

South East London Integrated Care Board (ICB) Individual Funding Requests (IFR) Policy

Version Control Record:

Version	Description of Change(s)	Reason for Change	Author	Date
1.0	Creation of SL CSU IFR Policy	Creating a single standard policy for all SL CCGs	SL CSU	October 2013
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1.5	Changes made following the release of V1.4. Amendment to section 3.0.2. Removal of rarity definition section 5.05. Amendment to section 6.2. Addition of other documents which have informed the policy.	Review of changes made to V 1.4	SLCSU	February 2014
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1.7 Draft	Updated to reflect establishment of South East London ICB and triage and panel changes	Transfer of IFR function to South East London ICB	Alison de Metz, Head of IFR, London Shared Service	June 2022

Equality Statement:

This document demonstrates the organisation's commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief, and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities".

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1 Introduction

1.0.1 Acute patient care for the population of South East London is delivered through contracts with acute care providers which are managed by the South East London (SEL) Integrated Care Board (ICB). The NHS exists to serve the needs of all patients but also has a statutory duty not to exceed the resources allocated to it by central government (NHS Act 2006). NHS organisations therefore need to use their limited resources effectively to obtain the best healthcare possible for their population. This sometimes results in difficult decisions having to be made about how resources should be prioritised when services are commissioned. There may be individual cases where a patient's needs cannot be met through existing contracts and commissioning arrangements but their GP or consultant considers that their patient has a need for a treatment that is not routinely commissioned and wishes to request funding on their patient's behalf. When requests occur, the ICB must have a robust and transparent system in place to assess and determine whether the request should be funded, demonstrating a rational decision making process for an individual patient. These are referred to as individual funding requests (IFRs).

1.0.2 The NHS Constitution¹ sets out the following public commitment:

'You have the right to expect local decisions on funding of drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.'

2 Purpose

2.0.1 A single SEL ICB Individual Funding Request (IFR) Policy ensures that each South East London Borough is operating to a model of best practice for IFRs; including governance, key performance indicators and statutory duties. This Policy sets out the principles, organisational structures and relationships that are required to be in place to assure the ICB that requests which fall outside the usual commissioning arrangements and contracts are dealt with efficiently, consistently, fairly and transparently.

2.0.2 Requests to continue funding for patients coming off drugs trials

The ICB does not expect to provide funding for patients who initially commenced a drug/treatment as a part of a clinical trial. The ICB policy is that the responsibility for ensuring a clear exit strategy from a trial and that those benefiting from treatment will have on-going access to it lies with those conducting the trial. The initiators of the trial (NHS Provider Trusts and drug companies) have a moral and ethical obligation to continue funding patients benefiting from treatment until such time as SEL ICB has agreed to commission the treatment.

3 Scope – Applications for Individual Funding Requests

3.0.1 This policy applies to all written requests for IFRs submitted on behalf of patients registered to GPs in the SEL ICB boundary by NHS contracted responsible clinicians (including GPs, Consultants and equivalent autonomous practitioners) who are

¹ NHS Constitution 2012– seven key principles

responsible for administering the treatment. This policy excludes treatments and interventions managed and commissioned by NHS England.

- 3.0.2 This policy excludes requests for funding approval made after an episode of care has commenced or requests from patients for reimbursement of the costs of a treatment which has been purchased privately. Retrospective funding requests for any care or treatment which has not been given prior approval will not be funded, unless it can be demonstrated that the treatment was needed urgently to avoid a life threatening situation or significant harm to the patient, and that unsuccessful efforts were made to contact the IFR Team.
- 3.0.3 This Policy is for implementation and use by the South East London ICB IFR team, ICB triage group, IFR Panel and IFR Appeal Panel and accessible to clinicians, patients and members of the public.
- 3.0.4 The Policy is to be formally approved by the ICB Governing Body or equivalent Transition Board during the ICB formation. It is to inform and provide assurance that the IFR service is administered in accordance with good practice, to the following:
- South East London ICB
 - Patients and Members of the Public
 - Referring GPs and consultants and equivalent autonomous practitioners who are responsible for administering the treatment
 - Acute Provider organisations within the boundaries of the SEL Integrated Care System.

It will also be made available for information to members of the public.

4 Responsibilities

The responsibilities for implementation of the IFR policy are set out below.

4.1 South East London ICB IFR team:

It is the responsibility of the SEL ICB IFR team, working on behalf of the SEL ICB:

- 4.1.1 To receive, acknowledge and process all requests for Individual Funding submitted to the ICB within the agreed time limits (see appendix G).
- 4.1.2 To undertake administrative triage to determine if the application is for the ICB, whether the request has sufficient information and to ensure appropriate confidentiality for patients and panel members (against the agreed minimum data set) for the request to be considered by the triage group.
- 4.1.3 Where an application is lacking sufficient information to contact the applicant for the additional information which would allow the request to be considered in the first instance by the triage group.
- 4.1.4 To re-direct applications as appropriate.
- 4.1.5 To prepare triage group, IFR panel and IFR Appeals panel papers and to forward to members in a manner that maintains patient confidentiality by emailing to a secure NHS email address.

- 4.1.6 To co-ordinate the process of triage assessment and consideration by IFR Panels in line with agreed policies and procedures and according to the timelines agreed (refer to appendix G).
- 4.1.7 To ensure that all appeals made against decisions of the IFR Panel are submitted to the Appeal Panel, if appropriate.
- 4.1.8 To communicate the outcome of the triage group, IFR panel or IFR Appeal panel to the applicant.
- 4.1.9 Report on IFR panel activity across South East London on a quarterly basis to identify approvals, appropriate requests and potential service developments to inform future decision making and determination of commissioning pathways.
- 4.1.10 To ensure that members are appropriately trained for participation in panels.

4.2 The ICB:

The responsibility of the ICB includes:

- 4.2.1 The appointment of IFR triage group and IFR Panel and IFR Appeal Panel members to act on behalf of the ICB.
- 4.2.2 To ensure that sufficient panel members are available from the ICB for panels to be quorate.
- 4.2.3 To ensure panel members:
 - have access to confidential meeting papers sent via a secure email address.
 - work to agreed frameworks for IFR panel decision making
 - attend appropriate training.
- 4.2.4 To identify an ICB IFR Lead who will be the primary ICB contact for the IFR team.
- 4.2.5 The IFR Lead will present reports and policies to the ICB Governing Body or equivalent for approval and adoption in line with the ICB Governance arrangements.
- 4.2.6 Having governance arrangements in place to ensure that the IFR Panel is accountable to the ICB Governing Body or equivalent. (TORs for IFR triage group, IFR Panel and IFR Appeals Panel can be found in appendices C, D and E)
- 4.2.7 To determine the Financial Limits to which the IFR panel can make funding decisions. To define the process for application outside Financial Limits in line with local Standing Financial Instructions (SFIs) ensuring that the ICB can act quickly to confirm authorised expenditure over the approved threshold.
- 4.2.8 Agree and sign-off the access policy (Treatment Access Policy (TAP) in South East London) against which applications for some procedures are considered.

4.3 IFR Panel and Appeals Panel:

The responsibilities of the IFR Panel and Appeal Panel include:

- 4.3.1 The IFR Panel and the Appeals Panel will be accountable to the ICB Governing Body or equivalent.
- 4.3.2 The IFR Panel is responsible for upholding and working within the ethical decision making framework with regards to consideration of applications Appendix F.
- 4.3.3 The IFR Panel will refer to the relevant ICB adopted access policies to determine whether a patient who does not meet the criteria in the policy can be considered to be exceptional taking the information provided with the application into account.
- 4.3.4 The Appeal Panel will review applications where the applicant appeals the decision making process of the IFR Panel and does not provide any new information for consideration.
- 4.3.5 The membership of an Appeal Panel will exclude any persons who have previously considered the application for which the decision is appealed.
- 4.3.6 An Appeal Panel may not change the decision of the IFR panel, but must consider whether the decision reached: (see also 7.0.6)
- Followed policy and procedures,
 - Took into account and weighed all relevant information available at the time,
 - Was reasonable and in line with the evidence,
 - Did not take into account any irrelevant information.
- 4.3.7 The Appeal Panel may refer the case back to the original IFR panel for a re-consideration of the case should it consider that the IFR Panel did not fully follow policies or procedures or had failed to take account of all relevant information.
- 4.3.8 The Appeal Panel will be provided with all relevant documentation, correspondence, a synthesis of the evidence base and minutes summarising the basis for the original decision.

4.4 IFR Panel and IFR Appeals Panel Chair

- 4.4.1 The Panel Chair will be nominated by the ICB. The Panel Chair:
- 4.4.2 Must be available to approve the minutes/letters within the specified time frame following IFR panel meetings and to ensure that decisions made are correctly reflected in the minutes.
- 4.4.3 Must confirm that the meeting is quorate in line with the terms of reference.
- 4.4.4 May take a decision as 'Chair's Action' for urgent cases discussed either at an urgently convened panel meeting or through a virtual panel comprising discussion and response from at least three panel members ensuring that this includes members with relevant clinical expertise.

5 Definitions

5.0.1 An Individual Funding Request (IFR) is a request for an individual patient to fund an episode of healthcare that falls outside existing contracts and commissioning arrangements entered into by South East London ICB.

5.0.2 An appropriate IFR is where:

- a patient's treatment falls outside generic or treatment-specific policies where an unusual ('exceptional') circumstance applies to the individual,
- a particular treatment or intervention could benefit a patient with a very rare clinical condition.

5.0.3 An inappropriate IFR is where:

- a request represents a service development and therefore needs to be triaged into the appropriate population decision making group,
- a request where no information is submitted in support of the individual's exceptionality,
- the request is for a service or procedure that is commissioned by another organisation where funding is not the responsibility of a South East London ICB.

5.0.4 Exceptionality:

An unusual clinical circumstance about the patient that suggests that they are:

- Significantly different from the general population of patients with the condition in question; **and**
- Likely to gain significantly more benefit from the intervention than might be normally expected for the average patient with the condition.

The fact that a treatment is likely to be efficacious for a patient is not, in itself a basis for exceptionality.

5.0.5 Rarity:

In the case of a rare indication, the incidence and prevalence information will be assessed. This assessment will be made using published epidemiological research and also taking into account other similar requests received.

6 The IFR Process

See Appendix A for an overview of the IFR Process and appendix G for the associated operating timescales.

6.1 Submitting an IFR

6.1.1 IFR applications should be submitted online via the IFR database Blueteq on the current application form – see Appendix B and current version of the IFR policy as on the SEL ICB website. IFRs submitted by email to the IFR inbox (ifr@selondonics.nhs.uk) on the current application form will also be accepted. Handwritten applications and those submitted on an out of date form will not be accepted and will be returned to the applicant.

6.1.2 The application must be submitted by a NHS clinician including a GP, Consultant or an equivalent autonomous practitioner who is responsible for administering the treatment.

6.1.3 Patients may not submit applications directly as these are made by the clinician responsible for treatment. Should a patient wish to explain why they believe their

circumstances are exceptional they may put this in writing and this information should be submitted with the IFR application.

- 6.1.4 It is the responsibility of the clinician administering the treatment /intervention to complete the IFR application form and to submit all relevant clinical information and supporting evidence to make the case needed for the consideration of the application.

6.2 Patient Consent

- 6.2.1 Gaining Patient Consent - It is the responsibility of the requesting clinician to:

- Discuss the IFR process in full with the patient;
- Ensure that the patient gives consent for an IFR to be submitted on their behalf;
- Ensure that the patient understands the local IFR Policy, including the timelines for decision making;
- Advise the patient that through the submission of an application, they are giving consent for ICB and Public Health staff members to contact/discuss their situation with appropriate clinicians and relevant NHS staff and this will include access to Personal Confidential Data (PCD).
- Confirm that the patient has provided their consent by signing the applicant's declaration on the application form. If the patient wishes, they are also entitled to sign the form to indicate their consent, however this is not necessary to evidence consent and the applicant's declaration alone is sufficient.

- 6.2.2 Where an adult patient lacks the mental capacity to give or withhold consent, any application should take into account the legal position regarding consent <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>.

- 6.2.3 Consent for children should be in line with the Children's Act, Mental Capacity Act and Mental health legislation.

- Children and young people should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.
- When obtaining consent, the doctor must establish whether the child is legally competent (in legal terms, 'have capacity' to give consent).
- All people aged 16 and over are presumed in law to have the capacity to consent to treatment unless there is evidence to the contrary.
- If the child is deemed not legally competent, consent will need to be obtained from someone with parental responsibility,
- The legal position differs, depending on whether the young person is aged over or under 16

6.3 Anonymity & Confidentiality

- 6.3.1 The application form has been designed so that all the personal and confidential information about the patient, and the clinician, are provided on the first page.

- 6.3.2 Anonymity is essential for two reasons:

- In order to protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.

- For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex.

6.3.3 Depending upon individual clinical circumstances the panel may consider it necessary to re-introduce information on the patient's age and/or sex for consideration by the IFR panel. (This may be relevant to some drug requests and requests where the policy includes an age threshold or where the natural history of a condition varies with age or sex.)

6.3.4 While maintaining the confidentiality of patients is of paramount importance the identity of the requesting GP should not be included in panel pack information. Given the size of South East London's population it is statistically unlikely that members of an IFR panel will be personally acquainted with the patients involved. However, the community of clinicians and staff post-holders is much smaller, and it is desirable to minimise any potential for bias arising from personal acquaintance or past interaction, and hence the details of the requesting GP are removed.

6.4 Evidence Base

6.4.1 The decision making process will follow the ethical decision making framework (see appendix F) and the IFR panel will consider the nature and extent of the evidence base for a treatment. The panel will use nationally commissioned independent Medicines Information services, available assessments or local independent evidence appraisals in line with the accepted hierarchy of evidence.

6.4.2 Public Health advice, including the population implications and evidence base of applications will be provided by a Public Health representative.

6.5 Correspondence and Communications

6.5.1 The SEL ICB IFR team, after acknowledging receipt of the application, will ensure that the applicant is kept fully informed of the progress of the application

6.5.2 The SEL ICB IFR team will liaise with the applicants to ensure patients are fully informed and where appropriate supported.

6.5.3 The SEL ICB IFR team will communicate decisions to the clinical applicant by letter or email. In the event of funding being refused this communication will include details of the appeal process.

6.5.4 The SEL ICB IFR team will communicate decisions to close cases to the applicant, by letter or email.

6.6 Urgent Applications

6.6.1 If an application is marked as urgent and there is a clear clinical reason that the patient's health will be compromised by waiting until the next scheduled IFR panel meeting for a decision to be made the application can be processed through the Urgent Application Route. It is expected that only a small minority of IFRs will be urgent and these will usually involve life-threatening conditions.

6.6.2 The decision to treat in the event of immediate or life-threatening circumstances must be made in accordance with NHS Approved Provider (Trust) governance mechanisms

and the Trust's Duty of Care towards the patient. However, treating without IFR funding approval will be at the Trust's own financial risk.

- 6.6.3 In order to ensure that a decision can be made quickly an urgent application may be considered by a specially convened group (See also 4.4.4).
- 6.6.4 The group considering an urgent case will usually confer either virtually on line or by telephone conference. However, in special circumstances when this is not possible this will be done via email.
- 6.6.5 The decision making process for urgent IFRs will follow the ethical decision making framework and will consider the nature and extent of the evidence base for a treatment. This will be fully documented and reported at the next full IFR Panel meeting for noting and information sharing with the full IFR panel.
- 6.6.6 Decision timeframes and deadlines for urgent cases are as per the ICB IFR Operating Procedures and Terms of Reference.

6.7 Triage

- 6.7.1 The purpose of triage is to determine that the IFR is eligible for consideration by the IFR Panel. The team members will reference the following questions:
 - Is the treatment requested funded within an existing commissioning policy?
 - Is the treatment requested covered by another SEL policy or process?
 - Is the treatment an obvious Service Development (i.e. a request pertaining to a cohort of patients and not reflective of an individual's clinical circumstances)?
 - Does the submission make an arguable case for clinical exceptionality or rarity? If submitted on the basis of exceptionality does the submission demonstrate why and how this patient might be expected to gain more benefit compared to other patients with this condition?
 - Is the request an appeal or resubmission of a previous case?
- 6.7.2 The triage group has the authority to close cases when further information has not been received in the given timescales or a repeat application containing no new or additional information has been received. All case closures are reported to the IFR Panel.

6.8 The IFR Panel

- 6.8.1 The IFR panel will be multi-disciplinary with membership and quoracy in line with the terms of reference for the IFR panel – see Appendix D.
- 6.8.2 Requesting clinicians or patients will not be invited to attend the IFR panel. However patients may submit, alongside the application by the treating clinician, additional information in writing for consideration. Any information submitted by a patient will be given due respect by the Panel. For guidance on complaints and the appeal process, see relevant sections of this policy.
- 6.8.3 Consideration of drugs applications requires the presence of a Pharmacist to present the drug case and another Senior Pharmacist as a decision maker.

- 6.8.4 Pharmacists and Public Health representatives will be asked to conduct evidence reviews to enable fully informed decisions to be made by the IFR panel (see section 6.4 Evidence Base).
- 6.8.5 Decisions made will follow the ethical decision making framework and will consider the nature and extent of the evidence base for a treatment. Clinical circumstances define the clinical features or progression of the named patient's medical condition as opposed to the patient's social or personal circumstances.
- 6.8.6 ICBs have to be mindful of the clinical consequences of any financial decisions, and a decision to fund an IFR has the potential to result in direct displacement of another service.
- 6.8.7 All IFR panel members must declare any known conflict of interest prior to the commencement of the meeting.
- 6.8.8 Should any of the cases being discussed relate to a panel member the administrator should bring this potential conflict of interest to the attention of the Chair.
- 6.8.9 Should the Chair have a known conflict of interest in any of the cases being discussed they must withdraw from discussions of those cases and an alternate chair nominated for the discussion.
- 6.8.10 In working towards a decision, the Chair will test whether there is a consensus within the meeting. If there is a difference of views, funding decisions shall be determined by a majority of the votes of members present and voting on the request. In the case of an equal vote, the Chair shall have the casting vote.
- 6.8.11 The IFR panel may make the following decisions:
- funding refused;
 - funding approved without conditions;
 - funding approved with conditions;
 - deferred pending further information.
- 6.8.12 Funding may be approved for an initial course of treatment with further funding conditional upon the patient's response. The submission to the Panel of a report detailing the response observed after the initial course of treatment would be required for further consideration to be given to the submission.
- 6.8.13 The IFR Panel may make decisions up to the following financial limits per patient per year:
- Drugs: £25,000
 - Non-drugs: £20,000
- The IFR Panel may make recommendations for funding beyond the above financial limits; the final ICB decision on any IFR Panel funding recommendations above the thresholds noted above will be made by an appropriate ICB committee or sub group of the ICB.
- 6.8.14 All discussions taking place during a panel meeting are confidential. Cases may not be discussed outside the panel meeting except with the explicit agreement of the chair.

7 Appeals Process

- 7.0.1 The IFR Appeal process enables applicants to appeal against the decision made by the IFR Panel.
- 7.0.2 The focus of the Appeals Panel is the process that the IFR Panel used to reach a decision and not the decision itself. Applicants or patients wishing to complain about the decision itself should contact the relevant PALS team for advice or complaints team to make a formal complaint.
- 7.0.3 Appeal requests must be submitted in writing to the SEL ICB IFR team within 30 days of the date of the decision letter to decline funding.
- 7.0.4 Appeal requests must be made by a clinician on behalf of the patient.
- 7.0.5 Supporting statements from the patient and third parties can be submitted to accompany the request for consideration as part of the appeal, but no new evidence can be submitted. If new evidence is provided following a decision to decline funding, the correct procedure is to resubmit a request for reconsideration as an IFR.
- 7.0.6 The appeal request must indicate the applicant's grounds for appeal. There are 3 grounds for appeal that can be considered:
- Illegality: the refusal of the request was not an option that could lawfully have been taken by the IFR panel.
 - Procedural impropriety: There were substantial and/or serious procedural errors in the way in which the IFR Process was conducted.
 - Irrationality: Whether the decision was irrational in light of the information available to the Panel.
- 7.0.7 The triage group will undertake a preliminary review of an appeal request assessing the submission against the grounds for appeal criteria listed above.
- 7.0.8 All IFR Appeal Panel members must be independent of any of the original decision making processes and not have been a member of the IFR Panel involved in the original decision.
- 7.0.9 In working towards a decision, the Chair will test whether there is a consensus within the meeting. If there is a difference of views, decisions shall be determined by a majority of the votes of members present and voting on the request. In the case of an equal vote, the Chair shall have the casting vote.
- 7.0.10 The Appeal panel may make the following decisions:
- IFR panel decision upheld
 - IFR panel decision not upheld; the case must be returned to the IFR panel for re consideration (see also 4.3.7)
- 7.0.11 When a decision is not upheld by the Appeal Panel, it will be returned to the IFR panel for reconsideration with the minutes from the Appeal Panel meeting detailing the grounds for the successful appeal.
- 7.0.12 When a decision is upheld by the appeal panel the appellant will be advised that if they wish to take the matter further this must be done through the NHS complaints process.
- 7.0.13 Applicants or patients who wish to complain about IFR decisions should contact the SEL ICB complaints team to submit a formal complaint. Applicants/patients should not use the IFR Appeal process to make a complaint about an IFR decision. The IFR

appeal process is solely for the purpose of appealing against the IFR decision-making process.

8 Commissioning Process

8.1 Service Developments

- 8.1.1 A Service Development is defined as a request pertaining to a cohort of patients and not reflective of an individual's clinical circumstances. The IFR Panel is not the appropriate route for service developments. These requests should go through the appropriate procedures within the requesting Trust in the first instance (see also 5.0.3).
- 8.1.2 If during the triage stage, a requested treatment is identified as a possible service development, the IFR Team will notify the applicant and the relevant commissioners.
- 8.1.3 Any drug service developments should go through the SEL Area Prescribing Committee. SEL ICB should develop a commissioning route for processing non-drug service developments.

8.2 Local decision-making (outside the IFR remit)

- 8.2.1 Where there is a clinical need for treatment but, due to a lack of exceptionality, the IFR process is not the correct funding approval route, such requests will be considered through a revision of the clinical policy (Treatment Access Policy - TAP) or through local commissioning.

9 Policy Review

9. 1 The IFR Policy will be reviewed annually or sooner in light of any changes in legislation, practice or local/national guidance.

Next review: June 2023

10 References

- 10.1 In constructing this policy a number of existing policy documents have been referred to, including:
- NHS Constitution 2012
 - 'Interim Standard Operating Procedures: The Management of Individual Funding Requests' NHS England, April 2013, Ref: NHSCB/COP/02
 - 'Interim Commissioning Policy: Individual Funding Requests' NHS England, April 2013, Ref: NHSCB/CP/03
 - NPC Supporting rational local decision-making about medicines (and treatments) 2009
 - Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatments 2009
 - South East London Individual Funding Requests Policy, April 2012

11 Associated Documentation

- South East London Treatment Access Policy (TAP)2019

Appendix A – IFR Process flowchart



SEL IFR process
flowchart IFR policy A)

Appendix B – IFR Application Form

IFR applications should be made online via Blueteq, the IFR database. Full details for registering with Blueteq and making an IFR application are in the following guide:



SEL Blueteq
submission guide 12.6

Applications submitted by email to the SEL IFR inbox (ifr@selondonics.nhs.uk) must be made on the current IFR application form as attached:



SEL ICB IFR
Application Form 2021

For further information or for support with applications please contact the IFR team on ifr@selondonics.nhs.uk.

Appendix C - IFR Triage Meeting: Terms of Reference



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Appendix D – IFR Panel Terms of Reference



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Appendix E – IFR Appeal Panel Terms of Reference



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Appendix E Appeal p:

Appendix F – Ethical Decision Making Framework



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Appendix G – IFR Operating timescales



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Appendix H – Governance: ICB Policy Approval

The South East London ICB IFR Policy was approved as follows: