Individual Funding Requests

Regional Scrutiny Committee

Standard Operating Procedure

IFR RSC
27 October 2020

Contents

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Target audience	Those responsible for the operation of the IFR process and related decision making, as well as healthcare professionals who wish to apply for treatments under the IFR policy. Those responsible for the governance and oversight of the IFR process.
Description	This standard operating procedure outlines how the management of the individual funding request process will operate.
Cross reference	DOH IFR policy IFR RSC Terms of Reference IFR Appeal Process IFR Guide for Patients
Contact details for further information	IFR RSC Secretariat ifrs@hscni.net
Document status	This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

1. Standard Operating Procedure statement

This document sets out how the process for managing Individual Funding Requests (IFRs) for Health and Social Care (HSC) in Northern Ireland will operate. IFRs are managed and considered for funding in line with the DoH Individual funding requests policy (https://www.health-ni.gov.uk/sites/default/files/publications/health/ifr-policy.pdf)

2. Equality Statement

Section 75 of the NI Act 1998 requires all public bodies in carrying out their functions to have due regard to the need to promote equality of opportunity between:

- Persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- Men and women generally;
- Persons with a disability and persons without; and
- Persons with dependants and persons without.

In addition, without prejudice to the above, public bodies must also in carrying out their functions have regard to the desirability to promote good relations between persons of a different religious belief, political opinion or racial group. This policy will apply regionally and should not present any specific rural impact.

An equality screening of this document applying the same parameters as were used in the DoH Equality screening of the new IFR policy has been undertaken. The outcome of the screening was that there was no evidence of disproportionate impact on any Section 75 Equality group and that a full equality impact assessment was not indicated.

3. Introduction

3.1 Overview of the process for the consideration of IFRs

3.1.1 Roles and responsibilities

This document sets out how the process for managing individual funding requests (IFRs) will operate. 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 DoH IFR policy. It should be read in conjunction with the *DoH IFR policy document*.

The Health and Social Care Board (HSCB) is the statutory body responsible for the consideration of IFRs. The DoH IFR policy describes the underpinning policy framework which will apply to the management of IFRs.

There is a single process for the operational management of all IFR requests. This process is the remit of the IFR RSC which includes an administrative team (IFR RSC Secretariat) which is flexible and responsive to requests and enquiries on a regional basis. Decisions are made by the regionally representative IFR RSC and members are expected to participate regularly to promote consistency in decision making. Consistency is particularly important for the roles of Chair and deputy Chair.

3.1.2 Patients' Best Interests

The primary purpose of the IFR process is to ensure that a robust mechanism exists for people to access medicines not routinely commissioned, subject to certain criteria being met.

The RSC aims to address patients' best interests in several ways, particularly regarding the timeliness of decision making and robust communication to the requesting clinicians. Specific steps include the following:

1. The RSC comprises clinicians across a broad range of specialities, ensuring a broad based discussion of the relevant clinical matters

2. The RSC ensures as timely a response as possible to all individual funding requests
    - It meets weekly to make decisions on non-urgent requests.
    - Additionally it has robust arrangements for the consideration of urgent requests as detailed in section 3.3.2.
    - A detailed response to the requesting clinician is issued within 5 working days, but where possible every effort is made to issue a response within 24 hours of the RSC meeting.
3. The RSC will reconsider the IFR if additional relevant information is provided by the requesting clinician. The timeliness of any reconsideration is consistent with that applied to the first consideration.

4. The RSC is aware of the close linkage to commissioning arrangements for new medicines, particularly the arrangement by which new medicines are monitored during the early phase of their commissioning (cost per case arrangements).

5. There is sometimes ambiguity regarding whether a request should be considered as a CPC or an IFR, and such ambiguity may result in unintended delays in a clinician receiving approval to prescribe a new medicine. To address this and to avoid any delay in patients receiving appropriate treatment, the RSC is working to establish close working arrangements with HSCB colleagues involved in the CPC process.

6. The HSCB has an appeals process which allows clinicians to appeal the decision of the RSC. The appeals procedure is set out in Section 5 and Appendix E of the SOP.

3.2 Individual Funding Requests

3.2.1 DoH IFR Policy

Hospital consultants, on behalf of their patients, can make an application to the Individual Funding Request (IFR) Regional Scrutiny Committee (RSC) for treatment which is not normally commissioned by the HSCB under defined conditions, specifically:

1. The patient is suffering from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment

   OR

2. The request is for a new intervention or, for an intervention for a new indication outwith the licensed indication, where no commissioning arrangements exist;

   OR

3. The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment outwith the licensed clinical indication, with the explicit consent of the patient.

3.2.2 Criteria for the consideration of treatments outwith their UK marketing authorisation

Specific criteria for the consideration of treatments outwith their UK marketing authorisation ('off-label treatments') is as follows:

- Requests should be supported by appropriate evidence (i.e. clinical trial, national/international guidelines etc.) and this should be included with the application;
- The treatment must be for a drug which currently holds a UK marketing authorisation;
- Sufficient detail should be provided on the likely costs incurred (including infrastructure costs);
- The relevant Trust must agree that the treatment can be delivered within existing Trust structures;
- The cost for the treatment is greater than £10,000 per year;

- Treatments included within the compendium of paediatric drugs do not require an IFR;
- All appropriate information is provided to the RSC within the application form with additional supporting information encouraged. Incomplete applications will be returned to the requesting clinician without consideration.

3.3 IFR timescales and urgent cases

3.3.1 Timescales

The IFR RSC will generally meet on one day each week to consider IFRs. Currently these are scheduled to take place each Tuesday. All IFR requests should be forwarded to the IFR Secretariat via the IFR Inbox (ifrs@hscni.net) by noon each Thursday.

The standard period for providing a substantive response to an IFR (i.e. a decision on the funding request) is a maximum period of 5 working days from the date of the IFR RSC meeting. In most circumstances the aim is to provide a response in 2 working days.

This 5 working day period excludes any working days where the IFR Secretariat is awaiting information sought from the requester. At any point in the IFR process further information can be requested to clarify the request. If the requester does not provide a response within 30 calendar days the IFR will be closed and the requester informed. Such a request can be reopened on submission of the additional information.

3.3.2 Urgent cases

It is recognised that there will be occasions when an urgent decision needs to be made to consider funding for treatment for an individual patient outside normal policies and processes i.e. a response is required within 48 hours of receipt of the request.

An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the RSC.

Any application received that requires a response within 48 hours will, if possible, be included on the agenda of a RSC meeting, if one is scheduled within the 48 hour period.

If this is not possible, the RSC Chair and vice-chair will discuss the request and provide a response to the requesting clinician within 2 working days of receiving the request. In this circumstance the IFR will be brought to the next RSC meeting for full discussion.

If the chair and vice-chair have approved the request that decision will stand. The Committee may however wish to consider learning arising from the request that may have a bearing on future IFRs.

If the chair and vice-chair have not approved the request, the Committee will have the discretion to amend this initial decision in light of the more detailed discussion among the full Committee.

4. The IFR Process

The IFR process is illustrated in the flowchart in Appendix A.

4.1 Administrative screening

4.1.1 The standard IFR RSC application form must be used for all requests. This form can be found at Appendix B and is also available in MS Word format alongside the published DoH IFR policy and the RSC Standard Operating Procedure on the HSCB website.

4.1.2 If a request for funding a treatment is not submitted on the IFR RSC form the requester will be asked to resubmit using this form.

4.1.3 All fields in the IFR RSC form need to be completed in order for the request to progress. Any request form which is incomplete will be returned to the requester for completion.

4.1.4 IFR RSC forms must be typewritten. Handwritten IFRs will be returned to the requester for amendment. This is ensure that all content is legible and the best case made on behalf of the patient.

4.1.5 A request should come from a medically qualified doctor directly responsible for the care of the patient.

4.1.6 The request must come from a provider who is contracted by the HSCB 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. The IFR will not progress at this point.

4.1.7 Requests cannot be accepted from General Practitioners. General Practitioners who request treatments will be advised to make a referral to an appropriate consultant clinician within a HSC Trust.

4.1.8 Requests cannot be accepted from a patient or their non-clinical representative. This is because the process is to enable an HSC clinician to apply for funding to support the provision of HSC treatment by that clinician to the patient.

4.1.9 Unless the following paragraph applies (4.1.10), 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 document *Individual Funding Requests – a Guide for Patients* (Appendix F) may be given to patients as part of the consent process to ensure that the patient has received sufficient information to support informed consent.

4.1.10 If the requesting clinician considers that the patient does not have capacity to give consent this should be indicated and explained on the IFR RSC 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 clinician explanation as to why the application is being made without consent cannot be processed and will be returned for amendment.

4.1.11 Requests should be supported by a clinical lead (Clinical Director or equivalent) and the relevant pharmacy lead should be made aware.

4.1.12 In order to be considered any published references or other supporting documents (e.g. Trust Guidance) must be provided in full text.

4.1.13 If a request for treatment that is not the commissioning responsibility of the HSCB is received the requester will be advised accordingly and the case record closed.

4.1.14 If an IFR application form (Appendix B) meets all requirements to be able to proceed, the request and all relevant documentation will be made available to the IFR RSC at least two working days prior to the IFR RSC decision meeting.

4.1.15 Each IFR RSC member will populate the IFR RSC Decision Framework Document (DFD) which can be found at Appendix C. This document will be the mechanism for recording the clinical considerations for each RSC member in advance of the RSC meeting.

Following the meeting of the RSC, the IFR RSC Secretariat will record the collective decision of the RSC for each IFR including the explicit reasons for thAT decision.

4.1.16 Where information is insufficient to permit the RSC to come to a decision the IFR will be returned to the requester specifying the additional information required to enable the request to proceed. The request can be re-submitted at any point.

4.2 The IFR Regional Scrutiny Committee (IFR RSC)

4.2.1 IFR RSC meetings and membership are scheduled in a rolling programme at least six months in advance.

4.2.2 When an IFR request is referred for consideration the IFR RSC secretariat will schedule the request to be considered at the next meeting.

4.2.3 The patient/patient representative, or their clinical or non-clinical representative, is not entitled to attend the proceedings in person.

4.2.4 The IFR RSC secretariat will provide the IFR RSC members with an information pack which will include the original request form, any supporting documents or correspondence and the IFR RSC DFD (Appendix C) for use during the IFR RSC meeting.

4.2.5 All documentation available to the IFR RSC will be anonymised to protect confidentiality and minimise the potential for identification bias.

4.2.6 A nominated member of the IFR RSC will introduce the clinical background to the case at the IFR RSC meeting. The Committee will discuss the case in relation to the questions outlined in the IFR RSC DFD and reach a decision on funding under the IFR process.

4.2.7 The terms of reference for the IFR RSC are in Appendix D.

4.3 IFR RSC decision making

4.3.1 The IFR RSC works on behalf of the HSCB and makes decisions in respect of funding for individual cases only. It is not the role of the IFR RSC, by its decisions, to make clinical commissioning policy on behalf of the HSCB.

4.3.2 The IFR RSC will apply the criteria in the IFR policy and record the decision of the IFR RSC. The IFR RSC must be clear about the rationale for the decision. Recording of the decision will be reflected in a summary statement which will be agreed by the Committee and used to communicate the decision to the requesting clinician.

4.3.3 If commissioning arrangements already exist the IFR RSC 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 requester with advice to consider the case against the commissioning arrangements.

4.3.4 There may be cases where the condition being treated is said to occur in a small number of patients, insufficient to trigger the need for a clinical commissioning policy. Such cases will be considered on a case by case basis and where there is a known cohort who could similarly benefit from the treatment requiring a commissioning decision/service development and funding source, approval will be given where significantly different clinical circumstances can be demonstrated for the individual patient. While the commissioning position is being considered, the IFR RSC will continue to consider requests for funding for treatment under the IFR process.

4.3.5 The IFR RSC may also seek scientific and technical information relating to the natural course of the condition, the place of the treatment in the patient pathway or the evidence base for the requested treatment.

4.3.6 The record of attendance and any general discussion or business of the IFR RSC, will form the minutes of the meeting. These will be agreed by the IFR RSC and signed off by the Chair.

4.4 Outcomes at IFR RSC

4.4.1 The decisions available to the IFR RSC are:

- The treatment is to be funded in line with the requesting clinician's request;
- The treatment is to be funded line with the requesting clinician's request with additional conditions e.g. duration of treatment;
- The treatment should not be funded;
- A decision cannot be reached based on the information provided.

Where a decision cannot be reached based on the information provided within the IFR, the RSC may request further detail and reconsider at a future date.

4.4.2 Where the decision by the IFR RSC is to fund the treatment requested a letter will be sent via electronic copy to:

a) the requesting clinician;

b) the Trust senior pharmaceutical officer and;

c) the Trust clinical director.

4.4.3 The IFR RSC will require an update on the clinical outcome of treatment to determine whether it has resulted in benefit to the patient. An appropriate review date will be recorded on the day the decision to fund is made. The IFR recording system will flag when review dates are due and the IFR RSC secretariat will request feedback on outcomes and forward to the IFR RSC.

4.4.4 Provider Trusts and their clinicians are expected to comply with such requests for information on the outcome of treatment for their patients. Non-compliance may have an impact on the consideration of future requests from the same clinician / provider.

4.4.5 The IFR RSC may wish to seek further information from requesting clinicians to clarify specific issues relating to the case. Information will only be sought at this stage if there is a clear understanding that an answer will lead to a decision by the IFR RSC.

4.4.6 Where the IFR RSC decision is not to fund a request a written response will be sent to the requesting clinician explaining the reasons for the decision and outlining the options that are available. This may be copied to the patient's GP in accordance with the patient consent arrangements.

4.4.7 Where the IFR RSC has decided to conditionally fund an IFR for a specified period of time the IFR RSC should receive evidence to enable a further decision to be made. A review date will be recorded on the day the decision to conditionally fund is made. The specifics of the decision will be communicated to the requesting clinician, who must provide the information before any further funding decision can be made by the IFR RSC. The IFR system will flag when the review date is due and the IFR RSC secretariat will request the further information from the clinician and forward to the IFR RSC. Where the requested information is not provided no further funding can be made and the clinician will be notified of this decision.

4.4.8 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 remains with the requesting clinician.

4.5 Reconsideration by the IFR RSC

4.5.1 If a requesting clinician believes they have significant new clinical evidence that was not provided in the original submission which they feel may have made a difference to the decision made, the clinician can submit a new IFR and include this new evidence.

4.5.2 The IFR RSC will determine if the new information provides a significantly different clinical picture when the case is presented at a subsequent IFR RSC meeting. The outcome of the reconsideration will be communicated as described for the first IFR RSC meeting.

5. Appealing IFR RSC Decisions

5.1 Requests for an appeal of the IFR RSC Decision

5.1.1 The requesting clinician may make a request for an appeal of an IFR RSC decision. The document *'Individual Funding Requests, Regional Scrutiny Committee, Appealing a Decision'* can be found at Appendix E.

5.1.2 The HSCB will adjudicate on appeals. The request should be made in writing and, addressed to the Chair of the IFR Appeal Panel. Such requests must be lodged within 30 calendar days of the date of the letter setting out the IFR RSC decision. The Chair of the IFR Appeal Panel may exercise discretion in accepting a request for a review outside this time limit if there is good reason to do so.

5.1.3 Appeal requests should be clearly marked as a 'Request for an IFR Appeal' and sent via the IFR RSC Secretariat using the contact details in the IFR outcome letter. An appeal must have the support of the relevant Trust Clinical Director and Senior Trust management colleagues.

5.1.4 The request for review must set the grounds on which the IFR RSC decision is being challenged. A review can only be requested on the grounds set out in the DOH IFR Policy document. The hospital consultant must explain his or her reasons for considering that the decision taken by the RSC was either:

- procedurally improper;

  and/or

- in his/her opinion a decision which no reasonable RSC could have reached.

5.1.5 The Appeal Process will be based on the criteria set out in the *DoH IFR Policy document, section 1.25.* In this context the role of the Appeal Panel is to determine:

- The process followed by the RSC was consistent with the operational policy;
- The decision reached by the RSC:
  i. was taken following a process which was consistent with the policy;
  ii. had taken into account and weighed all the relevant evidence;
  iii. had not taken into account irrelevant factors outwith the policy;
  iv. indicated that the RSC acted impartially and within their competence;.
  v. was a decision which a reasonable RSC was entitled to reach.

6. Monitoring the IFR Process

6.1 Outputs

6.1.1 The RSC Chair and the NICE/RSC Commissioning Team will be updated regularly on the outcomes of the IFR requests received, including estimates of the in-year financial impact.

6.1.2 A quarterly report to the Director of Commissioning providing oversight of the key performance indicators for the IFR process.

6.1.3 An annual report will be submitted to the Board of the HSCB and onward referral to the Department of Health as appropriate.

6.2 Key performance indicators

6.2.1 **Timeline: 5 working days from decision to outcome**
This period is from IFR RSC decision-making to the outcome of the request being communicated to the requester. It excludes days spent awaiting information from the requester. Monitoring and reporting will also include the average turnaround timelines.

6.3 Roles and Responsibilities

6.3.1 The IFR RSC manager will be responsible for ensuring that the appropriate processes and procedures are in place to enable production of the required outputs. The IFR RSC Manager is accountable to the NICE / RSC Commissioning Team and the Director of Commissioning, HSCB.

6.3.2 Reports to RSC Chair and the NICE / RSC Commissioning Team on data extracted from IFR Database will be the responsibility of the IFR RSC manager. The IFR RSC Manager is also responsible for ensuring that the live database is updated within a maximum of five working days of each RSC meeting.

6.3.3 Reports will be made available to the NICE / RSC Commissioning Team on a monthly basis.

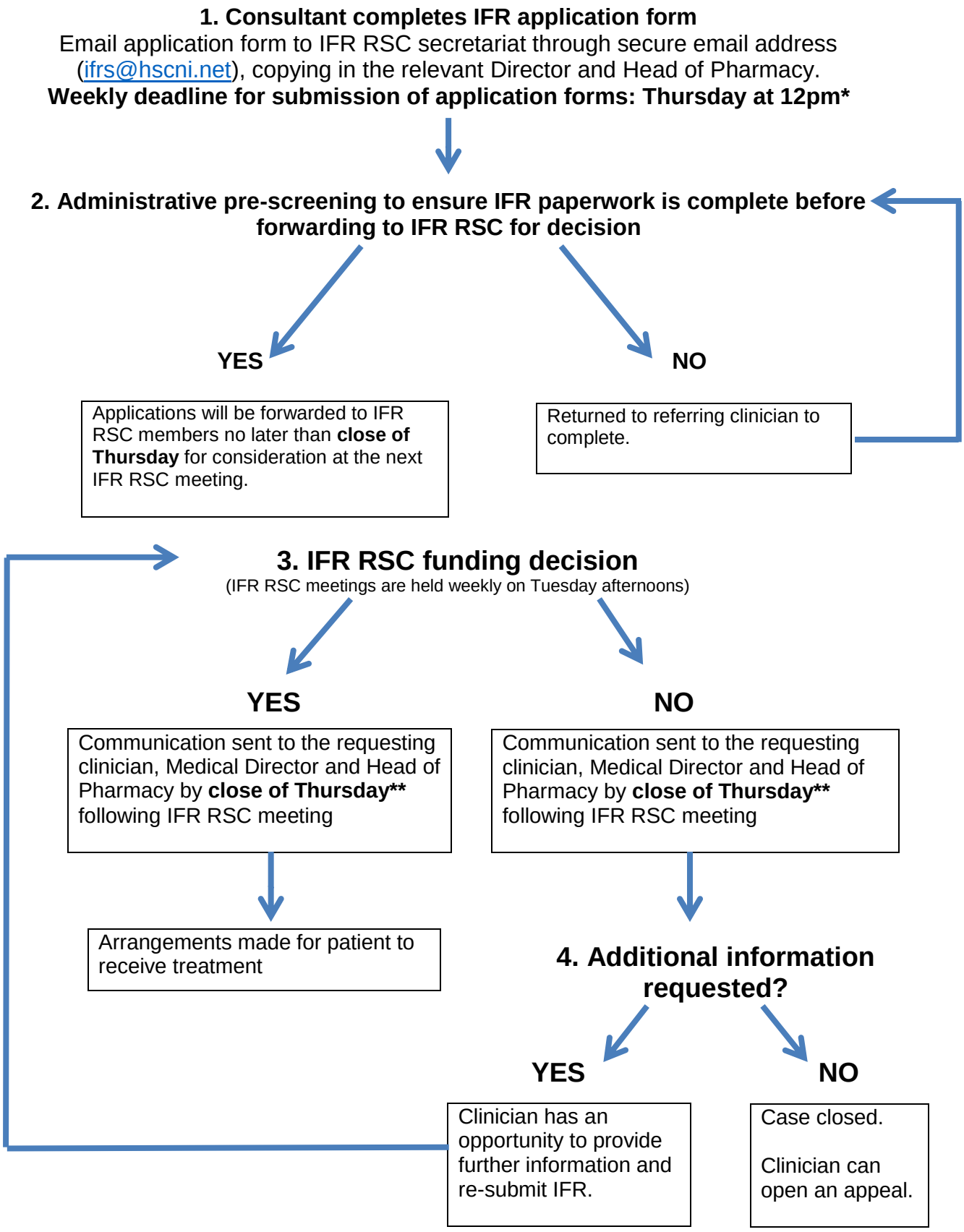
7. Glossary

DFD	Decision Framework Document
DoH	Department of Health
GP	General Practitioner
HSC	Health and Social Care
HSCB	Health and Social Care Board
IFR	Individual Funding Request
NICaN	Northern Ireland Cancer Network
NICE	National Institute for Health and Clinical Excellence
PCC	Patient and Client Council
PHA	Public Health Agency
RSC	Regional Scrutiny Committee
SOP	Standard Operating Procedure

8. Appendices

- Appendix A: IFR Process Flowchart
- Appendix B: Individual Funding Request (IFR) Form
- Appendix C: IFR Decision Framework Document
- Appendix D: Terms of Reference: IFR Regional Scrutiny Committee
- Appendix E: Individual Funding Request - Appealing a Decision
- Appendix F: Individual Funding Request - A Guide for Patients

Appendix A: IFR Process Flowchart



* Applications received after 12pm each Thursday will be processed the following week.

** Decisions will be communicated no later than 5pm on the following Monday.

*** An appeal must have the support of the relevant Trust Clinical Director and Senior Trust management colleagues.

Appendix B: Individual Funding Request (IFR) Application Form

Notes for completion:

When should IFR application form be completed?

Requesting clinicians are advised to review the Department of Health: Individual Funding Requests: Policy Document to ensure an IFR is the appropriate mechanism to obtain funding.

DoH IFR Policy Document –
https://www.health-ni.gov.uk/sites/default/files/publications/health/ifr-policy.pdf

How should an IFR application form be completed?

Responsibility lies with the requesting clinician to present to the Regional Scrutiny Committee a full submission which sets out:

- a comprehensive, accurate and balanced picture of the patient history (including previous treatments and results/outcome of these) and present state/severity of the patient's clinical condition.
- the nature of the treatment requested
- the evidence base for the anticipated benefits of treatment
- the associated costs.

The requesting clinician may include a covering letter or additional supporting information where required. Requests with incomplete information or where assessment of the request cannot be made on the information provided will be returned with a request for clarification.

What will the Regional Scrutiny Committee consider when making a decision?

The RSC panel will review the submission in line with the IFR policy and the criteria for funding approval. The RSC will seek to determine whether the application has demonstrated that a patient's clinical circumstances are significantly different to other patients. To make this determination the RSC will:

- compare the patient to other patients with the same presenting medical condition, at the same stage of progression.
- only consider the patient's presenting medical condition and the likely benefits from the proposed treatment.
- only consider clinical factors when reaching a decision. Non-clinical factors including age, marital status or employment, or any such information which does not have a direct clinical connection to the patient's clinical circumstances will not be considered.
- consider the relative cost of treatment and the likely benefit to the individual patient.

Where should the completed application form be sent?

Please email the application form and all relevant documentation to: ifrs@hscni.net.

1 - PATIENT DETAILS			
Urgent Request: Yes: ☐ No: ☐ *(Note: An urgent request is one which requires response within 48 hours of submission because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the RSC.)*		Date of Request:	
Patient Initials:		Gender:	
Date of Birth:		Age:	
Patient Postcode:		H&C No:	
GP Name & Practice:		GP Postcode:	

In accordance with guidance on eligibility given in "Healthcare for Frontier Workers" please confirm that the patient is ordinarily resident in Northern Ireland and automatically entitled to free HSC treatment:	☐
This IFR has been discussed in full with the patient or patient representative and are consenting for the RSC to receive and review confidential clinical information about their health to enable full consideration of this funding request.	☐

2 - PATIENT DIAGNOSIS	
Primary diagnosis related to this request:	
Significant co-morbidities:	
How many patients would HSCNI expect to see in one year with this condition:	

3 - CLINICAL BACKGROUND	
Outline the detailed background to the patient's clinical situation, timeline (including previous treatments with start and stop dates), current status symptoms, and any intolerance or adverse events.	
Current Treatment (avoid abbreviations or acronyms):	
4 - STANDARD TREATMENT	
What is the standard treatment for this condition?	
Why is the standard treatment not appropriate for this patient? *Please provide full explanation*	

5 - TREATMENT REQUESTED	
Name of treatment requested: *(include any alternative terms)*	
Is the treatment licenced in the UK for use in this particular indication?	Yes: ☒ No: ☐
Is this a single treatment or procedure or part of a course?	Single treatment ☐ Course ☐
If treatment is part of a course please provide further information:	
• *Treatment intervals:*	
• *Cost of requested treatment (e.g. per cycle / per month)*	
• *Total cost for requested treatment and assumptions used in determining this:*	
How will the intervention be given to the patient (e.g. oral / IV etc.)?	
How many patients currently attend HSCNI with this condition and these clinical circumstances for which you anticipate this treatment might be considered?	
Where will the treatment be provided? *If treatment is to be received outside NI, please include a copy of the referral letter.*	

6 - ANTICIPATED OUTCOMES	
What are the anticipated outcomes of the treatment requested for this patient?	

How will the outcomes of the treatment requested be measured?	
When will these outcomes be expected?	
What stopping criteria will be in place?	
7 - EVIDENCE APPRAISAL	
What is the evidence base for the clinical benefit and safety of this procedure / treatment? *Please include references and append these to this request.* *Please provide as much information as possible to allow for appropriate assessment of the request. Continue on a separate sheet if necessary.*	

Has the procedure / treatment been subjected to NICE appraisal or other scrutiny (for example SMC)?	Yes ☐ No ☐ If Yes, please give details:
Is the procedure/treatment part of a current or planned national or international clinical trial or audit?	Yes ☐ No ☐ If Yes, please give details:
Is the procedure being requested part of an EAMS?	Yes ☐ No ☐ If Yes please give details:

8 - CLINICAL CIRCUMSTANCES -
CRITERIA UNDER WHICH THIS APPLICATION IS MADE

(Non-clinical factors cannot be taken into account by the IFR Panel)

Do you consider this patient to: • Suffer from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy;	Yes ☐ No ☐
• Require a new intervention or, for an intervention for a new indication outwith its licensed indication, where no commissioning arrangements exists;	Yes ☐ No ☐
• Have a rare clinical circumstance for whom you wish to use an existing treatment outwith its licensed clinical indication.	Yes ☐ No ☐

Demonstrate why this patient is significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition.	

Demonstrate why this patient is likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.			
9 - TRUST SUPPORT /APPROVAL OF REQUEST			
Has the request been supported by appropriate clinical peers?	Yes ☐ No ☐		
Name of provider Clinical Director (or equivalent):			
Email address of Clinical Director:		Date of approval given:	
Signature of Clinical Director: *(may be electronic)*			
Name of provider Service Manager (or equivalent):			
Email address of Service Manager:		Date of approval given:	
Signature of Service Manager: *(may be electronic)*			

10 - REQUESTER DETAILS			
Name of Requester:			
Organisation:		Signature of Requester: *(may be electronic)*	
Contact telephone number:		Job role:	
HSCNI email address:			
Clinicians are required to disclose all material facts as part of this process including direct interest (e.g. financial, research, publication of opinion etc.)			
Are there any other comments/considerations that are appropriate to bring to the attention of the IFR RSC?			

Appendix C: IFR RSC Decision Framework Document

IFR RSC DECISION FRAMEWORK DOCUMENT

A copy of this form is provided to each IFR RSC member for each request. It should be completed and forwarded to the IFR RSC Secretariat in advance of the next scheduled IFR RSC meeting.

IFR RSC meeting date:		**Request reference:**	
IFR RSC Member:		**Intervention Requested:**	

NO.	POINTS FOR CONSIDERATION	NOTES	DECISION (Yes / No)
1	**PATIENT DETAILS**		
1.1	Have all the relevant patient details been provided?		

2	**PATIENT DIAGNOSIS**		
2.1	Has all the relevant information regarding the patient's diagnosis been provided?		
3	**CLINICAL BACKGROUND**		
3.1	Has all the relevant information regarding the clinical background been provided?		
4	**STANDARD TREATMENT**		
4.1	Has the standard treatment option been clearly specified and sufficient detail provided on why it is not an appropriate option for the patient?		

5	**TREATMENT REQUESTED**		
5.1	Has sufficient information been provided on the specific treatment requested including duration of treatment, mode of delivery and cost?		
6	**ANTICIPATED OUTCOMES**		
6.1	Has sufficient information been provided on the anticipated outcomes for this patient including how these outcomes will measured?		
7	**EVIDENCE APPRAISAL**		
7.1	Has sufficient evidence been provided on the clinical benefit and safety of this treatment?		
8	**CLINICAL CIRCUMSTANCES – CRITERIA UNDER WHICH THIS APPLICATION IS MADE**		
8.1	Has the criteria for submitting the request as an IFR been met?		

8.2	Has the request demonstrated why this patient is significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition?		
8.3	Has the request demonstrated why this patient is likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition?		
9	**TRUST SUPPORT / APPROVAL OF REQUEST**		
9.1	Has the request received the appropriate support/approval within the Trust?		
10	**REQUESTER DETAILS**		
10.1	Has the requester provided the appropriate information including any direct interests relevant to the approval of this request?		

11	SUMMARY OF DECISION		
11.1	**FUNDED** Summarise the reasons for the decision made, addressing all the arguments for clinical exceptionality made by the requester. Include any conditions, outcome measures to be monitored and review mechanisms required. Date of review (if applicable):		
11.2	**NOT FUNDED** Summarise the reasons for the decision made, addressing all the arguments for clinical exceptionality made by the requester.		

Appendix D: Terms of Reference: IFR Regional Scrutiny Committee

Individual Funding Request Regional Scrutiny Committee (IFR RSC) Purpose, terms of reference and membership

Background

There are treatments that are not routinely available within HSC for various reasons, but which can be made available through the Individual Funding Request (IFR) process, depending on eligibility.

Following an evaluation and subsequent consultation on proposals to change the IFR process which identified areas with the potential to improve patient access, a task and finish group (T&FG) was established to take forward this modernisation of the IFR process. The terms of reference for the T&FG were:

- To develop new clinically based exceptionality criteria, taking account of the findings of the evaluation which identified a 95% criterion as being too restrictive;
- Establish regional, clinically led scrutiny committee/s (RSC) to underpin the current process which will ensure all IFR applications are subject to regionally consistent clinical input and peer review;
- Revise existing IFR guidance to include greater transparency, accountability and governance, and enhance patient involvement;

The following paper sets out the terms of reference and the membership for the RSC.

TERMS OF REFERENCE AND MEMBERSHIP FOR AN INDIVIDUAL FUNDING REQUEST REGIONAL SCRUTINY COMMITTEE

Committee name

The committee shall be named the 'Individual Funding Request Regional Scrutiny Committee', which can be referred as the 'IFR RSC', 'RSC' or 'the Committee'

Type

The IFR RSC shall be a committee within existing Health and Social Care Board (HSCB) governance structures, with authority delegated by the Department of Health.

Purpose

The purpose of the IFR RSC is to consider IFRs for treatment that are not normally commissioned by the HSCB as described in the DoH policy document *Individual Funding Requests: Policy Document*, which will be called 'the DoH IFR Policy' throughout this paper. The DoH IFR Policy should be read in conjunction with this paper. In this context, a treatment usually refers to a specific drug or medicine.

Accountability

The IFR RSC shall be accountable to the Director of Commissioning, HSCB.

Scope

The IFR RSC shall be entitled to consider individual funding request from appropriate hospital consultants and decide on the approval of funding for treatment for an individual patient under the following defined conditions as set out in the DoH IFR Policy:

- The request does not apply to a cohort of patients;

  AND

- The patient is suffering from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment;

  OR

- The request is for a new intervention or, for an intervention for a new indication outwith its licensed indication, where no commissioning arrangements exist;

  OR

- The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment outwith the licensed clinical indication, with the explicit consent of the patient.

Specific criteria for the consideration of treatments outwith their UK marketing authorisation ('off-label treatments') is as follows:

- Requests should be supported by appropriate evidence (i.e. clinical trial, national/international guidelines etc.) and this should be included with the application;
- The treatment must be for a drug which currently holds a UK marketing authorisation;
- Sufficient detail should be provided on the likely costs incurred (including infrastructure costs);
- The relevant Trust must agree that the treatment can be delivered within existing Trust structures;
- The cost for the treatment is greater than £10,000 per year;
- Treatments included within the compendium of paediatric drugs do not require an IFR;
- All appropriate information is provided to the RSC within the application form with additional supporting information encouraged. Incomplete applications will be returned to the requesting clinician without consideration.

The IFR RSC shall not make funding decisions:

- Where there is a request for a service development, i.e. that the request represents a cohort of 3 or more patients in a 12 month period;
- For treatments where no marketing authorisation exists in the UK for any indication;
- Where the cost for an individual patient is less than the threshold (£10,000 per annum depending on list price of treatment);
- Where commissioning arrangements are already in place;
- Where there is no, or little, evidence that the patient would benefit significantly more from the treatment than other patients with the same condition at the same stage;
- Influenced by non-clinical factors such as age, marital status or employment or any such information which does not have a direct clinical connection to the patient's clinical circumstances.

Authority
The IFR RSC shall have the authority, delegated by the Department of Health through the HSCB, to make decisions regarding funding applications for treatment for individual patients.

The decisions available to the IFR RSC are:

- The treatment is to be funded without conditions;
- The treatment is to be funded with conditions;
- The treatment should not be funded;
- A decision cannot be reached based on the information provided.

Where the cost for an individual patient is more than the threshold of £150,000 per year the RSC must inform the Director of Commissioning, HSCB. This does not affect the RSC's ability to reach a decision on a specific IFR. Rather it is to ensure senior HSCB staff are made aware of a potential cost pressure.

Membership
The IFR RSC shall comprise a multidisciplinary pool of suitably qualified and trained members such as:

- HSC Trust Drugs and Therapeutics Committee members and/or Pharmacy representatives;
- Secondary care clinicians.
- Public Health representative
- HSCB Pharmacy representative

- Lay member or patient representatives – e.g. NICaN, PCC, specialty charities – due to data protection lay members will be confined to oversight and governance roles only – not to sit on decision making panels.

Examples of specialties available to the core and sub-membership should include senior clinicians in the following areas:

- cancer – oncology/haematology/radiotherapy
- dermatology
- endocrinology
- gastroenterology
- genetics
- immunology
- infectious diseases
- medicine
- neurology
- paediatric oncology/haematology
- respiratory
- rheumatology
- surgery

Members of the IFR RSC shall serve as individuals, not as representatives of a particular organisation or interest group. Indemnity is provided by the Department of Health.

Declaration of Interests

All members will complete, on an annual basis, a DOI form. If there is any changing circumstance applicable then members will update their DOI and submit to the RSC secretariat.

Each RSC member will advise the RSC chair and RSC secretariat of material conflicts of interest in advance of the RSC meeting - ideally at least 24 hours in advance. A material conflict of interest may include:

- The patient for whom the IFR is being submitted is or has been under the care of the RSC member
- The member has discussed the individual case and contributed to the information contained in the IFR
- The member has been part of a MDT discussion at which there was a decision to submit an IFR
- The member has been the clinical director supporting the request

If it is determined that there is a material conflict of interest the member will recuse themselves from part or all of the meeting or the chair may ask that they recuse themselves.

In addition to the above, each RSC member will be asked at the outset of each RSC meeting to declare and potential conflicts of interests. The RSC chair will determine whether the potential COI is one that requires the member to recuse themselves from discussion in regard to any/all of the IFRs.

When a member recuses themselves from discussion they will leave the meeting for the particular agenda item on which there is a conflict. They will not participate in any discussion nor observe any discussion on that particular matter.

Governance
To ensure appropriate governance of the RSC, an oversight group will meet on a quarterly basis to consider procedural issues (including the SOP), activity and outcomes.

The RSC Oversight Group will be chaired by the Director of Commissioning and comprise members of the RSC and lay representation e.g. PCC, NICAN Board, NIRDP and HSCB Finance.

Training
The IFR RSC will be responsible for agreeing a standard operating procedure (SOP) which will be reviewed at regular intervals with appropriate version control. The DoH IFR Policy document and guiding principles agreed by the IFR Reform Task and Finish Group are available for direction as required.

Members must have received induction training to ensure that they are fully familiar with the DoH IFR Policy and the IFR RSC Standard Operating Procedure, before sitting on an IFR RSC.

Members should attend a training session at least once every year and sit on a IFR RSC at least twice a year in order to retain their qualification to serve on the Committee.

Quoracy
The IFR RSC will be considered quorate if, at a minimum, five members are present to make a decision, three of whom must be clinicians from Secondary Care.

The IFR RSC will be chaired by any of the members provided that s/he has sat as an IFR RSC member at least four times.

To ensure consistency the IFR RSC should have the same individual chairing as many meetings as feasible. In the absence of the regular Chair a deputy may preside.

Frequency
The IFR RSC will normally meet weekly, subject to submission of IFRs. The frequency of meetings may be subject to variation over time. Video conference and/or

other methods of remote communication should be available if and when required providing there is an accurate and auditable record of the decision making process.

Urgent Requests
Any application received that requires a response within 48 hours will, if possible, be included on the agenda of a RSC meeting, if one is scheduled within the 48 hour period.

If this is not possible, the RSC Chair and vice-chair will discuss the request and provide a response to the requesting clinician within 2 working days of receiving the request. In this circumstance the IFR will be brought to the next RSC meeting for full discussion.

If the chair and vice-chair have approved the request that decision will stand. The Committee may however wish to consider learning arising from the request that may have a bearing on future IFRs.

If the chair and vice-chair have not approved the request, the Committee will have the discretion to amend this initial decision in light of the more detailed discussion among the full Committee.

Confidentiality
IFR information will routinely be exchanged via secure HSC email, letter, fax or by telephone and will be anonymised to maintain the highest level of confidentiality. General Data Protection Regulation (GDPR) shall be observed at all times.

Reporting
An annual IFR performance report will be submitted via the IFR RSC Chair and Director of Commissioning, HSCB to the Department of Health. The performance report should have, at the minimum, a financial statement, an IFR decisions statement and an outcomes statement.

General information about the IFR process should be made available on the HSCB's website.

Resources and budget
The IFR RSC shall be supported by an administrative team to include at least one suitably qualified individual at HSC Band 8 who will be responsible for creating and managing a team which will incorporate IFR secretariat responsibilities.

The administration team will be responsible for liaison with and between IFR RSC members, hospital consultants, GPs and patients through appropriate communication channels, observing confidentiality at all times.

The administration team will be responsible for scheduling IFR RSC meetings as well as arranging training and/or any other management requirements. In addition the

administration team will be responsible for arranging an appeal procedure if this is required (see *'IFR RSC Appealing IFR Decisions'*).

The IFR RSC shall be initially allocated a budget of £300k for the administration team and IFR RSC members' remuneration (paid to employing Trusts). Other costs may include equipment, materials, room hire and miscellaneous costs such as legal advice. Funding will be allocated to Trusts based on the time commitment required by clinicians representing respective Trusts at the RSC, anticipated as one PA per RSC member and two PAs for the RSC chair.

Providing the resources to support the provision of the medicines for which the RSC has agreed funding will be the responsibility of the HSCB. Specific funding will be made available to Trusts and will be based on the cost of the medicine and duration of actual use.

The total annual expenditure for all IFRs should not exceed £5.5m. If costs are projected to exceed this, the HSCB will notify the Department as early as possible.

Review
The terms of reference of the IFR RSC shall be reviewed by the Oversight Group, initially on an annual basis.

Appendix E: Appealing IFR RSC Decisions

1. Requesting an appeal of an IFR RSC Decision

1.1 The requesting clinician may make a request for an appeal of an IFR RSC decision.

1.2 The request for review must set out the grounds on which the IFR RSC decision is being challenged. A review can only be requested on the grounds set out in the DoH IFR Policy document. The hospital consultant must explain his or her reasons for considering that the decision taken by the RSC was either:

- procedurally improper;

  and/or

- in his/her opinion a decision which no reasonable RSC could have reached.

1.3 The Appeal Process will be based on the criteria set out in the *DoH IFR Policy document, section 1.25.* In this context the role of the Appeal Panel is to determine:

- The process followed by the RSC was consistent with the operational policy;

- The decision reached by the RSC:
  i. was taken following a process which was consistent with the policy;
  ii. had taken into account and weighed all the relevant evidence;
  iii. had not taken into account irrelevant factors outwith the policy;
  iv. indicated that the RSC acted impartially and within their competence;
  v. was a decision which a reasonable RSC was entitled to reach.

1.4 The Health and Social Care Board (HSCB) will adjudicate on appeals. The request should be made in writing, addressed to the Chair of the IFR Appeal Panel. Such requests must be lodged within 30 calendar days of the date of the letter advising of the IFR RSC decision. The Chair of the IFR Appeal Panel may exercise discretion in accepting a request for a review outside this time limit if there is good reason to do so.

1.5 Appeal requests should be clearly marked as a ‘Request for an IFR Appeal’ and sent to the IFR RSC Appeal Chair via the IFR RSC secretariat using the contact details in the IFR outcome letter.

1.6 The request for review must set the grounds on which the IFR RSC decision is being challenged. A review can only be requested on the grounds set out in the DoH IFR Policy.

2. Organisation of the IFR Appeal Panel

2.1 The IFR Appeal Panel will normally be convened within 10 working days of the decision to accept the case for appeal.

2.2 The Terms of Reference for the IFR Appeal Panel are in Annex A.

2.3 The IFR Appeal Panel will examine all of the papers and correspondence considered by the IFR RSC, the Decision Framework Document of the IFR RSC meeting, the decision letter and the grounds of appeal. They will examine the process followed by the IFR RSC and the decision made by the IFR RSC. The IFR Appeal Panel will examine the issues raised in the grounds and the tests set out for an Appeal in the IFR Policy.

2.4 There will be no representation at the IFR Appeal Panel meeting from the IFR RSC or the requesting clinician. The IFR Appeal Panel will not consider new information or receive oral representations. If there is significant new information not previously considered by the IFR RSC, it will be referred and considered as set out in 'Reconsideration by the IFR RSC' in sections 4.2.22 and 4.2.23 of the Individual Funding Request, Regional Scrutiny Committee Standard Operating Procedure.

2.5 Reasons given for an IFR Appeal outcome will only refer to the IFR policy as this is the basis on which the original IFR RSC decision is made.

3. Outcome from the Appeal Panel

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

- To uphold the decision reached by the IFR RSC;

  OR

- To refer the case back to the IFR RSC with detailed points for reconsideration.

3.2 The IFR Appeal Panel Chair will write to the requesting clinician and the IFR RSC Chair within five working days of the IFR Appeal Panel meeting. This is to inform them of the outcome of the Appeal Panel meeting with the reasons for the decision. The IFR RSC secretariat will receive a copy of the outcome. The outcome letter will be emailed via secure email.

3.3 If the IFR Appeal Panel determines that the IFR RSC needs to reconsider the case, the IFR RSC should reconvene within 10 working days of the date of decision letter from the Chair of the Appeal Panel. The IFR RSC will reconsider its decision and in doing so will formally address the detailed points raised by the IFR Appeal Panel.

3.4 The IFR RSC is not bound to change its decision as a result of the IFR Appeal Panel's decision to refer the case back, but if the IFR RSC confirms its original decision then clear reasons must be given for not agreeing to fund the treatment request.

3.5 Complaints at any point in the IFR process should be addressed initially to the IFR Secretariat via email (preferred) or post:

Post:
IFR RSC Secretariat
Commissioning Department
Health and Social Care Board
12-22 Linenhall St
Belfast
BT28BS

Email: ifrs@hscni.net

If the complaint remains unresolved, it can be addressed to the dedicated HSCB Complaints department:

Post:
Complaints Department,
Health and Social Care Board,
12-22 Linenhall Street,
Belfast
BT2 8BS

Email: complaints.hscb@hscni.net

Annex A - Individual Funding Request (IFR) Appeal Process

Terms of Reference

The terms of reference will be reviewed annually for applicability and effectiveness.

1. Membership

The IFR Appeal Panel will consist of the following:

- HSCB SMT Director x2
- Non-Executive Director, HSCB
- Medical Director, HSCB
- Patient Representative (e.g. PCC, NIRDP etc.)

A Legal representative from BSO Legal Service will be present to provide advice.

The IFR Appeal Panel will be chaired by the Non-Executive Director, HSCB. It is important that the IFR Appeal Panel is impartial and independent. To be eligible for this role none of the panel members should have been involved in the case prior to the IFR Appeal Process, nor had any involvement in the IFR process at any stage. Panel members must also be able to demonstrate that they are completely removed from any of the issues at stake. This is to ensure that there are sufficient safeguards against undue pressure or influence on the panel.

The Appeal Process Panel will not consider either new information that was not available to the IFR RSC or receive oral representations.

2. Purpose

The IFR Appeal Panel will determine whether the original decision is valid in terms of procedure followed, the evidence/factors considered and the criteria applied. In deciding the outcome of an appeal, the IFR Appeal Panel will consider whether:

- The process followed by the RSC was consistent with the operational policy;
- The decision reached by the RSC:
  i. was taken following a process which was consistent with the policy;
  ii. had taken into account and weighed all the relevant evidence;
  iii. had not taken into account irrelevant factors outwith the policy;
  iv. indicated that the RSC acted impartially and within their competence;.
  v. was a decision which a reasonable RSC was entitled to reach.

'Acted impartiality' in this instance (iv) means that IFR RSC members had either no conflict of interest or had declared any conflict of interest prior to the decision being made.

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

- To uphold the decision reached by the IFR RSC;

  OR

- To refer the case back to the IFR RSC with detailed points for reconsideration.

Where the IFR Appeal Panel considers that there may have been a procedural error in the decision, i.e. that the decision may not have been consistent with the IFR Policy, the IFR RSC may not have taken into account and weighed all the relevant evidence, or may have taken into account irrelevant factors or reached a decision which a reasonable IFR RSC was not entitled to reach, the IFR Appeal Panel shall refer the matter to the IFR RSC if they consider that there is an arguable case that requested treatment will be funded.

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

3. Frequency of meetings

The IFR Appeal Panel will be scheduled as required. A case may need to be considered urgently. The timing of the urgent IFR Appeal 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 Appeal 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

Three panel members to include two directors must be present to be quorate.

6. Documentation

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

- The original IFR request form submitted;
- The IFR RSC process records in handling the request;
- The IFR RSC records, including Decision Framework Documents and any additional supporting information considered by the IFR RSC;

- The grounds submitted by the requesting clinician in their request for an appeal.

There will be no representation at the IFR Appeal Panel from the IFR RSC or the requesting clinician.

The IFR Appeal Panel will not consider new information or receive oral representations. If there is significant new information not previously considered by the IFR RSC Panel, it will be considered as set out in *Reconsideration by the IFR RSC* (section 4.5) in the *RSC Standing Operating Procedure.*

All documentation will be anonymised to protect confidentiality and minimise the potential for identification bias.

7. Authority

The IFR Appeal Panel has the responsibility to undertake a review of IFR RSC procedure in respect of individual cases. It is not the role of the IFR Appeal Panel to reach a decision on funding of an IFR, nor does the Panel make commissioning policy on behalf of the HSCB.

8. Accountability

The IFR Appeal Panel works on behalf of the Health and Social Care Board (HSCB).

9. Reporting and Monitoring

The IFR database will be reviewed on a quarterly basis by the IFR RSC with the IFR RSC secretariat to evaluate the Appeal Process and to consider any improvements that could be made. The IFR RSC secretariat will produce a quarterly report which will be considered by the Director of Commissioning and inform the programme for commissioning policy development and provide oversight of the key performance indicators for the IFR process.

The terms of reference of the IFR Appeal Process will be reviewed annually by the RSC Oversight Group.

10. Training

All members of the IFR Appeal Process must undergo mandatory induction training organised by the IFR RSC secretariat. This will cover both the legal and ethical framework for IFR decision making, commissioning processes and structures and the interpretation of clinical evidence. This training will be refreshed annually to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

Appendix F: Individual funding requests (IFR) - A guide for patients

What is an individual funding request?

An individual funding request, or IFR, can be made by your hospital consultant if they believe that a particular treatment or service that is licensed but is not routinely offered by Health and Social Care in Northern Ireland (HSCNI) is the best treatment for you, given your individual clinical circumstances.

The DoH IFR policy document which outlines the conditions and criteria under which hospital consultants, on behalf of their patients, can make an application for treatment can be found on the Department of Health website:

https://www.health-ni.gov.uk/publications/individual-funding-request-policy-document

Why are some treatments not routinely offered by the health service?

The vast majority of treatments and services that patients need are offered routinely by HSCNI. However there may be some cases where a decision has been taken not to offer the treatment to groups of patients with a particular clinical need. This may be because there is limited evidence for how well the treatment works or a treatment is still very new and a decision hasn't been taken yet on whether it should be offered routinely by the health service.

When can an individual funding request be made?

An IFR can be made for a treatment that is not routinely offered by the health service when a hospital consultant believes that their patient is clearly different to other patients with the same condition or where their patient might benefit from the treatment in a different way to other patients. This is known as "significantly different clinical circumstances".

Hospital consultants can also make a request for funding where a decision hasn't yet been taken on whether a treatment should be offered by HSCNI and where their patient's condition is likely to get a lot worse very quickly and without any prospect of recovery, unless they receive the treatment. This is known as "critical clinical urgency".

Where a request is made on grounds of critical clinical urgency, the hospital consultant will need to show that the evidence for use of the treatment is strong.

Your hospital consultant should explain to you why they believe that a treatment that is not routinely offered by HSCNI is the best treatment option for you.

Who can make an individual funding request?

Your hospital consultant will make the funding request on your behalf and will discuss the outcome with you. Individual funding requests cannot be accepted directly from patients or General Practitioners (GPs).

Who considers the application?

Applications will firstly be checked to make sure the right information has been submitted.

From 9 June 2020 the new Individual Funding Request (IFR) Regional Scrutiny Committee will make decisions regarding the availability of unapproved drugs for individual patients in NI. The new IFR Regional Scrutiny Committee has been established by the Health and Social Care Board following a review and reformation of the IFR process. The Committee replaces the previous IFR Panel, which has now been stood down.

The IFR Regional Scrutiny Committee places clinical expertise at the heart of this sensitive and important decision making process, ensuring that all IFR applications are subject to clinical input and peer review, as well as regional consistency.

In most cases the application will then be considered by a regional scrutiny committee made up of clinicians who will not have been involved in your treatment. All committee members have received training to enable them to assess IFRs fairly and thoroughly. Your personal details will be kept confidential.

The committee will let your hospital consultant know the outcome of the funding request and your consultant will then discuss the outcome with you. If the application is unsuccessful then the letter will explain the reasons. Your hospital consultant will also discuss with you what other treatment options might be available.

How long will an application take?

In most cases, applications will usually be considered within two weeks however in critically urgent cases, applications will be considered within 24-48 hours.

How can I find out how my application is progressing?

The committee's administrators will keep in contact with your hospital consultant during the application process and let them know how the application is progressing and if there are any delays. You should therefore speak to your hospital consultant in the first instance.

Where can I find more information?

Further information on IFRs can be found on the HSCB website.