Hull Clinical Commissioning Group

Individual Funding Request Policy and Procedure

Version 1.6

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Name of Responsible Committee/Individual:	CCG Board
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Target Audience:	CCG Staff (especially those involved in commissioning and contracting), Commissioning Support (CS) staff involved in delivering the IFR service and referring clinicians (primary, secondary and tertiary care).

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1 Introduction

1.1 NHS Hull Clinical Commissioning Group (The CCG) has a statutory responsibility to commission care, including medicines and other treatments, for the population it serves within available resources by prioritising between competing demands. The CCG will therefore ensure that it does not use scarce resources on health care interventions that are not considered to be clinically effective or cost effective in meeting the health needs of patients. (The term 'health care intervention' includes use of a medicine or medical device, diagnostic technique, surgical procedure and other therapeutic intervention.)

1.2 There is considerable variation in the evidence of clinical effectiveness of health care interventions, where costs may vary. Individual requests for treatment which are not covered by existing contracts are received by the CCG. Some requests are for treatments for rare conditions where local services are not developed, while others are for health care interventions that the CCG will not commission as a matter of routine, but where the referring clinician believes that there are exceptional circumstances that justify a request for referral. The CCG will ensure fairness of access to treatments which may normally be restricted, but which may offer specific benefits in an individual context.

2 Purpose

2.1 The purpose of the IFR policy is to:

- Explain the difficult choices faced by the CCG and how the CCG has made the decision to prioritise resources to ensure the best health outcomes for the population it serves;
- 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 appeals 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;
- Demonstrate a clear process for decision making;
- Demonstrate that CCG decisions not to commission or to restrict access to certain healthcare interventions are lawful and taken in line with government directions.

3 Scope

This policy applies to:

3.1 All employees of the CCG, any staff who are seconded to the CCG, contract and agency staff and any other individual working on CCG premises.

3.2 Employees of the North Yorkshire and Humber Commissioning Support (the CS) who work within the IFR team, any staff who are seconded to the IFR team, contract and agency staff, together with other staff who contribute to the IFR process.

3.3 All referring clinicians within primary, secondary and tertiary care.

3.4 Those treatments and services which continue to be subject to CCG commissioning post 1 April 2013. There are however a range of specialised services which are currently the commissioning responsibility of NHS England and this policy does not apply to such services and treatments, NHS England will manage any Individual Funding Requests relevant to policies or specialised services commissioned by them.

4 Responsibilities

4.1 All CCG staff (especially those involved in commissioning and contracting), all members of staff in the CS IFR team, and referring clinicians (primary, secondary and tertiary care) are responsible for following the procedures as set out in this policy.

4.2 The Chair of the IFR Panel will be responsible for overseeing adherence to the Policy as set out below.

5 Definitions

5.1 Cost effectiveness - The cost-effectiveness of a treatment or intervention is the ratio of its cost to a relevant and accepted clinical measure of its benefit. Cost-effectiveness is concerned with gaining maximum health impact for the resource used on a treatment.

5.2 Clinical effectiveness - The application of interventions which have been shown to be efficacious to appropriate patients in a timely manner to improve patients' outcomes.

5.3 Randomised Controlled Trial (RCT) - A clinical trial that involves at least one test treatment and one control treatment, concurrent enrolment and follow-up of the test and control-treated groups, and in which the treatments to be administered are selected by a random process, such as the use of a random-numbers table.

6 Equality and Diversity

6.1 The CCG is committed to:

- Eliminating discrimination and promoting equality and diversity in its Policies, Procedures and Guidelines, and

- Designing and implementing services, policies and systems that meet the diverse needs of its population and workforce, ensuring that no individual or group is disadvantaged.

6.2 To ensure the above, this Policy and Procedure has been Equality Impact Assessed. Details of this assessment is available on the CCG's website

6.3 Each member of the Panel should undertake an Equality and Diversity e-learning package (or the equivalent) and should be able to demonstrate an understanding of the CCG Equality strategy/objectives and the issues that may be relevant to each Individual funding request.

7 NHS Constitution

7.1 The CCG is committed to:

- the achievement of the principles, values, rights, pledges and responsibilities detailed in the NHS Constitution, and
- ensuring they are taken account of in the production of its Policies, Procedures and Guidelines.

7.2 This Policy supports the NHS Constitution (see 8.1.3 below).

8 The Individual Funding Request Policy

8.1 Context

8.1.1 This policy has been developed in response to the legal duties set out in the NHS Constitution, and a range of guidance as set out below:

- The NHS Confederation guidance on managing Individual Funding Requests (The NHS Confederation, 2008) (Ref 12.1)
- Regulation 35 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibility and Standing Rules) Regulations 2012 (SI 2012 No 2996) (Ref 12.2) which imposes a duty to give reasons for either declining to adopt a policy on any particular intervention or declining a particular treatment for a patient where the policy is not to fund that intervention,
- The NHS Constitution (DoH, March, 2013) (Ref 12.3); two rights relate specifically to the availability of medicines and other treatments:
  - *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*.

- *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*.

- Guiding principles for processes supporting local decision-making about medicines and a Handbook of good practice guidance (Department of Health / National Prescribing Centre, February 2009). (Ref 12.4)

- Guidance on NHS patients who wish to pay for additional private care (Department of Health, March 2009). (Ref 12.5)

- The Operating Framework for the NHS in England 2012/13 (DoH, December 2011) (Ref 12.6)

- NHS Hull CCG Operational Plan

8.2 Development of General Policies for Interventions

8.2.1 Each year, the CCG plans investment in health care interventions and services as part of its operating plan development process to meet the needs of its local population. Commissioning decisions are usually made in collaboration with health care providers and other stakeholders, and are taken in the context of the CCG's available resources to ensure that care is fairly allocated to all patients and, where appropriate, measured against the CCG's other service development priorities, NICE guidance and national priorities.

8.2.2 When planning its investments, the CCG works with provider partners and stakeholders to identify, as far as possible, those new interventions that are likely to have a significant clinical impact and require potential commissioning. This is often referred to as horizon scanning.

8.2.3 Most health care interventions are commissioned as part of contracts with provider partners. However, it is likely that, during the year, there will be requests for interventions not covered by the CCG's commissioning policies. The CCG, therefore, needs to be able to make decisions about these requests that are fair and consistent.

8.2.4 All Individual Funding Requests are triaged to identify whether a request submitted on behalf of an individual would apply to a population of patients. Where that is the case, the request may trigger the development of a new policy for that intervention and indication (called a general commissioning policy) or modification of an existing general commissioning policy. This, however, does not remove the obligation to consider the application received.

8.2.5 Arrangements for the development and revision of general commissioning policies by the CCG for health care interventions are available from the CCG.

8.2.6 The CCG will make its general commissioning policies available on request or at http://www.hullccg.nhs.uk/

8.3 Health Care Interventions that the CCG will not Commission Routinely

8.3.1 There are a number of heath care interventions (under regular review) that the CCG will not commission as a matter of routine. The reason for the CCG taking that decision may be due to uncertainties over clinical effectiveness, cost-effectiveness or patient safety. Some health care interventions are restricted in their availability by requiring specific criteria to be met.

8.3.2 In reviewing the procedures which will not be routinely available the CCG will follow guidance that may be issued from time to time by the Department of Health and that complies with relevant UK law. The CCG will also seek to achieve a high degree of consistency with equivalent lists from other CCGs.

8.3.3 Commissioners, general practitioners, service providers and clinical staff considering treating patients for whom the CCG is responsible will be expected to consider the CCG's clinical commissioning policies in their decision making. Exceptions to the general clinical commissioning policies will only be considered for approval via an Individual Funding Request.

8.3.4 In addition to the group of health care interventions that the CCG will not commission as a matter of routine, the CCG **generally**:

- will not commission the use of new surgical techniques until the Safety and Efficacy Register of New Interventional Procedures (SERNIP) now run by the National Institute of Health and Clinical Excellence (NICE), has awarded category A or B status, unless the technique is part of a randomised controlled trial (RCT)
- will only implement screening programmes approved by the National Screening Committee
- will follow agreed national policy from NHS England on the continuation of treatment at the end of clinical trials
- will follow national guidance in respect of co-payments.

8.4 Definition of an Individual Funding Request

8.4.1 An Individual Funding Request is a request to the CCG to commission healthcare for an individual who falls outside the range of services and

treatments that the CCG has agreed to commission as a matter of routine.

8.4.2 Individual Funding Requests are not the same as:

- Decisions that are related to care packages for patients with complex healthcare needs
- Prior approvals, which are used to manage contracts with providers. For example the CCG might have agreed a prior approval scheme in a contract with an acute hospital that requires the hospital to obtain approval to treat in cases where the CCG has commissioned a better value service with another provider (such as a community based service).

8.4.3 Individual Funding Requests generally arise in one of four circumstances:

- the patient has a rare condition and makes the request to commission the usual way of treating the condition (i.e. referrals for the treatment are too low/unpredictable to warrant having a contract with any provider)
- the patient has a specific condition where the usual care pathway or treatment threshold is deemed inappropriate for that individual on clinical grounds (this may involve an elective tertiary referral outside agreed pathways).
- the clinicians involved in the patient's care want to take advantage of a healthcare intervention that is novel, developing or unproven, and which is not part of the CCG's commissioned treatment plans.
- the clinician would like to make available to a patient an intervention which is not medically necessary but is aesthetically desirable and the distinction between clinical and cosmetic need is not clear

8.4.4 Occasionally some healthcare providers and clinicians might try to establish early access to new treatments (service developments) via an Individual Funding Request. However, the NHS Contract requires hospital providers to seek commissioning of new treatments through submission of a business case to their commissioners. Thus, clinicians are asked not to use the Individual Funding Request process to circumvent the remit of the Hull and East Yorkshire Hospitals Trust Clinical Practice Development Committee or Drugs & Therapeutics Committee (or equivalent committees in other providers) to approve the introduction of new health care interventions.

8.4.5 Similarly, the Individual Funding Request Panel must not be put in a position where it would be asked to make policy decisions for the CCG. Policy questions should always be referred for consideration to the Governing Body, or another appropriate policy-making committee, before the Individual Funding Request is considered.

8.4.6 This Policy in general relates to requests for elective treatments and procedures. A separate contractual obligation applies to providers in cases of emergency lifesaving treatment. In such cases providers are required to notify the CCG retrospectively of any decision to treat outside the Individual Funding Request Policy. A process exists for urgent (but not emergency) Individual Funding Requests where a decision is required outside of the monthly scheduled panel. (See section 9.26)

8.5 Requests for cross-border treatment and treatment outside the European Economic Area (EEA)

8.5.1 Cross border healthcare requests, i.e. requests for treatment outside of England but within the European Economic Area (EEA) should be made directly to NHS England via nhscb.europeanhealthcare@nhs.net

Guidance available at:
http://www.nhs.uk/nhsengland/healthcareabroad/plannedtreatment/pages/introduction.aspx

8.5.2 Requests for healthcare intervention outside of the EEA should be made directly to Specialised Services within the NHS England North Yorkshire and Humber Local Area Team, providing the requested intervention is routinely commissioned locally.

For interventions which are not routinely commissioned locally, the request should first be considered through the CCG IFR process. If CCG approval is granted, the case should then be passed to Specialised Services within the NHS England North Yorkshire and Humber Local Area Team for further consideration.

8.6 Definition of Exceptionality

8.6.1 Exceptionality is difficult to define, therefore pragmatism and flexibility are necessary. However it may be summarised by asking the question "on what grounds can the CCG justify funding treatment for this patient when others from the same patient group are not being funded" ("Priority setting: Managing Individual funding requests" 2008 NHS confederation. .

8.6.2 In making a case for special consideration in relation to a restricted treatment on grounds of exceptionality, it needs to be demonstrated that:

- The patient is 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.

8.6.3 The CCG will only allow clinical considerations (including mental health issues) to decide whether or not a patient is different to other patients. If there are clinical features that make the patient unique or unusual compared to others in the same group, the CCG would then consider whether there are sufficient grounds for believing that this unusual clinical factor means the patient would gain significantly more benefit than would be expected for the group.

8.6.4 When considering Individual Funding Requests, the CCG will use the same ethical framework and guidelines for decision-making that underpin its general policies for health care interventions. Where social, demographic or employment circumstances have not been considered relevant to population-based decisions, these factors will equally not be considered for individual requests.

9 The Individual Funding Request Process

9.1 Appendix 1 shows the process flowchart for consideration of Individual Funding Requests. Further detail is given below.

9.2 Individual Funding Requests should originate either from the patient's GP or from a hospital consultant (to whom the patient has been referred), or in certain circumstances (to be decided by the Panel), other registered health practitioners. Requests will not be accepted from a GP registrar unless endorsed by a salaried GP or partner of the practice.

9.3 Requests will only be accepted when made using the standard application forms; see Appendix 5. Forms should be completed electronically where possible; illegible forms will be returned.

9.4 Requests should be submitted by the following methods:

Secure Email: HULLCCG.ETP@nhs.net

PLEASE NOTE: Emails are only secure when sent between encrypted mail servers e.g. @nhs.net to @nhs.net. Email submissions should not be made via a non-encrypted mail server.

9.5 Referring clinicians are asked to note that the Individual Funding Request form must be completed in full, and submitted with all relevant clinical information and supporting documentation Failure to provide relevant and clear supporting information with the referral, in sufficient detail may cause delays in the decision making process and risk the request being declined due to insufficient clinical information

9.5.1 Supporting information for requests cannot include non-clinical photographs. Any correspondence from patients will not be accepted in any circumstances, including that submitted by clinicians on their patient's behalf.

9.6 To define the level of the supporting clinical evidence base, the standard hierarchy of evidence criteria is used. The higher up a methodology is ranked, the more robust and closer to objective truth it is assumed to be, (though in cases of rare diseases where small numbers may limit the potential for published studies, the threshold for evidence may be varied):

Rank	Methodology	Description
1	Systematic reviews and meta-analyses	Systematic review: review of a body of data that uses explicit methods to locate primary studies, and explicit criteria to assess their quality. Meta-analysis: A statistical analysis that combines or integrates the results of several independent clinical trials considered by the analyst to be "combinable" usually to the level of re-analysing the original data, also sometimes called: pooling, quantitative synthesis. Both are sometimes called "overviews."
2	Randomised controlled trials (RCTs)	Individuals are randomly allocated to a control group and a group who receive a specific intervention. Otherwise the two groups are identical for any significant variables. They are followed up for specific end points.
3	Cohort studies	Groups of people are selected on the basis of their exposure to a particular agent and followed up for specific outcomes.
4	Case-control studies	"Cases" with the condition are matched with "controls" without, and a retrospective analysis used to look for differences between the two groups.
5	Cross sectional surveys	Survey or interview of a sample of the population of interest at one point in time
6	Case reports.	A report based on a single patient or subject; sometimes collected together into a short series
7	Expert opinion	A consensus of experience from the good and the great.
8	Anecdotal	Something someone told you once.

9.7 An Individual Funding Request that comes from a GP will not usually be deemed to have started the 18-week Referral to Treatment (RTT), as it would be a request for a referral for treatment. Requests from secondary care consultants will need to provide an 18 week RTT ‘clock start date’ (the date of referral into secondary care).

9.8 In order to direct requests along the appropriate decision making pathway, the Individual Funding Request Panel will give formal delegated authority to staff of the Commissioning Support Unit Individual Funding Request team to triage all Individual Funding Requests. Triage must be undertaken by two members of staff, one of whom must be a healthcare professional. Where a consensus opinion cannot be reached by the two staff undertaking triage, the request should proceed to Panel for full discussion. An accurate record of all decisions taken at triage will be presented at the Panel meeting for discussion and ratification.

The role of triage is to assess and deal with any requests:

- that have not been submitted by a healthcare professional
- for which relevant clinical information has been omitted
- for which there clearly is no clinical case
- that do not meet criteria outlined in an agreed commissioning policy and for which no case has been made for exceptionality
- that can be commissioned because they meet criteria outlined in an agreed commissioning policy
- that can be commissioned because they meet pre-agreed exceptions (some of which are set through precedent)
- that represent service developments
- that raise a major policy issue and need more detailed work
- that can be dealt with under another existing contract
- for which an alternative satisfactory solution can be found.

9.9 The CCG will convene a formal Individual Funding Request Panel which will meet at least monthly and will have the following membership:

- Chair of the Individual Funding Request Panel
- Vice-Chair of the Individual Funding Request Panel
- Clinical representative(s)
- Lay-member(s)
- Commissioning Manager – Clinical (NHS Hull CCG)

The following attendees will be available in an advisory capacity but are not decision-making members of the Panel.

- Public Health Specialist or representative (Hull City Council)
- Learning Disability & Mental Health Specialist or representative (CS)
- Medicines Management lead or representative(CS)

9.10 The Panel may also seek legal advice from the CS Legal and Governance Manager, as and when required.

9.11 Patients will **not** be invited to attend the Panel at which their request is being considered, but they will be kept informed of progress and outcomes by being copied into all correspondence between the Individual Funding Request Panel and the requesting doctor. Individual exceptions may be made in circumstances where the Panel consider that it would be more appropriate for the outcome of the case to be communicated via the requesting clinician to the patient; in these individual cases the decision not to send the patient copies of any correspondence and the rationale for this decision will be documented in the record of the Panel's discussion of the case. Evidence papers however will not routinely be copied to the patient unless requested.

9.12 Requesting clinicians will not be invited to attend the Panel except in the most unusual cases.

9.13 Administrative support to the Panel will be provided by the Commissioning Support Individual Funding Request team.

9.14 The CCG will provide and document training for all individuals involved in decision making for Individual Funding Requests, covering legal and ethical issues as well as the CCGs own approach to priority setting.

9.15 The Panel may from time to time ask other CCG staff or other individuals with knowledge of the particular procedure or intervention being considered to attend to further inform the consideration by the Panel of the request. Where possible, however, the CCG will ensure separation between those who review the clinical evidence for a request and those who make commissioning decisions.

9.16 If there is any circumstance where any Panel member may have a conflict of interest in a case put before the Panel, they shall acknowledge this at the outset and will remove themselves from the proceedings for the time required.

9.17 To ensure effective, fair and transparent decision making the Panel must be quorate to agree decisions. To ensure this the chair or vice-chair, one clinical representative, and a lay-member should be present (i.e. 3 members).

9.18 All Individual Funding Requests received by the CCG will be given a case reference number and logged on a secure database maintained by the CS IFR team. Correspondence and other records relating to Individual Funding Requests, whether paper or electronic, will remain confidential and records will be managed so that access is restricted to the CS IFR team and members of the Panel.

9.19 In advance of each meeting of the Panel, a list of cases will be prepared for consideration at that meeting. Papers will be sent out by secure means one week in advance to enable Panel members to seek clarification or further information as necessary. Where the information provided to support the request is thought to be insufficient for the Panel to undertake a valid consideration of the request, the CS IFR team will liaise with the relevant clinician to obtain further information. Usually, requests will be taken to the next scheduled meeting of the Panel. Where further information is required, requests may be deferred for consideration until the requested information has been received. Where such additional information has not been received within a reasonable period (which will normally be three months unless the clinician has requested additional time to gather the information) the request will ordinarily be refused.

9.20 In considering requests, the Panel may decide to ask for further information from the relevant clinician and may also seek a review of the evidence of the clinical and cost effectiveness of a particular procedure or intervention. This may be as a result of a decision not being reached.

9.21 In making a collective decision on the request, the Panel should take the following into account:

Clinical Effectiveness and Safety

- Is the treatment effective – i.e. of proven benefit for this category of patient?
- What is the nature, extent and significance of the health gain for the individual?
- How have similar cases been dealt with in the past?

Cost Effectiveness

- The CCG does not undertake individual economic assessments itself, but draws on expert reviews, clinical papers and assessments, in order to ascertain cost-effectiveness estimates. In the decision making process the cost--effectiveness criteria upper threshold of £20,000 - £30,000 per QALY, which is consistent with NICE decisions, is used.
- Are there alternative, comparable and more cost effective interventions and/or providers available?

Appropriateness

- Are there agreed patient selection criteria? Does the patient fit the criteria? If not, what is the case for expanding the selection criteria?
- Are alternative treatments available?
- What would the impact of refusal be?
- Has appropriate clinical advice been sought?

Equity

- Is this patient or patient subgroup being treated differently in relation to others?
- What is the priority in relation to opportunity costs and alternative spend on other needs of the whole population?

9.22 The Panel will not:

- part –commission treatment
- commission elective treatment requested retrospectively
- commission equipment ordered prior to Panel approval
- recommend alternative treatments for a particular condition or patient

9.23 Minutes will be taken at every Panel meeting. The minutes of the meeting will include a record of the discussion and outcome of each case so as to maintain accurate documentation of the whole decision making process; the minutes will then be taken to the next available meeting of the Panel for review of accuracy and ratification. A decision record and outcome will be maintained by the CS IFR team on the secure database for each request the Panel considers.

9.24 Decisions made by the Panel will be communicated by the Chair of the Panel in writing to the requesting clinician and/or to the patient's General Practitioner (and

copied to the patient) within 10 working days of the date of the Panel at which the request was considered.

9.25 From time to time, the particular clinical circumstances of an Individual Funding Request may mean that delaying a decision to the next scheduled meeting of the Panel is likely to have a significant detrimental effect on the patient's 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 and views of Panel members will be sought in advance of the next scheduled meeting by e-mail, phone or in person to consider whether, in the circumstances, a decision needs to be made in advance of the next scheduled meeting of the Panel and, if so whether the requested procedure or intervention should be approved. The agreement of two members of the Panel (including a clinically qualified Panel member) will be required to make a decision outside of a formal meeting of the Panel.

Where necessary for reasons of expediency, virtual meetings will be carried out by telephone, fax or email as necessary. These are 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. In such circumstances a decision will be taken on a consensus view; with the final decision endorsed by the Chair or vice chair of the IFR panel and confirmed by the membership for the record.

9.26 It is understood that at all times, the provider partner is able to fund a health care intervention pending a decision from the CCG and the CCG accepts no responsibility for the clinical consequences of any delay in responding to the request.

9.27 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 patients GP within 2 working days of the date of the decision (and copied to the patient).

9.28 In responding to an Individual Funding Request, the CCG accepts no clinical responsibility for the health care intervention or its use, or for the consequences of not using the intervention. It is the responsibility of the treating clinician to determine the most appropriate treatment for a particular patient from amongst those which are available.

9.29 The CS Patient Relations Manager will be made fully aware of the Individual Funding Request policy (not individual cases) so they can offer patients information and support throughout the processes. For patients whose first language is not English, Patient Relations staff have access to translation services. A Patient Information Leaflet is available to explain the Individual Funding Request and Appeal processes.

9.30 Case notes for each request to the Individual Funding Request Panel (irrelevant of outcome) will be filed securely by the Commissioning Support Individual Funding Request team in accordance with *Records Management: NHS Code of Practice*, DoH (March 2006). Case files will be securely archived after 2 years and securely destroyed after 8 years (or 8 years after the patient's death).

10 The Process for Appeals

10.1 The requesting clinician may appeal against the decision of the IFR Panel to support their request for a procedure or intervention, and must submit the appeal in writing within 3 months of the date of the decision letter from the IFR Panel.

10.2 The CCG will establish a separate clinically led Appeals Panel to consider appeals against decisions of the IFR Panel. The Appeals Panel will meet monthly (where there are cases to be considered) and its business and decisions will be fully recorded.

10.3 The Appeals Panel will include the following members (and should be different to the original Panel that considered the case in question):

- CCG Director of Commissioning and Partnerships (Chair)
- Director of Clinical Quality and Governance
- CCGB GP Member
- CCGB Lay Member

10.4 The Appeals Panel will be considered quorate if all 4 members are present. Legal support will also be provided by the CS.

10.5 All requests to appeal against the decision of the IFR Panel should be sent to the same contact details as for all other IFR requests, and will be logged by the CS IFR team.

10.6 Appeals will usually be considered within 30 days of the date of the CCG receiving notification of a request to appeal against the decision of the IFR Panel.

10.7 The Appeals Panel will review the correspondence, evidence, and any other information considered by the IFR Panel in reaching its original decision.

10.8 The Appeals Panel will be established on a 'quality control check' model. Under this model the Appeals Panel would consider whether the IFR Panel:

- followed the CCG's own procedures and policies
- considered all relevant factors and did not take into account immaterial factors
- made a decision that was not so unreasonable that it could be considered irrational or perverse in the light of the evidence
- had all the relevant evidence before it for consideration.

10.9 At the discretion of the Appeals Panel, the outcome will be either:

- they reject the appeal and support the original decision of the IFR Panel;
- they identify a flaw in the process followed to reach the previous decision such that the decision of the original IFR Panel may be overturned without referral back;
- they consider that the evidence needs reconsideration by referral back, with full documentation, to the next IFR Panel meeting.

10.10 The patient or their clinicians should normally not be permitted to introduce additional evidence at the appeal stage, but if there is new evidence to support a case, this does not mean that the original decision – made on the evidence then available – was wrong. Instead the case should be referred back to the IFR Panel to decide whether the information is significant enough to merit reconsideration.

10.11 The decision of the Appeals Panel will be communicated by the Chair of the Appeals Panel to the requesting clinician and/or patient's General Practitioner (and copied to the patient) within 10 working days of the date of the appeal decision.

10.12 The Appeals Panel decision is the final decision of the CCG.

10.13 Patients wishing to challenge the Appeals Panel decision must do so through the NHS Complaints Procedure. Where that process is completed without satisfactory resolution, a complainant may take their case to the NHS Ombudsman and/or to Judicial Review. Where Judicial Review is initiated, the CCG response will be guided by legal advice and all correspondence will be through the CCG's legal representative.

Once a case is with the Ombudsman, it may be referred back in to the CCG Panel to consider the Ombudsman's ruling and comply with any suggestions made.

11 Monitoring Compliance with and Effectiveness of this Policy

11.1 As part of the annual review procedure, there will be an independent internal audit of a selection of Individual Funding Requests, which will form part of an annual report from the Individual Funding Request Panel to the CCG Board. 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.

12 References

12.1 "*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

12.2 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/uksi/2012/2996/made

12.3 *The NHS Constitution for England*. DoH. March 2013. Available at https://www.gov.uk/government/publications/the-nhs-constitution-for-england

12.4 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

12.5 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/Responsestoconsultations/DH_096428

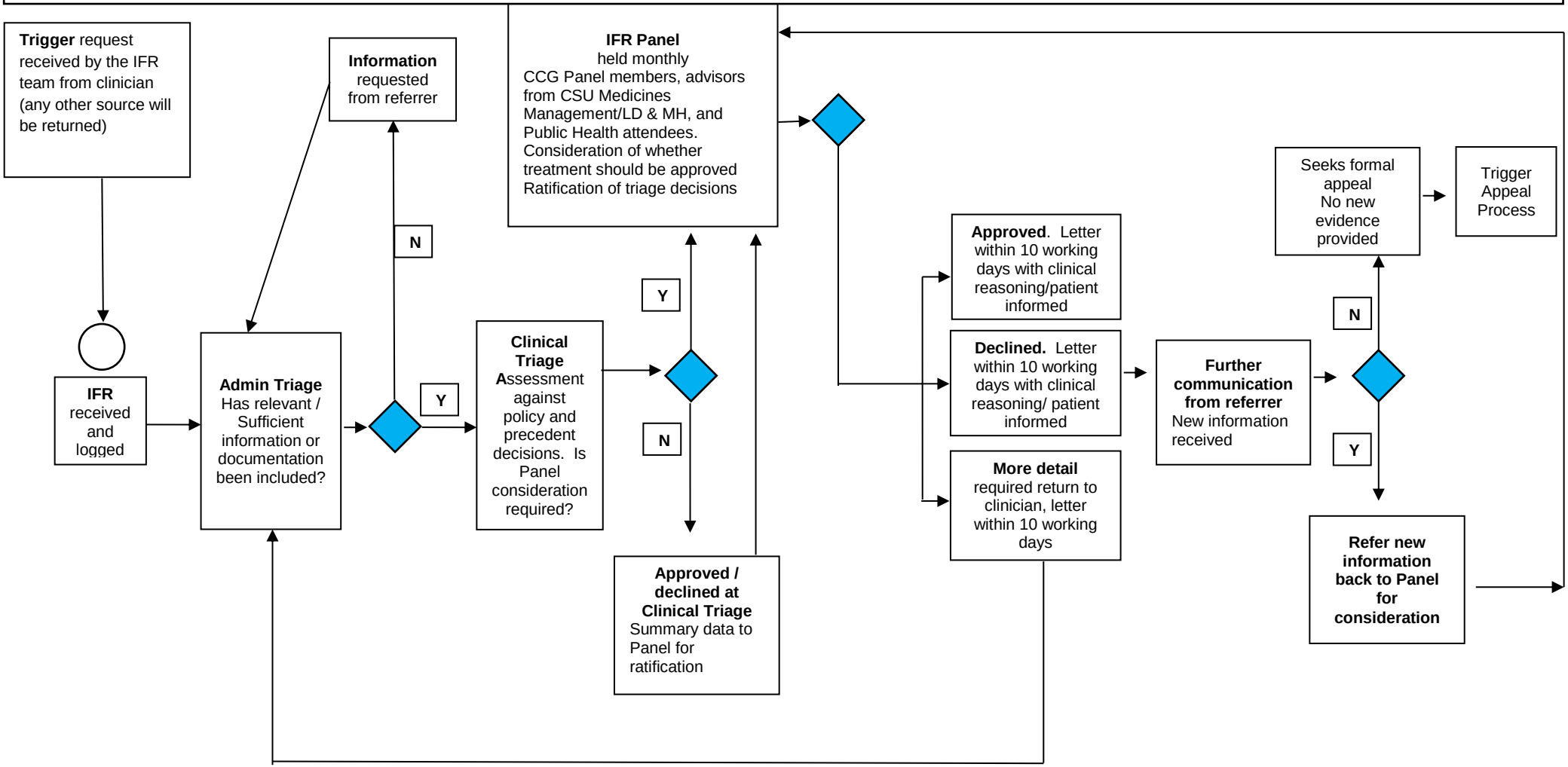
12.6 The Operating Framework for the NHS in England 2012/13. DoH, December 2011. Available at: https://www.gov.uk/government/publications/the-operating-framework-for-the-nhs-in-england-2012-13

13 Review

13.1 General commissioning policies and the Individual Funding Request Policy will be reviewed at least every two years (unless otherwise required by national guidance or other imperatives) and will form part of the Individual Funding Request annual report to the CCG Board.

13.2 Minor amendments (such as changes in title) may be made prior to the formal review, details of which will be monitored/approved by the Head of Corporate Affairs in consultation with the Director of Human Resources and Trade Union Representative(s) where relevant. Such amendments will be recorded in the PPG Register and a new version of the PPG issued.

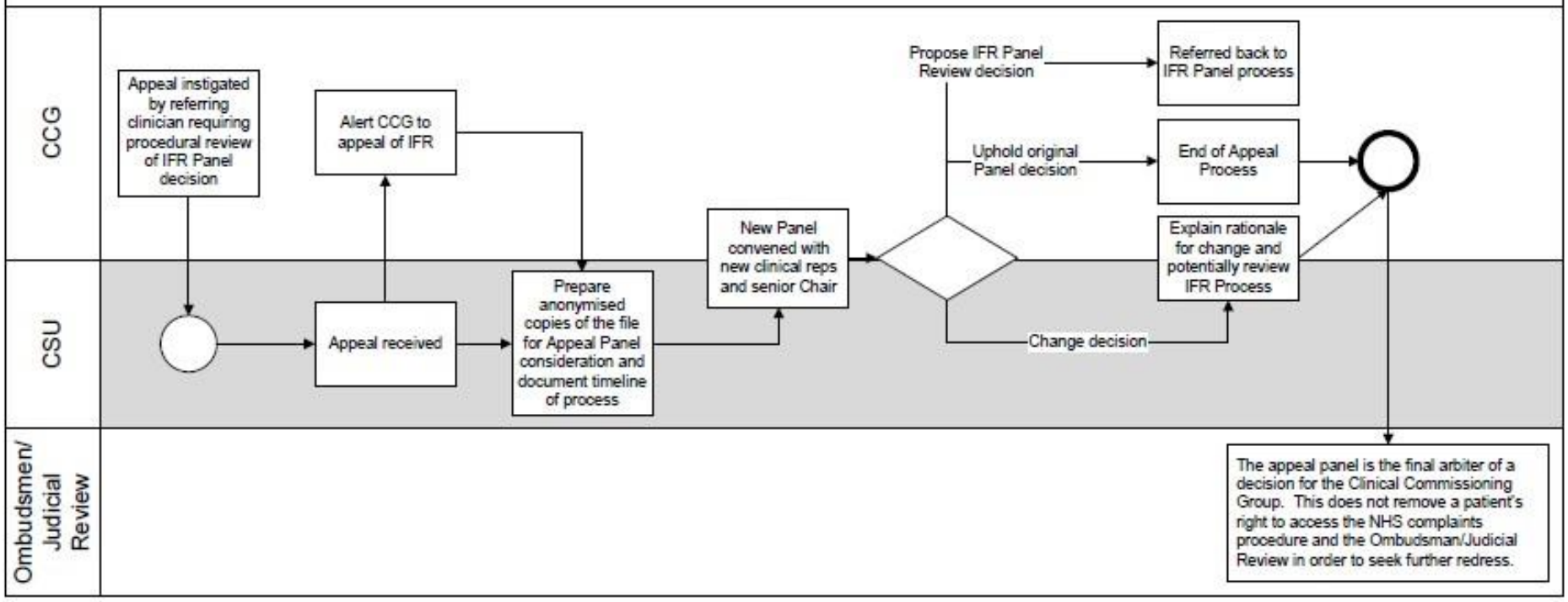
Appendix 1: IFR Panel Process Map



Other **Public Health, Meds Management as necessary**

= Start = Flow of Process Map = Activity = decision point

Appendix 2: Appeals Panel Process Map



Key

= Start process

= Activity

= CCG decision point

= End process

APPENDIX 3

NHS HULL CCG INDIVIDUAL FUNDING REQUEST PANEL

TERMS OF REFERENCE

Scope and Purpose

An Individual Funding Request is a request to the Commissioner to commission healthcare for an individual who falls outside the range of services and treatments that the Commissioner has agreed to commission as a matter of routine.

Commissioning decisions on these requests are made collectively by a specially convened group – the CCG Individual Funding Request Panel.

Terms of Reference

- Patients will **not** be invited to attend the Panel at which their request is being considered.
- Requesting clinicians will not be invited to attend the Panel except in the most unusual cases.
- The CCG will provide and document training for all Individual Funding Request Panel members, covering legal and ethical issues as well as the CCG'S own approach to priority setting.
- The Panel may from time to time ask other CCG staff or other specific individuals with knowledge of the particular procedure or intervention being considered to attend to further inform the consideration by the Panel of the request.
- If there is any circumstance where any Panel member may have a conflict of interest in a case put before the Panel, they will remove themselves from the proceedings.
- Papers for the Panel meetings will be sent out by secure means one week in advance to enable members to seek clarification or further information as necessary.
- In considering requests, the Panel may decide to ask for further information from the relevant clinician and may also seek a review of the evidence of the clinical and cost effectiveness of a particular procedure or intervention. This may be as a result of a decision not being reached.
- In making a collective decision on the request, the Panel should take the following into account: Clinical Effectiveness and Safety / Cost Effectiveness / Appropriateness / Equity
- The Panel will not:
    - Part-commission treatment
    - Commission elective treatment requested retrospectively
    - Commission equipment ordered prior to Panel approval.

- 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 Panel meeting. Decisions made in advance of a Panel Meeting will be communicated to the referring clinician and/or the patients GP within 2 working days of the date of the decision (and copied to the patient).

Membership

- Chair of the Individual Funding Request Panel
- Vice-Chair of the Individual Funding Request Panel
- Clinical representative(s)
- Commissioning representative – Clinical (NHS Hull CCG)
- Lay-member(s)

Advisory input

- Public Health Specialist or representative (Hull City Council)
- Learning Disability & Mental Health Specialist or representative (CCG)
- Medicines Management lead or representative (CS)

Administrative support: provided by the Commissioning Support Individual Funding Request team.

Quorum: To ensure effective, fair and transparent decision making, the chair or deputy chair, one clinical Panel member and a lay-member should all be present for decision making (i.e. 3 members).

Meeting Frequency: Monthly

Reporting: Every Panel meeting will produce a 'decision record' so as to maintain accurate documentation of the whole decision making process. A decision record and outcome will be maintained by the CS IFR team on the secure database for each request the Panel considers.

Decisions made by the Panel will be communicated by the Chair in writing to the requesting clinician and/or to the patient's General Practitioner (and copied to the patient) within 10 working days of the date of the Panel at which the request was considered.

Case notes for each request to the Individual Funding Request Panel (irrelevant of outcome) will be filed securely by the Commissioning Support Unit Individual Funding Request team in accordance with the Hull CCG Records Management Policy. Case files will be securely archived after 2 years and securely destroyed after 8 years (or 8 years after the patient's death).

The Panel also provides an anonymised annual report to the CCG Board, summarising the decisions for the previous year.

APPENDIX 4

NHS HULL CCG APPEALS PANEL

TERMS OF REFERENCE

Scope and Purpose

If the IFR Panel turns down a request to commission an individual request for treatment, the requesting clinician can appeal against the decision by submitting a request in writing to the CCG within 3 months of the date of the decision letter from the IFR Panel.

The CCG will establish a separate clinically led Appeals Panel to consider appeals against decisions of the IFR Panel.

The Appeals Panel will be established on a 'quality control check' model. Under this model the Appeals Panel would consider whether the IFR Panel:

- followed the CCG's own procedures and policies

- considered all relevant factors and did not take into account immaterial factors

- made a decision that was not so unreasonable that it could be considered irrational or

- perverse in the light of the evidence

- had all the relevant evidence before it for consideration.

Terms of Reference

- All requests to appeal against the decision of the IFR Panel should be sent to the same contact details as for all other IFR requests, and will be logged by the administrator.
- Appeals will usually be considered within 30 days of the date of the CCG receiving notification of a request to appeal against the decision of the IFR Panel
- The Appeals Panel will review the correspondence, evidence, and any other information considered by the IFR Panel in reaching its original decision.
- At the discretion of the Appeals Panel, the outcome will be either:
  - They reject the appeal and support the original decision of the IFR Panel;
  - They agree with the grounds for appeal such that the decision of the original IFR Panel may be overturned without referral back;
  - They identify a problem with the original process or consider that the evidence needs reconsideration by referral back, with full documentation, to the next IFR Panel meeting.
- The patient or their clinicians should normally not be permitted to introduce additional evidence at the appeal stage, but if there is new evidence to support a case, this does not mean that the original decision – made on the evidence then available – was

wrong. Instead the case should be referred back to the IFR Panel to decide whether the information is significant enough to merit reconsideration.

- The decision of the Appeals Panel will be communicated by the Chair or other clinical representative to the requesting clinician and/or patient's General Practitioner (and copied to the patient) within 10 working days of the date of the appeal decision.
- The Appeals Panel decision is the final decision of the CCG

Membership

The Appeals Panel will include the following members (and should be different to the original Panel that considered the case in question):

- CCG Director / Commissioning (Chair)
- CCG Director of Quality & Clinical Governance Executive Nurse
- CCGB GP Practitioner and Board Member
- CCGB Lay Member

Administrative support: provided by the CS IFR team.

Legal support: provided by the CS Legal and Governance team

Quorum: The Appeals Panel will be considered quorate if all 4 members are present.

Meeting Frequency:

The Appeals Panel will meet monthly (where there are cases to be considered)

Reporting:

The business and decisions of the Appeals Panel will be fully recorded and these will be reported to the Chair of the IFR Panel.

In addition a summary of the decisions made on appeals will be sent to the Clinical Commissioning Group Board as part of an anonymised annual report.

Appendix 5: IFR Request forms

Individual Funding Request Panel
GP Request Form

N.B. Requests from GP registrars must be countersigned by a salaried GP or partner of the practice

***Please complete this form electronically and send to*: HULLCCG.ETP@nhs.net**

This form must be completed in FULL, and submitted with ALL relevant clinical information and supporting documentation. This cannot include patient letters or non-clinical photographs.

To assist in full completion of the IFR form and provision of all required clinical information, please reference the policy relevant to your request via: http://www.hullccg.nhs.uk/policies

1. Referring Clinician	**GP name:**			
	Salaried GP or Partner:	**Please tick to confirm** ☐		
	Practice name and address:			
	Tel:			
	Email:	**(Please provide an nhs.net email address to enable secure email communication regarding the case)**		
2. Patient Details ***Please keep patient identifiable information to a minimum throughout the request***	**Responsible CCG:**			
	NHS Number:		**DOB:**	
	Current Body Mass Index (BMI):			
	Provider to be referred to:			
3. Patient Diagnosis/Condition				
4. Intervention Requested (NB: Intervention refers to requested treatment, investigation, etc.)				

5. Significant clinical history e.g. duration of symptoms, co-morbidities	
6. Give details of relevant treatment/management/ investigations carried out in primary/secondary care (please include past medical history, any relevant medications and clinical correspondence from clinicians relating to intervention requested)	
7. Please describe the **clinical** need for this intervention	
8. Please explain why this patient is likely to have exceptional benefit from this intervention, i.e. significantly more benefit than might be expected for the average patient with that particular condition.	

9. What would be the estimated impact of denying access to the intervention? For example, on mobility, self-care, pain/discomfort, anxiety/depression?	
10. I confirm that this Individual Funding Request (IFR) has been discussed in full with the patient. The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request **YES/NO**	
Signed:	
Print Name and Designation:	
Countersigned: (If request from GP registrar)	
Print Name and Designation:	

Please ensure that you enclose a copy of the referral letter and copies of any other relevant clinical correspondence with this form.

N.B. The request will not be taken forward for consideration by the Panel until all relevant information has been submitted.

NHS
Yorkshire and Humber
Commissioning Support

Individual Funding Request Panel
Consultant Request Form

***Please complete this form electronically and send to*: HULLCCG.ETP@nhs.net**

This form must be completed in FULL, and submitted with ALL relevant clinical information and supporting documentation. This cannot include patient letters or non-clinical photographs.

To assist in full completion of the IFR form and provision of all required clinical information, please reference the policy relevant to your request via: http://www.hullccg.nhs.uk/policies

1. Referring Service	**Trust:**			
	Address:			
	Tel:			
2. Referring Clinician	**Name:**			
	Designation:			
	Email:	**(Please note that email correspondence relating to the case can only be sent from an nhs.net address to an nhs.net address. If a trust email address is provided no patient identifiable information can be included)**		
3. Application reviewed by Chief Pharmacist or nominated deputy (in the case of a drug intervention)	**Name:**			
	Signature or email authorisation:			
4. Patient Details ***Please keep patient identifiable information to a minimum throughout the request***	**Responsible CCG:**			
	NHS Number:		**DOB:**	
	Current Body Mass Index (BMI):			

	Registered Consultant:	
	Registered GP:	
	Registered GP Practice:	
	Start date of 18 week Referral to Treatment (RTT):	
	Date of referral to IFR Panel:	

5. I confirm that this Individual Funding Request (IFR) has been discussed in full with the patient. The patient is aware that they are consenting for the Individual Funding Request Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request

YES/NO

INTERVENTION REQUESTED (NB: Intervention refers to requested treatment, investigation, etc.)

6. Patient Diagnosis/Condition		
7. Details of Intervention Requested	Name of intervention:	
	Dose and frequency:	
	Planned duration of intervention:	
	Route of administration:	
	Anticipated cost (inc VAT):	
8. Is requested intervention part of a clinical trial?	Delete as appropriate: **NO / YES** If **Yes**, give details (e.g. name of trial, is it an MRC/National trial?)	
9. (a) What would be the standard intervention at this stage?		
(b) What are the exceptional clinical circumstances that make the standard intervention inappropriate?		

10. What is the patient's clinical severity? (Where possible use standard scoring systems e.g. WHO, DAS scores, walk test, cardiac index etc.)			
11. Summary of previous intervention(s) this patient has received for the condition. * Reasons for stopping may include: ▪ Course completed ▪ No or poor response ▪ Disease progression ▪ Adverse effects/poorly tolerated	**Date**	**Intervention (e.g. drug / surgery)**	**Reason for stopping* / response achieved**
12. Anticipated start date	**Please state if the request is CLINICALLY URGENT and if so, why**		
CLINICAL EVIDENCE			
13. Is requested intervention licensed for use in the requested indication in the UK?	Delete as appropriate: **NO** / **YES** (refer to pharmacy if required)		
14. Has the Trust Drugs and Therapeutics Committee or equivalent Committee approved the requested intervention for use? (if drug or medical device)	Delete as appropriate: **YES / NO** If **No,** Committee Chair or Chief Pharmacist approved:		
15. Give details of National or Local Guidelines/ recommendations or other published data supporting the use of the requested intervention for this condition?	**PUBLISHED trials/data** - **Full published papers, rather than abstracts, should be submitted, unless the application relates to the use of an intervention in a rare disease where published data is not available**		

16. (a) How will you monitor the effectiveness of this intervention?	
(b) Detail the current status of the patient according to these measures.	
(c) What would you consider to be a successful outcome for this intervention in this patient?	
17. What is the anticipated toxicity of the intervention for this patient?	

Please note: the request will not be taken forward for consideration by the Panel until all relevant information has been submitted.