treatment (“the requesting clinician”). Patients may not submit applications directly.

IFR applications should only be submitted when the procedure or high cost drug requested is not routinely funded (For IFR’s see Policy No. TNRF1, For High Cost Drugs see commissioners list of medicine exclusions

OR

Applications can be submitted where the patient does not fully meet the clinical threshold for procedures that with the List of Procedures with Restrictions and Thresholds policy (Policy No. TNRF2). This is on the basis that they have an exceptional need or an extremely rare condition.

Funding applications for Assisted Conception

If a patient does not fully meet the criteria, the requesting clinician will be the Fertility Clinic not the treatment provider.

Responsibilities of the requesting clinician

- The requesting clinician is required to confirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the application is made for funding on his/her behalf.
- The requesting clinician is required to confirm 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 clinical information including the rationale for clinical exceptionality or rarity, required in support of an application is provided.
- If the IFR application is considered eligible for the IFR 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 provide additional clinical information.
Application Form- Drug IFR’s;

Applications for drug IFR’s must be sent electronically as an attachment to highcost.drugs@nhs.net

All drug applications 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 CCG 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)

Intervention IFR’s;

All intervention IFR’s should be submitted via the IFR database (Blueteq). See Appendix 4.

When submitting applications for Drug and Intervention IFRs, requesting clinicians are advised that failure to use the correct paperwork (including the most up to date IFR application form), failure to follow the above process and/or failure to submit the form in the required format may result in a delay in the CCG’s considering IFRs. Incomplete applications will not be considered.

The CCG’s do not fund retrospectively and the onus is on the requesting clinician to ensure that IFR’s are submitted and funding is approved before treatment is initiated. Please note: The CCG’s will not authorise payment for treatments that have not been agreed.

3.2 On receipt, all IFR applications (drug or intervention) will be checked 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 application has been approved by a suitable representative of the Trust providing the treatment (as appropriate)

A file for each IFR application will be created on the Blueteq database. All applications received will be allocated a unique identifier.

If the application is not sufficiently complete, the requesting clinician will be contacted within 5 working days of receipt of the form.
3.3 Checking for eligibility for consideration by the IFR Panel (see also Appendix 5)

3.3.1 Within 14 working days of receipt of the completed paper work, application forms will be screened to check whether the IFR is eligible for consideration by the IFR Panel.

The applications will be screened as eligible for consideration by the IFR Panel by reference to the following criteria:

1. The requested treatment is funded within existing commissioning policy AND patient meets any thresholds
   - *IFR is not required and funding for treatment should be approved by the IFR team without reference to the IFR panel.*

2. The requested treatment is not funded within an existing commissioning policy
   a. The CCG has a policy to commission for a group of patients who have the same medical condition but the thresholds for funding are not met (the individual patient's clinical circumstances do not match the criteria in the policy)
      - *IFR screening will check that clinical exceptionality has been described by the requesting (NHS) clinician.*
   b. The CCG has a policy not to routinely commission the treatment for the requested treatment for patients suffering from the same medical condition as the requesting patient.
      - *IFR screening will check that clinical exceptionality has been described by the requesting (NHS) clinician.*
   c. The CCG does not have a policy for the requested treatment for patients suffering from the same medical condition as the requesting patient.
      - *IFR screening will check that the IFR describes ‘rarity’ of the condition. Defined as 1 person/2.5 million population*

The IFR team will seek additional clinical input during the screening process in at their discretion.

3.3.2 Does the patient belong to a cohort?

A cohort is determined if 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.

Psychological elements alone are unlikely to be sufficient to demonstrate exceptional clinical circumstances. Social and non-clinical factors are not considered clinically exceptional under IFR policy.
3.3.3 Service Development

Requests made under the IFR process will be classified as a request for a service development if, in the opinion of the IFR team, there are likely to be a defined group of patients in similar clinical circumstances who form a cohort. Such patients will be regarded as forming a cohort if the information in the application, supplemented by other published sources if needed, leads the IFR team to believe that there are likely to be other patients across the CCG in any single financial year:

a. Who are in the same or similar clinical circumstances as the patient who is the subject of the request or their clinical condition is such that they could make a similar request; and
b. Who could reasonably be expected to benefit from the requested treatment to the same or a similar degree as the patient on whose behalf the request is made.

If a decision is made by the IFR team based on the application and other information available that the request is properly classified as a request for a service development then the request will be considered to be ineligible for consideration at the IFR panel and will be considered in Part 2 of the IFR panel meeting (See section 3.8). The requesting patient or clinician will be entitled to question the decision to classify the treatment as a service development, but should do so on the basis of clinical exceptionality, by arguing that the clinical circumstances of the patient are such that he or she is not in fact representative of a cohort. For any such question, the requesting clinician may submit new clinical information to substantiate the argument for clinical exceptionality. The IFR team will take the IFR back through the IFR process, if new and relevant clinical information is provided.

3.3.4 Urgent Clinical Need

Where an IFR application describes urgent clinical need, the fast track process should be followed. See section 3.6

3.3.5 Requests for equipment/devices

Funding requests received by the IFR Team which are for either equipment or devices to be used in the community will be sent via secure email to the patients CCG for a decision to be made based on the information provided. The IFR Team will then relay the outcome to the requesting clinician.

3.4 Redirection of requests that are considered to be ineligible for consideration by the IFR Panel

If an IFR application is ineligible for consideration by the IFR Panel as a result of the IFR screening process, the reason(s) for that decision will be given within 14 working days of IFR screening. The requesting clinician will be notified electronically either directly via the Blueteq database or by email.
Where an IFR is considered to be ineligible for consideration at the IFR Panel, the Blueteq database will be updated to reflect this and the ineligibility information will be uploaded to the patient’s record.

In the event that the application is ineligible, neither the requesting clinician nor the patient has the right to request a review. However if an IFR application is ineligible for consideration by the IFR Panel on account of missing or inadequate information, the clinician may re-submit the application with the necessary information.

3.5 Dealing with an eligible request

3.5.1 Anonymity and IFR Tracking Record

The application form (and all copies) will be anonymised and identified only by the unique identifier, in keeping with the Caldicott principles.

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

3.5.2 Acknowledgement of Requests

All IFRs will normally be considered within 35 working days of receipt of a fully completed IFR form, including all supporting documentation.

3.5.3 Identification of time limits and potential cost pressures

In respect of each application received, it is the responsibility of the requesting clinician to establish and notify the IFR Team of any time-limited procedures, such as the 18-week rule, that apply to each application and whether any special circumstances exist which may interact with the timing and progress of the IFR process.

Additionally, the CCG’s finance directorate will be notified of any applications received which, if approved, are likely to lead to substantial cost pressures. Such notification is not to be taken as an indicator that the application will be approved.

3.5.4 Call for more information/evidence review/specialist advice

Applications for Drug IFRs

Each individual IFR high cost drug application will be processed by a member of the Medicines Management Team. The onus is on the applying Trust clinician, as the expert in the area, to submit all relevant clinical information with the application.

The Medicines Management Team, following receipt of the application, and confirmed eligibility for the IFR Panel will routinely perform a literature search to identify relevant clinical information.

When editing the IFR, the Medicines Management Team will ensure that this is clearly annotated into the relevant boxes (so that it is clear which information was from the Trust / applying clinician and which came from the CCG).
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 provide a copy. 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.
- **Identified Information** for all information identified by the processor whilst conducting a search or review.

The processor will ensure that clinical trials are summarised and a comment made which makes reference to the relevance of the particular trial/information to the particular patient.

Check the wording of the license on summary of product characteristics (SPC) ([http://emc.medicines.org.uk/](http://emc.medicines.org.uk/)).

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.).
- Where a drug has been appraised by other networks e.g. London new drugs group. Then include that in the evidence review too although you will probably pick this piece of work up when you look at NHS evidence.
- 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](http://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

a. Areas of interest (clinical, commissioning, education & training)
b. Types of information (e.g. care pathways, evidence summaries)
c. Clinical queries
d. Sources
e. Medicines and devices
f. Published date
Other Resources should include:

- 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).
- Portal for rare diseases and orphan drugs www.orpha.net
- Summary of Product Characteristics accessed via www.medicines.org.uk
- National Institute for Health and Care 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
- Medicines Strategy Group accessed via www.wales.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

It may also be relevant to contact a Drug Company’s Medical Information department especially when published information is lacking.

The processor must also ensure that prevalence data is incorporated in the request and 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.

IFR applications must always be processed in sufficient detail to allow a Panel member to reach a decision without further contact with the enquirer. If there are any doubts about any aspect of the IFR, this will be clarified with the Trust before submitting to the Panel.

Once processed; a summary will be provided at the end of the application form headed ‘points for discussion’. The following is a list of minimum points that will 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
- Comment on alternative treatments (if applicable)
- Comment on cost effectiveness
- Any other relevant information
- IFR case prepared by
The date of the IFR Panel meeting should be included in the document.

It is the responsibility of the member of the Medicines Management Team processing the high cost drug IFR to decide what further information, specialist advice, and/or review of evidence, is required to enable the IFR Panel to consider the application.

Each case is likely to be different and so will be handled on a case-by-case basis. When requesting more information, the Medicines Management Team member will make it clear what further information is required and the timeframe within which it should be received.

The member of the Medicines Management Team processing the high cost drug IFR will make a note of any further information, specialist advice and/or evidence review requested in respect of each application on the Blueteq database and will take any steps necessary to ensure that the application is fully complete and all supplementary information has been received prior to circulation of the IFR application to the IFR Panel.

**Applications for Intervention IFRs**

If the IFR is for treatment that is new or unusual, the IFR Team will ask the Public Health Team to provide an evidence review for the requested treatment.

If an evidence review for a new or unusual treatment is required from the Public Health Team, 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.

The Public Health Team will endeavor 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 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 in writing to the requesting clinician by the IFR Team.

### 3.6 Fast tracking all urgent IFR’s (urgent clinical need)

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 percentage 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 the IFR Team will contact the Clinical Lead at the 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 comprise 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 the 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; a virtual IFR Panel.

A fast-track decision will be made by reference to the Ethical Framework (Section 2) 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 application will be funded without conditions
- the application will be funded with conditions attached
- the application 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 application will be re-considered by the group.

The IFR Team are responsible for managing the fast-track process and the distribution of information/evidence among the group for fast tracked IFRs.

The IFR team have the responsibility to ensure that the fast-track decision is communicated to the requesting clinician (and the patient, if appropriate), that the decision is documented, and that the reasons behind the decision and the consensus reached are uploaded onto the Blueteq database.

All information relating to the fast-tracked IFRs (the processed IFR application form, emails and the decision made) must then be included in the papers for the next scheduled IFR Panel meeting for ratification.
3.7 Agenda and supporting papers

The IFR Panel agenda will list general business, the applications requiring consideration, fast-tracked applications and any other business including Part 2 applications for consideration of service development.

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

- the unique identifier and relevant CCG
- status (i.e. new submission, resubmission)
- the procedure requested

IFR Panel members will receive the agenda and supporting papers via email links no less than 3 working days before each scheduled 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 IFR Team are responsible for all the logistical and administration arrangements for IFR Panel meetings. The IFR Team will prepare the agenda and co-ordination of the Panel papers for each Panel meeting.

3.8 The IFR Panel meeting

All eligible IFR’s will be considered by a Surrey-wide collaborative IFR Panel. Those requiring an urgent response will be considered via the fast-track procedure and subsequently noted at the next IFR Panel meeting.

The IFR Panel’s report specific to the CCG will be sent to the CCG Executive Team and Head of Planned Care.

The Chair of the Surrey-wide collaborative IFR Panel is responsible for the conduct of the meeting, determining whether the meeting is quorate and ensuring that the agenda is completed.

Patients will not be invited to make representations in person.

During the meeting, the Panel members will consider:

- new applications
- applications 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
- applications that have been declined and resubmitted with new clinical information.

In the second part of the IFR Panel Meeting (Part 2), the IFR Panel will consider new applications 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 annually in advance (see Appendix 1 for Terms of Reference and constitution of the Panel).

3.9 **Principles to be applied by the IFR Panel**

Each IFR will be considered on its own merits. Decisions will be taken using the agreed Consensus Decision-making Process (see Appendix 3) and IFR Panel members will have received training on this as part of their induction training. The Ethical Framework (see Section 2) will be used to support the decision-making process and will help to promote consistency across the patient population.

In keeping with the principles of the Ethical Framework, the IFR Panel will need to take an objective view of the application 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’s have no policy or (b) an exceptionality request for funding for treatment in connection with a medical condition for which the CCG’s have a policy and where the requesting clinician on behalf of 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’s take to the assessments of costs for other treatments outside this policy, the cost to the CCG’s 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 a patient has demonstrable specific clinical exceptionality or rarity. This will depend on the precise and particular clinical facts of the individual case and whether those can genuinely be described as exceptional or rare. 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 rarity, the IFR Panel will use NHS England’s definition which is 1 case in 2.5 million.

When considering clinical exceptionality, the IFR Panel will consider that the anonymised patient subject to the request 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 anonymised patient, could show that their clinical circumstances were sufficiently unusual that they could properly be described as being exceptional. Whether or not an anonymised 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, by 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, by itself, to be sufficient to demonstrate exceptional circumstances.

In Part 2 of the meeting the following conditions must be met and decisions made will not set a precedent for future applications:

- There is sufficient evidence to show that, for the anonymised patient, the proposed treatment is likely to be clinically effective;
- Applying the approach that the CCG’s take to the assessments of costs for other treatments outside this policy, the cost to the CCG’s of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the anonymised patient by the requested treatment.

3.10 Decisions available to the IFR Panel

When considering a new application, the IFR 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 application cannot be decided at this meeting because more evidence/information is required and is therefore deferred

3.11 Requests that are funded without conditions

The IFR Panel may decide that the clinical information provided demonstrates that a patient is either rare or exceptional by definition, therefore funding will be approved as requested within the IFR application.
3.12 Requests that are funded with conditions

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. The Panel may require a report from the requesting clinician detailing the patient’s response to the first 3 cycles. The Panel will make a further decision on funding the remaining cycles once it has considered the clinician’s report. This will be considered at the next available IFR Panel.

3.13 Requests that are not funded

When reaching their decision, the IFR Panel will use the Ethical Framework set out at Section 2 of this document. If, based on the information provided, the IFR Panel agree unanimously that the patient is neither rare nor clinically exceptional then funding will not be approved and the patient and/or requestor will be provided with a clear rationale in writing as to why the treatment is not funded.

The Panel’s decision, including the rationale for the decision, will be clearly recorded in the minutes and will be sent to the IFR Panel Chair for sign off.

3.14 Requests that are deferred

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 IFR 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 reconsidered at the next Panel meeting providing the information is available.

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

3.15 Withdrawing an IFR

IFRs can be withdrawn at any time by written notice/email from the requesting clinician and/or from the patient. The IFR application will be marked as withdrawn on Blueteq database.
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.

### 3.16 Record of IFR Panel meetings and confidentiality

All discussion during a meeting of the IFR Panel will remain confidential.

If Panel papers have been printed for or by Panel members the copies of the Panel papers will be collected and destroyed at the end of the meeting. The Panel’s decision, including the rationale for the decision will be clearly recorded in the minutes and will be sent to the IFR Panel Chair for sign off. The Panel are to consider the Ethical Framework at Section 2 when reaching and recording their decision. The minutes for each individual case will then be entered onto the patient’s records on the Blueteq database (by the IFR Team).

The IFR Panel outcome letter to the requesting clinician will adequately explain the reason, the rationale and any conditions relating to 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 IFR Panel Chair signing off the minutes and outcome letter.

When preparing minutes, both the IFR Team leader, medicines management team member (high cost drug IFRs) and the IFR Panel Chair should bear in mind that these are documents which could be discloseable, and therefore use language accordingly. The decisions of an IFR Panel are attributable to the Panel as a whole. The minutes of
the discussion about specific concerns raised by individual applications 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 observer / expert adviser who attended and the items for which they were present

For each individual application considered by the IFR Panel, the minutes should record:

- The unique reference number of the application
- The status of the application (i.e. new submission, resubmission)
- Confirmation of the patient's CCG
- The name of any member who declared an interest in or association with the application, 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 application
- Note of the written comments on the application 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 application and the Panel's response to them
- The decision reached, the number of Panel members and the total number of votes cast.
- 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 detailed rationale for the decision, including consideration of the Ethical Framework set out at Section 2. (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 may be by definition dealing with rare conditions. The singularity of these may be enough to identify an individual.

Notes for applications considered by the IFR Panel will be taken by a member of either the IFR Team or the Medicines Management 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.

One complete set of original IFR applications submitted and considered by the IFR Panel will be retained electronically on the Blueteq database. This information is retained indefinitely.
3.17 Communicating the IFR Panel’s decision

The IFR Panel’s decision will be communicated by letter or email to the requesting clinician who submitted the IFR. The letters communicating the decision are signed on behalf of the Panel Chair. The letter should convey the Panel’s decision, with reasons. If funding is approved with any conditions attached to the decision, which might include the requirement for an interim report, these must be set out clearly.

Once the minutes and letters are signed off and approved then within 5 working days of the IFR Panel meeting, a member of either the IFR Team or the Medicines Management Team will:

- Post the letter conveying the Panel’s decision to the requesting clinician
- Update the IFR/High Cost Drugs Database

3.18 Time periods for the IFR process

The CCG will work to the standard that funding decisions will be provided within 35 working days. Achievement of this standard is dependent upon receiving completed requests together with the relevant references to support the application. This standard applies from the point at which full information from the requesting clinician is received.

4 Review of the IFR Panel process (Review Panel)

A review of the IFR Panel decision process enables patients and their clinicians to appeal against a decision made by an IFR Panel. This is independent of the IFR process. See Appendix 2 for the Terms of Reference of the Review Panel.

A review 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 application form supported by the new evidence, not to request a review of the existing decision.

The numbers of reviews requested are difficult to predict and therefore arrangements for review meetings are to be flexible and will be made in response to demand. The review Panel will aim to meet within 20 working days of a review request being received by the CCG but this may not always be possible.

4.1 Grounds for a review of the IFR Panel decision process

The decision of an IFR Panel can be reviewed on the grounds:

- That there was procedural irregularity in the original decision making process
- That there is evidence to suggest that the IFR Panel failed to consider and take into account relevant information when reaching its decision.
4.2 Remit of the review panel

The Review Panel will consider all the documents relating to the request, the original IFR application and the IFR Panel’s decision. The Review 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 Ethical Framework for decision-making and the principles set out in the Operating Policy 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 all relevant factors.

If the Review 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 reconsideration by the IFR Panel. Please note: The original IFR Panel members should not be present when the IFR is reconsidered.

4.3 Lodging a review request

The review request should be lodged within one calendar month of the date of the outcome letter to the requesting clinician, notifying them of the decision of the IFR Panel.

The request for a review 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 a review request themselves
- A third party (e.g. friend or relative) with the documented consent of the patient

If the requesting clinician lodges the review request s/he is required to confirm that s/he has discussed the process fully with the patient and is acting with his/her consent. If the patient or his/her representative lodges the review request the representative must have the support of the clinician who originally submitted the IFR.

The person lodging the review request should write to the IFR Team who will work in conjunction with the CCG stating that they are requesting a review and the grounds on which the review request is being made, confirming that they have the consent of the patient (if the review request is submitted by the clinician).

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

The Review Panel will meet in private and the patient or his/her clinician will not be invited to attend. The review requestor 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 request. 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.

The correct procedure is for the requesting clinician to submit a new IFR application form supported by the new evidence, not to request a review of the existing decision.

4.5 Actions in advance of the review panel

As soon as the date of the Review Panel meeting is confirmed the requestor will be informed of that date.

Review Panel members will receive the agenda and papers via email in support of the request no less than 3 working days before the meeting. For each review request the members will receive the following

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

If a Review 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 Review Panel may, in appropriate cases, seek external advice.

4.6 Review panel meeting and decision

All discussions during the Review Panel meeting will be confidential. Decisions will be taken using the Consensus Decision-Making Process (Appendix 3).
The Ethical Framework for decision making (Section 2) will be applied throughout the review process.

The Review Panel may uphold or overturn the decision of the original IFR Panel. Reasons for their decision must be made clear.

A decision to overturn does not mean that the request will be funded: it means that the request will be re-considered by the next available IFR Panel. The Review Panel may not defer a decision.

4.7 Review panel meeting minutes

Notes of a Review Panel meeting will be taken and written up as formal minutes within 2 working days.

The minutes will record:

- The decision taken
- The reasons for the Panel’s decision
- The consensus reached

The minutes will be written up then verified and approved by the Chair of the meeting within five (5) working days of the meeting. The text of the minutes will be used in communicating the Panel’s decision to the requestor. 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.

4.8 Communicating the decision

The decision of the Review Panel will be notified in writing and sent by secure means to the requestor within ten (10) working days of the meeting.

4.9 Next steps

If the Review Panel upholds the original IFR Panel’s decision, the requestor will be advised that if they wish to take the matter further this must be done through the NHS Complaints process.

If the Review Panel overturns the original IFR Panel’s decision, the requestor will be advised that the original IFR application will be reconsidered by the next available IFR Panel, with that Panel taking into account any additional evidence which has become available in the interim. The CCG’s will ensure the IFR application is reconsidered at the earliest possible opportunity. The review Panel will not take new or additional information into account. This will only occur if the decision is overturned and will be reconsidered by the IFR Panel.

If the IFR Panel that reconsiders the application upholds the original IFR Panel’s decision, the requestor will be advised that if they wish to take the matter further this
must be done through the NHS Complaints process and the application can no longer be considered through the IFR route.

5 Policy 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.

6 Policy 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 CCG’s website
- A copy of the policy will be sent to all GPs/PM’s within the CCG’s
- 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.

7 Glossary

- CCG Clinical Commissioning Group
- SEC South East Coast
- IFR(s) Individual Funding Request(s)
- HPSU Health Policy Support Unit
- TOR Terms of Reference
- PCT Primary Care Trust
- Service Development Clinical need identified for a group of patients where a business case is required to provide the service
APPENDIX 1 – 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 NHS England).
- Review complex follow up cases where the decision to approve long term funding is not straightforward.
- Review decisions made for individual funding request applications where new information is available.
- Consider in part 2 of the meeting funding requests for applications 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 CCG’s
- Commissioning Pharmacist, 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 Cedar Court unless notified otherwise
• Four core members should be present to make a decision on an IFR, one of whom must be a clinician from the patient’s CCG

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

The IFR Panel reports to the Governing Body. The IFR Panel will provide reports quarterly to both the Governing Body and the Quality and Governance Committee. The report will include; number of applications 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.

- Quality & Governance Committee
- CCG Governing Body
- Surrey Priorities Committee
- Prescribing Clinical Network (Drugs only)

**Process for Monitoring Effectiveness of the IFR Panel 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 CCG’s Policy and Operating Procedures for dealing with IFRs and process before sitting on a Panel. Panel members should attend at least 1x a year to retain their qualifications. All IFR Panel members will undergo an annual appraisal.

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.

<table>
<thead>
<tr>
<th>NHSLA standard</th>
<th>Method of review of effectiveness</th>
<th>Lead</th>
<th>Frequency of review</th>
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<tr>
<td>Duties of the committee</td>
<td>Review of TOR</td>
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<td>Reporting arrangements into high level committees( if appropriate) and Board</td>
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<td>Membership including nominated deputy</td>
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**Date and Review**

The terms of reference will be reviewed at least annually.
APPENDIX 2 – Individual Funding Requests (IFR) Review Panel - Terms of Reference

Purpose
Consider reviews 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 Review Panel will review all the documents relating to the case, the original IFR application 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 Review Panel will not consider new evidence.

If the IFR Review 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 the CCG’s through the IFR process and their next recourse must be to the NHS Complaints process.

If the Review Panel decides to overturn the original IFR Panel’s decision the patient and his/her clinician will be advised that their IFR application will be reconsidered by the IFR Panel, which will take account of any additional evidence which has become available in the meantime.

Chairman
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
• Independent member  
• Lay member  
• GP’s from the respective CCG governing bodies  

During their membership of the IFR Review 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."

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**Frequency of meetings and quorum arrangements**

- The numbers of review requests received are difficult to predict and therefore arrangements for the IFR Review Panel meetings are worked on a flexible basis in response to demand. The IFR Review Panel will usually meet within 20 working days of a review request being received by the CCG’s.  
- The IFR Review 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)**

- Executive Team  
- Governing Body

---

**List of dependent sub committees / groups / functions / programmes**

The IFR Review Panel will link with the following committees/groups providing quarterly reports on the activity of the Panel as relevant to the particular committee.  
- Executive Team  
- Head of Planned Care

---

**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 CCG’s 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.

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**Date and Review**
The terms of reference will be reviewed at least annually.
APPENDIX 3 – 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

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

<table>
<thead>
<tr>
<th>Number of Panel Members Present</th>
<th>Number of Fingers required for 75%</th>
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<tr>
<td>12</td>
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APPENDIX 4 - IFR Online Portal User Guide for non-drug related IFRs

Presentation of proposal

- Proposal circulated 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

PHASE 1
Initial broad discussion

- 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?”

Unresolved?

PHASE 2
Identify and resolve concerns

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

Unresolved?

PHASE 3
Address remaining concerns

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

Unresolved?

Ask those with concern whether prepared to stand aside

Declare block – concern must be based on principles of group to justify block

EVALUATE THE PROCESS

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.

Appendix 4 - IFR Online Portal User Guide for intervention requests only

CONTENTS

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To Find a Patient ............................................................................................................................ 6
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Notes Screen .................................................................................................................................. 7
Request History ............................................................................................................................ 7

[2]
Quick Notes for Using the System

LOGGING ONTO THE SYSTEM

1. Open your web browser and type in the following address: https://www.blueteq-secure.co.uk/trust
2. Enter your name and password, Click the ‘Login’ button
3. If you are registered for both Individual Funding Requests (IFR) and Hi-Cost Drugs, you will need to choose which “trust mode” you will be working on in the top left corner. This step does not apply if you are registered only for IFR.
4. You are now logged in

ADDING A PATIENT AND UPLOADING A REQUEST

1. To Fast Track adding a request, click on the "Requests" menu option (do not use “Patient”).
2. Enter the patient’s details (note to find a GP practice you enter the practice’s name) and press save.

3. If the patient already exists, you will be offered a choice as to whether to choose an existing patient or add a new one.
4. If you choose a patient that already exists you will be taken to the patient notes screen that looks as follows:
5. If you want to add another form click the Add Request Button

6. You will be shown the current registered practice for the patient, which you have just set in "Add Patient" so leave this as is and click on "Next".

7. If you wish to review or amend a live form please click on the "edit" button in the patient records
8. If the patient does not exist you will be asked which form type you need to add. For IFR you will choose "On-Line Form".

9. You will be shown the "Form Selector" Tree View. The form for an Individual Funding Request is to be used for procedures not routinely funded and can be amended once saved.

10. Providers will be able to give administrative rights to staff which will enable them to edit the incomplete IFR Form. If you wish to revisit an IFR form check the "Incomplete" box at the bottom and click on save.

11. Once the IFR form has been saved or submitted you will be taken to the patient notes page as below.
TO FIND A PATIENT

1. In the top right hand corner of the screen, first choose whether you wish to search by:

Find Patient: [ ] By: [ ]

   a. **Patient** or **NHS Number** - Enter the surname followed by initial/first name, or the Date of Birth or NHS Number with/without spaces. You can also enter the first name by itself. The search box will allow part of a surname as well.

   b. **Hospital Number** - Choose hospital number from the adjacent drop down list and enter the number in the box.

2. Press return or click on Go

3. You will be offered a list of patients, click on "Go" on whichever is the relevant patient.

4. You will be taken to the patient's notes screen.

5. Wherever you are you can always return to this screen by clicking on Notes and then the View menu option.

[6]
EDITING A PATIENT'S DETAILS

1. Find the patient as previously described.
2. Click on the "Patient" and "Edit" menu options.
3. Edit the details as needed and Save.

NOTES SCREEN

1. Add a Request - you can add a request using this option if the patient already exists on the system. Click this option and follow the instructions under "Uploading a request".
2. Comment - If you wish to add a comment (e.g. to note a telephone conversation re a patient) click on the "Comment" menu option. If you need to remind yourself of an action required as a result of a comment, click on the "Send to Admin" checkbox. This adds this comment to the "Messages to Admin" list.
3. Upload Docs - this option can be used for uploading a scanned document into the notes that is not a referral. Clicking on "Upload" will add a line to the notes. Click on the - icon to view the document.

REQUEST HISTORY

To view the request history for your Trust, including the request's current status, click on the Administration then Request History. By default you will be shown the "Incomplete" requests but you can change this by choosing "All" or "Pending" from the drop down list.
Appendix 5

IFR Screening Process (June 2017)

1. Administrative process complete.
   - Does CCG have a policy? Are policy thresholds met?
     - Yes: there is a policy, thresholds are met
       - IFR not necessary.
       - Policy allows treatment to proceed
     - No: there is no policy
       - No: the thresholds for funding are not met
       - Proposed treatment is within CCG policy but thresholds are not met OR CCG has policy not to fund in the patient group
         - Check exceptionality information has been described?
           - Yes: Back to clinician for new information for new case.
           - No: Back to clinician for new information for new case.

2. Does application state “rare” and shows prevalence of 1 per 2.5 million of population?
   - Yes: Eligible for IFR Panel or Fast Track.
     - Panel to decide if rarity is demonstrated.
   - No: Does the application describe urgent clinical need?
     - Yes: Eligible for IFR Panel (as a Part 2) or Fast Track.
     - Panel to decide if exceptionality is demonstrated.
     - No: This represents a possible service development opportunity.

3. Is this a cohort?
   - Yes: Has the information provided been used in previous applications or is it likely to be in the future?
     - Yes: Eligible for IFR Panel or Fast Track.
     - Panel to decide if exceptionality is demonstrated.
   - No: Back to clinician for new information for new case.

Notes: If there is any doubt as to whether a case should be referred to Panel, then the screeners should err on the side of caution and send the case to Panel.