The Office *of the*
Committee *for*
Health & Social Care

Individual funding requests

This document sets out the policy for dealing with individual funding requests.

The individual funding request process is designed to assess requests to access treatments not normally funded by the Committee for Health and Social Care (CFHSC).

This document is linked to Policy G1033: Guiding principles, rules and policy statements to underpin resource allocation in health and social care.

There are separate policies and policy statements setting out the funding position for some individual treatments which may be relevant to individual cases.

Lead Professional/Author	Corporate Commissioning Policy
Consultation List	Professional Guidance Committee (2017 version), Daphne Austin, IFR Administrator, organisation-wide consultation, HSC Corporate Management Team.
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Committee for Health and Social Care Policy

Document Control

Individual funding requests

This is a controlled document. As a controlled document, the correct version of the document is the one available on HSC intranet and the States of Guernsey website. Printed copies may become obsolete without notice.

Version History

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
5	Dec 2021	Director of Public Health	IFR Administrator & IFR Advisor	Approved	Full review of the policy.
4.2	Oct 2017	Director of Public Health	Public Health Advisor	Superseded	Addition of another IFR Panel member in order that affordability can better be considered.
4.1	July 2017	Director of Public Health	Public Health Advisor	Superseded	Minor amendment to section 14 to allow greater discretion in relation to informing the patient is going to Panel.
4.0	Sept 2016	Director of Public Health	Public Health Advisor	Superseded	Full review of the policy Additional clause to enable Screening Officers to seek the view of the Panel about individual cases at the screening stage. 'Authorised officers' under the urgent decisions has been substituted by the term Screening Officer as all screening officers are the senior healthcare professionals involved in IFR processes G1002 is now a sub-policy document of G1033
3.0	Sept 2015	Director of Public Health	Public Health Advisor	Superseded	Combines IFR policy and its supporting operational policy into one policy Insertion of a new section on

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
					screening for experimental and unproven treatments Revision of aspects of the processes Insertion that allows officers to refer funding queries to the IFR process Removal of the role of IFR administrator which is not currently funded
2.0	2014	Director of Public Health	Public Health Advisor	Superseded	Minor revisions made.
1.0	2013	Director of Public Health	Public Health Advisor	Superseded	New policy

Important contact details

Application forms can be obtained from The States of Guernsey website or The Off Island Team

Address:
Individual Funding Requests c/o The Off-Island Island Team
Le Vauquiedor Office
Rue Mignot
St Andrew
Guernsey GY6 8TW

Telephone:
01481 220000

Safe-haven email address: Guernsey.oiacute@nhs.net

Applications should be sent to the following email address:
individualfundingrequests@hsc.gov.gg

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1. Background

The Committee for Health and Social Care (C*f*HSC) each year receives a budget from the States of Guernsey to provide health and social care services. It has a responsibility to keep its spending within that budget and, in order to discharge this obligation; C*f*HSC must decide how and where those finite local resources are to be allocated.

The need and demand for health care is always greater than the resources that are available to C*f*HSC and it is therefore not possible to meet all needs. As a result, C*f*HSC will need to prioritise the care it commissions and provides on a principled and ethical basis.

Those with responsibility for healthcare commissioning have to take decisions about priorities at three levels:

- when developing strategic plans
- when deciding year on year which investment and disinvestments to make
- at the individual patient level.

The Individual Funding Request (IFR) process is addressing decision making which can only be taken at the level of the individual patient. It is the means by which C*f*HSC considers and prioritises requests for individuals with exceptional health care needs which cannot be accommodated through its other planning and resource allocation processes and for which the IFR Panel believes there is a treatment that has the evidence base to indicate that the treatment provides the benefit required at an acceptable risk and represents value for money.

Being part of C*f*HSC's priority setting processes, the decision taken by the IFR Panel must be guided by the same principles for priority setting which underpins all other decisions of C*F*HSC about priorities. These principles are set out in CFHSC's healthcare policy *G1033: Priority setting in health and social care.* This policy requires affordability to be considered at all levels of decision making. Considering affordability involves assessing how much

funding is available to spend (i.e. whether there is funding available to CFHSC to commit to unplanned expenditure and the relative priority of funding a proposal against other competing calls on that funding).

This policy sets out the decision-making framework for individuals funding requests and how they are operationally managed.

Part 1 — The IFR Policy

2. Policy and Process

2.1. This policy applies to any patient for whom C*f*HSC has responsibility for funding defined elements of their healthcare.

2.2. Clinicians and dental practitioners, on behalf of their patients, may make an IFR to C*f*HSC for treatment that is not normally funded by C*f*HSC, if the request satisfies the following conditions:

2.2.1. The patient is suffering from a medical condition for which:

- a defined healthcare policy or care pathway exists; *and*
- the patient's particular clinical circumstances fall outside the criteria for funding set out in that healthcare policy.

OR

2.2.2. The request is to use an experimental or unproven treatment for a rare/unusual health problem, but which cannot be robustly evaluated because of the small of the patient population in the UK.

AND

2.2.3. The request does not constitute an application for a service development (as defined in G1033).

2.2.4. The request does not constitute an application for an experimental or unproven treatment that should be subject to robust evaluation.

3. Making an Application

3.1. All individual funding requests must be made by the appropriate responsible clinician for the patient from either:

- the Medical Specialists Group (MSG);
- a general practitioner.
- a general dental practitioner
- an NHS provider organisation, under its formal approval mechanisms;
- a private provider of healthcare from whom HSC commissions care; or
- CfHSC's own directly provided service

3.2. All applications must be accompanied by CfHSC's IFR application form.

3.3. This requirement may be waived at the discretion of the IFR Chair, however in these cases forms will still be required to be submitted retrospectively and prior to any related IFR Panel meeting.

3.4. Any clinician submitting an IFR must attempt to ensure that no immaterial information, including information about the social or personal circumstances of the patient or information which does not have a direct connection to the patient's clinical circumstances, is included in the application. Any information which is not relevant will be disregarded by the IFR Panel.

4. Screening of Applications

4.1. All individual funding requests submitted to C*f*HSC will be subject to screening by a screening officer. The screening officer will be the IFR Advisor, or a substitute nominated from among the screening trained clinicians on the IFR Panel.

4.2. Applications that are not complete or which have insufficient information to assess the funding requests will be returned to the applicant for resubmission.

4.3. Applications for which the IFR route is not appropriate will also be returned to the application. These include (but are not limited to) the following

requests for:

4.3.1. Treatment or services that should be classified as a request for a service development.

4.3.2. Experimental or unproven treatments for which there are sufficient numbers of similar individuals to conduct such a trial within the United Kingdom or a multi-centre trial in Europe. (*See policy G1033 — section on experimental and unproven treatments*.)

4.4. The Screening Officer will also make an assessment of whether the application contains sufficient grounds for forwarding the application to the IFR Panel, namely the applicant has put forward sufficient evidence to indicate that the patient may have an exceptional health care need.

4.5. The Screening Officer has discretion to seek further information to ensure that all relevant evidence that the IFR Panel may need to make a decision is made available to it.

4.6. The IFR Administrator will notify the applicant of the Screening Officer's decision within 7 working days.

5. Referral to the IFR Panel

5.1. All requests that meet the above criteria as decided by the screening officer will be considered for funding by the IFR Panel.

5.2. An applicant or the affected patient can appeal the decision of the screening officer by submitting a complaint to the CHSC Customer Care team (*See policy G107*).

6. Assessment by the IFR Panel

6.1. The IFR Panel will first assess the screening officer's decision and make a decision as to whether or not the case should have been put before the Panel.

6.2. The IFR Panel is not required to accept views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual

patient of the proposed treatment.

6.3. Applications assessed against the experimental and unproven treatments policy

6.3.1. Applications to use an experimental treatment (for example to use a licenced medicine for an off-label indication) will be assessed against the C*f*HSC policy *Experimental and unproven treatments as set out in G1033*.

6.3.2. Under these circumstances the grounds on which the IFR Panel can agree to making an exception is when the IFR Panel is satisfied that:

6.3.2.1. the patient has a health care problem that is only shared, at most, by a small number of patients; [1] **and**

6.3.2.2. because of the incidence or prevalence of the health care problem it is not feasible to gather evidence about the treatment for the health care problem of interest through a robust clinical study; **and**

6.3.2.3. there is good argument from the existing evidence (either direct evidence from case reports and/or case series or extrapolating evidence from a similar disease and consideration of biological mechanisms) to support the argument that the patient could benefit from treatment; **and**

6.3.2.4. the benefits and the value for money considerations are comparable to the treatments that are already routinely funded by the CFHSC; **and**

6.3.2.5. the risks (both clinical and financial) are acceptable; **and**

6.3.2.6. the funds are available; **and**

6.3.2.7. other relevant considerations meet satisfactory

[1] The numbers sharing the same health care need would be expected to be in the order of less than 1 per 1,000,000

requirements.[2]

Rarity, in itself, is not a basis for agreeing an exception. In each case there should be evidence that supports the argument that the experimental or unproven treatment has the potential to be clinically and cost effective in the particular case.

6.4. Applications assessed against other policies

6.4.1. Very occasionally, a clinician may think that their patient's clinical situation is so different to other patients with the same condition that it is appropriate that they should have different treatments to the others. In such circumstances, clinicians, on behalf of their patient, may submit an IFR for a treatment that is not normally made available to other patients. This route should only be used for those patients that have exceptional health care needs within a patient group[3] and not as an alternative route to submitting a request for a treatment to be considered as a service development.

The policies against which such an application can be made include:

- A service specification which sets out access criteria for that service
- A funding policy which sets out the access criteria for a treatment
- Recommendations issued by the National Institute for Health and Social Care under its technology appraisal programme and highly specialised technologies programme
- A funding position which has been set down by the C*f*HSC but not necessarily in the form of a published policy
- The default commissioning policy

[2] For example if an application is for treatment in the outside the UK, other factors have to be considered such as financial risk, governance etc.

[3] The patient group would normally be the epidemiological cohort. So for example, when an application is being made for a treatment for a diabetic patient – the applicant will need to demonstrate that there is something different about the patient's diabetes from other diabetics and not just other diabetics living on Guernsey. There are some instances where the relevant patient cohort is the local population. An example might be a request for a particularly high cost artificial limb, where the question would have to be asked why this patient and not others living on the Island.

6.4.2. Under these circumstances the grounds on which the C*f*HSC can agree to making an exception is when the IFR Panel is satisfied that:

6.4.2.1. that the patient has a distinct health problem when compared to other patients with the same condition and (if relevant) at the same stage of progression; **and**

6.4.2.2. that health problem is shared, at most, by a small number of patients nationally (namely, the patient is not part of a significant cohort within the group for whom a policy variation should be considered); **and**

6.4.2.3. because of that difference, the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient; **and**

6.4.2.4. there is sufficient evidence to support the arguments that the patient will benefit from treatment; **and**

6.4.2.5. the benefits and the value for money considerations are comparable to the treatments that are already routinely funded (excluding those that are legally mandated by the National Institute of Health and Care Excellence); **and**

6.4.2.6. the risks (both clinical and financial) are acceptable; **and**

6.4.2.7. the funds are available; **and**

6.4.2.8. other relevant considerations meet satisfactory requirements.[4]

The IFR Panel will need to consider, whether, on balance, there are clear clinical justifiable grounds for funding a particular patient when others from the same patient group are not being funded for the requested treatment.

[4] For example if an application is for treatment in the outside the UK, other factors have to be considered such as financial risk, governance etc.

The IFR Panel will, during its assessment, need to consider whether an application, when properly analysed, should be considered against the *Experimental or unproven treatments policy*.

6.5. Requests for the continuation of funding for a treatment not normally funded and which has been started by a third party without prior approval by the CfHSC.

6.5.1. The C*f*HSC does not normally take over responsibility of funding a treatment started by a third party without prior agreement. The C*f*HSC has policies which set out its funding position relating to request for the C*f*HSC to continue funding treatment that was initiated and funded by a third party which includes:

- A trial of treatment by a provider (see *G1033: On-going access to treatment following a trial of treatment which has not been sanctioned by the CfHSC for a treatment and which is not routinely funded or has not been formally assessed and prioritised]*
- Funding by the patient (see *G1033 The boundaries between healthcare funded by CfHSC and privately funded healthcare*
- Participation in a commercial clinical study (see *G1033: On-going access to a treatment following the completion of an Industry sponsored clinical studies*
- Funding provided under by industry under an early access scheme or individual patient sponsorship (see *G1033: Early Access Schemes of licensing bodies*).

6.5.2. Under these circumstances the grounds on which the IFR Panel can agree to making an exception is when the IFR panel is satisfied that:

6.5.2.1. the patient meets the criteria set out under sections 6.3 and 6.4; **and**

6.5.2.2. the reasons why the clinician failed to make an IFR application prior to starting treatment are justified; **and**

6.5.2.3. the risks (ethical, financial and/or behavioural) of picking up funding in the specific situation are acceptable.

In particular, when a case engages a key principle set out in G1033, the IFR Panel must consider the risks associated with not acting in accordance with the principle or requirement. So, while the IFR Panel will have regard to the patient's individual circumstances, these will need to be weighed against the risks of breaching a key principle. In each case, the relevant policy documents should be referred to and considered.

Illustrations include:

- A request to continue funding from an Industry sponsored clinical trial which engages the principle that a third party cannot commit funding (and therefore distort the C*f*HSC funding priorities) of the C*f*HSC without the C*f*HSC's consent. Picking up funding in this situation would bypass usual prioritisation of potential services developments and risk inequity should the C*f*HSC decide not to fund the new treatment for all patients.
- A request to continue funding a patient who has funded a treatment privately engages the principle that care should be provided through public funded on the basis of need and not ability to pay.

6.6. Applications which, when assessed, require a policy position to be taken before the application can be considered

If an IFR request poses a question of a policy, ethics or law, then the Screening Officer and the IFR Panel have the discretion to request that the issue must be resolved prior to the application to being considered. In these instances, the application should be stopped and the position decided before the application is allowed to proceed further.

6.7. Applications for medicines that have a licence for extremely rare conditions

Applications for medicines that have a licence for an extremely rare conditions for which the C*f*HSC does not as yet have a commissioning position will be considered through the service development route.

6.8. The IFR Panel has the right to return the application to the referring clinician and ask for further information or to undertake its own research

and investigations before a decision is taken.

6.9. The IFR Panel may at its discretion request the attendance of any clinician to provide clarification on any issue or request independent expert clinical advice for consideration by the Panel at a further date.

6.10. C*f*HSC is to use every reasonable effort to process requests within a maximum period of 40 working days calculated from the date of the receipt of a completed IFR application to the date of the IFR Panel outcome to the applicant. If this timescale will not be met the requesting clinician must be informed of the delay, the reason(s) for it, and the new anticipated date for processing.

6.11. The decision of the IFR Panel will be communicated to the requesting clinician. The IFR Panel will consider in each case whether there is any reason that the outcome should not also be communicated directly to the patient.

7. Review of the Decision

7.1. If the referring clinician and or the patient (or their guardian or carer) believes that there is further relevant information that was not considered by the IFR Panel **which was not available to them at the time of submission of the IFR**, they may ask C*f*HSC to reconsider the case specifically in the light of the new information. The additional information must be submitted to the IFR Lead within 20 working days of the date of the decision letter from the IFR Panel.

7.2. The role of the IFR Review Panel is to ascertain whether due process was followed by the IFR Panel in reaching its decision. The IFR Review Panel will not consider fresh evidence that was not before the IFR Panel but will, instead, direct that a further IFR Panel is convened to consider the fresh evidence.

7.3. Where an IFR has been considered at an IFR Panel and a decision has been reached:

- not to support the request for funding;
- to approve funding for the treatment, subject to conditions, the patient,

or the clinician acting on the patient's behalf, is entitled to ask that the outcome be reviewed if they believe that the decision-making process was flawed.

7.4. At the IFR Review Panel, consideration shall be given to whether:

7.4.1. The IFR Panel followed the correct decision-making process and adhered to the required standards set out in this Policy.

7.4.2. The decision not to fund was reasonable in light of the available evidence and individual circumstances of the case.

7.4.3. The IFR Panel took into account all material factors including all evidence (i.e. IFR Form, medical history, case studies etc. but excluding social factors) relating to the application.

7.5. In the event that it is considered that the decision was procedurally flawed in that it did not comply with the grounds for funding as set out in this policy, the IFR Review Panel shall consider whether there was any reasonable prospect that the IFR Panel would have reached a different conclusion, had due process been followed.

7.6. If the IFR Review Panel considers that there was no reasonable prospect that the IFR Panel would have come to a different conclusion, the decision not to fund or only to fund subject to certain conditions shall be approved, notwithstanding the non-compliance.

7.7. If the IFR Review Panel considers that there was a reasonable prospect that the IFR Panel may have reached a different decision, the IFR Review Panel shall refer the funding application back to the IFR Panel for reconsideration settings out its concerns.

8. Administration of the IFR Process

8.1. The IFR Administration Officer shall ensure incoming requests are logged and that a record is kept of:

- The date of the original request
- The date a completed form was received

- The condition for which treatment is needed
- The name of the requesting clinician and their parent organization

8.2. Cases that pass the screening stage will be sent on for formal consideration by the panel.

8.3. Panel decisions can be taken by virtual agreement in the case of urgent cases.

8.4. The IFR Administration Officer shall provide redacted copies of the IFR form and any supporting materials to the panel not less than 4 working days prior to a convened IFR panel meeting.

8.5. The IFR Administration Officer shall draft any requested correspondence from the panel prior to agreement and signing by the IFR Chair.

8.6. The IFR Administration Officer is responsible for the booking of meetings and ensuring all panel members are aware of any convening of the IFR Panel.

8.7. Extraordinary meetings of the IFR Panel may be called to discuss significant issues if they are considered necessary.

8.8. Virtual meetings by telephone or web conferencing may be held as and when required.

8.9. The discussion of the convened panel shall be minuted and their decisions recorded in the decision-making framework document.

Part 2 — Responsibilities of requesting Clinicians and Organisations

9. The clinicians of all provider organisations will take C*f*HSC's healthcare policies into account in the advice and guidance given to patients prior to deciding to submit an IFR.

10. Provider organisations must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process.

11. If a clinician decides to commence treatment **prior to the funding being formally approved**, all proper advice will be given including all available options and care pathways to be adopted, and the consequences for that patient, in the event that funding is not subsequently approved by C*f*HSC.

12. It is the responsibility of the person making the application to ensure that all relevant information on which they rely in support of the application is made available to the IFR Panel to enable the IFR Panel to properly evaluate and assess the IFR in accordance with the relevant policies.

Appendix A — IFR Panel Terms of Reference

1. IFR Panel Purpose

1.1 The Individual Funding Request Panel (IFR Panel) is a sub-committee of the Committee for Health and Social Care.

1.2 Its primary role is to take decisions about individual funding requests and provide assurance to C*f*HSC that resource allocation is equitable, represents value for money and is in the interests of the whole population, thereby supporting the delivery of the organisational objectives. A key element of this will be consideration of the cases based on evidence of effectiveness, cost effectiveness, impact on health and affordability as well as evidence of clinical exceptionality.

2. IFR Panel Scheme of Delegated Authority

2.1 The IFR Panel has delegated power under Rule 54 (3) 'Sub-Committees – other' of the Constitution and Operation of States Departments and Committees.

2.2 The IFR Panel must not make decision that could be regarded as a policy decision or precedent setting for C*f*HSC. This includes taking decisions relating to service developments.

2.3 Any decision which is at risk of setting a policy or precedent should be referred to the appropriate committee or person within C*f*HSC.

2.4 In taking its decisions, the IFR Panel must take affordability into account. The IFR Panel's authorisation limit is set at £50,000.

2.5 Any decisions which may incur a financial cost in excess of £50,000 must be referred to the Director of Operations of C*f*HSC before a final decision can be made in order to assess affordability.

3. IFR Panel Membership and Quoracy

3.1 Membership of the IFR Panel will consist of the following:

- Director of Public Health (Chair)
- Medical Director (Vice Chair)
- C*f*HSC Nurse nominated by the Director of Operations.
- C*f*HSC Chief Pharmacist or a CFHSC pharmacist nominated by the chief pharmacist
- Specialist Consultant nominated by the Medical Specialist Group
- General Medical Practitioner nominated by the Primary Care Group
- Director of Operations or a representative

- 2 Lay members appointed by the Director of Operations

3.2 The IFR Panel is quorate when:

3.3 Four members are present including at least 1 lay member and 2 clinicians.

3.4 The IFR Advisor or Screening Officer for the case and IFR Administrator should also be present as non-voting members.

3.5 All Panel members must undergo appropriate training, no less than every two years.

4. IFR Panel Declarations of Interest

4.1 At the start of a sitting of the IFR panel members will declare any interests (raise any conflicts of interest) they may have with a particular case. Where there is (a conflict of) an interest the panel will decide whether the member in question should excuse themselves from the discussion, the vote, both or neither. Where the panel is undecided the final decision will lie with the Chair.

5. Voting Rights

5.1 IFR Panel members will seek to reach decisions by consensus. If a consensus cannot be achieved decisions will be taken by a majority vote with each panel member having a single vote. If the Panel is equally split, then the Chair of the Panel will have a second casting vote.

6. Corporate Governance and Risk Management

6.1 The IFR Panel will adhere to all the appropriate C*f*HSC corporate governance and risk management arrangements including the development, implementation and monitoring of agreed strategies, policies and procedures.

7. Frequency of Meetings

7.1 The IFR Panel will meet as required by the case load.

8. Reporting Framework

8.1 The Chair of the IFR Panel will write to the applicant with the decision. The Chair may choose to write to the affected patient at the same time.

8.2 The Chair of the IFR Panel shall draw to the attention of CFHSC any issue that requires disclosure to the Committee or require executive action.

8.3 The IFR Chair will submit an annual report to CFHSC.

8.4 Where possible the IFR panel will identify the need for future service developments or specific policy and communicate that advice to the appropriate committee or person.

Appendix B — IFR Review Panel Terms of Reference

9. IFR Review Panel Purpose

9.1 The Individual Funding Request Review Panel (IFR Review Panel) is a sub-committee of C*f*HSC.

9.2 Its role is to consider appeals against decisions taken by the IFR Panel, to ensure that decisions have been taken in accordance with the policies and processes of C*f*HSC and the specific processes and jurisdiction are contained in this operational policy.

9.3 The IFR Appeal Panel will reach its decision based on all the written evidence which is provided to it.

9.4 The IFR Appeal Panel may request the attendance of legal, clinical or public health expertise to clarify any points for consideration by the Panel.

10. IFR Appeal Panel Membership and Quoracy

10.1 The IFR Appeal Panel will be chaired by the Director of Quality & Governance or in his/her absence another individual will be nominated by the Director of Operations.

10.2 The Director of Quality & Governance, in liaison with the Director of Operations, will form an IFR Appeal Panel which will consist of three Associate Directors/Business Partners/Heads of Service of C*f*HSC who were not on the original IFR panel which considered the case.

10.3 All members must be in attendance to consider the meeting quorate. In the event of one of the members not being able to attend, an appropriate Assistant Director may be substituted for the absent member.

10.4 The IFR administrator shall be present at all meetings to take minutes.

10.5 A representative of the Law Officers' Chambers shall be present to advise the Panel as required.

11. IFR Review Panel Voting Rights

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

12. IFR Appeal Panel Corporate Governance and Risk Management

The IFR Review Panel will adhere to all the appropriate C*f*HSC corporate governance and risk management arrangements including the development, implementation and

monitoring of agreed strategies, policies and procedures.

13. Frequency of Meetings

13.1 The IFR Review Panel will be convened within 25 working days of an appeal being received.

14. Reporting Framework

14.1 The Chair of the IFR Review Panel will write to the applicant with the decision. The Chair may choose to write to the affected patient at the same time.

14.2 The decisions of the IFR Review Panel will be reported to C*f*HSC as part of annual report.

Appendix C — Roles and responsibilities of IFR Advisor, IFR Administrator and screening officer

15. The Role of the IFR Advisor

15.1 The IFR Advisor will work jointly with the IFR Administrator to coordinate, manage and develop the IFR process and the work of the IFR panels.

15.2 Key elements of the role will be:

- Preparing papers for the IFR Panel
- Attending IFR panel meetings in the role of advisor.
- Contributing to the recruitment and training of panel members
- Contributing to the continuing development of the IFR process
- Liaising with C*f*HSC's committees and officers responsible for priority-setting and policy development to deal with situations where there is a lack of existing policy.

15.3 The IFR Advisor will not sit as a member of the IFR panel but will attend the meetings in an advisory role.

15.4 The IFR Advisor must have a clinical background and population health training.

16. The Role of the IFR Administrator

16.1 The IFR Administrator will work jointly with the IFR Advisor to coordinate, manage and develop the IFR process and the work of the IFR panels.

16.2 Key elements of the role will be:

- Managing the IFR Process
- Deciding which submissions are urgent and should be fast-tracked
- Determining the additional information, specialist advice and reviews of evidence necessary to inform the panel's decision
- Preparing papers for the IFR Panel
- Writing the minutes
- Contributing to the recruitment and training of panel members
- Contributing to the continuing development of the IFR process
- Liaising with CFHSC's committees and officers responsible for priority-setting and policy development to deal with situations where there is a lack of existing policy.

16.3 The IFR Administrator will not sit as a member of the IFR panel but will attend the meetings in a supporting role.

16.4 The IFR Administrator will be the single point of contact for patients and clinicians involved in the IFR.

17. The Role of the Screening Officer

17.1 Key elements of the role will be:

- Screening submissions to the IFR process, identifying service developments, and redirecting inappropriate submission as required
- Deciding which submissions are urgent and should be fast-tracked
- Determining the additional information, specialist advice and reviews of evidence necessary to inform the panel's decision
- Preparing papers for the IFR Panel

17.2 The Screening Officer will not sit as a member of the IFR panel but will attend the meetings in an advisory role.

17.3 The Screening Officer must have a clinical background and adequate screening training.

Appendix D — Principles and Guidance for the IFR Panel

IFR Panel Principles

Rarity — Rarity of itself is not a basis for agreeing an exception.

The Rule of Rescue — The IFR Panel will not adopt the approach described as "the rule of rescue". The fact that a patient has exhausted all treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate that there are exceptional circumstances. Equally, the fact that the patient is not responding to existing treatments (including drugs) where a recognised proportion of patients with the same presenting medical condition at a similar stage are, to a greater or lesser extent, refractory to existing treatments (or those drugs) is unlikely, of itself, to be sufficient to demonstrate that there are exceptional circumstances.

Independence — The IFR Panel is not required to accept views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on the likely clinical outcomes for the individual patient of the proposed treatment and the quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

What is meant by exceptional health care needs?

C*f*HSC must have good reasons for not adhering to approved healthcare policies or care pathways. There can be no exhaustive definition of the conditions which are likely to come within the definition of an exceptional individual case. The word 'exceptional' means 'a person, thing or case to which the general rule is not applicable'. However, it is easy for there to be a misunderstanding by the patient or the clinical team as to what is meant by this expression.

Some requests under the IFR process argue the case that an individual should be treated differently than other apparently similar patients and their treatment should be funded when other patients will not be funded. These may relate to the moral or compassionate case for funding.

The IFR Panel should bear in mind that, whilst everyone's individual

circumstances are, by definition, unique, and reasons can always be found for funding on compassionate grounds, very few patients have *clinical* circumstances which are exceptional so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance to assist the Panel. However, the overriding question which the Panel needs to task itself remains: has it been demonstrated for this patient that his or her clinical circumstances are exceptional?

If a patient has a condition for which there is an established care pathway, the Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that same medical condition.

The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which a Panel could find that a patient is exceptional.

However, the Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was genuinely exceptional circumstance. For example:

- If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or is not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason) the fact that the requesting patient falls into that group is unlikely to be a proper ground on which to base a claim that the requesting patient is exceptional.
- If the usual treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, the fact that the co-morbidity is present in this patient and its impact on treatment options for the requesting patient is unlikely to make the patient exceptional.

The most appropriate response in each of the above 2 situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a

change to the policy adopted by C*f*HSC for funding that patient pathway so that a change can be made to that policy to benefit a subgroup of patients (of which the requesting patient is potentially one such person). This change needs to be considered as a service development.

Non-clinical factors

It is common for an application for individual funding to be on the grounds that a patient's personal circumstances are exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed or is continuing to contribute to society. C*f*HSC understand that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However, including non-clinical, social factors in any decision-making raises at least three significant problems for C*f*HSC.

- Across the population of patients who make such applications, C*f*HSC is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult for the Panel to be confident of dealing in a fair and even-handed manner in comparable cases.

- The essence of an individual funding application is that C*f*HSC making funding available on a one-off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision-making process, the C*f*HSC does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.

- C*f*HSC is committed to a policy of non-discrimination in the provision of medical treatment. If for example, treatment was to be provided on the grounds that would enable an individual to stay in paid work then this would potentially discriminate in favour of those working compared to not working. To offer a treatment to one patient and not another on the basis that the funded patient was working and the patient denied funding was out of work breaches C*f*HSC 's principles underpinning decision making. Such a decision would also set a precedent for C*f*HSC to always favour those in work over those not currently in work. The same can be said of many other social factors such as having children / not having children, being a carer / not being a carer and so on. Requests to fund treatment for adolescents on the grounds that they wish to go to university (and therefore not funding treatment would not

enable the individual to fulfil their true potential) or because of a person's role in society (e.g. professional) is also discriminatory and would contribute to social inequality.

Non-clinical factors rarely have any bearing on the nature of the health problem or the treatment and the requirement is for the patient to have an exceptional health care need. A health care need is a health problem for which there is a targeted treatment for which there is evidence of benefit at reasonable cost and risk.

Generally, C*f*HSC does not take into account social factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to normally provided care or treatment. It does not seek to deny treatment to smokers on the grounds that they have caused or contributed to their own illnesses through smoking, nor does it deny treatment to those injured participating in sports in which they were voluntary participants. However there will be times when personal factors have clinical relevance.

In general, C*f*HSC treats the presenting medical condition and does not inquire into the background factors which led to that condition as the basis on which to decide whether to make treatment available or not. The policy of C*f*HSC is that it should continue to apply these principles in individual applications for funding approval. C*f*HSC will therefore seek to invest in treatments based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances.

In reaching a decision as to whether a patient's circumstances are exceptional, the Panel is required to follow the principles that non-clinical or social factors including social value judgements about the underlying medical condition or the patient's circumstances are not relevant.

Clinicians are asked to bear this Policy in mind and not refer to social or non-clinical factors to seek to support the application for individual funding.

Demonstrating that the patient's health care needs are exceptional

The onus is on the person making the request to set out the grounds clearly for

the Panel on which it is said that this patient is exceptional. The grounds will usually arise out of exceptional clinical manifestations of the medical conditions, as compared to the general population of patients with the medical condition which the patient has.

These grounds must be set out on the form provided by C*f*HSC and should clearly set out any factors which the clinician invites the Panel to consider as constituting a case of exceptional clinical circumstances. If, for example, it is said that the patient cannot tolerate the usual treatment because of the side effects of another treatment, the referring clinician must explain how usual it is for the patient with this condition not to be able to be provided with the usual treatment. The clinician should be able to provide scientific evidence to verify their opinion on the likelihood of this situation.

If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, then the Panel is obliged to refuse the application. The Panel recognises that the patient's referring clinician and the patient together are usually in the best position to provide information about the patient's clinical condition as compared to a subset of patients with that condition. The referring clinician is advised to set out the evidence in detail because the panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that speciality. C*f*HSC therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said as to be exceptional.

The policy of C*f*HSC is that there is no requirement for the Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, if a clear case of an exceptional health care need is not made out by the paperwork placed before a screening officer or the IFR Panel, either would be entitled to turn down the application.

Multiple claimed grounds of exceptionality

There may be cases where clinicians and/or patients seek to rely on multiple grounds to show their case is exceptional. In such cases the Panel should look at each ground individually to determine (a) whether the factor was capable of making the case exceptional and (b) whether it did in fact make the patient's case

exceptional. The Panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored on one ground, but it might be relevant on another ground. That is a judgment within the discretion of the Panel.

If the Panel is of the view that none of the individual factors on their own make the patient's clinical circumstance exceptional, the Panel should then look at the combined effect of those factors which are, in the Panel's judgement, capable of supporting a possible finding of exceptionality. The Panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional. In reaching that decision the Panel should remind itself of the difference between individual distinct circumstances and exceptional clinical circumstances.

Consequence of a funding request being classified as a potential service development

Refer to G1033 for what constitutes a service development.

The IFR Panel has no power to make policy decisions for C*f*HSC. Accordingly, if a funding request has been classified as a potential service development, the IFR Panel has no jurisdiction to consider the application.

In those circumstances the application will not be submitted to the IFR Panel but will be subject to the usual business planning and priority setting processes of C*f*HSC.

C*f*HSC may, where the request has been classified as a service development:

- Refuse funding, and refer the case back to the provider organisation (which may be the provider arm of C*f*HSC) and take no further action; refuse funding, and request the provider organisation to prioritise an application for that service development and, if supported by C*f*HSC.
- Invite the provider organisation to submit a business case as part of the yearly cycle for considering service developments.
- Refuse funding and refer the request to the appropriate director within CFHSC for an assessment with a view to determining its priority for funding as a service development proposal in the next financial year.

- Refuse funding and refer the request to the appropriate director within CFHSC for an immediate workup of proposals as a potential candidate for funding as a service development in the current financial year.

Appendix E — Requests to fund a single patient to enter a clinical trial

Policy G0133 states that treatments that are experimental (i.e. where there is no evidence base) or unproven (i.e. where there is an insufficient evidence base to have demonstrated a positive benefit) will not normally be commissioned outside the context of a clinical trial.

The C*f*HSC may agree to fund clincail studies as part of a Research and Development Programme. Some treatments (particularly cancer treatments for children) are routinely provided in the context of a clinical study.

In considering whether to recommend supporting a single patient to enter a clinical study outside of the C*f*HSC usual R&D funding programme IFR Panel must consider:

1. The potential strategic importance of the treatment to the patient group and to the health service generally. A judgment shall be made on whether the trial will address priorities for the relevant programme area.
2. The status of the clinical trial including whether the trial has been ratified by the National Institute for Health Research and/or other relevant United Kingdom clinical and research bodies.
3. The quality of the trial and whether or not it is likely to generate the information that is needed to enable those funding healthcare to reach a view on the clinical effectiveness and cost effectiveness of the treatment. Specialist advice may be sought by the IFR Panel on the methodology to be adopted within any trial.
4. The ownership of the data. Trials which do not guarantee that the data will be made available in the public domain will not be considered for funding.
5. The affordability and priority of the requested trial compared to the other competing needs and unfunded service developments.

All applications must be accompanied by the trial protocol or a sufficiently detailed summary of the trial protocol when this is not available on the national trial register.