

# Individual Funding Request (IFR) Policy

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## POLICY AMENDMENTS

Amendments to the Policy will be issued from time to time. A new amendment history will be issued with each change.

New Version Number	Issued by	Nature of Amendment	Approving Body	Approval Date	Date Published on Website
0.1	Executive Director of Clinical and Professionals	New Document	ICB Quality Committee	1 July 2022	14 July 2022

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## 1.0 Introduction

Humber and North Yorkshire Integrated Care Board (H&NY ICB) has a statutory responsibility for commissioning services including medicines and other treatments for the population it serves within available resources and by prioritising between competing demands. As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities, and represent value for money.

The Individual Funding Request policy has been developed in response to the legal duties set out in the NHS Constitution (DH, March 2013) (Ref 12.3), which identifies two patient rights specifically related to the availability of medicines and other treatments i.e.:

1. You have the right to drugs and treatments that have been recommended by NICE for use in the NHS if your doctor says they are clinically appropriate for you.
2. You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.

Whilst most of the service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the NHS.

An Individual Funding Request (IFR) is a request received from a clinician or health care professional providing care to a patient in one of the following circumstances:

- a specific treatment, intervention or procedure is requested that is not commissioned and not covered by existing policy; *or*
- a Category 1 treatment, intervention or procedure is requested that is specifically not commissioned under current policy: *or*
- the patient does not meet the clinical criteria for a Category 2 commissioned service  
*and* their clinician believes they can demonstrate clinical **exceptionality** in accordance with the definition.

The NHS Evidence Based Interventions programme identifies the difference between groups of procedures which are not routinely commissioned as:

- a. **Category 1** - treatments with no or very limited evidence for effectiveness. Not routinely funded unless the patient is considered clinically exceptional following a successful Individual Funding Request (IFR).
- b. **Category 2** - treatments that are more effective in groups of patients that meet clinical criteria where the health benefit is greater than the risks. Funded when the patient meets specified clinical criteria (Prior Approval), but not otherwise funded unless a patient is considered clinically exceptional following a successful IFR.

Exceptionality is defined as:

*‘The patient or their circumstances are significantly different from the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.’*

## **2.0 Purpose**

The IFR process provides a mechanism to allow medicines/ treatments that are not routinely commissioned by the ICB to be considered for individuals in exceptional circumstances. It also provides a framework for officers of the H&NY ICB to exercise their responsibilities properly and implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of each ICB.

The purpose of the Individual Funding Request (IFR) policy is to:

- Set the decision-making process within an ethical context and to demonstrate a clear process for decision making.
- Inform health professionals about the policy in operation and how to request restricted treatments or appeal against individual decisions to decline a request for a restricted treatment.
- Ensure decisions are made in a fair, open, transparent and consistent manner.
- Provide a firm and robust background against which appeals can be judged.

## **3.0 Definitions / Explanation of Terms**

A glossary to this policy can be found on page 17. It provides definitions of terms used within the policy and defines roles and responsibilities of key individuals and groups in delivery of the policy, both within H&NY ICB and NECS.

## **4.0 Scope of the Policy**

This policy applies to all Individual Funding Requests (IFRs) for people registered with General Practitioners in the area covered by the Humber and North Yorkshire ICB. This policy does not apply where the ICB is not the responsible commissioner, e.g., specialised commissioning would be via NHS England (NHSE).

It is not generally the role of the IFR process to fund experimental treatment. Robust trials are needed for new treatments, and experimental treatment should generally be given only as part of a research trial with appropriate clinical governance arrangements. Separate mechanisms exist for H&NY ICB to be engaged in funding for such treatments during and after appropriate trials. These are not covered by this policy.

Personal Health Budgets (PHB), Continuing Healthcare (CHC) for adults, and Children’s Continuing Care (CCC) fall outside of the IFR process and as such, are not covered within this policy and applications should not be submitted via the IFR process.

This policy does not include the process for considering requests for mental health medicines or treatment, but this intention is to align/ merge the processes.

This policy is supported by commissioning policy statements, which are used as a basis

for making decisions. This policy outlines the review process for those policy statements and includes interim arrangements to allow for the review of Individual Funding Requests, which have been appealed on the basis of differential commissioning policy statements across the ICB until such time that those statements have been aligned.

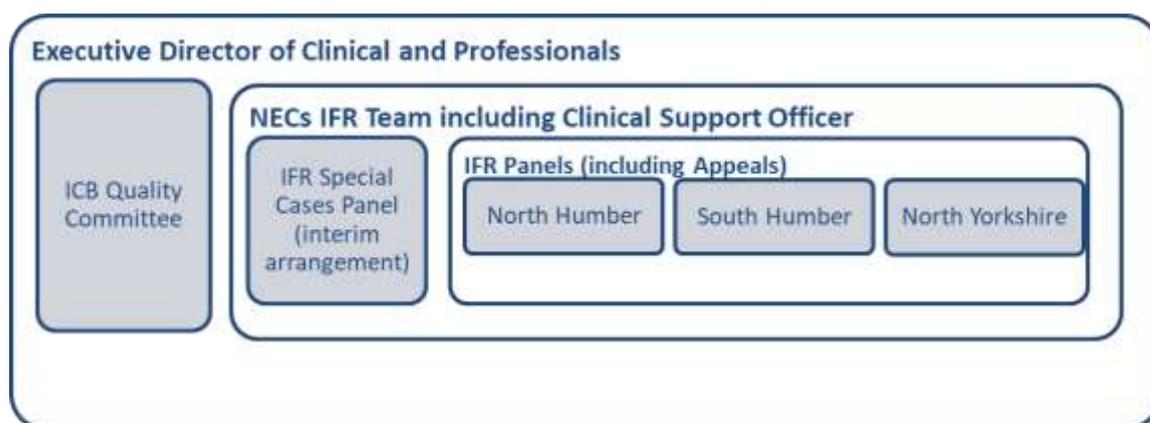
## 5.0 Duties / Accountabilities and Responsibilities

### 5.1 Chief Executive

The Chief Executive has overall accountability for the commissioning services including medicines and other treatments for the population and will discharge these duties through delegation to the ICB Executive Director of Clinical and Professionals who will ensure decisions are made fairly and consistently.

### 5.2 Executive Director of Clinical and Professionals

The Executive Director of Clinical and Professionals is responsible for the strategic co-ordination of this policy and will be supported by Clinical Leads/ IFR Leads and through the appointment of clinicians to IFR panels. The Executive Director of Clinical and Professionals will be supported through the operating model below and must ensure that members of staff are aware of this policy and the processes to be followed.



### 5.3 IFR Place Lead

The IFR Lead will be appointed by the Place Director and act as the link between the local clinicians and commissioning teams to ensure the Policy is applied and that decisions are taken in a timely manner. The IFR Lead will be supported in this task by the IFR Service Senior Manager, a Clinical Support Officer, an administrative team, by the availability of expert advice when required, and by an IFR Panel.

### 5.5 IFR Panels

H&NY ICB will delegate authority to three IFR Panels to make decisions about individuals IFR cases. Whilst discussions take place amongst the Panel members, accountability for the respective case decisions rests with the individual clinical representative(s) on the Panel referred to as Decision Makers. IFR Panels will also act as an Appeals Panel for neighbouring areas. Panel members are expected to commit to at least 6 panels per year.

### 5.6 IFR Service Lead (NECS)

The IFR Service Lead and Administrative Team is provided through a contract with NECS. The IFR Service Lead has overall responsibility for the IFR Administration service and its performance, providing strategic leadership to the service/team within NECS.

### **5.7 IFR Clinical Support Officer (CSO) (NECS)**

Responsible for clinically triaging all cases before they are brought to Panel the IFR Clinical Support Officer (CSO) will make a recommendation on whether the request should be approved, declined, decide if the case should be discussed fully at Panel, or whether further information is required before a recommendation can be made.

### **5.8 IFR Administration Team (NECS)**

Provides administrative support for all IFR cases receives, monitors and coordinates responses within the set time frames, and communicates with the referring clinician/ healthcare professional regarding process and decisions. The IFR Admin Team will support the IFR Panel preparing papers, drafting the minutes and maintaining the action log.

## **Responsibilities for Approval**

The ICB Quality Committee, a sub-committee of the Humber and North Yorkshire Integrated Care Board (ICB), has responsibility for approving and monitoring compliance with the IFR Policy.

### **6.0 Public Sector Equality Duty**

Promoting equality and addressing health inequalities are at the heart of the Humber and North Yorkshire Integrated Care Board's (H&NY ICB) values. Throughout the development of this policy statement, H&NY ICB has:

- Given due regard to the need to eliminate discrimination, harassment, and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

As a result of performing the analysis, the policy, project or function does not appear to have any adverse effects on people who share protected characteristics, and no further actions are recommended at this stage.

### **7.0 Consultation**

All stakeholders involved in developing, implementing, managing and monitoring the IFR systems and processes were engaged in the development of the IFR Policy.

### **8.0 Training and Awareness**

All staff involved in the IFR process should have the necessary skills and expertise to enable them to make effective decisions and will be required to attend regular training. This will include (but is not limited to):

- Legal update - provided by Solicitors.
- Peer learning - this is to provide Panel members/ Decision Makers with the opportunity to review cases and the decisions which have been made by all panels over the quarter.
- Reflective learning - reviewing the numbers of IFRs/ cases presented at panel including the outcome.
- IFR Team workshops
- Conflicts of Interest e-learning
- Data Security e-learning

An anticipated annual training plan is provided in Appendix 7 to this policy.

## **9.0 Monitoring Compliance with the Policy**

Numbers/ types of cases considered at Panel(s) across the ICB locality will be collated and presented regularly to each Panel. This will enable Panel members/ Decision Makers to undertake reflective learning and self-moderation and give an overview of the clinical areas which are being requested. This reflection will fulfil part of the training needs, with additional annual training being made available to allow relevant individuals to carry out their roles consistently.

An annual report will be provided to ICB Quality Committee outlining the cases referred and decisions taken through the IFR process which will include the number of IFRs received and the clinical areas being requested.

An internal audit of a selection of Individual Funding Requests undertaken by an appointed independent clinician. This report will cover compliance, effectiveness and outcomes of the Policy, together with a summary of all the Individual Funding Request Panel decisions for that financial year.

## **10.0 Arrangements for Review of Clinical Commissioning Policy Statements**

The Health and Care Act 2022 has dissolved Clinical Commissioning Groups (CCGs) and transferred statutory functions (duties and powers) to Integrated Care Boards (ICBs) from 1 July 2022. As with CCGs ICBs have a statutory responsibility for commissioning services for the population within available resources. Whilst most service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the NHS. The Individual Funding Request policy is how these decisions are taken. Decisions are taken on a case-by-case basis supported by clinical commissioning policies / statements which set out the evidence base (cost, clinical, and health outcomes), quality and equality impacts, and value for money. CCG policies were developed over many years to reflect local populations, service provision and clinical practice, all of which can differ from place to place.

The ICB recognises that the act of transfer illuminates a variation in clinical commissioning policies across the geographic areas of Humber and North Yorkshire. The ICB also recognises that the CCGs undertook significant and robust authorisation processes to develop local policies for local populations, and that adopting a single policy is not always desirable or achievable quickly, for example due to differences in provision and local GP

knowledge about service availability, and a statutory duty to engage on matters of proposed service change.

For these reasons the ICB has adopted an interim approach to Individual Funding Requests, using commissioning statements aligned to the CCG boundary as it was on the 30 June 2022. Alternative arrangements which seek to remove variation for patients cannot be achieved for the reasons above.

The ICB has established a clinically and professionally led Group comprised of former CCG experts, which includes GPs representing each local area, to lead the review of all clinical policies as well as new areas brought about by national Evidence Base interventions guidelines. The group aims to prepare commissioning policies in two waves – wave one will be completed by the end of March 2023 and wave two by the end of March 2024. The process for Individual Funding Requests will be clearly communicated to all GPs and referring specialists to ensure that patients remain well informed. The Individual Funding Request Policy will be monitored and will be reviewed within the first 9 months following approval and will form part of the Individual Funding Request annual report to the ICB Quality Committee.

#### **11.0 Any medical procedure or treatment not routinely commissioned where there is not a specific policy statement**

This Policy also allows for referrals where there is not a specific commissioning policy statement to support the decision making. Clinicians or healthcare professionals can make Category One requests where the referrer identifies a clinical need to recommend an intervention for their patient.

The clinician/ healthcare professional must provide a reasoned application for the request outlining why the intervention is indicated, how the intervention meets the evidence base (including but not limited to NICE and Royal College guidance) and the intended/ predicted benefits/ outcome for the patient if they receive treatment.

#### **12.0 Dissemination**

The policy will be shared with the staff, healthcare professionals and the public via the ICB website and through relevant communication tools/ meetings.

#### **13.0 Associated Documentation**

ICB Commissioning Policy Statements.

#### **14.0 References**

“Priority Setting: managing individual funding requests”. The NHS Confederation, 2008. NHS Institute for Innovation and Improvement. Available at

<http://www.nhsconfed.org/Publications/Pages/Prioritysettingfunding.aspx>

Regulation 35 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibility and Standing Rules) Regulations 2012 (SI 2012 No 2996). Available at

<http://www.legislation.gov.uk/ukxi/2012/2996/made>

The NHS Constitution for England. DH. March 2013. Available at <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>

Supporting rational local decision-making about medicines (and treatments), a handbook of good practice guidance. National Prescribing Centre, February 2009. Available at: [http://www.npc.co.uk/local\\_decision\\_making/resources/handbook\\_complete.pdf](http://www.npc.co.uk/local_decision_making/resources/handbook_complete.pdf)

Guidance on NHS patients who wish to pay for additional private care. DoH, March 2009. Available at: [http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Consultations/Response/consultations/DH\\_096428](http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Consultations/Response/consultations/DH_096428)

The Operating Framework for the NHS in England 2012/13. DoH, December 2011. Available at: <https://www.gov.uk/government/publications/the-operating-framework-for-the-nhs-in-england-2012-13>

## **15.0 Appendices**

Appendix 1: Decision Making Process- Standard Operating Procedure

Appendix 2: Standard Process / Urgent Requests Flowchart

Appendix 3: Reconsideration Flowchart

Appendix 4: Appeals Flowchart

Appendix 5: Terms of Reference for each panel

Appendix 6: Training Plan for IFR Panel / Admin

Appendix 7: Relevant IG agreement(s) & Clinical Safety Standards

## 16. Policy Document Requirements Details

### 16.1. Submission of Funding Requests

The ICB has adopted an online self-service system called Check+.

EBI Check+ allows registered users/ GPs to generate a prior approval ticket (PAT), subject to compliance with the agreed local policy criteria, to attach to the patient record before referral or treatment for Evidence Based Interventions (EBI), related conditions. EBI Check+ is used for Category 2 Interventions, which are restricted and should only be performed after specific criteria are met via the Prior Approval process.

EBI is a programme of work that aims to reduce harm and unnecessary interventions, by ensuring that interventions routinely available on the NHS are evidence-based and appropriate. Local EBI (or equivalent) policies detail the procedures which the NHS commissions, along with the specific clinical criteria. This ensures patient safety and best use of NHS resources.

IFR Check+ supports referrals for Category 1 Interventions, interventions that are not routinely commissioned due to there being little evidence to support the intervention are examined on an individual basis where clinical exceptionalism is considered. The platform will allow primary and secondary care users to submit and track the progress of their IFR cases. It also supports two-way communication with the IFR team and a referring clinician and provide email notifications to the respective users of any status update.

Any funding request received outside of the web-based system (including any requests directly made by patients) will not be accepted.

The IFR process only considers clinical information, and it is the referring clinician's/ healthcare professional's responsibility to ensure that all relevant clinical information has been included in the funding request. This could include, but is not limited to, copies of letters from secondary care consultants, details of the anticipated costs and length of treatment or copies of reports (e.g., physiotherapy assessments). The funding decision will only be made on the information submitted as part of the request.

### 16.2. IFR Panels

Three IFR Panels will be convened to cover the North Humber, South Humber and North Yorkshire geography with delegated authority to make funding decisions on individual cases. These are the **North Humber Panel** (Hull and East Riding of Yorkshire), **South Humber Panel** (North East Lincolnshire, North Lincolnshire) and the **North Yorkshire Panel** (North Yorkshire and Vale of York). Each Panel will generally consider cases referred for peer discussion by the CSO of its local Panel. Each Panel may also act as an Appeal Panel for cases referred from its neighbouring Panel.

Membership of the relevant Panel will be taken from clinical and healthcare professionals within the Panel's constituency. It is anticipated that a pool of 4-6 GPs/ clinicians will be appointed to each Panel to ensure that quoracy requirements can be met. GPs will be remunerated for their time in line with the ICB remuneration policy. Additional support for the Panels is provided in areas of Medicines Optimisation, Commissioning and Public Health through access to specialist advisers as required.

Each Panel will appoint Chair and further Panel members are permitted at the discretion of ICB Quality Committee but must be reflected in the Terms of Reference of the Panel.

Panels will generally be expected to reach consensus decisions on the cases referred. If a consensus cannot be reached the Chair will request further information from the referring clinician/ healthcare professional and/ or refer to the IFR Lead Officer for a commissioning statement review.

The Terms of Reference of the IFR Panels will be agreed and kept under review by the ICB Quality Committee. Model Terms of Reference are included as Appendix 6 to this policy.

### **16.3. Decision Making**

The ICB must identify, via its scheme of delegation, a panel of individuals given authority to act as Decision Makers for Individual Funding Requests made to the ICB. These individuals will generally be clinicians working in the ICB area, who will ensure that this Policy and related systems and procedures are followed when making individualised decisions about whether a patient's circumstances are exceptional enough to qualify for individual funding.

Considering the definition of exceptionality IFR Panels apply a two-step process to making decisions about exceptionality. They first decide whether;

1. *"the patient or their circumstances are significantly different from the general population of patients with the condition in question" and then*
2. *whether "the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition."*

The answer to both questions must be a "yes" for clinical exceptionality to be established.

There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances (as defined above). The onus is on the referring clinician/ healthcare professional to set out the grounds for the patient's clinical exceptionality clearly in the funding request. However, it is possible to give some guidance outlined in this document.

### **16.4. Step One – Significant Difference from the General Population**

'Exceptional' in IFR terms means a person to whom the general rule should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the appointed IFR Panel need to be satisfied that the referring clinician/ healthcare professional has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.

#### **16.4.1. Clinical exceptionality: severity / failure to respond to standard care**

The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common co-morbidities for many conditions. Again, these considerations are likely to have been considered in formulating the general policy.

Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient’s condition does not in itself usually indicate exceptionality.

Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

If the proposed intervention is thought to offer a benefit to patients in some groups generally (i.e., those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority, and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

#### **16.4.2. Clinical exceptionality: genotypes**

When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient different to others in terms of clinical management and able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

#### **16.4.3. Clinical exceptionality: multiple grounds**

There may be cases where clinicians seek to rely on multiple factors to show that their case is clinically exceptional. In such cases each factor will be looked at individually to determine whether the factor is capable, potentially, of making the case exceptional and whether it does in fact make the patient’s case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but it might be relevant on another factor. That is a judgment within the discretion of the IFR Panel.

If it is determined that none of the individual factors on their own mean that the patient’s clinical circumstances are considered exceptional, the combined effect of those factors will be considered. In this way a decision can be reached on whether the patient’s clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

#### **16.4.4. Clinical Exceptionality: non clinical, psychological and social factors**

The IFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual’s situation, background, ambition in life, occupation or family circumstances, consideration of these non-clinical factors would introduce this concept of ‘worth’ into clinical decision making.

As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone’s individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar

arguments could be made for all or many of the patients who cannot routinely access the care requested.

Therefore, non-clinical, psychological, and social factors must be disregarded for this purpose for the IFR Panel, to be confident of dealing in a fair manner in comparable cases.

Consideration of social factors would also be contrary to policy of non-discrimination in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the IFR Panel should not make.

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

#### **16.4.5. Pain**

Pain has been defined as an “unpleasant sensory and emotional experience arising from actual or potential tissue damage” with clinical pain being “whatever the person says he or she is experiencing whenever he or she says it occurs” and is therefore subjective.

There is insufficient evidence to use questionnaire derived scores to evidence pain in individuals. Therefore, in lieu of a standard assessment tool, alternative clear and objective evidence must be provided when demonstrating patient pain and significant functional impairments/ limitations to activities of daily living.

This evidence should include documented assessments and/ or patient history, including:

- Significant functional impairment is defined as: Symptoms that result in a physical/ functional inability to sustain employment/ education despite reasonable occupational adjustment, or act as a barrier to employment or undertaking educational responsibilities.
- Symptoms preventing the patient carrying out routine domestic or carer activities.
- Symptoms preventing the patient carrying out self-care or maintaining independent living.

#### **16.4.6. Photographs**

Photographs are not to be submitted for use in the consideration of exceptionality. Cosmetic appearance is not considered when judging exceptionality. A detailed description of any functional impairment is much more important. Any photographs received will be returned to the sender upon receipt and an incident will be logged by the NECs team on Safeguard Incident and Risk Management System (SIRMS).

### **16.5. Step Two – Significantly more benefit from an intervention than the general population**

The referring clinician/ healthcare professional should include within the body of the application evidence for superior clinical effectiveness of the proposed intervention for the

individual concerned.

Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a specific group of patients.

Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR Panel. It is the sole responsibility of the referring clinician/ healthcare professional to provide this information and the IFR team will not be responsible for undertaking any evidence searches. Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However, it is important that the referring clinician/ healthcare professional makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

When considering clinical effectiveness, the IFR Panel will consider:

- How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician.
- The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied.
- The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome.
- Any complications and adverse events of the treatment including toxicity and rates of relapse. The Panel will take account of side effects when considering the benefits from the treatment.
- Reported treatment outcomes and their durability over the short, medium, and longer term, as relevant to the nature of the condition. The requesting clinician must demonstrate why they consider that the proposed treatment will be effective for the whole period for which it will be given.

## **16.6. IFR Decision Making Timescales**

Requests will be reviewed daily by the IFR Administration (Admin) Team. Any further information requests will be made to the referring clinician within five working days of receipt of the original request. The IFR Admin Team will send requests to the Clinical Support Officer (CSO) via the web-based system daily and will also request further information from specialist advisors as and when they assess a case. Requests will be sent containing all information submitted including patient identifiable information (PID), but it is important to note that because of this, printing of requests is not permitted and should be discouraged.

It is expected that the CSO will review cases sent to them for a decision in a timely manner (5 working days) and review the system each day where possible. The CSO recommendation can be reviewed by the locally appointed IFR Panel so it is expected that they will log into the system and consider all requests outstanding every week. This will enable a response to be provided for standard requests in a timely manner. It is expected that when specialist advisors (Commissioning/ Public Health/ Medicines Optimisation) have been asked to review a case or provide input, they will do so in a timely manner and always within 5 working days of receipt of the request.

## 16.7. Reconsideration

Where a funding request is declined by the IFR Panel, the requesting clinician has the right to request reconsideration but only on the presentation of **new clinically significant** information and/or evidence.

Such requests should be submitted by the referring clinician via the web-based system within **three months** of the original funding decision.

Requests for reconsiderations of decisions received from non-referring clinicians or directly from patients will be returned to the sender and advised of the procedure outlined above.

Upon receipt of an application for a reconsideration request, the IFR Admin Team will screen the original application, the notes of the original decision, all correspondence, any new information and the reconsideration request. The application will then be referred to the original IFR Panel for review.

If a reconsideration request is received outside of this three-month period, it will be classed as a new request and the referrer will be asked to submit the application as a new request. However, unless a funding policy has changed between the original decision and the reconsideration request which directly affects the treatment/procedure, new information must be submitted that wasn't taken into consideration at the time of the original application for it to be presented again. If no new information is presented, the reconsideration request will not be granted and the IFR Admin Team will correspond with the referring clinician advising them of this.

A flow-chart detailing the procedure followed in assessing a reconsideration request is provided in Appendix 4 to this policy.

## 16.8. Appeals

Each IFR Panel will act as an Appeals panel for its neighbouring area. NECS will manage the appointment of panels to ensure that there is a fair and equitable approach and to minimise any conflicts of interest.

An appeal will only be instigated where there are grounds for an appeal i.e., where there is evidence that the IFR Administration Team/ Panel may not have acted in accordance with the agreed IFR process, for example, they have not considered the relevant evidence, material factors or inappropriately applied the criteria (where applicable) in reaching this decision. In this case, the request will be considered as an appeal and referred to another IFR Panel in the area for consideration.

The appeals panel process has been modified to enable a pan-ICS Special Case Panel to consider appeals for IFRs dated on or after the 1 July 2022, on the basis of differential policies.

This panel will be Chaired by the Executive Director of Clinical and Professionals. Any policies subject to a special case would immediately be re-prioritised as high risk for review.

The Appeal Panel will review cases against the agreed IFR process, assessing if the original decision considered the relevant evidence/ material factors only and appropriately applied the criteria in making the decision. The Appeal Panel will decide to make a recommendation to either overturn the original decision and support the request or uphold the original decision and reject the request.

Once a case has been presented as an appeal and discussed at an Appeal Panel, the outcome will be final and no further appeal requests can be made. The IFR Admin Team will produce a decision letter and will send this to the Chair of the Appeal Panel for approval. Once approval is received the IFR Admin Team will then send this to the referring clinician who requested the appeal.

Applicants not satisfied with the Individual Funding Requests Panel process have the right to make a complaint in line with NHS national complaints regulations. This complaint should be submitted in writing to the appropriate complaints team. Concerns regarding the outcome of the Panel will not be dealt with through the NHS complaints procedures. However, the complaints process does not have the right to challenge or overturn an IFR decision.

A flow-chart detailing the procedure followed in assessing an appeal request is provided in Appendix 5 to this policy.

### **16.9. Data Collection / Sharing & Conflicts of Interest**

Personal Identifiable Data (PID) is needed to allow the IFR Admin Team to effectively administer the process. Appropriate agreements and safeguards have been developed to ensure legal processing of data and seek consent of patients for the use of their data (see appendix 9).

As Panel members and their supporting admin teams are often members of the communities for whom they are responsible for making decisions, conflict of interest may arise where an applicant is a patient, an employee or a friend / relative of a Panel member or administrator. The IFR Admin Team will screen out patients at the practice at which a Panel member works as a GP and ensure that the conflict is registered and managed. It is essential; therefore, those identifiable details are shared with the Panel members, and that the Panel members and Administrators conduct themselves with the highest standards of probity in declaring any conflicts of interest that arise. Administrators must similarly pass cases in which they have a conflict of interest to an alternative colleague to manage.

Aggregate anonymised data may be collected by the team for purposes of effective administration of the system, quality improvement, and development of commissioning policy.

### **16.10. Influencing Value Based Clinical Commissioning Policies (VBCCP)**

Sometimes an IFR presents a new type of clinical case which needs a substantial piece of work by local commissioners before a conclusion can be reached. This may require policy development and wider consultation. The IFR Admin Team will collect data on which interventions are being requested via the IFR system and refer this to local commissioners for consideration.

The IFR Admin Team should seek feedback from the relevant responsible commissioners about the timescale for policy development in these cases and provide that information to DMs tasked with either deferring or making individual funding decisions on requests.

The IFR process provides a unique opportunity to identify potential service gaps on an ongoing basis. The IFR Admin Team will ensure effective feedback systems are in place to inform future service developments.

## Glossary

Below are a list of definitions, roles and responsibilities used within the IFR service:

<b>IFR System</b>	The web-based system used by H&NY ICB for the submission and processing of IFRs. <a href="https://checkplus.nhs.uk">Log in - Check+ (checkplus.nhs.uk)</a>
<b>Referring Clinician/ Healthcare Professional</b>	The clinician making the request for the treatment/procedure in question on behalf of the patient. This can be the patient's GP, a professionally qualified healthcare practitioner or the secondary care clinician proposing to undertake the said treatment/procedure.
<b>Provider</b>	The healthcare service provider which will or is proposing to undertake the said treatment/procedure.
<b>Check+</b>	Online self-service system. GPs use EBI Check+ to see if their patient is eligible for treatment – if they don't meet the criteria then it directs them to the IFR Check+ system where the referrer can then put in an IFR if the patient is clinically exceptional.
<b>Clinical Decision Maker (DM)</b>	A senior GP within the ICB with delegated authority to make decisions on behalf of their locality in relation to IFR applications. Decisions can be made by the Decision Maker in isolation or can be referred to the IFR Panel for consideration.
<b>IFR Panel</b>	The IFR Panel has delegated authority from the ICB to make decisions about individuals IFR cases. Whilst discussions take place amongst the Panel members, accountability for the respective case decisions rests with the individual representative(s) on the Panel.
<b>Funding Policy / Protocols</b>	Documents which outline a set of criteria that must be met for a said treatment/procedure to be provided
<b>Humber and North Yorkshire (H&amp;NY) Integrated Care Board (ICB)</b>	Responsible for health and care services across Humber and North Yorkshire geographical area.
<b>ICB Quality Committee</b>	The Quality Committee is a sub-committee of the Humber and North Yorkshire Integrated Care Board
<b>Evidence Based Interventions (EBI) / Value Based Clinical Commissioning Policies (VBCCP)</b>	Documents which outline treatments / interventions / procedures not normally provided by the NHS and a set of criteria that must be met for some treatments / interventions / procedures to be provided.
<b>Eligibility</b>	The patient's circumstances meet the defined protocols and/or criteria for the treatment/intervention/procedure at the time of application against the protocol/criteria in place at the time of the request.
<b>Standard Request</b>	A standard funding request is a request for a non-urgent clinical intervention for which a decision can be provided, usually within 40 working days of receipt of the request, where all relevant information required is available.
<b>Urgent Request</b>	From time to time, the clinical circumstances of an Individual Funding Request may mean that delaying a decision until the next scheduled meeting of the Panel is likely to have a significant detrimental effect on the

	patients' health and well-being (threat of death or serious disability) or adversely affect eligibility for that treatment. In these circumstances the request will be deemed as urgent. Urgent requests will be considered in line with the NHS Standard Contract. SC29.27
<b>Pre-screening</b>	Once an IFR has been submitted, the IFR Admin Team will review and pre-screen the detail of the request and assess whether the application is deemed appropriate for IFR and complete
<b>Prior Approval</b>	Whereby approval can be given by the IFR Admin Team for a defined treatment/eligibility as agreed with ICB and local providers
<b>Medicines Optimisation</b>	The IFR Panel have timely access to specialist support from the NECS Medicines Optimisation team and the Medicines Management Leads for York and North Yorkshire in relation to any drug-related funding requests.
<b>Population Health Advisors (Specialist Public Health Support)</b>	The IFR Panel have timely access to Population Health Advisors (specialist public health) advice on the review of evidence and policy. This is provided to ICBs by the Local Authorities of the region under arrangements made between ICBs and the regional Directors of Public Health (DsPH).
<b>Commissioning Support</b>	The IFR Panel have timely access to specialist support from the NECS Provider Management (including Mental Health/Learning Disabilities), Commissioning Delivery Teams in relation to any contracting and commissioning queries.
<b>Reconsideration</b>	Where an application for funding has been declined, the referring clinician has the opportunity to present new clinical information in support of the application being reconsidered.
<b>Appeal</b>	Where the referring clinician feels that due process in considering the IFR application has not been followed, a procedural appeal can be requested. Interim arrangements will be in place for any appeals against requests made after 1 July 2022 on the basis of unaligned policy and may result in the convening of a Special Case Panel.

# Appendix 1: Decision Making Process- Standard Operating Procedure

## Standard Operating Procedure statement

This document sets out how the process for managing individual funding requests (IFRs) for the Humber and North Yorkshire Integrated Care Board. Such requests are managed in line with the IFR & VBC Policies.

## Standard Requests

Once an IFR has been submitted, the IFR Admin Team will review and pre-screen the detail of the request and assess whether the application is deemed complete. If it is felt that further information is required to fully assess the request, the IFR Admin Team will contact the referring clinician via the web-based system to request the additional information. The referrer will have two months from that date of to provide the requested information. The IFR will only be considered as being complete once the service has received all relevant additional information required to consider the case.

As soon as all of the relevant information has been made available and the request is deemed complete, the IFR Admin Team will review the request, against any protocols/ criteria available (including the ICB Value Based Clinical Commissioning Policy and consider if the procedure for which the prior approval is required can be obtained via the Check+ and NHSE Specialised Commissioning Manual) and seek any relevant advice from specialist advisors from Commissioning, Population Health and/or Medicines Optimisation. The IFR Admin Team may at this stage refer requests elsewhere (for example to specialist commissioning colleagues / CHC commissioners etc.) if during their review it has become clear that an IFR is not the appropriate route by which the referrer should be seeking funding for the intervention requested.

## The role of Clinical Triage:

Triage is recommended as good practice by the NHS Confederation (2008b). The role of triage is to review all applications in relation to national, regional, and local guidance and/or policies, as well as to identify any previous precedents that have been set. This stage will also identify where important and relevant documentation or information may not have been included.

Where it is clear from the application that the individual does not meet criteria, and/or there is no clear evidence supporting the treatment, or where the clinician has not made a case for exceptionality, the IFR may be declined.

Clinical triage enables requests to be returned to the referring clinician where:

- The request has not been submitted by a healthcare professional
- Relevant clinical information has been omitted
- The request does not need to go through the IFR process as it meets the threshold criteria for that intervention
- The request can be dealt with under another existing contract

Clinical triage provides a summary for review and ratification by IFR Panel where it appears:

- There is no clinical case
- The request does not meet criteria outlined in an agreed commissioning policy and for which no case has been made for exceptionality

- That treatment can be commissioned because they meet pre-agreed exceptions (some of which are set through precedent)
- The request raises a major policy issue and needs further discussion and work

### **Cases Referred to IFR Panel**

If a case needs to go to an IFR Panel (see below for more information) for a case to be considered for peer review, the case will be added to the agenda of the next available meeting, (i.e., if it is a North Yorkshire patient, it will be added to the next North Yorkshire IFR Panel). Once this meeting has taken place and the case has been presented and a decision made by the IFR Panel, a response will be drafted by the IFR Admin Team and shared with the panel members by way of the minutes of the Panel meeting. Once the Panel members have confirmed the rationale, the IFR Admin Team will generate the decision letter. Responses will be sent to referring clinicians within 7 working days of the decision being made.

In exceptional circumstances, when a request has been presented to a Panel for a decision to be made, the Panel may feel that they cannot make a decision based on the information available and may choose to defer the decision for further information. In cases such as this, the further information requested will be discussed and agreed at the Panel meeting and the IFR Admin Team will send these queries/questions to the referring clinician after the meeting has taken place. Once a response is available, the case will be either reviewed by the Panel members out with the Panel meeting or presented again to the next available meeting for further discussion.

### **Urgent Requests**

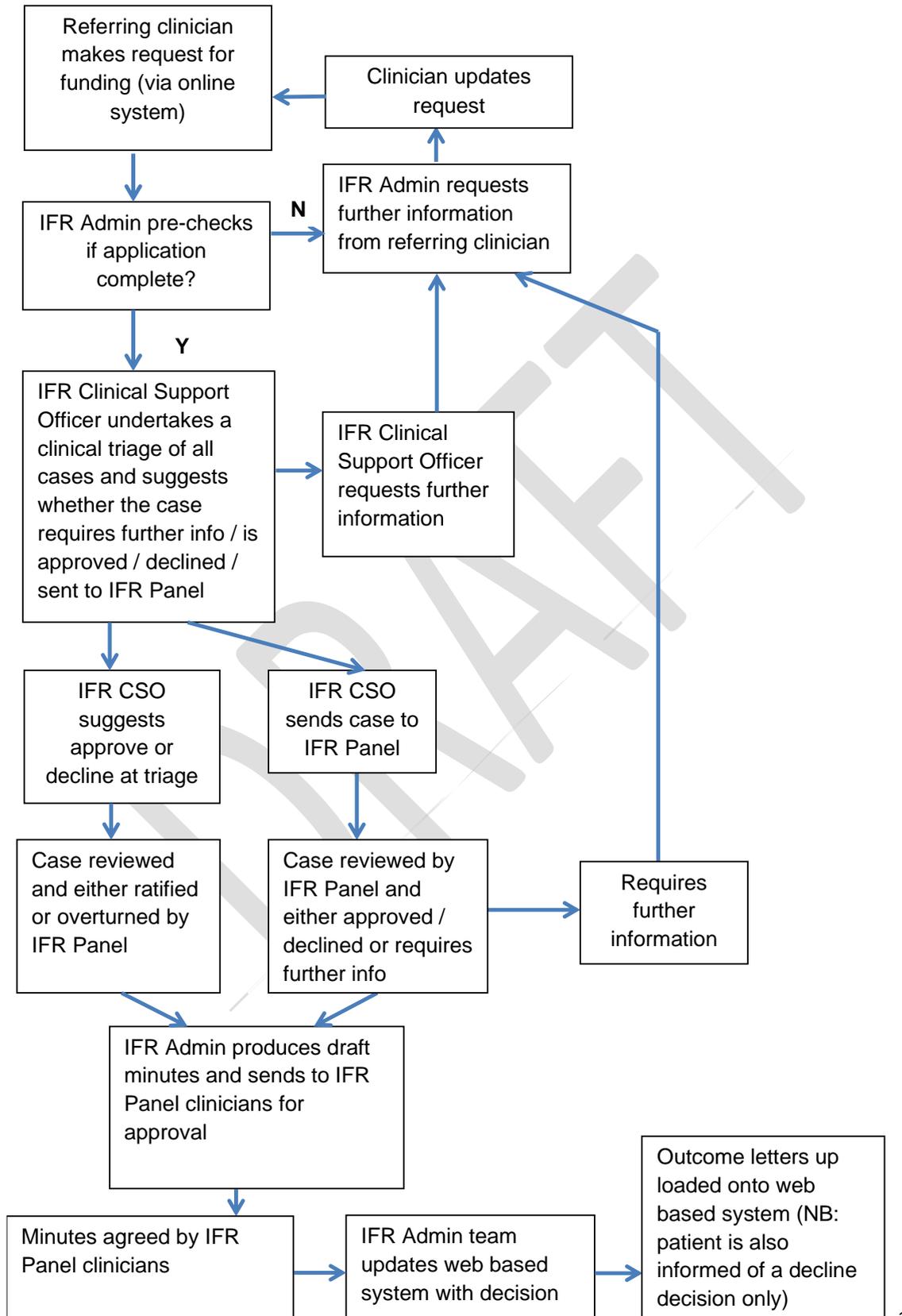
From time to time, the clinical circumstances of an Individual Funding Request may mean that delaying a decision until the next scheduled meeting of the Panel is likely to have a significant detrimental effect on the patients' health and well-being (threat of death or serious disability) or adversely affect eligibility for that treatment. In these circumstances the request will be deemed as urgent.

Urgent requests will be considered in line with the NHS Standard Contract. SC29.27. The information will be communicated to each of the Panel members via NHS net in line with the agreed process and a decision will be made within 5 working days of receipt.

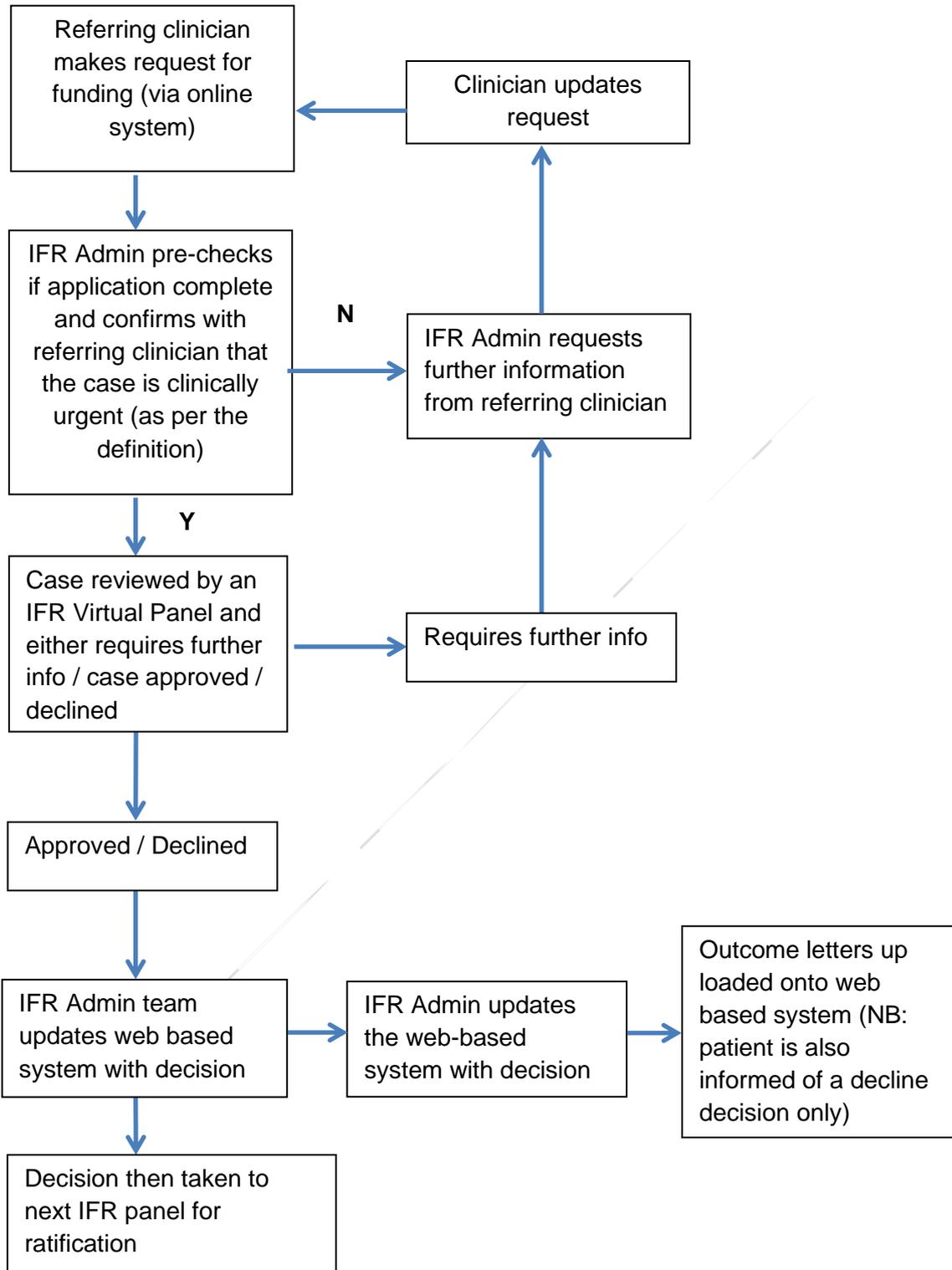
If an urgent decision is required outside of a scheduled meeting and the request cannot be heard by the alternative ICB Panel, for reasons of expediency, virtual meetings will be carried out by email. This is not normally a substitute for routine meetings of the IFR panel but will be used only in unavoidable circumstances so as not to compromise the pace of decision making for urgent individual cases.

Where a request has been considered and a decision made in advance of a formal Panel meeting, the decision will be reported and recorded at the next meeting. Decisions made in advance of a Panel meeting will be communicated to the referring clinician and/or the patient's GP and copied to the patient within 2 working days of the date of the decision.

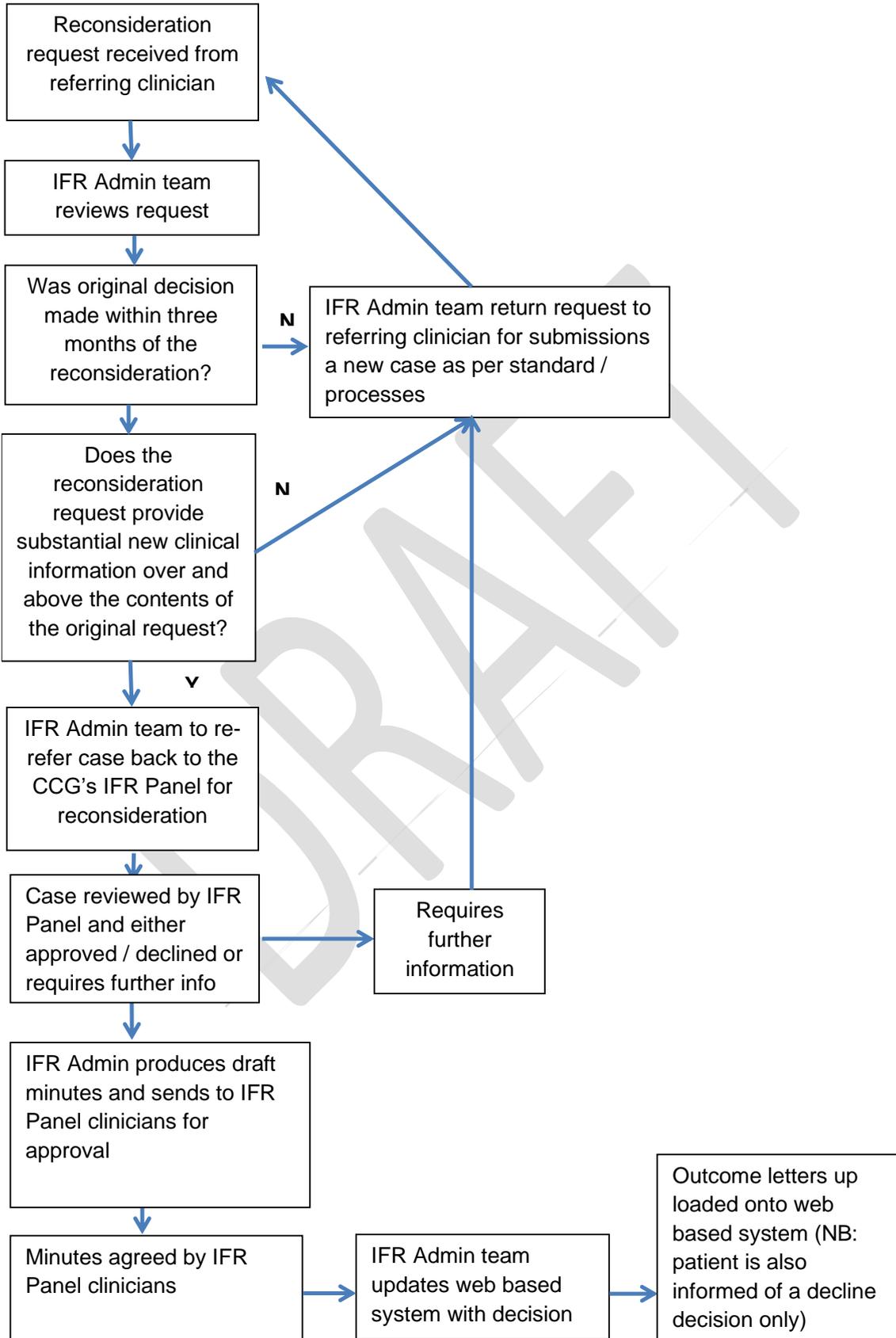
## Appendix 2: Standard Process / Urgent Requests Flowchart



## Flow chart for urgent process

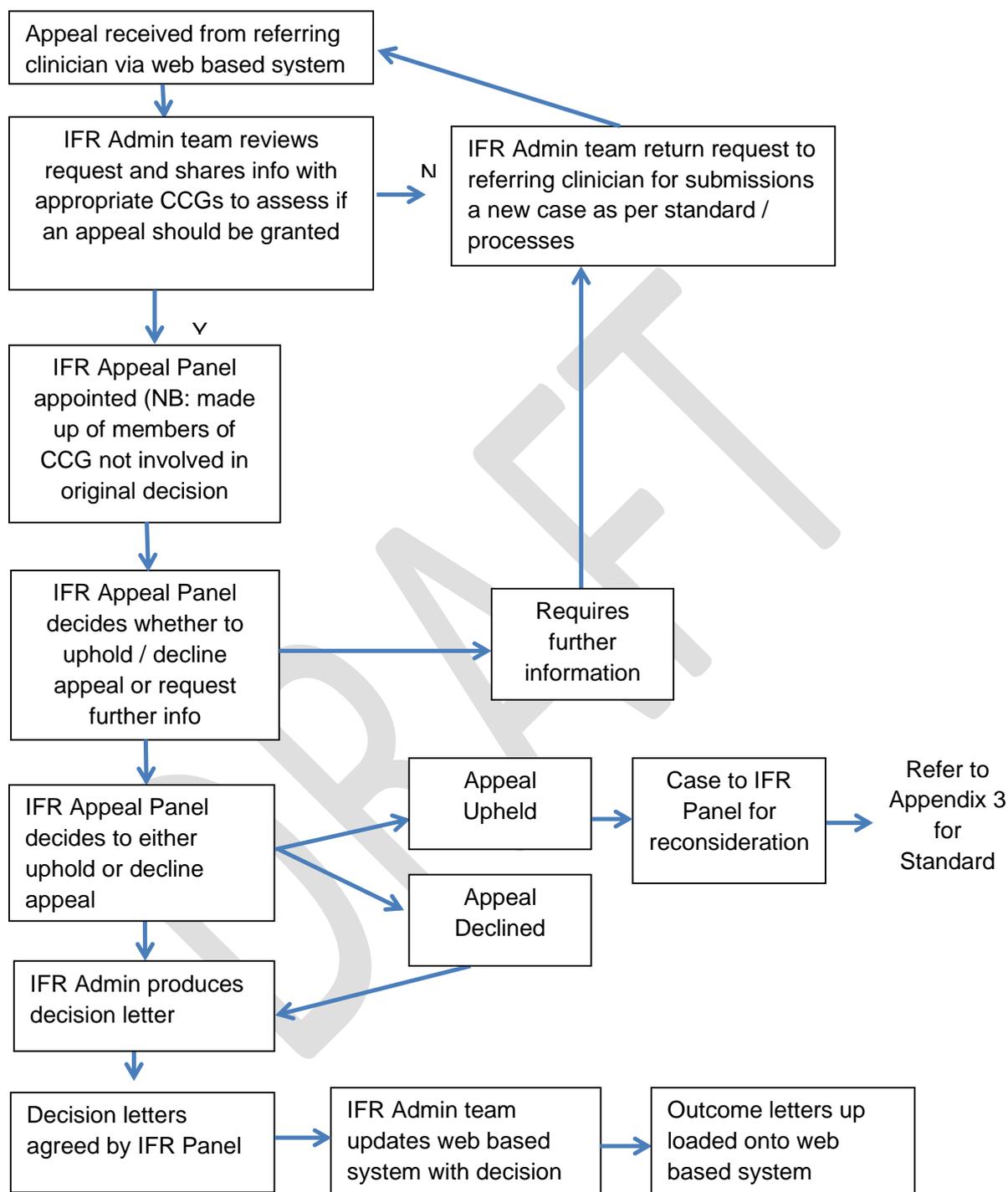


### Appendix 3: Reconsideration Flowchart



## Appendix 4: Appeals Flowchart

Interim arrangements are in place to allow for the review of Individual Funding Requests, appealed on the basis of differential commissioning policy statements across the ICB until such time that those statements have been aligned. In these cases a pan-ICB Special Case Panel will be convened and with any policies subject to a special case immediately re-prioritised as high risk for review.



### **INDIVIDUAL FUNDING REQUESTS PANEL (North Humber/ South Humber/ North Yorkshire)**

#### **TERMS OF REFERENCE**

#### **1. Constitution**

- 1.1 The Humber and North Yorkshire Integrated Care Board hereby resolve to establish an Individual Funding Request Panel (The Panel) which will report to the ICB Quality Committee. The Panel has delegated powers of approval in accordance with the operational delegated limits within the Scheme of Reservation and Delegation.

#### **2. Principal Functions**

- 2.1 The IFR Panel will be responsible for approving decisions on funding for treatment requests for exceptional cases or for rare conditions. The main functions of the Individual Funding Request Panel (the Panel) are as follows:
- 2.1.1 To consider Individual Funding Requests and make decisions of behalf of the ICB whether to support or not support these individual requests based on the information provided.
  - 2.1.2 To ratify triage decisions.
  - 2.1.3 To provide feedback to the ICB on the commissioning policy statements to inform future policy developments.

#### **3. Membership**

- 3.1 NECS IFR Admin Team manages the funding requests for the ICB.
- 3.2. There are three IFR Panels – North Yorkshire IFR Panel (North Yorkshire and Vale of York), North Humber IFR Panel (East Riding of Yorkshire, Hull) South Humber (North Lincolnshire, and North East Lincolnshire).

Membership of the Individual Funding Request Panel will comprise of:

- Chair
- IFR Lead
- Local H&NY GPs/Clinical Decision Makers (with voting rights)
- NECS IFR Clinical Support Officer (no voting rights)
- NECS IFR Case Assistant (no voting rights)
- Public Health Specialist or representative (for advice only, no voting rights)

The following is not an exhaustive list but are specialist advisors to the Panel and can attend IFR Panel meetings to offer advice and technical support as and when necessary.

- Learning Disability and Mental Health Specialist or representative
- Medicines Management lead or representative
- Secondary Care Consultant

The Panel may also seek legal advice from the Legal and Governance teams within H&NY ICB as and when required.

#### **4. Conflicts of Interest**

- 4.1 If a member of the Panel has a conflict of interest with an individual request, they will not take part in the decision making to ensure that a robust process is maintained. The chair of the meeting has responsibility for deciding whether there is a conflict of interest and the appropriate course of corresponding action.
- 4.2 A record of any declarations of interest will be made in the formal record of the Panel meeting.

#### **5. Quorum**

- 5.1 For the meetings to be quorate, they must consist of a Chair and at least three local ICB clinicians (this can include any registered clinician/ medic). The IFR Admin Team must also be in attendance and will support the presentation of cases where required and take notes of each meeting.
- 5.2 An Officer in attendance for an Executive Director (Officer Member) but without formal acting up status may not count towards the quorum.
- 5.3 If the Chair or a voting Panel member has been disqualified from participating in the discussion on any matter and/ or from voting on any resolution due to a declaration of a conflict of interest that person shall no longer count towards the quorum. If a quorum is then not available for the discussion and/ or the passing of a resolution on any matter, a decision cannot be taken at that meeting. Such a position shall be recorded in the minutes of the meeting. Consideration/decisions can be deferred to the next meeting or, in urgent circumstances, be considered via a virtual meeting if required (see below).

#### **6. Frequency of meetings**

- 6.1 Meetings will be convened monthly, at a time to be agreed, with the ability to call an extra Panel in the event of a backlog of cases or stand down a Panel in the event of no cases. This will be reviewed in the light of the number of applications received and the development of protocols which define criteria for approving or rejecting requests.
- 6.2 Three IFR Panels will be held per month – North Yorkshire IFR Panel (North Yorkshire and Vale of York), North Humber IFR Panel (East Riding of Yorkshire, Hull) South Humber (North Lincolnshire, and North East Lincolnshire).
- 6.3 Panel meetings will be held in private. Requesting patients will not be invited to attend. Requesting clinicians will not be invited to attend except in the most unusual cases.

- 6.4 Papers will be prepared before each meeting and will be circulated to all members 5 working days in advance of the meeting taking place. These papers will include an overview of the case developed by the IFR CSO and copies of information/evidence provided by the referring clinician (including any new evidence that has been provided for cases requiring a reconsideration) plus any further information/evidence regarding the request the IFR CSO/IFR Admin Team deems appropriate. If no cases are required to be presented at an IFR Panel meeting, the meeting will be stood down. The IFR Admin Team will advise all members of this in advance.

## **7. Remuneration**

Remuneration for those representatives that undertake this duty outside of existing roles will be made at the agreed rate in line with ICB policy.

## **8. Urgent Requests**

- 8.1 Urgent requests will be considered in line with the NHS Standard Contract. SC29.27.
- 8.2 If an urgent decision is required outside of a scheduled meeting and the request cannot be heard by the alternative ICB Panel, for reasons of expediency, virtual meetings will be carried out by email. This is not normally a substitute for routine meetings of the IFR panel but will be used only in unavoidable circumstances so as not to compromise the pace of decision making for urgent individual cases.
- 8.3 The information is communicated to each of the Panel members via NHS net in line with the agreed process and a decision will be made within 5 working days of receipt.
- 8.4 Where a request has been considered and a decision made in advance of a formal Panel meeting, the decision will be reported and recorded at the next meeting. Decisions made in advance of a Panel meeting will be communicated to the referring clinician and/or the patient's GP and copied to the patient within 2 working days of the date of the decision.

## **9. Reconsideration**

- 9.1 A reconsideration request should be made within three months of original decision, via documented correspondence stating why the reconsideration request is being made and must include any new information / evidence.
- 9.2 On receipt of an application for reconsideration, the IFR Admin Team will screen the original application, the notes of the Panel decision, all correspondence, any new information and the reconsideration request.
- 9.3 Where it is evident that substantial new information has been made available over and above the contents of the original request, the request should be reconsidered within the Panel.

## **10. Appeals**

- 10.1 Where there are grounds for an appeal hearing, i.e., where there is evidence that the IFR Admin Team/ Panel may not have acted in accordance with the agreed IFR process, considered the relevant evidence, considered material factors only or

appropriately applied the criteria in making this decision, a recommendation will be made to send the case to another IFR Panel in the ICB area.

- 10.2 The outcome of the Appeal Panel is the final decision and will be communicated by written correspondence usually within 5 working days of the Appeals Panel meeting. For all cases the IFR Admin Team as role of co-ordinator, will write on behalf of the ICB, to the referring clinician, with the decision(s) and reason(s) for the decision(s) reached by the Panel. It is expected that the referring clinician will then discuss the outcome of the Panel with the patient(s) concerned.

## **11. Reporting**

- 11.1 The minutes of the Panel shall be formally recorded and submitted to the ICB Quality Committee. The Chair of the Panel shall draw to the attention to any issues that require disclosure to the appropriate committees for H&NY ICB.

## **12. Confidentiality**

Anonymity is essential for two reasons:

1. In order to protect patient's identity, for this reason the requesting clinician is asked not to refer to the patient by name or initials within the rest of the application form.
2. For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex.

Depending upon individual clinical circumstances it may be necessary to re-introduce information on the patient's age and/or sex for consideration. When cases are considered which require access to confidential clinical information through triage, implied consent to disclosure of such information to all members of the IFR Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in IFR publicity material.

## **13. Other Matters**

- 13.1 The Panel will be supported administratively by the IFR Admin Team, whose duties in this respect will include:
- Agreement of the agenda with the Chair and the collation and distribution of the papers.
  - Taking the minutes and keeping a record of matters arising and issues to be carried forward.
  - Circulating the minutes to all Panel members, confirmation of the minutes is required from the Chair and decision maker prior to the decision letter being sent to the referring clinician. Panel members will aim to confirm acceptance within 5 days of circulation.
  - Advising the Panel on pertinent matters.
  - Maintain a register of all applications considered and the outcome of each (via the electronic system in place).

- In their role as co-ordinator, will write on behalf of the ICB and Funding Panel to the referring clinician with the decision(s) and rationale(s) for the decision(s) reached by the Panel.

#### **14. Review of Terms of Reference**

14.1 The ICB Quality Committee will review these Terms of Reference annually.

#### **Panel Arrangements**

<b>Panel</b>	<b>Locality</b>
<b>North Humber</b>	Hull
	East Riding
<b>South Humber</b>	North East Lincolnshire
	North Lincolnshire
<b>North Yorkshire</b>	North Yorkshire
	Vale of York

## Appendix 6: Training Plan for IFR Panel / Admin

The following training plan for IFR Panel members and IFR Admin Team has been developed to provide:

- Legal update.
- Peer learning review – this is to provide Panel member/ Decision Makers with the opportunity to review cases and the decisions which have been made across the ICB over the previous quarter.
- Reflective review – reviewing the numbers of IFRs received per quarter and those cases presented at panel and the outcome.

Training Plan		Month											
Training/Course	Attendees	April	May	June	July	August	September	October	November	December	January	February	March
Legal update	Panel members								3hr session				
	Band 5 / 8A								3hr session				
Peer Learning	Panel members	1 hour			1 hour			1 hour			1 hour		
	Admin for Panel	1 hour			1 hour			1 hour			1 hour		
IFR Team workshop	NE&NC/Y&H Teams			1 full day									
Reflective Report	Panel members			1 hour			1 hour			1 hour			1 hour
	Admin for Panel			1 hour			1 hour			1 hour			1 hour

## Appendix 7: Relevant IG agreement(s) & Clinical Safety Standards

All Data Processing Agreements can be found in Appendix F within the ICBs SLA with NECS for commissioning support services.

Each ICB has signed and retained the SLA variation sent to them by NECS to update Appendix F for GDPR in 2018, within which the Data Processing Protocol (Annex 2) specifically includes Individual Funding Request services.

NHS Digital (NHSD) Information Standards define the requirements to which the NHS and those with whom it commissions services and its IT System Suppliers must conform. As an organisation which manufactures and deploys health IT systems, NECS must put in place the mechanisms necessary to establish and maintain compliance with these relevant Clinical Safety Standards, namely DCB0129 (manufacture) and DCB0160 (implementation). When any change to the IFR system is required, to meet the national standards we follow NECS clinical safety assurance process and discuss any potential changes with the Clinical Safety Officer to define whether they are in scope and if further action is required.