

# CLIN 12

## Standard Operating Procedure: Individual Funding Requests

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## Equality statement

Surrey Heartlands Clinical Commissioning Group (CCG) is committed to promoting equality and diversity in all its activities and to promoting inclusive processes, practices and culture.

- We will strive to work to eliminate any unlawful or unfair discrimination including direct or indirect discrimination, discrimination by association, discrimination linked to a perceived characteristic, harassment and victimisation.
- We will remain proactive in taking steps to ensure inclusion and engagement for all the people who work for and with us.
- We will continue to strive towards a culture that is diverse and inclusive that recognises and develops the potential of all staff and service users.
- We recognise the business benefits and opportunities of having a diverse community of staff who value one another and realising the contribution they can make to achieving the CCG's vision.

This includes promoting equality and diversity for all irrespective of:

- age\*
- disability\*
- ethnic group\*
- gender\*
- gender reassignment\*
- religion or belief\*
- sexual orientation\*
- marriage and civil partnership\*
- pregnancy and maternity\*

\*Under the Equality Act (2010) these are known as “protected characteristics”.

In addition, it includes promoting equality and diversity for carers, people with diverse communication needs and veterans.

The CCG aims to meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. We take into account the Human Rights Act 1998 and promote equal opportunities for all. We embrace the seven staff pledges in the NHS Constitution that represent a commitment by the NHS to provide high-quality working environments for staff. This policy is consistent with these pledges.

This document has been assessed to ensure that no employee or member of the public receives less favourable treatment based on their protected characteristics.

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

## Equality analysis

Equality analysis is a way of considering the effect on different groups protected from discrimination by the Equality Act, such as people of different ages. There are two reasons for this:

- to consider if there are any unintended consequences for some groups
- to consider if the policy will be fully effective for all target groups

<ul style="list-style-type: none"> <li>○ <b>Title of Policy:</b> Clinical Commissioning Policy: Individual Funding Requests and associated appendices (including Standard Operating Procedure)</li> </ul>	<ul style="list-style-type: none"> <li>○ <b>Policy Ref:</b> ○ CLIN12</li> </ul>
<ul style="list-style-type: none"> <li>○ <b>Assessment conducted by (name, role):</b></li> <li>○ Clare Johns (Lead Commissioning Pharmacy Technician – Pharmaceutical Commissioning- Surrey Heartlands CCG)</li> <li>○ Maria Bruce (Continuing Healthcare (CHC) programme manager- Surrey Heartlands CCG)</li> </ul>	<ul style="list-style-type: none"> <li>○ <b>Date of analysis:</b> ○ 28<sup>th</sup> May 2020 ○</li> </ul>
<ul style="list-style-type: none"> <li>○ <b>Give a brief summary of the policy. Explain its aim.</b></li> <li>○ To provide users of the policy with a framework for decision making. To ensure that all decisions made, by the CCG, regarding funding for treatments are made in a fair, open and consistent manner</li> </ul>	
<ul style="list-style-type: none"> <li>○ <b>Who is intended to <u>benefit from</u> this policy? Explain the aim of the policy as applied to this group.</b></li> <li>○ All users of the policy will benefit because they will have a framework to work from and all individual patients and their clinicians can be assured that the CCG has a robust policy &amp; process in place in relation to individual funding requests.</li> </ul>	
<p><b>1. Evidence considered:</b> <i>What data or other information have you used to evaluate if this policy is likely to have a positive or an adverse impact upon protected groups when implemented?</i></p> <ul style="list-style-type: none"> <li>○ The IFR policy and the associated standard operating procedure (SOP) were considered in providing this EQIA</li> </ul>	
<p><b>2. Consultation:</b> <i>Give details of all consultation and engagement activities used to inform the analysis of impact.</i></p> <ul style="list-style-type: none"> <li>○ Request for clarification on the policy and SOP were required during the EQIA process with the IFR (ECI) team and the pharmaceutical commissioning team.</li> <li>○</li> </ul>	

<p><b>3. Analysis of impact:</b> <i>In the boxes below, identify any issues in the policy where equality characteristics require consideration for either those abiding by the policy or those the policy is aimed to benefit, based upon your research.</i></p> <ul style="list-style-type: none"> <li>○ <i>Are there any likely impacts for this group? Will this group be impacted differently by this policy? Are these impacts negative or positive? What actions will be taken to mitigate identified impacts?</i></li> </ul>	
<p><b>a) Age</b></p> <ul style="list-style-type: none"> <li>○ Ageism is prejudice or discrimination on the grounds of a person's age. Ageism can affect anybody, regardless of their age</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○ The patient's age is available to the IFR team but all information is anonymised prior to the decision making process (IFR panel)</li> </ul>
<p><b>b) Disability</b></p> <ul style="list-style-type: none"> <li>○ A person has a disability (by law) if they have a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○ Patients will be asked for consent for personal &amp; clinical information to be shared with appropriate teams at the CCG.</li> <li>○ Where a patient is not able to give informed consent, a carer or patient representative will give that consent on behalf of the patient.</li> </ul>
<p><b>c) Gender reassignment</b></p> <ul style="list-style-type: none"> <li>○ Gender reassignment is a personal, social, and sometimes medical process by which a person's gender appears to others to have changed. Anyone who proposes to, starts or has completed a process to change his, her or their gender is protected from discrimination under the Equality Act. A person does not need to be undergoing medical supervision to be protected.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> </ul>
<p><b>d) Marriage or civil partnership</b></p> <ul style="list-style-type: none"> <li>○ This is the relationship between two people who are husband and wife, or a similar relationship between people of the same sex (as defined by Marriage (Same Sex Couples) Act 2013).</li> <li>○ Civil partners must be treated the same as married couples on a wide range of legal matters.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○</li> </ul>

<p>e) <b>Pregnancy and maternity (adoption is covered within this)</b></p> <ul style="list-style-type: none"> <li>○ Pregnancy - being pregnant or expecting a baby. Maternity is the period after the birth or adoption and is linked to maternity and adoption leave in the employment context.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○</li> </ul>
<p>f) <b>Race</b></p> <ul style="list-style-type: none"> <li>○ Race characteristics refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○</li> </ul>
<p>g) <b>Religion and belief</b></p> <ul style="list-style-type: none"> <li>○ Religion refers to any religion while belief comprises religious and philosophical beliefs including lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> </ul>
<p>h) <b>Sex</b></p> <ul style="list-style-type: none"> <li>○ This is defined as a person's legal sex; in the UK this is recognised as either being a man or a woman. Sex is more commonly referred to as gender identity, which is the internal sense of being male, female, a combination of male and female, or neither male or female.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○ The patient's gender is available to the IFR team but all information is anonymised prior to the decision making process (IFR panel)</li> </ul>
<p>i) <b>Sexual orientation</b></p> <ul style="list-style-type: none"> <li>○ Refers to a persons' orientation or attraction towards; the same sex, opposite sex or to both sexes.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> </ul>
<p>j) <b>Carers</b></p> <ul style="list-style-type: none"> <li>○ A carer is anyone, including children and adults who looks after a family member, partner or friend who needs help because of their illness, frailty, disability, a mental health problem or an addiction and cannot cope without their support. The care they give is unpaid.</li> </ul>	<ul style="list-style-type: none"> <li>○ Neutral impact</li> <li>○ Patients will be asked for consent for personal &amp; clinical information to be shared with appropriate teams at the CCG.</li> <li>○ Where a patient is not able to give informed consent, a carer or patient representative will give that consent on behalf of the patient.</li> </ul>

**4. Monitoring:** *How will you review/monitor the impact and effectiveness of your actions?*

- An equality impact assessment will be completed each time there is a review of the IFR policy.

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## 1. Introduction

- 1.1 This document sets out how the process for managing individual funding requests (IFRs) for Surrey Heartlands CCG (hereinafter referred to as “the CCG”) will operate. Such requests are managed in line with the CCG Individual Funding Request Policy (CLIN01).
- 1.2 The intended audience is those responsible for the operation of the IFR process and related decision making. It will also be of interest to those wishing to apply for funding of treatments under the IFR policy.
- 1.3 It should be read in conjunction with the following CCG commissioning policies / guidelines:
  - CCG Commissioning Policy: Individual funding requests CLIN01
  - CCG Ethical decision-making Framework
  - TNRF1
  - Assisted Conception Policy
  - Area Prescribing Committee policies (<http://pad.res360.net/>)
  - Department of Health. Guidance on NHS patients who wish to pay for private additional care. 23 March 2009  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/404423/patients-add-priv-care.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404423/patients-add-priv-care.pdf)
  - CCG Policy on NHS Prescribing recommended during or after an episode of private care <https://surreyccg.res-systems.net/PAD/Guidelines/Detail/4410>
- 1.4 IFR applications should only be submitted using the correct form (Appendix One) when the procedure or high cost drug/device is not routinely funded (for interventions see Policy TNRF1 or 2, Assisted Conception Policy and for National Tariff-exempt drugs/devices, see “commissioner’s list of medicine exclusions”).
- 1.5 The application will also be checked to ensure that it is being submitted by a provider who has an NHS contract to provide the service/treatment being requested. Providers may be challenged to provide copy of their NHS contract.
- 1.6 This Standard Operating Procedure (SOP) does not cover IFRs for treatments and services which are the commissioning responsibility of NHS England.

## 2. IFR timescales and urgent cases

- 2.1 The standard period for providing a substantive response to an IFR (i.e. a decision on the funding request) is a maximum period of 35 working days from the date of the receipt of a fully completed IFR form to the date the requesting clinician is informed of the outcome (inclusive).

- 2.2 This 35 working day period discounts any working days where the IFR team are awaiting information sought from the requesting clinician. At any point in the IFR process, the IFR team can ask for further information to clarify the request. If the requesting clinician does not provide a response to the IFR team within 10 working days the request record will be closed and the requesting clinician informed. Such a request can be reopened on submission of the additional information.
- 2.3 Clinicians are encouraged to submit IFRs in a timely manner which has regard to the standard decision-making timescale set out above. As far as possible clinicians should avoid waiting until a case becomes clinically urgent before submitting an IFR.
- 2.4 The CCG makes funding decisions in line with the IFR policy however, the clinical responsibility and decision to treat a patient lies with the treating clinician and/or the provider. If, pending the outcome of any IFR application, a patient is presenting as clinically urgent, clinicians should seek advice from their provider Medical Director.
- 2.5 Should a decision be made by the provider to start treating a patient due to clinical urgency, and an IFR application is still required, a completed IFR application must be submitted to the IFR team within two working days of the intervention first taking place. If the IFR has been received within this timeline and the IFR Panel subsequently supports the funding of the IFR request, treatment funding will be back dated to the date on which the intervention was started. Costs will not be reimbursed if the IFR Panel decline the request.

### **3. Identification of time limits and potential cost pressures**

- 3.1 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 impact on the timing and progress of the IFR process.
- 3.2 Additionally, the CCG's Finance Director will be notified of any applications received which, if approved, are likely to lead to cost pressures, as per the CCG Scheme of Delegation. The CCG Finance Director may wish to attend Panel meetings. Such notification is not to be taken as an indicator that the application will be approved.

### **4. Withdrawing an IFR**

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

## **5. IFR screening process**

- 5.1 The applications are initially received and reviewed by the IFR team administrators and then where appropriate, forwarded to the IFR Screening Group. This process is known as 'pre-screening'.
- 5.2 The IFR Screening Group meetings and membership are scheduled in a rolling programme in advance. The Terms of Reference for the IFR Screening Group are in Appendix Two.

### **5.3 Pre-Screening by IFR team administrators**

- 5.3.1 IFRs are put through a pre-screening process in order to ensure that the Screening Group is screening appropriate applications.

### **5.4 Pre-Screening for sufficient information**

- 5.4.1 A member of the IFR team will be assigned to each individual case as the IFR Case Manager at this point, if not nominated already.
- 5.4.2 The standard CCG IFR application form must be used for all requests. The request will not be progressed if not completed on a CCG IFR form. This form can be found at Appendix One and is also available in MS Word format alongside the published IFR policy and guidance for clinicians online or via Blueteq system. The MS word version should be submitted (and PDF copy with signatures if necessary) to the IFR team (via email address on form) only if access to the Blueteq system is problematic.
- 5.4.3 Submissions on IFR application forms from other commissioning organisations cannot progress through the CCG IFR process. This is to ensure that all CCG IFR requests contain the same depth and range of information and so can be equitably presented for consideration. If a request for funding of a treatment which is a CCG commissioning responsibility is not submitted on the CCG IFR form the requesting clinician will be asked to resubmit using this form.
- 5.4.4 Every section in the IFR form needs to be completed in full in order for the request to progress. Any request form which is incomplete will be returned to the requesting clinician for completion and the application will not progress any further until completed and resubmitted.
- 5.4.5 IFR application forms must be received as typewritten only. Handwritten IFRs will be returned to the requesting clinician for amendment. This is to ensure that all content is legible.
- 5.4.6 The application form must come from a healthcare professional directly involved in the care of the patient. This should be the most senior clinician responsible for the care of the patient usually at consultant level and should be the clinician with responsibility for delivering the proposed treatment.
- 5.4.7 The application form must come from a provider who is contracted by the NHS to provide the services which are the subject of the IFR. Providers who are not so

contracted will be advised to make an appropriate referral to the relevant specialised centre providing the requested service/treatment.

- 5.4.8 Requests will not be accepted from a patient or their non-clinical representative. This is for two reasons. Firstly, it is because it is unlikely that the patient would be in possession of the technical clinical detail that is necessary for consideration of the case and secondly, the process is to enable an NHS clinician to apply for funding to support the provision of NHS treatment by that clinician to the patient.
- 5.4.9 The patient / patient's representative or guardian can submit information in support of the request. A patient representative is a person who has the legal authority to take decisions about medical care and treatment on behalf of a patient who lacks capacity to take these decisions themselves. Such information can only be considered if it relates to the patient's clinical circumstances. Non-clinical factors cannot be taken into account and should not be submitted. Non-clinical factors are described in more detail in the IFR Policy.
- 5.4.10 Unless the following paragraph applies, the requesting clinician should complete the consent section of the form to confirm that the patient is aware of the application and has agreed to their personal clinical information being shared. The CCG guide 'Individual funding requests – information for patients' should be given to patients as part of the consent process to ensure that the patient has received sufficient information to support informed consent.
- 5.4.11 If the requesting clinician considers that the patient does not have capacity to give informed consent this should be indicated and explained in the IFR form. In these circumstances the submission should also confirm whether consent has been obtained instead from a patient representative and, if not, the basis on which the IFR is nevertheless being made by the clinician. Submissions which do not include either confirmation of appropriate informed consent by the patient or a patient representative, or a satisfactory clinical explanation as to why the application is being made without consent cannot be processed and must be returned for amendment.
- 5.4.12 All applications should be submitted via the online Blueteq system. However, applications in MS Word can be accepted at IFR team discretion.
- 5.4.13 Provider support is a mandatory section of the application form. The application will not progress in the absence of this support.
- 5.4.14 Application forms for funding of interventions must be supported by a relevant multidisciplinary team (MDT) and by the provider Medical Director / Deputy Medical Director
- 5.4.15 Application forms for funding of drugs must be supported by the provider Drugs & Therapeutics Committee (or equivalent) (DTC) and by the provider Chief / Deputy Chief Pharmacist

- 5.4.16 It is mandatory to provide copies of the MDT / DTC minutes of the discussion to the IFR team, alongside the application.
- 5.4.17 IFR applications should be supported by electronic copies of the published clinical research evidence papers or other supporting documents (e.g. provider guidance or supporting clinical letters). Evidence should directly support the use of the requested treatment for the condition in cases similar to the patient in question, and the requesting clinician should highlight links between the evidence submitted and the particular patient circumstances. Evidence should be submitted as pdf or word documents. The IFR team is unable to accept abstracts or web links.
- 5.4.18 If a request for treatment that is not the commissioning responsibility of the CCG is received, the requesting clinician will be advised accordingly and the case record closed. The IFR team will consider whether existing directly commissioned services would cover the requested treatment. If commissioning arrangements exist the IFR team will assess whether the requested treatment specifically falls outside the relevant commissioning criteria. Where commissioning arrangements exist which may apply to the patient the request will be returned to the requesting clinician with advice to review the case against the commissioning arrangements and will not progress further as an IFR until this is completed.
- 5.4.19 If an IFR meets all requirements to be able to proceed as an IFR, the IFR screening group will begin to complete the Pre-Panel Screening Document (Appendix Four). This document will be the mechanism for recording and sharing information with decision makers at each stage of the IFR process. It forms a record of the outcome of screening and will detail the explicit reasons for the outcome.

## **5.5 Pre-Screening for service development**

- 5.5.1 Requests made under the IFR process will be classified as a request for a service development if, there is likely to be a defined group of patients in similar clinical circumstances who therefore 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 decide that there are likely to be other patients across the CCG in any single financial year:
- 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
- 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.
- 5.5.2 If a decision is made by the IFR team based on the application and other information available that the application is properly classified as a service development, then the application will be considered to be ineligible for further

consideration within the IFR process. The requesting clinician will then be redirected, by the IFR team, to the relevant contact point to start the service development process (see summary in Appendix Three).

## **5.6 Screening by the IFR Screening Group**

- 5.6.1 All the documents will be made available to the Screening Group without patient identifiers (except for Blueteq database number) to protect confidentiality and minimise the potential for identification bias.
- 5.6.2 The purpose of the Screening Group is to determine whether the requesting clinician appears to present an arguable case for the clinical exceptionality of their patient compared with other patients with the condition. If the screening process determines that the request is not a service development (i.e. that patient is not part of a wider group who could equally benefit from the treatment) and there is sufficient information to consider the case, the IFR Screening Group will then determine whether the documentation sets out a clearly presented and arguable basis for how the request meets the IFR policy criteria.
- 5.6.3 The Screening Group may also regularly seek scientific and technical information relating to the natural history and usual course of the condition, the place of the treatment in the patient pathway or the evidence base for the requested treatment. Such advice will be sought through the CCG clinical structure. Any advice received will be shared with the requesting clinician at the same time that the screening outcome is communicated.
- 5.6.4 A request will normally be screened and the outcome communicated by the CCG within 10 working days of the date of receipt of a completed IFR form. If further information is required from the requesting clinician, the timeline for the request is suspended until this is received.

## **5.7 Outcomes of IFR Screening**

- 5.7.1 The IFR Screening Group will have the following outcomes available to them:
  - IFR is not required and funding should be approved by the IFR screening team without reference to the IFR Panel - if an individual meets the criteria for funding within a CCG clinical commissioning policy or commissioned service, and this is confirmed by the IFR Screening Group the requesting clinician should be advised of this and the request does not need to proceed any further. Clinicians are advised that if they are unsure about whether something is commissioned at their provider, they should discuss with their provider contracts team whether the treatment is covered by their NHS contract, in the first instance.
  - Patient cohort / service development identified – 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.

- Returned for further information - to seek further clinical information to clarify specific issues relating to the case from a reliable information source. This may be from the requesting clinician or from the CCG clinical advice structure at the IFR Screening Group's discretion. Information will only be sought at this stage if there is a clear understanding that an answer is necessary for a decision by the IFR Screening Group.
- Ineligible for IFR consideration - an arguable case on exceptionality has not been presented on the basis of the criteria for consideration as an IFR (as outlined in the IFR policy). If this is the case, the IFR Screening Group is required to decline the request without referring the case to the IFR Panel.
- Eligible for IFR consideration - there is sufficient information for the IFR to be forwarded to the IFR Panel for consideration and an arguable case for exceptionality has been presented.

5.7.2 The Pre-Panel Screening Document will be completed with the detail of the screening outcome and included as part of the pack of information for the IFR Panel to consider.

5.7.3 The IFR team will advise relevant applicants (via email) of the status of their application, explaining the screening outcome and possible next steps within 2 working days of decision.

5.7.4 The responsibility for discussing the outcome of the funding request and answering any questions which the patient may have about the request or their clinical options will lie with the requesting clinician. That clinician should contact the patient in order to discuss the outcome and implications for future care.

5.7.5 If the IFR Screening Group concludes that the request is either a service development or there is not sufficient information or evidence, the IFR policy does not provide a right for the case to be considered by the IFR Panel and does not provide a right to request that the screening outcome should be reviewed by the IFR Process Review Panel. However, the requesting clinician may feel that in the light of the reasons for refusal, there is new clinical information that should be included. If this is so, the case can be reconsidered by the IFR Screening Group.

## **5.8 Reconsideration by the IFR Screening group**

5.8.1 If an application is considered ineligible for further consideration by the IFR Screening Group and the requesting clinician believes they have significant new clinical evidence that they did not previously provide which they think may have made a difference to the decision made, or if the IFR Screening Group sought additional advice through the CCG clinical advice structure and the requesting clinician disagrees with that advice, then they can submit this new evidence or



explain the basis of their disagreement and request reconsideration of their decision by the IFR Screening Group.

- 5.8.2 The new clinical evidence or explanation of disagreement must be completed on the reconsideration form (Appendix Five). The IFR Screening Group will determine if the new information provides a different clinical picture warranting a different screening outcome using the reconsideration pre-panel screening document (Appendix Four).
- 5.8.3 The IFR Screening Group will determine, normally within 10 working days of receipt of the reconsideration form, whether the additional information materially alters the nature and strength of the evidence that was initially submitted.
- 5.8.4 If a decision is made to refer the case to IFR Panel following reconsideration, the IFR Panel decision should be communicated within 35 days of the receipt of the reconsideration request.

## **6. Dealing with an eligible request**

- 6.1 The application form (and all copies) will be suitably anonymised and identified by a unique identifier, in keeping with the Caldicott principles. (<https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx>).
- 6.2 All actions, decisions and reasons for decisions relating to each application will be recorded on the Blueteq IFR database.
- 6.3 A member of the IFR team will be nominated as the IFR Case Manager for the application.

### **6.4 IFR applications for prescribed items**

- 6.4.1 IFR applications for prescribed items will be processed by a member of the Pharmaceutical Commissioning team. It is their responsibility to decide what further information, specialist advice and/or review of evidence, is required to enable the IFR Panel to consider the application.
- 6.4.2 Each case is likely to be different and so will be handled on a case-by-case basis. When requesting more information, the Pharmaceutical Commissioning team member will make it clear what further information is required and the timeframe within which it should be received.
- 6.4.3 The Pharmaceutical Commissioning Team will endeavour to obtain this information prior to the scheduled IFR Panel meeting date.
- 6.4.4 Where further information is sought but is either insufficient or not given in time for the next IFR Panel meeting then consideration of the prescribed item IFR may be deferred until such information is available.
- 6.4.5 Clinical advice may be sought from CCG clinicians, relevant specialist clinicians, hospital consultants and specialist commissioning services.

## **6.5 IFR applications for non-prescribed items i.e. surgical intervention**

- 6.5.1 If an evidence review for items outside of the TNRF policy is required this will be provided by the Public Health (Surrey) Team. This takes on average up to 10 working days to enable members of that team to access information from diverse sources including published research and expert opinion.
- 6.5.2 The Public Health Team will endeavour to obtain this information prior to the scheduled IFR Panel meeting date.
- 6.5.3 Where 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 non-prescribed item IFR may be deferred so as to enable an informed Panel decision to be made.
- 6.5.4 Clinical advice may be sought from CCG clinicians, relevant specialist clinicians, hospital consultants and specialist commissioning services.

## **7. The IFR Panel**

- 7.1 IFR Panel meetings and membership are scheduled in a rolling programme in advance. The Terms of Reference for the IFR Panel are in Appendix Six.
- 7.2 When a request is referred for consideration by the IFR Panel, the IFR Case Manager will book the case onto the next meeting date and inform the requesting clinician. The case will be prepared for panel.
- 7.3 The patient / patient representative, or their clinical or non-clinical representative, is not entitled to attend the panel in person. This is to ensure objective decision making by the IFR Panel in a fair and equitable manner to all patients.
- 7.4 The IFR team will provide the IFR Panel members with an information pack which will include the original request form, any supporting documents or correspondence, the Pre-Panel Screening Document and a blank IFR Panel Decision Framework Document (DFD) (Appendix Seven) for use during the panel meeting. All the documentations will be made available to the panel completely anonymised and redacted to protect confidentiality and minimise the potential for identification bias.
- 7.5 The IFR Case Manager will introduce the case at the meeting. The presentation will not include their opinion on the clinical exceptionality of the case in question.
- 7.6 The IFR Panel will then discuss the case in relation to the questions outlined in the IFR Panel DFD and reach a decision on whether funding can be approved under the IFR Policy.

### **7.7 IFR Panel decision making**

- 7.7.1 Each IFR will be considered on its own merits. Decisions will be taken using the agreed Decision Framework Document (DFD) and IFR Panel members will have received training on this as part of their induction training.

- 7.7.2 The Ethical decision-making Framework (Appendix Eight) will be used to support the decision making process and will help to promote consistency across the patient population.
- 7.7.3 The IFR Panel works on behalf of the CCG and makes decisions in respect of funding for individual cases. It is not the role of the IFR Panel, by its decisions, to make clinical commissioning policy on behalf of the CCG.
- 7.7.4 The IFR Panel will apply the criteria in the IFR Policy and the IFR Case Manager will record the decision of the IFR Panel against each of the questions on the IFR Panel DFD. The panel will be clear about the rationale for the decision at each stage and this will be recorded in the document. A summary statement will be agreed by the IFR Panel Chair and this will support communicating the decision.
- 7.7.5 The completed DFD for each case, together with the record of attendance and any general discussion or business of the IFR Panel, will form the business notes of the meeting. These will be agreed and signed off by the Chair (or deputy) of the IFR Panel. Any notes made by individual panel members will be destroyed confidentially after the meeting.

## 7.8 Outcome at IFR Panel

- 7.8.1 The options available to the IFR Panel are to decide:
- To **approve** funding on one of two grounds:
    - To approve funding if the patient and the treatment requested meet the criteria outlined in the IFR Policy for a defined course of treatment.
    - To approve with conditions/restrictions - Where an IFR is approved the IFR team will require an update on the clinical outcome of treatment from the requesting clinician in order to determine whether it has resulted in the anticipated level of benefit to the patient. An appropriate review date will be determined by the IFR Panel and recorded. The IFR system will flag when review dates are due. The IFR team will ensure that feedback on outcomes is requested. Providers and their clinicians are required to comply with such requests for information on the outcome of treatment for their patients, in compliance with the IFR Policy. Funding is conditional on this. (Appendix Nine provides information on the process for requesting continued funding for treatment approved under an IFR).
  - To **decline** funding on one of two grounds:
    - That the request does not meet the criteria outlined in the IFR Policy.
    - That there is insufficient information presented to enable the panel to reach a decision.
- 7.8.2 Where funding has been declined as there is insufficient information presented for the panel to make a decision, the IFR Panel may wish to seek further information to

clarify specific issues relating to the case. This may be from the requesting clinician or from the CCG clinical structure.

- 7.8.3 Where this is the case the IFR Panel Chair will clearly outline the action to be taken and this will be shared with the requesting clinician at the same time that the IFR outcome is communicated.
- 7.8.4 Communicating the IFR Panel's decision
- 7.8.5 If funding is approved, the requesting clinician will be notified by email (the email will include the pharmacy department if request is for drugs). If any conditions are attached to the decision, which might include the requirement for an interim report, these must be set out clearly in the email. The Blueteq system will also be updated with the same information.
- 7.8.6 If funding is declined, a written response will be sent to the clinician, within 5 working days of the IFR Panel meeting, explaining the reasons for the decision and outlining the options that are available. This will usually be copied to the patient's GP. The patient / parent or patient representative, in accordance with the patient consent arrangements, will be notified of the outcome by receiving a letter. The Blueteq system will also be updated with the same information.
- 7.8.7 The responsibility for explaining the reasons for the decision (based on the information provided by the CCG) and answering any questions which the patient may have about the request or their clinical options will lie with the requesting clinician. This is because the clinician will have the full details of the reasons for the decision and will need to share these. The clinician should contact the patient in order to discuss the outcome.

## **7.9 Reconsideration by the IFR Panel**

- 7.9.1 If a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they consider may have made a difference to the decision made if it had been available to the IFR Panel, or if the IFR Panel sought additional advice through the CCG clinical advice structure and the requesting clinician disagrees with that advice, then the clinician can submit the new clinical evidence or explain the basis of their disagreement and request reconsideration of the decision by a IFR Screening Group. The IFR Screening Group will determine if the new information or disagreement provides a different clinical picture warranting a further referral to the IFR Panel.
- 7.9.2 If the new information is considered to be material the case will be presented at the next appropriate IFR Panel. The outcome of the panel reconsideration will be communicated as described for the first IFR Panel meeting.
- 7.9.3 With IFR reconsiderations, the focus of the IFR Panel discussion will be on the new information submitted by the clinician and this will be made clear in the rationale for the decision. The focus of the IFR Panel discussion will be on the content of the

new information. A reversal of an earlier decision will not be on the basis of previously provided information only.

## **7.10 Review of IFR Panel Decisions (IFR Process Review)**

- 7.10.1 The referring clinician, the patient or a patient representative may make a request to the CCG for a process review of an IFR Panel decision.
- 7.10.2 The request should be made in writing, addressed to CCG Clinical Director for Planned Care. Such requests must be lodged within 20 working days of the date of the letter from the CCG setting out the IFR Panel decision. The CCG Clinical Director for Planned Care may exercise discretion in accepting a request for a review outside this time limit if there is good reason to do so.
- 7.10.3 Requests for a review should be clearly marked as a 'Request for an IFR Panel Review' and sent via the IFR team using the contact details in the IFR outcome letter.
- 7.10.4 The request for review must be supported by the requesting clinician who will set out the grounds on which the IFR Panel decision is being challenged. A review can only be requested on the grounds set out in the IFR Policy.
- 7.10.5 The IFR Review Panel will only be able to consider whether the process followed by the IFR Panel was fair and consistent, based on whether the decision reached:
  - Was taken following a process which was consistent with the policies of CCG;
  - Was a decision which a reasonable IFR Panel was entitled to reach;
  - Understood, took into account and weighed, all the relevant evidence; and
  - Did not take into account any irrelevant factors
- 7.10.6 In the circumstances of a legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by the CCG.

## **7.11 Screening of a Request for a Process Review**

- 7.11.1 The request for a review will be considered by an IFR Screening Group formed of individuals who were not involved in the original IFR application. If they consider that, on the basis of the information provided, there is an arguable case for a review of the IFR process, a formal IFR Process Review Panel meeting will be convened.
- 7.11.2 If this IFR Screening Group does not accept the grounds put forward for a review, they will report the rationale for their decision to the CCG Clinical Director for Planned Care who will consider and, if in agreement, will ratify the decision.
- 7.11.3 The CCG Clinical Director for Planned Care will then write a letter to the referring clinician and / or the patient / patient representative explaining the reasons for the decision not to review the IFR Panel decision.

## **8. Organisation of the IFR Review Panel**

- 8.1 The IFR Review Panel will normally be convened within 20 working days of the CCG accepting the case for a review.
- 8.2 The Terms of Reference for the IFR Review Panel are in Appendix Ten. Their role is to determine whether the original IFR Panel followed IFR Policy and the process as written in the IFR SOP, properly considered the evidence presented to it and came to a reasonable decision based on that evidence.
- 8.3 The IFR Review Panel will examine all of the papers and correspondence considered by the IFR Panel, the DFD, the decision letter and the grounds of for a process review. They will examine the process followed by the IFR Panel and the decision it made. The IFR Review Panel will examine the issues raised in the process review request.
- 8.4 The IFR Review Panel will not consider new information (i.e. that was not presented before the original IFR Panel, including on any reconsideration) or receive oral representations. If there is significant new information, not previously considered by the original IFR Panel, it can only be referred and considered as set out in the 'Reconsideration by the IFR Panel' section above.
- 8.5 Reasons given for a process review outcome will only refer to the IFR Policy as this is the basis on which the original IFR Panel decision is made.

## **8.6 Outcome of the IFR Review Panel**

- 8.6.1 The IFR Review Panel will be able to reach one of two decisions:
- Uphold the decision reached by the original IFR Panel
  - Refer the case back to the IFR Panel with detailed points for reconsideration.
- 8.6.2 The IFR Review Panel Chair will write to the referring clinician, the patient / patient representative and GP, and the IFR Panel Chair within 7 working days of the review meeting. This is to inform them of the outcome with the reasons for the IFR Review Panel decision.
- 8.6.3 If the IFR Review Panel determines that the IFR Panel needs to reconsider the case, then that case will be discussed at the next IFR Panel meeting. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the IFR Process Review Panel.
- 8.6.4 The IFR Panel is not bound to change its decision as a result of the IFR Review Panel's decision to refer the case back. The decision by the IFR Panel will be clearly explained to the requesting clinician and patient.

## **8.7 Monitoring and reporting of the IFR Process**

- 8.7.1 An annual report (which includes the number of cases received, the number presented to the IFR Panel, outcomes, spend, trends, KPIs, attendance) is presented to the CCG Clinical Chair and the Quality & Performance Board.

#### 8.7.2 1. Timeline: 35 working days from receipt to outcome

- This is from receipt of a completed IFR form to the outcome of the request being communicated to the requesting clinician. It excludes days spent awaiting information from the requesting clinician. Monitoring and reporting will also include the average turnaround timelines. ECI Team are responsible for ensuring that the database is updated as the information is received and any action is taken.

#### 8.7.3 2. Timeline: Urgent cases; 7 working days from receipt to outcome

- This is from receipt of a completed IFR form to the outcome of the request being communicated to the requesting clinician. It excludes days spent awaiting information from the requesting clinician. Monitoring and reporting will also include the average turnaround timelines. ECI Team are responsible for ensuring that the database is updated as the information is received and any action is taken.

#### 8.7.4 3. Incomplete applications returned within 7 working days

- This is from receipt of an IFR form from the requesting clinician to advising that additional information is required in order for an informed decision to be made.

#### 8.7.5 4. Out of scope IFR applications returned within 7 working days

- This is from receipt of an IFR form that is not within the commissioning remit of the IFR Panel

## 9. Appendix One - IFR application form

**Please note;** preferred submission method would be using an online form available via Blueteq system

<p>Requesting clinicians are advised to review the CCG IFR Policy, Patient information leaflet and the Guidance for Clinicians at <a href="http://www.surreyheartlandscg.nhs.uk">www.surreyheartlandscg.nhs.uk</a>. The CCG requires providers and clinicians to take CCG clinical commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient.</p> <p>It is the responsibility of the referring clinician to ensure all the appropriate and required clinical information is provided to CCG. This includes full text copies of all the published papers of clinical evidence that have been cited, a list of the published papers submitted and an indication of which points within them are relevant in respect to the IFR application and criteria. Requests will only be considered on the information provided in the application and supporting papers.</p> <p><b>DO NOT</b> include patient or provider/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included the application will be returned to you for redaction and resubmission.</p> <p><b>Please note:</b> Applications presenting incomplete information will be returned for amendment/completion prior to consideration by CCG.</p>	
<b>Section 1 – PROVIDER DETAILS</b>	
1a) Name of provider:	Click here to enter text.
1b) Name of clinician who will undertake the intervention:	Click here to enter text.
1c) Job title/role:	Click here to enter text.
1d) Secure NHS email:	Click here to enter text.
1e) Telephone number:	Click here to enter text.
<b>Section 2 – PATIENT/GP DETAILS</b>	
2a) First name:	Click here to enter text.
2b) Last name:	Click here to enter text.
2c) NHS number:	Click here to enter text.
2d) Patient's hospital no:	Click here to enter text.
2e) Date of birth:	Click here to enter text.



2f) Patient's age at time of submission:	Click here to enter text.	
2g) Gender	Choose an item.	
2h) Ethnicity	Choose an item.	
2i) Patient's email address:	Click here to enter text.	
2j) Patient's postal address, including postcode:	Click here to enter text.	
2k) GP name:	Click here to enter text.	
2l) GP practice name:	Click here to enter text.	
2m) GP postcode:	Click here to enter text.	
<b>Section 3 – REQUEST DETAILS</b>		
3a) Direct commissioned service type:	Choose an item.	
3b) Please detail the clinical reasons for urgency if appropriate i.e. the risks of adverse clinical outcome to the individual patient:	Click here to enter text.	
3c) Proposed start date of treatment:	Click here to enter a date.	
3d) If treatment has commenced more than 2 working days before submission of this application please provide an explanation for the delay in application:	Click here to enter text.	
3e) Proposed treatment stop date (if applicable):	Click here to enter a date.	
<b>Application Support</b>		
<p>The IFR Policy and SOP highlight that Provider support of an IFR application is mandatory. The IFR application will not progress in the absence of this support.</p> <ul style="list-style-type: none"> <li>• Requests for interventions must be supported by a relevant multidisciplinary team (MDT) <b>AND</b> by the provider Medical Director.</li> <li>• Requests for drugs/devices must be supported by provider Drugs and Therapeutics Committee (DTC) <b>AND</b> by the provider Chief Pharmacist.</li> </ul>		
3f) DTC or equivalent approval and provide a copy of the minutes:	Please provide details of outcome  Click here to enter a date.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

3g) MDT approval and provide a copy of the minutes:	Please provide details of outcome  Click here to enter a date.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3h) Name and email of Chief or, in exceptional circumstances to avoid delays in submission the Deputy Chief Pharmacist:	Click here to enter text - name. Click here to enter text – email.	
3i) Confirm that the Chief/Deputy Chief Pharmacist supports this drug application:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
3j) Name and email of Medical Director or, in exceptional circumstances to avoid delays in submission, the Deputy Medical Director:	Click here to enter text - name. Click here to enter text – email.	
3k) Confirm that the Medical Director/Deputy Medical Director supports this application:	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Consent</b>		
3l) This IFR has been discussed in full with the patient or patient representative. They are aware that they are consenting for the IFR Team to receive and review confidential clinical information about their health to enable full consideration of this funding request.  <b>I confirm all of the above.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3m) In submitting this application you are under obligation to advise the patient or patient representative of the details of the reasons for the decision.  <b>I confirm that I will advise the patient or patient representative of the reasons for the decision.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3n) The patient or patient representative will receive a letter (usually via email) outlining that a decision has been made and what that decision is, although will not receive the detail for that decision.  <b>I confirm that it is clinically appropriate for the patient to be informed of the outcome of this IFR.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3o) I understand that by indicating that it is NOT clinically appropriate for the IFR Team to contact the patient or patient representative with the outcome, I will be fully responsible to do this.  <b>I will inform the patient or patient representative of the outcome and the reasons for the decision.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	

<b>Section 4 – TREATMENT</b>			
4a) Primary diagnosis most relevant to this IFR request and any relevant co-morbidities:	Click here to enter text.		
4b) Intervention details including treatment modality (if applicable), how and where the treatment will be given:	Intervention - Click here to enter text. Modality - Click here to enter text. How will treatment be given - Click here to enter text. Where will treatment be given - Click here to enter text.		
4c) Is there is an existing clinical policy for this treatment and condition? Please provide explicit reasons why your patient does not meet the access criteria within that policy.	Click here to enter text.		
<b>Cost</b>			
4d) What are the costs of the intervention? <i>Where appropriate include here the total cost of the treatment, any loading doses required and the number of cycles applied for.</i>	<input type="checkbox"/> Single treatment	Total cost Click here to enter text.	
	<input type="checkbox"/> Multiple treatments Click here to enter text – load dose. Click here to enter text – subsequent doses.	Cost per treatment: Click here to enter text. Click here to enter text.	Total cost: Click here to enter text.
4e) Additional comments on the costs of the intervention:	Click here to enter text.		
4f) What are the total costs of standard therapy (estimate annual costs if applicable)?	Click here to enter text.		
4g) Are there any offset costs (provide details)?	<input type="checkbox"/> Yes <input type="checkbox"/> No Click here to enter text.		
<b>Clinical Outcomes</b>			

4h) What are the intended clinical outcomes and how will the benefits of the procedure/ treatment be measured (including where appropriate the validated clinical tools to be used)?	Click here to enter text.					
4i) Within what timeframe will these outcomes be determined?	Click here to enter text.					
4j) What 'stopping' criteria will be in place to assess when the treatment is ineffective and treatment will be withdrawn?	Click here to enter text.					
4k) What mechanisms will be in place to provide CCG with clinical outcome reports if the treatment is approved? Please provide detail of how you will report to CCG upon request.	Click here to enter text.					
<b>Section 5 – Clinical Background</b>						
5a) Outline the background to the patient's clinical situation relevant to this request, timeline, current status and symptoms. Please give validated clinical measures, named in full.	Click here to enter text.					
<b>Treatment History</b>						
	Treatment	Regimen	Start	Stop	Response	Funding source
5b) Current	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5c) Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5d) Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5e) Additional comments on current or previous treatments	Click here to enter text.					
<b>Additional Treatment Information</b>						
5f) What are the alternative (including CCG commissioned) standard treatments available to patients with this condition/stage of the disease and why are they not appropriate for this patient?	Click here to enter text.					

5g) Prognosis – what are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options?	Click here to enter text.
5h) Risk/benefit profile of this treatment compared to standard treatments in this individual case:	Click here to enter text.
5i) Anticipated prognosis if treatment requested is not funded:	Click here to enter text.
<b>Section 6 – Clinical Exceptionality</b> Is there evidence that this patient has exceptional clinical circumstances, demonstrating that:	
6a) There is an CCG clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and the patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and that because of that difference the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.  <b>OR</b>	<input type="checkbox"/> Yes  Click here to enter text – provide comprehensive comments.
6b) There is not a relevant CCG clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance in place for the management of the patient's condition or combination of conditions, and the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken.	<input type="checkbox"/> Yes  Click here to enter text – provide comprehensive comments.
<b>Genotypes</b>	
6c) When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile) please provide evidence of the prevalence of the genotype in that patient group and how the specific genotype would make the patient:  I. Different to others in terms of clinical management	Click here to enter text.  Click here to enter text.
<b>AND</b>	

<p>II. Able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.</p>	<p>Click here to enter text.</p>	
<p><b>Section 7 – Clinical Supporting Information</b></p>		
<p><b>Incidence and Prevalence – for this patient’s individual circumstances</b></p>		
<p>7a) Incidence</p>	<p>Estimate the number of patients expected to be diagnosed with this specific condition per million population per year.</p> <p>Where a patient has one or more conditions, the figures provided should be for patients expected to have the combination of conditions. Please provide specific details.</p>	<p>Click here to enter text.</p> <p>Click here to enter text.</p>
<p>7b) Prevalence</p>	<p>Estimate the number of patients expected to have this condition per million population at any one time.</p>	<p>Click here to enter text. Per million</p>
<p>7c) Do you consider that there are likely to be other patients presenting in <b>England</b> in the next 12 months with this patient’s condition at the same stage of this condition? If so, provide the number.</p>		<p><input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> N/A  Click here to enter text.</p>
<p>7d) How many patients currently attend your service with this condition for which you would wish to use this treatment?</p>		<p>Click here to enter text.</p>
<p>7e) Is this a service development that has been discussed with commissioners?</p>		<p><input type="checkbox"/> Yes  <input type="checkbox"/> No  Click here to enter text. - If yes, please provide details</p>
<p>7f) Do you plan to submit a future preliminary policy proposal for consideration of funding of this treatment (rather than submit individual requests for single patients)?</p>		<p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
<p><b>Evidence</b></p>		
<p>7g) Please provide a summary of the evidence base relevant to this application to demonstrate the clinical effectiveness, good use of NHS resources and safety of this procedure/treatment. (Published papers must be provided in full in order to be considered by the IFR Panel. A list of the published papers submitted must be provided with an indication of which points within them are specifically relevant to the case using the proforma at the end of the application form).</p>		<p>Click here to enter text</p>

7h) Is the procedure/treatment part of a current or planned national or international clinical trial or audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please give details: <a href="#">Click here to enter text.</a>	
<b>Section 8 – SUBMIT</b>	
When you are satisfied that you have completed all sections you will need to submit the request for consideration by the CCG IFR Team. If the CCG Team needs more information they will email you to ask that you provide more details and if this happens, the timeline for the request is suspended until this is received.	
<p>Clinicians are required to disclose all material facts to CCG as part of this process.</p> <p>Are there any other comments / considerations that are appropriate to bring to the attention of the IFR Team?</p>	<a href="#">Click here to enter text.</a>

## Evidence Proforma

Please provide reference to the key evidence for clinical exceptionality, clinical effectiveness, good use of resources and safety of this procedure/treatment in each of the papers submitted as part of the evidence base relevant to this application.			
No.	Title submitted paper	Topics	Specific sections with key evidence (page number/paragraph or section)
1.	Article one	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
2.	Article two	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
3.	Article three	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
4.	Article four	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
5.	Article five	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
6.	Article six	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.



## **10. Appendix Two – Terms of Reference IFR Screening Group**

### **Terms of Reference Individual Funding Request Screening Group**

#### **1. Purpose**

All IFRs submitted to the CCG will be considered by the IFR Screening Group to determine whether the request appears to present an arguable case for clinical exceptionality.

The IFR Screening Group will establish whether there is an arguable case for clinical exceptionality compared to other patients with the same condition and should be put forward for consideration by the IFR Panel.

The IFR Screening Group will work in accordance with the published CCG IFR Policy and each request will be processed by following the CCG IFR Standard Operating Procedures (SOP). This will ensure that all requests are considered in a fair and transparent way in line with the CCG's commissioning principles and, outcomes are based on the available clinical evidence presented by the referring clinicians.

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

#### **2. Membership**

The IFR Screening Group will have a core membership of:

- At least 1x CCG clinician (ideally a GP)
- At least 1x CCG clinician (ideally from the Pharmaceutical Commissioning Team)
- Member of the IFR team or IFR Case Manager (if already nominated)

#### **3. Roles and responsibilities**

A member of the IFR team will be nominated to chair the meeting, ask for declarations of interest and will record the decision of the IFR Screening Group against each of the questions in the pre-panel screening document

Cases may be presented by a member of the IFR team or the IFR Case Manager if one has already been nominated.

Each case presentation will include, but is not limited to the clinical background to the case.

#### **4. Frequency of meetings**

The IFR Screening Group will normally be held once a week. IFR Screening Group meetings may be held in person or by tele-digital communication authorised by the CCG.

#### **5. Voting Rights**

Only the clinical members of the IFR Screening Group will agree whether a case should go forward to the IFR Panel. If a consensus cannot be achieved the case will go forward to the next available IFR Panel.

#### **6. Quoracy**

At least 1 clinician member must be present in addition to the IFR team member / IFR Case Manager for the meeting to be quorate.

#### **7. Documentation**

IFRs will be logged onto the IFR database on the date received and will be allocated an individual case reference number. It is the responsibility of the IFR team to manage all

requests received and correspondence relating to each case in line with the IFR Policy and SOP.

All the documents will be made available to the IFR Screening Group without patient identifiers to protect confidentiality and minimise the potential for identification bias. This will include the removal of patient's name, date of birth, NHS number, the name of requesting clinician, medical director, the requesting provider and any other identified clinicians and organisations.

The IFR team will produce a summary of the key information using the pre-panel screening document (Appendix Four) during the meeting. The IFR screening group's decision, including the rationale for the decision will be clearly recorded in the document and will be sent to the IFR Panel for sign-off when they next meet.

Only documentation received from the referring clinician will be used when reaching an outcome. All other documentation that has been received regarding the case will also be available to the IFR Screening Group.

## **8. Authority**

The IFR Screening Group has delegated authority from the CCG to make judgements in line with the IFR Policy and SOP and will seek additional clinical advice at their discretion.

It is not the role of the IFR Screening Group to make commissioning policy on behalf of the CCG, but it might highlight potential commissioning requirements to the CCG.

## **9. Accountability**

The IFR Screening Group is accountable to the CCG. The pre-panel screening document is the record of the IFR Screening Group and is approved by the clinical members.

## **10. Reporting and Monitoring**

The IFR team / IFR Case Manager will record the decision of the IFR Screening Group against each of the questions in the pre-panel screening document. The completed pre-panel screening document will be recorded against the individual case on the CCG IFR database and forwarded to the next IFR Panel for their consideration and noting.

The referring clinician will be advised of the outcome of the IFR Screening Group as detailed in the IFR SOP.

## **11. Training**

All members of the IFR Screening Group must undergo mandatory induction training approved by the CCG. This will cover both the legal and ethical framework for IFR decision making, the CCG commissioning processes and structures.

This training will be refreshed annually to ensure that all members maintain the appropriate skills and expertise to function effectively.

All members of the IFR screening group are expected to have had an annual appraisal in which their role within the IFR process is discussed and evaluated.

## **12. Review of Terms of Reference**

The Terms of Reference of the Panel will be reviewed annually.

## 11. Appendix Three – Service development process

The consideration for a service development can be initiated following:

1. The submission of more than one IFR for the same treatment or indication.
2. The submission of an IFR citing circumstances which could equally apply to a cohort of patients.
3. The submission of a business case application from a provider and/or clinical teams to commission services which are not routinely commissioned.

The provider will be required to fully complete a business case request application. This will be made available upon request.

Submission of a case is no guarantee of funding, and conversely, the absence of a business case will not make requests for funding any more or less likely to be accepted as exceptional cases.

Clinical urgency will be dealt with outside of this consideration. The process is expected to take several months from submission.

In the interim, the provider cannot expect any CCG to fund any further IFRs, solely on the basis that they have submitted a business case or that a commissioning policy is being developed.

Following evaluation of the business case the review will be submitted to the SCPC or APC for consideration so that a commissioning recommendation can be made.

If a prior approval process is to be initiated or a contract variation is required than, this needs to be considered by the CCG's Contract Management Team.

If a business case results in a change of service or pathway, then the CCG's Service Redesign team should be consulted.

## 12. Appendix Four – Pre-Panel Screening Document

<b>Ref. no.</b>					
<b>Intervention</b>					
<b>Condition</b>					
<b>PRE-SCREENING CHECKLIST COMPLETED BY IFR CASE MANAGER (Name - _____ Date _____)</b>					
<b>Question</b>	<b>Answer (circle)</b>				<b>Comments</b> (Please provide as much detail as possible)
	<b>Yes / No / Unclear / N/A</b>				
1. Has the form been completed correctly, and no sections omitted? E.g. mandatory governance requirements are present?	Y	N	U	N/A	If no, stop here
2. Is this within the CCG commissioning responsibility? Is it a request for a CCG patient and not NHS E responsibility? Is the condition or treatment detailed in the Specialised Services Manual?	Y	N	U	N/A	If no, stop here
3. Is this treatment excluded from tariff?	Y	N	U	N/A	If no, stop here
4. Is this Provider commissioned to provide this service?	Y	N	U	N/A	If no, stop here
5. Is this treatment already routinely commissioned? Is there a CCG Clinical Policy? If so, does the patient meet the access criteria? Is there NICE Technology Appraisal or other relevant clinical guidance? If so, does the patient meet the criteria?	Y	N	U	N/A	If yes, stop here
6. Have all the supporting documents been provided in full text?	Y	N	U	N/A	Please provide the number of attached articles (each document will be listed in the PDF Contents page)

7. Is the request is marked as urgent? <b>Has the requesting clinician provided information on the clinical reasons for urgency? If so, provide details</b>	Y	N	U	N/A	
8. Is there any indication that the patient has been approved for any treatment previously? <b>If so, how was this treatment funded?</b>	Y	N	U	N/A	
<b>PRE-SCREENING OUTCOME</b>	<b>Tick</b>			<b>Comments</b>	
Proceed to IFR Screening Group – first application					
Redirected - Back to Referrer with Advice					
Redirected – Already Routinely Commissioned					
Redirected - To other commissioner					
Other outcome – please give detail					

CHECKLIST – SCREENING TO BE COMPLETED BY IFR SCREENING GROUP MEMBERS					
Names: _____					
Date _____					
Question	Answer (Circle/ cross through as appropriate)				Screener notes / Comments (as much detail as possible)
	Yes / No / Unclear / N/A				
9. Is the information that has been provided in questions 1-8 correct and appropriate? If not please give details and /amendments.	Y	N	U	N/A	
10. If this is a drug, is it licensed for the requested indication? If this is a device does it have the relevant safety authorisations?	Y	N	U	N/A	
11. Does the requested treatment appear to be experimental?	Y	N	U	N/A	Please use the <b>IDEAL</b> framework where possible <a href="http://www.ideal-collaboration.net/framework/">http://www.ideal-collaboration.net/framework/</a> Please note that clinical effectiveness alone is not sufficient to justify funding
Or Unproven?	Y	N	U	N/A	
12. Are the incidence and prevalence figures clear and correct?	Y	N	U	N/A	Have the clinicians shown their calculations
13. Is this patient part of a larger group of patients with similar circumstances e.g. a patient cohort? Please provide details	Y	N	U	N/A	If yes, does this highlight a service development?
14. Is the supporting clinical evidence provided by the requesting clinician relevant to the case and have they indicated which points within them are specifically relevant to the case?	Y	N	U	N/A	
15. Has a strong clinical rationale for the treatment been made for this individual patient e.g. diagnosis, biological pathway, evidence, treatment pathway and expected outcomes?	Y	N	U	N/A	

16. Has the requesting clinician provided sufficient detail on the clinical history and provided adequate information on the responses to previous treatment?	Y	N	U	N/A	
17. Has the requesting clinician clearly outlined why the patient cannot use an alternative commissioned treatment / service?	Y	N	U	N/A	
18. Are there sufficient grounds put forward by the referring clinician making an arguable case suitable for IFR Panel consideration in line with the IFR Policy (including clinical rationale for exceptionality and stated factors indicating likelihood or uncertainty of anticipated outcomes being achieved)?	Y	N	U	N/A	You must provide specific reasons in this section detailing a point by point answer to the claims for exceptionality made by the clinician
19. If the answer to Q18 is yes, has the requesting clinician provided sufficient information in relation to clinical outcomes and how they will be monitored?	Y	N	U	N/A	
<p><b>Summary</b> – Include clear reasons for the outcome which address all points raised by the requesting clinician. This applies to both request that are declined and those that are forwarded to IFR panel.</p>					

SCREENING OUTCOME Date:	Tick	Comments
Eligible for IFR Panel - Please give reasons		
Ineligible for IFR Panel - Please give reasons		
Other outcome – please give detail		
Completed Pre-panel decision document shared with screeners		

### 13. Appendix Five – Reconsideration of screening outcome form

Requesting clinicians are advised to review the CCG IFR Policy, Patient information leaflet and the Guidance for Clinicians at [www.surreyheartlandsccg.nhs.uk](http://www.surreyheartlandsccg.nhs.uk). The CCG requires providers and clinicians to take CCG clinical commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient.

It is the responsibility of the referring clinician to ensure all the appropriate and required clinical information is provided to CCG. This includes full text copies of all the published papers of clinical evidence that have been cited, a list of the published papers submitted and an indication of which points within them are relevant in respect to the IFR application and criteria. Requests will only be considered on the information provided in the application and supporting papers.

**DO NOT** include patient or provider/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included the application will be returned to you for redaction and resubmission.

**Please note:** Applications presenting incomplete information will be returned for amendment/completion prior to consideration by the CCG.

1	Case reference number:	For CCG use
2	NHS Number:	Click here to enter text.
3	Patient's age at time of resubmission:	Click here to enter text.
4	Please detail the clinical reasons for urgency if appropriate i.e. the risks of adverse clinical outcome to the individual patient:	Click here to enter text.
5	Proposed start date:	Click here to enter a date.
6	If treatment has commenced more than 2 working days before submission of this application please provide an explanation for the delay	Click here to enter text.
7	Proposed treatment stop date:	Click here to enter a date.
8	Name and email of Medical Director/Chief Pharmacist:	Click here to enter text - name. Click here to enter text – email.



9 Confirm that the Medical Director/Chief Pharmacist supports the resubmission of this application	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Updated information not originally included in the IFR application</b>	
<b>Section 3 – request details</b>	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
<b>Section 4 – Treatment</b>	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
<b>Section 5 – Clinical Background</b>	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
<b>Section 6 – Clinical Exceptionality</b>	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
<b>Section 7 – Clinical Supporting Information</b>	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
<b>Tab 8 – SUBMIT</b>	
When you are satisfied that you have completed all sections you will need to submit the request for consideration by the CCG IFR team. If the team needs more information they will email you to ask that you provide more details and if this happens, the information tab will be enabled for editing.	
Clinicians are required to disclose all material facts to CCG as part of this process.  Are there any other comments / considerations that are appropriate to bring to the attention of the IFR Team?	Click here to enter text.

## 14. Appendix Six – Terms of Reference IFR Panel

### Terms of Reference Individual Funding Request Panel

#### 1. Purpose

The Individual Funding Request (IFR) Panel will consider individual requests for Surrey Heartlands/Surrey Heath CCG. The IFR Panel will work to the published Surrey Heartlands/Surrey Heath CCG IFR Policy and each request will be processed by following the Standard Operating Procedures (SOP). This will ensure that all requests are considered in a fair, consistent and transparent way, with decisions based on the available clinical evidence presented by the treating clinicians and commissioning principles.

#### 2. Membership

The IFR Panel will have a core membership of:

- Clinical Chair
- Lay Member
- 1 GP from each Surrey Heartlands ICP / Surrey Heath ICP
- Public Health Consultant
- Pharmacy Lead
- ECI Administrator

The Panel membership will be representative of a range of competencies, as outlined in the National Prescribing Centre Competencies Framework<sup>1</sup>.

The IFR Panel and its processes should reflect best practice as outlined in the National Prescribing Centre Handbook of Good Practice Guidance.

The IFR Case Manager will introduce the case to the Panel members. A member of the Public Health team will present interventional cases where an evidence review has been required. Clinical members of the IFR Panel who have had any clinical involvement with an individual case cannot be part of the Panel meeting for that request.

The IFR Case Manager will record the decision of the IFR Panel against each of the questions in the Decision Framework Document.

#### **In attendance:**

- For particularly complex cases, other individuals with clinical, pharmacy or commissioning expertise and skills, unconnected with the requesting provider, may also be invited to participate in a Panel meeting.
- Public Health trainees can also contribute to the work of the IFR Panel, which may include presentation of cases, as part of their training, a member of the Pharmaceutical Commissioning Team may present drug cases as necessary. They can attend panels as non-voting members.

#### 3. Chair

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.

#### 4. Frequency

The IFR Panel will normally be held once a month in Leatherhead as face to face meetings and will run for no more than 2 hours (meetings may be held in person or by tele-digital communication authorised by the CCG).

#### 5. Voting Rights

IFR Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each panel member present having an equal vote. If the panel is equally split then the Chair of the Panel will have the casting vote.

#### 6. Quoracy

The Panel will be quorate if 4 of the core members are present, one of whom must be a GP.

#### 7. Documentation

IFRs are submitted electronically via the Blueteq database by the requesting clinician or their representative (or in exceptional circumstances using a MS Word template submitted via secure email). Each application is given a unique reference ID by Blueteq at the time of screening. It is the responsibility of the IFR Team to manage all requests received and correspondence relating to each case as per the IFR Standard Operating Procedures.

All cases will be anonymised appropriately before consideration by the IFR Panel (as stated in the SOP). The IFR Team will produce a summary of the key information using the Decision Framework Document which will be considered by the IFR Panel.

Patients will not be permitted to attend Panel meetings in person or be represented by any person at the meeting.

The completed Decision Framework Document, together with the record of attendance, will form the business notes of an individual case. These notes will be used to form the basis of the outcome letter to the clinician, if required.

Any error or ambiguity in this wording is the responsibility of the IFR Panel Chair signing off the business notes and outcome letter.

When preparing the business notes, members of the IFR team and the IFR Panel Chair should bear in mind that these are documents which could be disclosable, therefore use language accordingly. The decisions of an IFR Panel are attributable to the Panel as a whole. The notes of the discussion about specific concerns raised by individual applications should avoid personalities.

Patients will not be permitted to attend IFR Panel meetings in person or be represented by any person at the meeting.

The IFR Chair will be copied into all agenda and minutes generated by IFR Panel meetings held in his/her absence.

## 8. Authority

The IFR Panel works on behalf of Surrey Heartlands CCG and make decisions in respect of funding of individual cases. It is not the role of the IFR Panel to make commissioning policy on behalf of the CCG.

The IFR Panel has delegated authority from Surrey Heartlands CCG governing bodies to make decisions to approve individual funding requests of up to £25k. Above that, the panel will make a recommendation to the Chief Financial Officer of the responsible CCG for funding agreement.

## 9. Accountability

The minutes of the IFR Panel will be approved by the Chair of the IFR Panel. The IFR Panel is accountable to Surrey Heartlands CCG Executive Board.

## 10. Reporting and Monitoring

The IFR Case Manager will record the decision of the IFR Panel against each of the questions in the Decision Framework Document.

The completed Decision Framework Document, together with the record of attendance, will form the minutes of each individual case.

The IFR Case Manager will produce a regular report relating to all IFR's received, not necessarily considered by the IFR Panel, which will be reviewed by the CCG Clinical Chair (and directors of the ICP if Surrey Heartlands).

## 11. Training

All members of the IFR Panel are expected to have had an annual appraisal in which their role within the IFR process is discussed and evaluated.

All members of the IFR Panel must undergo mandatory induction training. This will cover legal considerations and case law, the principles for IFR decision making, CCG commissioning processes and structures, and the interpretation of clinical evidence. Once they have completed IFR induction training, IFR Panel members will be expected to attend the annual "refresher" IFR training session to ensure that all members maintain the appropriate skills and expertise to function effectively. In order to become a voting member of the Panel, a minimum of 2 Panel meetings must be observed.

## 12. Review of Terms of Reference

The Terms of Reference of the Panel will be reviewed annually.

<sup>1</sup> National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments). A Handbook of good practice guidance. First Edition. February 2009.

**15. Appendix Seven – IFR Panel Document (DFD)**

**Notes:**

1. A copy of this form is provided to each Panel member for each Panel case.
2. The copies will, at the end of the meeting, be collected by the IFR Team.
3. Those copies will then be used to produce one summary DFD. That summary will give reasons for the decision at each stage of the process.
4. Individual Panel member forms will not be retained.
5. The summary DFD will be used to record the key points discussed by the IFR Panel and the views of the IFR Panel.

<b>Panel meeting date:</b>				
<b>Request reference:</b>				
<b>Panel Membership</b>	<b>Name</b>	<b>Designation</b>	<b>Declaration of interest</b>	<b>Decision</b>
		Chair		<b>Unanimously approved</b>
		Lay member		
		GP (ES ICP)		
		GP (G&W ICP)		<b>Approved by vote: _ / _</b>
		GP (NWSy ICP)		
		GP (SD ICP)		<b>Unanimously declined</b>
		GP (SH ICP)		
		Public Health Consultant / Specialist from Public Health England		<b>Declined by vote: _ / _</b>
		Pharmacy Lead		
		ECI Administrator		

Intervention Requested:			
No.	Points for decision	Discussion notes	Decision
Individual Need for Care			Yes/No
1.1	<p>Does CCG have a clinical commissioning policy and/or is there NICE Technology Appraisal (TA) / Highly Specialist Technology (HST) guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient</p> <p><b>AND</b></p> <p>Is this patient outside the access criteria for treatment under that policy/guidance, where applicable?</p> <p><i>If Yes, there is a policy/guidance and the patient is outside it, record and go to question 2.1.</i></p> <p><i>In any other case, go to question 1.2, below.</i></p>		
1.2	<p>There is no CCG clinical commissioning policy or NICE TA/HST guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient</p> <p><b>AND</b></p> <p>The intervention is not routinely funded?</p> <p><i>If there is no policy/NICE guidance and the intervention is not routinely funded, record, and go to question 2.2.</i></p> <p><i>In any other case, the application is outside the scope of the policy, record and go to question 5.</i></p>		

Evidence of clinical effectiveness and exceptionality			Yes/No
2.1	<p>If the answer was Yes to question 1.1:</p> <p>Does the evidence included within the application demonstrate that the patient is in a different clinical condition when compared to the typical patient population with the same condition</p> <p><b>AND</b> (if relevant)</p> <p>at the same stage of progression</p> <p><b>AND</b> that <b>because of that difference</b> the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient?</p> <p>Guidance for Panel: In answering this question, have regard to the guidance on clinical exceptionality in the IFR policy (section 3).</p> <p><i>If Yes, record and go to question 3.1.</i></p> <p><i>In any other case, record and go to question 5.</i></p>		
2.2	<p>If the conditions in question 1.2 were satisfied:</p> <p>Is the patient's clinical presentation so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken?</p> <p>Guidance for Panel: To understand what is meant by "so unusual", have regard to the guidance on clinical exceptionality in the IFR policy (section 5).</p> <p><i>If Yes, record, and go to question 3.1.</i></p>		

	<i>In any other case, record and go to question 5.</i>		
<b>Experimental and Unproven treatment</b>			<b>Yes / No</b>
<b>3.1</b>	<p>Is this treatment experimental [or unproven] (as defined in section 5.4)?</p> <p><i>If Yes, record and go to question 3.2. If No, record and go to question 3.3.</i></p>		
<b>3.2</b>	<p>If the treatment is experimental [or unproven] as per question 3.1, what is the Panel's assessment of the following in relation to the submitted evidence of effectiveness (sections 5.4):</p> <ul style="list-style-type: none"> <li>a) The potential benefit and risks of treatment; AND</li> <li>b) The biological plausibility of benefit based on other evidence; AND</li> <li>c) The estimated cost of the treatment and anticipated value for money; AND</li> <li>d) The priority of the patient's needs compared to other competing needs and unfunded developments?</li> </ul> <p>Will funding the treatment contribute to the knowledge base relevant to treatment of the condition in question?</p> <p>Is it appropriate to consider funding through an IFR rather</p>		



	<p>than research funding?</p> <p><i>If the assessment of factors a-d above is satisfactory and the two questions set out above are answered positively, record and go to question 4.</i></p> <p>Guidance for Panel: keep in mind the additional requirements that the IFR policy applies to evaluating both clinical efficacy and the use of NHS resources when a treatment is experimental or unproven.</p> <p><i>In any other case, record and go to question 5.</i></p>		
<p><b>3.3</b></p>	<p>If the treatment is <i>not</i> experimental and/or unproven as per question 3.1:</p> <p>Is there sufficient evidence to show that the proposed treatment is likely to be clinically effective in this individual case?</p> <p>Guidance for Panel: In answering this question have regard to the guidance on clinical effectiveness in the IFR policy (sections 5.2).</p> <p><i>If Yes, record and go to question 4.</i></p> <p><i>In any other case, record and go to question 5.</i></p>		

Good use of NHS resources and affordability		Yes/No
<p><b>4.</b></p> <p><b>Consider as a minimum:</b></p> <p>a) What are the absolute costs involved in funding this treatment, considering cost and time receiving treatment?</p> <p>b) Is this cost one-off or is there a need for recurrent funding?</p> <p>c) What benefit can the patient expect to receive and for howlong?</p> <p>d) How certain are costs and benefits?</p> <p>As uncertainty increases, the likelihood of the anticipated benefits being realised decreases.</p> <p>e) Is there another source of funding known to be available or that could be available, for example industry funding for those who have taken part in clinical trials?</p> <p>f) Taking these and any other factors considered relevant into account, does the Panel consider that use of this drug/intervention in this individual case is a good and equitable use of NHS resources?</p> <p><i>Record the answers and go to question 5.</i></p>		

Equalities		Yes/No
5	<p>Guidance for Panel (section 5.1.4) In general issues of equality and diversity are addressed in clinical policy development (see question 6).</p> <p>Considering only clinical factors, does the application raise any clinically relevant equality concerns that have not already been considered above?</p> <p>Is the fact that the applicant has a particular protected characteristic (age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief, sex; sexual orientation) clinically relevant to the application?</p> <p>Would allowing or refusing the application represent an opportunity to eliminate discrimination or to advance equality of opportunity, or to reduce health inequalities?</p> <p><i>If Yes, review the decision in light of these concerns, if they have not been discussed and recorded earlier. Be willing to reach a different decision if you consider that appropriate, and record that review.</i></p> <p><i>If No or after review, go to 'RECORD OF DECISION' below.</i></p> <p><i>Additionally, consider question 6, although this is not part of the consideration of the IFR.</i></p>	
Policy developments		Yes / No
6	<p>Has this case brought to light any issues which should be referred on within the CCG to inform policy development?</p> <p>If so refer them to [ ]</p>	

RECORD OF DECISION	SUM M A R Y
<p><b>Funding Approved:</b></p> <p>Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requesting clinician.</p> <p>Include any conditions, outcome measures to be monitored and review mechanisms required.</p> <p>Date of review:</p>	
<p><b>Funding Declined</b></p> <p>Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requesting clinician.</p>	

**RETURN THIS FORM TO THE ECI ADMINISTRATOR AFTER THE MEETING**

## 16. Appendix Eight - Ethical Decision-making Framework

### NHS Surrey Heartlands IFR Team:

#### Ethical framework (Interim)

Adapted from the NHS Commissioning Board Policy first published April 2013

Commissioning Policy – Ethical Framework NHSCB/CP/01 V1

#### Policy Statement

This ethical framework should be the basis for decision-making in the management of individual funding requests.

The purpose of setting out the principles and considerations is to:

- provide a coherent framework for decision making
- promote fairness and consistency in decision making
- ensure that the reasons behind decisions that have been taken are clear and comprehensive.

#### Equality Statement

The CCG has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the CCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

#### Guidance Notes

The core principles have been taken from the NHS Commissioning Board Ethical Framework and as such cover aspects of resource allocation wider than simply IFR. The principles should be applied when dealing with individual funding requests, in conjunction with other general or treatment-specific commissioning policies, which might be relevant to the case.

Five important themes can be found within the principles.

1. The first is that, as budget holder for a defined population and a range of clinical services, the CCG and its committees should ensure that all decisions are framed and considered in such a way that all options for investments are considered. This means that there should not be a parallel system operating, which allows individual treatments or patients to bypass prioritisation. The commissioning and operating policies that have been adopted by the CCG allow for the funding of high priority service developments, or of individuals who have unusual and high priority clinical needs. This principle prevents patients, patient groups or services who lobby being given undue priority.

2. The second theme is that a commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal need to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. The CCG considers that if funding for a treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory.  
A treatment policy approved by the CCG should therefore not be approved unless the CCG has made funds available to allow all patients within the clinical group identified in the policy to have equal access to treatment.  
Individual patients may be considered for funding through the individual funding request process if their clinician can demonstrate that the patient is clinically exceptional.
3. The need to demonstrate clinical effectiveness and value for money is only the first stage in assessing priority. Effectiveness and value for money are minimum requirements to enable prioritisation for funding, but are not the sole criteria that must be met for funding to be agreed.
4. Commissioners are frequently asked to take on funding commitments made by another statutory body or other type of organisation (including pharmaceutical companies, research bodies or acute trusts) or indeed an individual who has funded the treatment themselves. The CCG, like any other organisation, cannot assume responsibility for a funding decision in which it played no part unless there is a legal requirement to do so.
5. Related to point 4 is the issue of financial support provided to research and development (R&D). Commissioner support for R&D is highly desirable but it needs to be placed within appropriate constraints. These constraints should protect high priority treatments and services of established value.

## **Core Principles**

### **Principle 1**

The values and principles driving priority setting at all levels of decision-making must be consistent.

### **Principle 2**

The NHS has a duty to provide a comprehensive healthcare service. Within that duty the CCG must meet all reasonable requirements for healthcare, subject to the duty to live within its allocated resources.

### **Principle 3**

The CCG has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly commissions. It must act fairly in balancing competing claims on resources between different patient groups and individuals.

### **Principle 4**

Competing needs of patients and services within the areas of responsibility of the CCG should have an equal chance of being considered, subject to the capacity of the CCG to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services, clinicians and individual patients should not be allowed to bypass normal priority setting processes.

### **Principle 5**

Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual / cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting the needs of sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

### **Principle 6**

The CCG should only invest in treatments and services which are of proven cost-effectiveness unless it does so in the context of well designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention.

### **Principle 7**

New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness and then prioritised in a way which supports consistent and affordable decision-making.

### **Principle 8**

The CCG must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

### **Principle 9**

The CCG should strive, as far as is practical, to provide equal treatment to individuals in the same clinical circumstance where the healthcare intervention is clearly defined. The CCG should not, therefore, agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

## **Principle 10**

Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

## **Principle 11**

Because the capacity of the NHS to fund research is limited, requests for funding to support research on matters relevant to the health service have to be subject to normal prioritisation processes.

## **Principle 12**

If a treatment is provided within the NHS which has not been commissioned in advance by the CCG save for those treatments approved by other NHS bodies eg NHS England, the responsibility for ensuring on-going access to that treatment lies with the organisation that initiated treatment.

## **Principle 13**

Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. They should be fully informed of the arrangements for continuation of treatment after the trial has ended. The responsibility for this lies with the party initiating and funding the trial and not the CCG unless the CCG has either funded the trial itself or agreed in advance to fund aftercare for patients entering the trial.

## **Principle 14**

Unless the requested treatment is approved under existing policies of the CCG, in general it will not, except in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.

Documents which have informed this policy

- NHS Commissioning Board Policy (first published April 2013)  
<https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf>
- Department of Health, Health and Social Care Act 2012  
<http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>
- Department of Health, The NHS Constitution for England  
<https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england#contents>



## 17. Appendix Nine – Funding for Continuation Requests

1. DETAILS OF ORIGINAL IFR			
IFR reference: for CCG use		Date of IFR submission:	
2. PATIENT PERSONAL DETAILS			
Patient Name:			
Date of Birth:		NHS Number:	
Patient Address:			
GP Name			
GP Practice name:		GP Postcode:	
3. CONSENT			
This request for funding for continuation of treatment (originally approved via the CCG Individual Funding Request (IFR) route) has been discussed in full with the patient or patient representative <sup>2</sup> . They are aware that they are consenting for the IFR Team to receive and review confidential clinical information about their health to enable full consideration of this funding request. I confirm all of the above.			Yes <input type="checkbox"/> No <input type="checkbox"/>
I understand that by indicating that it is NOT clinically appropriate for the IFR Team to contact the patient, I am responsible for sharing information relating to this request with the patient /patient representative. Their GP will be included in any responses and be aware of the request and its outcome.			Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Name of Requesting clinician :			
Signature of Requesting clinician:			
Date continuation request submitted:			
Responsibility lies with the requesting clinician to present to CCG a full continuation request submission which sets out a comprehensive and balanced picture of the history and present state of the patient's clinical condition, the nature of the treatment requested and the anticipated benefits of treatment. Requesting clinicians are advised to review the CCG IFR policy, IFR Standard Operating procedures and the Guidance for Clinicians at <a href="http://www.surreyheartlandsccg.nhs.uk">www.surreyheartlandsccg.nhs.uk</a>			

<sup>2</sup> This means a person with legal authority to take decisions about medical care and treatment on behalf of the patient, on the basis that they lack capacity to take these decisions themselves. The source of that legal authority should be clearly identified.

4. DETAILS OF REQUESTING CLINICIAN			
Name:		Title:	
Job role:			
Provider organisation:			
Clinical department / specialty:			
Contact telephone number:			
Secure NHS.net email or postal address:			

5. PROVIDER SUPPORT	
Provider Medical Director/Chief Pharmacist approval ( <b>Mandatory</b> ): Date approval given:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Name of provider Medical Director/Chief Pharmacist:	
Email address of Medical Director/Chief Pharmacist:	
Signature of Medical Director/Chief Pharmacist:	
Pharmacy contact: Name and NHS.net email address:	

6. PROVIDER SERVICE AND AUDIT	
Is your organisation commissioned by CCG to provide this service or treatment? If No, state why the patient hasn't been referred to an NHS commissioned provider:	Yes <input type="checkbox"/> No <input type="checkbox"/>

7. PATIENT DIAGNOSIS	
Primary diagnosis related to this request:	

8. TREATMENT REQUESTED	
Name of treatment: (Include any alternative terms)	
Dose/Frequency of treatment:	
Start/Stop dates of approved treatment:	

<b>9. CLINICAL REPORT</b>	
i. What clinical measures were used to record the outcome of the treatment requested?	
ii. Please report on the observed response to treatment in relation to the change in the specific outcome measures identified in the original IFR application. How does this compare to the anticipated change stated in the IFR application: have these been achieved and to what extent?	
iii. Describe how the observed clinical outcomes meet the original criteria for deciding whether the treatment was successful or unsuccessful	
iv. What are the anticipated outcomes of the continued treatment requested for this patient? This should relate to the agreed 'stopping' criteria	
v. What is the future care plan for this patient, including long term plans(>2yrs)?	
vi. What are the current clinical condition/ functional status of the patient?	
vii. Any other clinical information relevant to this patient's treatment?	

<b>10. TREATMENT / PROCEDURE COSTS</b>	
<p>Actual (i.e. based on observed rather than estimated) costs.</p> <p>Please <b>itemise</b> the costs (e.g. drug/attendance costs / staff / follow up / diagnostics costs etc.).</p> <p>Please provide breakdown of this cost per annum, per cycle etc. as appropriate:</p>	£.....

<b>11. DECLARATION OF INTERESTS</b>	
<p>Clinicians are required to disclose all material facts to CCG as part of this process.</p> <p>Are there any other comments / considerations that are appropriate to bring to the attention of the IFR Team?</p>	

**For CCG use only**

<b>1. POLICY UPDATES</b>	
Has there been any policy updates related to this particular request and condition since the original IFR request was approved?	
Y / N	
If Y please provide details:	
<b>2. Continuation of funding approved?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Date of decision:	
Continuation request reviewed by:	
Reasons for decision made:	
(If approved), continuation request funded for a further:	6 months <input type="checkbox"/> 12 months <input type="checkbox"/> Other <input type="checkbox"/> Please provide detail on this:

## 18. Appendix Ten – Terms of Reference – IFR Review Panel

### Terms of Reference CCG Individual Funding Request Review Panel

#### 1. Membership

The IFR Review Panel will consist of:

- Lay Chair
- Independent Member
- GP from the patients respective ICP

*OR if a reciprocal agreement with a neighbouring CCG IFR team is in place, a review panel using their IFR-trained staff (but referring to this SOP, and associated IFR Policy) in conjunction with a GP from the patient's respective ICP.*

None of the panel members should have been involved in the case prior to the IFR Review Panel. The IFR Review Panel will not consider either new information that was not available to the IFR Panel or receive oral representations.

#### 2. Purpose

The IFR Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the IFR Review Panel will consider whether:

- The process followed by the IFR Panel was consistent with that detailed in the IFR SOP
- The decision reached by the IFR Panel:
  - had taken into account and weighed all the relevant evidence
  - had not taken into account irrelevant factors
  - indicates that members of the panel acted in good faith
  - was a decision which a reasonable IFR Panel was entitled to reach.

The IFR Review Panel will be able to reach only one of two decisions:

- Uphold the decision reached by the IFR Panel
- Refer the case back to the IFR Panel with detailed points for reconsideration

Where the IFR Review Panel consider that there may have been a procedural error in the decision, i.e. a) the IFR Panel may not have taken into account and weighed all the relevant evidence available to them, and / or b) the IFR Panel may have taken into account irrelevant factors or reached a decision which a reasonable IFR Panel was not entitled to reach, the IFR Review Panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that requested treatment will be approved.

If the IFR Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different, the IFR Review Panel shall uphold the decision of the IFR Panel.

### **3. Frequency of meetings**

The IFR Review Panel will be scheduled as required. A case may need to be considered urgently after consultation with the patient's clinicians. The timing of the urgent IFR Review Panel will be based on the individual clinical circumstances and the risk of an adverse clinical outcome if a funding decision on treatment is delayed. Ideally, all urgent cases will be considered by face-to-face meeting, but where the clinical urgency makes this impossible, communication by phone or e-mail will be deemed appropriate.

### **4. Voting Rights**

The IFR Review Panel members will seek to reach a decision by consensus. If this is not possible, a decision will be made by a vote with each member having one vote.

### **5. Quoracy**

All three panel members must be present for the IFR Review Panel to be quorate.

### **6. Documentation**

The IFR Review Panel will only consider the following written documentation:

- The original Treatment Request Form submitted to the ECI Team
- The IFR process records in handling the request
- The IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- The grounds submitted by the referring clinician and/or the patient/patient representative in their request for review.

There will be no other representation at the IFR Review Panel from the IFR Panel or the referring clinician and/or the patient/patient representative.

The IFR Review Panel will not consider new information or receive oral representations.

If there is significant new information, not previously presented to and considered by the IFR Panel, it will be considered as set out in the section on reconsideration in the IFR SOP. All information will be anonymised before consideration by the IFR Review Panel.

### **7. Authority**

The IFR Review Panel has the responsibility to undertake a review of IFR Panel decisions in respect of funding of individual cases. It is not the role of the IFR Review Panel to reach a decision on funding of an Individual Funding Request nor does the Panel make clinical commissioning policy on behalf of the CCG.

### **8. Accountability**

The IFR Review Panel works on behalf of the Surrey Heartlands CCG Executive Board

### **9. Reporting and Monitoring**

The IFR Team will review on a regular basis any Review Panel requests and outcomes in order to evaluate the process and to consider any improvements that could be made.

### **10. Training**

All members of the IFR Review Panel are expected to have had an annual appraisal in which their role within the IFR process is discussed and evaluated.

All members of the IFR Review Panel must undergo mandatory induction training. This will cover legal considerations and case law, the principles for IFR decision making, CCG commissioning processes and structures, and the interpretation of clinical evidence. Once they have completed IFR induction training, IFR Panel members will be expected to attend the annual IFR workshop to ensure that all members maintain the appropriate skills and expertise to function effectively.

#### **11. Review of Terms of Reference**

The Terms of Reference of the IFR Review Panel will be reviewed annually.