NHS
Vale of York
Clinical Commissioning Group

INDIVIDUAL FUNDING REQUEST POLICY AND PROCEDURE

January 2015

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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	Approved by & Date	Date on Intranet
0.6	YHCS	1. The document is for Individual Funding Requests process only and no longer covers the detail of the process for development of commissioning policies. The Clinical Exceptionality statement has changed as follows: • *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* 2. The Panel membership has been amended and the level of which the Panel is quorate has also changed. 3. Chair of the Panel is now CU IFR Service Senior Manager of	Clinical Research and Effectiveness Committee 11th February 2015	

		delegate, not Assistant Director of Strategy 4. Relevant Legal requirements and Acts are included i.e. Bribery Act and Sustainability, Equality Impact Assessment 5. Process for Appeals have been amended to reflect changes in commissioning responsibility i.e. the appeal Panel is Chaired by a Senior CCG Representative (Chair) 6. Panel meets bi-monthly as opposed to weekly.		

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1. INTRODUCTION

1.1 NHS Vale of York 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 treatments, 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 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. ENGAGEMENT

2.1 This policy has been considered and approved by a number of other CCGs across the NY and Humber locality. Prior to going to the Governing Body of the CCG it has also been considered by Business Committee.

3. IMPACT ANALYSES

Equality

3.1 The CCG is committed to:

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

3.2 To ensure the above, this Policy and Procedure has been Equality Impact Assessed. Details of this assessment are attached at **Appendix 1** available on the CCG's website.

3.3 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.

3.4 As a result of the Equality Impact Assessment (EIA) there are no additional identified risks or related actions required other than the training of Panel members.

Sustainability

3.5 Completed Sustainability Impact included in **Appendix 2**. Commissioning policies are agreed against clinical and cost effective considerations.

Bribery Act 2010

3.6 The CCG follows good NHS business practice as outlined in the Business Conduct Policy and the Conflicts of Interest Policy and has robust controls in place to prevent bribery. Due consideration has been given to the Bribery Act 2010 in the development of this policy document and no specific risks were identified.

3.7 Further information on the Bribery Act can be found at www.opsi.gov.uk/acts. A list of frequently asked questions is available from the CS Corporate Strategy and Policy Manager.

3.8 The Bribery Act is particularly relevant to this policy. Under the Bribery Act it is a criminal offence to:

- Bribe another person by offering, promising or giving a financial or other advantage to induce them to perform improperly a relevant function or activity, or as a reward for already having done so
- Be bribed by another person by requesting, agreeing to receive or accepting a financial or other advantage with the intention that a relevant function or activity would then be performed improperly, or as a reward for having already done so

3.9 These offences can be committed directly or by and through a third person and other related policies and documentation (as detailed on the CCG intranet) when considering whether to offer or accept gifts and hospitality and/or other incentives.

Anyone with concerns or reasonably held suspicions about potentially fraudulent activity or practice should refer to the Local Anti-Fraud and Corruption Policy and contact the Local Counter Fraud Specialist.

4. SCOPE

4.1 This policy applies to:

- 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
- Employees of the North Yorkshire and Humber Commissioning Support Unit (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 contributes to the IFR process
- All referring clinicians within primary, secondary and tertiary care
- 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

5. POLICY PURPOSE AND AIMS

5.1 The purpose of the Individual Funding Request (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 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
- Demonstrate a clear process for decision making
- Demonstrate that CCG decisions not to commission or to restrict access to certain health care interventions are lawful and taken in line with government directions

6. POLICY STATEMENT

6.1 This policy describes the roles and responsibilities of the Vale of York CCG in providing support for patients and clinicians to access treatments which are not routinely commissioned. It describes a process which is in line with the relevant legislation and standards described in section 8. See **Appendix 4 and 5** for process flowchart.

7. DEFINITIONS

7.1 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.

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

7.3 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.

7.4 An Individual Funding Request is a request to the CCG to commission health care 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. RELEVANT LEGISLATION AND STANDARDS

8.1 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

8.2 The NHS Constitution (DH, 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*

8.3 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 (Department of Health, December 2011) (Ref 12.6)
NHS Vale of York CCG Operational Plan

9. POLICY IMPLEMENTATION

Development of General Policies for Interventions

9.1 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.

9.2 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.

9.3 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.

9.4 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.

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

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

Health Care Interventions that the CCG will not Commission Routinely

9.6 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.

9.7 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.

9.8 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.

9.9 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

10. DEFINITION OF AN INDIVIDUAL FUNDING REQUEST

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

10.2 Individual Funding Requests are not the same as:

- Decisions that are related to care packages for patients with complex health care 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)

10.3 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 health care 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

10.4 Occasionally, some health care 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 Secondary Care providers, Development Committee or Drugs & Therapeutics Committee (or equivalent committees in other providers) to approve the introduction of new health care interventions.

10.5 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.

10.6 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 scheduled Panel (see section 9.25).

11. REQUESTS FOR CROSS-BORDER TREATMENT AND TREATMENT OUTSIDE THE EUROPEAN ECONOMIC AREA (EEA)

11.1 Cross border health care 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

11.2 Requests for health care 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.

11.3 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.

12. DEFINITION OF EXCEPTIONALITY

12.1 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", NHS Confederation 2008).

12.2 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

12.3 Only evidence of clinical need will be considered. Factors such as gender, ethnicity, age, lifestyle or other social factors such as employment or parenthood cannot lawfully be taken into account.

12.4 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.

12.5 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 Funding Requests.

13. THE INDIVIDUAL FUNDING REQUEST PROCESS

13.1 **Appendix 5** shows the process flowchart for consideration of Individual Funding Requests. Further detail is given below:

13.2 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. Requests received directly from patients, without clinical support, are unlikely to be approved.

13.3 Requests will only be accepted when made using the standard application forms (see **Appendix 4**). Forms should be completed electronically where possible; illegible forms will be returned.

13.4 Requests should be submitted by the following methods:

Secure Email: yhcs.exceptions@nhs.net (preferred)

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.

By Post to: NHS Vale of York CCG Individual Funding Request Panel
Triune Court
Unit 1
Monks Cross
York YO32 9GZ

Safe Haven Fax: (01904) 694702

13.5 Referring clinicians are asked to note that providing relevant and clear supporting information with the referral, in sufficient detail will assist in the decision making process and reduce the risk of delay. Supporting clinical evidence will **not normally** include any photographs. Hospital photographs will be accepted if deemed clinically appropriate.

13.6 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.

13.7 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).

13.8 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 health care 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.

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

- That have not been submitted by a health care 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

13.10 The CCG will convene a formal Individual Funding Request Panel which will meet bi-monthly and will have the following membership:

- CS IFR Service Senior Manager or delegate (Chair)
- Two NY CCG GPs
- CS Legal and Governance Lead
- Principal or Senior Pharmacist (as appropriate)
- NHS Clinical Therapist(s) (as appropriate)
- Mental Health Commissioner (as appropriate)
- CS IFR Case Manager(s)

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

- CS IFR Service Senior Manager or delegate (Chair)
- CS IFR Case Manager(s)
- CS Legal and Governance Lead
- CS Principal or Senior Pharmacist (as appropriate)
- NHS Clinical Therapists(s) (as appropriate)
- Mental Health Commissioner (as appropriate)
- Other commissioners (as appropriate)

13.12 Patients will **not** be invited to attend the Panel at which their request is being considered, however, they will be informed in writing when the Panel have made a decision to decline funding.

13.13 It is believed that neither the clinician nor the patient should attend the IFR Panel or IFR Appeal Panel in person in order to ensure that decisions are based entirely on independent consideration of the clinical and cost effectiveness evidence provided.

13.14 It also ensures that Panel members are not unduly influenced, either negatively or positively, by attendance in person of the parties concerned. R (otao Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust [2007] EWHC 1927 (Admin)[1].

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

13.16 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 CCG's own approach to priority setting.

13.17 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.

13.18 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.

13.19 Two medically qualified members of the IFR Panel and a case manager will be present to ensure the meeting is quorate. The frequency of Panel meetings will be agreed between the relevant CCG and the CS, but in any event will be held in a timely manner in order to ensure that due consideration is given to IFR requests.

13.20 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.

13.21 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.

13.22 If the requested health care intervention meets criteria within a general policy, the referring clinician will be advised appropriately and the case will not require consideration by the Panel.

13.23 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

[1] Mr Justice Mitting said, at para 25 "*At some stage, although not relied upon by him, it was even suggested in correspondence that the Panel should allow her lawyers to attend its meeting. These procedures, which may be appropriate for trials and inquiries into such matters as whether or not to grant planning permission play no part in my view in decisions of the kind which this Panel had to take*."

has not made a case for exceptionality, the IFR may be declined at the triage stage without being considered by the Panel. In this event, the referring clinician will be advised of the reason for refusal and any future submission will have to clearly address these issues before a request can be referred to the IFR Panel.

13.24 Where possible, the CS will ensure a separation between those who review the clinical evidence for a request at the triage stage and those who make the Panel funding decision.

13.25 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 in advance to enable Panel members to review the cases prior to the meeting. 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 one month unless the clinician has requested additional time to gather the information) the case will ordinarily be considered closed. However, cases will be re-opened on receipt of further information.

13.26 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.

13.27 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?

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

13.28 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. A draft version of the minutes will be circulated to the Panel members for comment. Once all comments have been received, the minutes will then be taken to the next available meeting of the Panel for ratification. A decision record and outcome will be maintained by the CS IFR team on the secure database for each request the Panel considers.

13.29 Decisions made by the Panel will be communicated in writing by the CS IFR team to the requesting clinician and/or to the patient's General Practitioner within 10 working days of the date of the Panel at which the request was considered. If funding has been declined, the patient will also receive a letter informing them of the decision and the reasons behind it.

13.30 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 email, 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 generally be required to make a decision outside of a formal meeting of the Panel; however, if this is not possible, the approval of the IFR Service Senior Manager or an appropriate Senior Manager will be sought.

13.31 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.

13.32 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.

13.33 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.

13.34 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 has access to translation services. A Patient Information Leaflet is available to explain the Individual Funding Request and Appeal processes.

13.35 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 *Records Management: NHS Code of Practice*, Department of Health (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).

14. THE PROCESS FOR APPEALS

14.1 The requesting clinician may appeal against the decision of the IFR Panel not 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.

14.2 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.

14.3 The Appeal Panel will include the following members (and, where possible, should be different to the original Panel that considered the case in question):

- Senior CCG Representative (Chair)
- Two NY CCG GPs **who were not involved in considering** the case at the Individual Funding Request Panel (where possible)
- Relevant IFR Case Manager(s) (to prepare all documentation and service the Appeal Panel)
- CS Legal and Governance Lead

- Expert advisors (e.g. pharmacist, mental health commissioner, etc.) as required

14.4 The IFR Case Manager responsible for the case will prepare all documentation, including a timeline detailing each step of the process. The IFR Case Manager will ensure receipt of the documentation by Panel members at least 3 working days in advance of the meeting.

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

14.6 All requests to appeal against the decision of the IFR Panel should be made directly to the CS IFR Team and will be logged accordingly by the team.

14.7 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 (providing all necessary clinical information has been made available).

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

14.9 The Appeal Panel will be established on a 'quality control check' model. Under this model, the Appeal 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

14.10 At the discretion of the Appeal Panel, they will either:

- Reject the appeal and support the original decision of the IFR Panel
- 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
- Consider that the evidence needs reconsideration by referral back, with full documentation, to the next IFR Panel meeting

14.11 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.

14.12 The decision of the Appeal Panel will be communicated by the Chair of the Appeal 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.

The Appeal Panel decision is the final decision of the CCG; the next step would be formal complaint.

15. IMPLEMENTATION

15.1 The Individual Funding Request function of the CCG is supported by North Yorkshire and Humber Commissioning Support Unit.

- Receiving IFR Requests and supporting the Panel in their considerations
- Supporting both clinician and patient as appropriate
- Communicating panel decisions to clinicians and patients
- Providing regular reports to the CCG on IFR activity

15.2 Breaches of this policy may be investigated and may, if appropriate, result in the matter being treated as a disciplinary offence under the CCG's disciplinary procedure.

16. TRAINING & AWARENESS

16.1 The IFR Policy, if agreed, will be made available on the CCG's Intranet and Internet. Training is available by the North Yorkshire and Humber CS Service to local Commissioners and clinicians as and when required. All IFR Panel members receive training prior to taking full Panel responsibilities.

17. MONITORING AND AUDIT

17.1 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. 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. In addition a monthly activity report is provided to the CCG.

18. POLICY REVIEW

18.1 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.

18.2 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 Patient Participation Group (PPG) Register and a new version of the PPG issued.

19. REFERENCES

19.1 "*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

19.2 13.2 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

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

19.4 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

19.5 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

19.6 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

20. ASSOCIATED DOCUMENTATION

Terms of Reference.

APPENDICES

Appendix 1 - Equality Impact Analysis
Appendix 2 - Sustainability Impact Assessment
Appendix 3 - Bribery Act
Appendix 4 - IFR Application Forms
Appendix 5 - IFR Panel Process Map
Appendix 6 - Appeals Panel Process Map

1 APPENDIX 1: Equality Impact Analysis Form

January 2015

For support with completion of this documentation, please see the accompanying guidance and/or contact the Equality Lead in the Yorkshire and Humber Commissioning Support

1. Equality Impact Analysis	
Policy / Project / Function:	IFR Policy
Date of Analysis:	January 2015
This Equality Impact Analysis was completed by: (Name and Department)	Catherine Lightfoot Service, Delivery and Assurance North Yorkshire and Humber Commissioning Support Unit
What are the aims and intended effects of this policy, project or function?	The aim of the policy is to: Identify the reasons for having an Individual Funding Request for a treatment which is restricted Explain the difficult choices faced by the CCG and how the CCG has decided to prioritise resources to ensure the best health outcomes for the community Set the decision making process within an ethical context Inform health professionals about the IFR 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 and consistent manner Provide a background against which appeals can be judged Demonstrate clear processes for decision making Be able to defend legal challenges against the decision not to commission certain interventions or to limit the number of such interventions commissioned
Please list any other policies that are related to or referred to as part of this analysis?	NICE Guidance National EIA Vale of York Joint Strategic Needs Assessment Census 2011
Who does the policy, project or function affect ? Please Tick ✔	Employees ☐ Service Users ☒ Members of the Public ☐ Other (List Below) ☐

2. **Equality Impact Analysis: Screening**					
	Could this policy have a positive impact on…		Could this policy have a negative impact on…		Is there any evidence which already exists from previous (e.g. from previous engagement) to evidence this impact
	Yes	No	Yes	No	
Race	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process race will be addressed in any screening on potential impact for each IFR if appropriate.
Age	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process age will be addressed in any screening on potential impact for each IFR case if appropriate.
Sexual Orientation	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process sexual orientation will be addressed in any screening on potential impact for each IFR case if appropriate.
Disabled People	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process disabled people will be addressed in any screening on potential impact for each IFR case if appropriate.

Gender	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process gender will be addressed in any screening on potential impact for each IFR case if appropriate.
Transgender People	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process Transgender people will be addressed in any screening on potential impact for each IFR case if appropriate.
Pregnancy and Maternity	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process pregnancy and maternity will be addressed in any screening on potential impact for each IFR if appropriate.
Marital Status	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process marital status will be addressed in any screening on potential impact for each IFR if appropriate.
Religion and Belief	☐	☒	☐	☒	The overarching IFR policy includes the commissioning position for a number of procedures and treatments. Through the IFR process Religion and belief will be addressed in any

					screening on potential impact for each IFR if appropriate.
Reasoning	The ethos of the IFR process ensures that decisions are made based on clinical grounds and that people are not disadvantaged because of a protected characteristic, without an objectively justifiable reason.				
If there is no positive or negative impact on any of the Nine Protected Characteristics go to Section 7					

3. **Equality Impact Analysis: Local Profile Data**	
Local Profile/Demography of the Groups affected (population figures)	
General	For the 336,330 patients who are registered with 17 GP practices in Vale of York CCG.
Age	21.5% of the population (Joint Strategic Needs Assessment) are aged 0-19. The CCG has a relatively elderly population with 18.5% of its population aged over 65 (Joint Strategic Needs Assessment).
Race	The Census 2011 indicates the race of the population in Vale of York CCG as: White 92.5% White Other 3.5% Mixed 1.0% Asian 2.2% Black 0.4% Other 0.3%
Sex	The gender split in the Vale of York CCG area is 48.7% male and 51.3% female (Joint Strategic Needs Assessment).
Gender reassignment	There are no official statistics nationally or regionally regarding transgender populations, however, GIRES (Gender Identity Research and Education Society - www.gires.org.uk) estimated that, in 2007, the prevalence of people who had sought medical care for gender variance was 20 per 100,000, i.e. 10,000 people, of whom 6,000 had undergone transition. 80% were assigned as boys at birth (now trans women) and 20% as girls (now trans men). However, there is good reason, based on more recent data from the individual gender identity clinics, to anticipate that the gender balance may eventually become more equal.
Disability	15.8% of people within the Vale of York CCG population are living with a limiting long term illness or disability.
Sexual Orientation	Local population data is not available for sexual orientation. In part, this is because until recently national and local surveys of the population and people using services did not ask about an individual's sexual orientation. However, Stonewall estimates that 5 - 7% of the national population are lesbian, gay or bisexual.
Religion, faith and belief	According to the 2011 Census, 64.3% of the population identified themselves as Christian and 1.9% of the population is made up of other religions. The remainder of the population (33.8%) did not state anything or stated 'no religion'.
Marriage and civil partnership	This protected characteristic generally only applies in the workplace. Data from the Office of National Statistics covering the period 2008-2010 indicates that there were 18,049 Civil Partnerships in England and Wales during this three-year period – 52% men and 48% women.

Pregnancy and maternity	North Yorkshire has a lower than national average rate of infant mortality and low birth rate.

4. **Equality Impact Analysis: Equality Data Available**	
Is any Equality Data available relating to the use or implementation of this policy, project or function? Equality data is internal or external information that may indicate how the activity being analysed can affect different groups of people who share the nine *Protected Characteristics* – referred to hereafter as *'Equality Groups'.* Examples of *Equality Data* include: (this list is not definitive) 1. Application success rates *Equality Groups* 2. Complaints by *Equality Groups* 3. Service usage and withdrawal of services by *Equality Groups* *4.* Grievances or decisions upheld and dismissed by *Equality Groups* 5. *Previous EIAs*	Yes ☐ No ☒ Where you have answered yes, please incorporate this data when performing the *Equality Impact Assessment Test* (the next section of this document). Provision of relevant equality data has been agreed as part of the future commissioning arrangements for the complaints / PALS service through a voluntary questionnaire.
List any Consultation e.g. with employees, service users, Unions or members of the public that has taken place in the development or implementation of this policy, project or function	The policy has undergone consultation with the North Yorkshire and Humber Commissioning Support unit. The contents of this policy is based on similar policies which have been agreed and adopted by several North Yorkshire and Humber CCGs.
Promoting Inclusivity **How does the project, service or function contribute towards our aims of eliminating discrimination and promoting equality and diversity within our organisation**	The ethos of the IFR process ensures that decisions are made based on clinical grounds and that people are not disadvantaged because of a protected characteristic, without an objectively justifiable reason.

5. Equality Impact Analysis: Assessment Test

What impact will the implementation of this policy, project or function have on employees, service users or other people who share characteristics protected by *The Equality Act 2010* ?

Protected Characteristic:	No Impact:	Positive Impact:	Negative Impact:	Evidence of impact and if applicable, justification where a *Genuine Determining Reason* exists
Gender (Men and Women)	✔			
Race (All Racial Groups)	✔			
Disability (Mental and Physical)	✔			
Religion or Belief	✔			
Sexual Orientation (Heterosexual, Homosexual and Bisexual)	✔			

What impact will the implementation of this policy, project or function have on employees, service users or other people who share characteristics protected by *The Equality Act 2010* ?

Protected Characteristic:	No Impact:	Positive Impact:	Negative Impact:	Evidence of impact and if applicable, justification where a *Genuine Determining Reason* exists
Pregnancy and Maternity	✔			
Transgender	✔			
Marital Status	✔			
Age	✔			

6. Action Planning				
As a result of performing this analysis, what actions are proposed to remove or reduce any risks of adverse outcomes identified on employees, service users or other people who share characteristics protected by *The Equality Act 2010* ?				
Identified Risk:	**Recommended Actions:**	**Responsible Lead:**	**Completion Date:**	**Review Date:**
There are no identified risks				

7. Equality Impact Analysis Findings				
Analysis Rating:	□ Red	□ Red/Amber	□ Amber	□ Green

		Actions	Wording for Policy / Project / Function
Red **Stop and remove the policy**	**Red:** As a result of performing the analysis, it is evident that a risk of discrimination exists (direct, indirect, unintentional or otherwise) to one or more of the nine groups of people who share *Protected Characteristics.* It is recommended that the use of the policy be suspended until further work or analysis is performed.	**Remove the policy** Complete the action plan above to identify the areas of discrimination and the work or actions which needs to be carried out to minimise the risk of discrimination.	No wording needed as policy is being removed
Red Amber **Continue the policy**	As a result of performing the analysis, it is evident that a risk of discrimination exists (direct, indirect, unintentional or otherwise) to one or more of the nine groups of people who share *Protected Characteristics.* However, a genuine determining reason may exist that could legitimise or justify the use of this policy and further professional advice should be taken.	**The policy can be published with the EIA** List the justification of the discrimination and source the evidence (i.e. clinical need as advised by NICE). Consider if there are any potential actions which would reduce the risk of discrimination. Another EIA must be completed if the policy is changed, reviewed or if further discrimination is identified at a later date.	As a result of performing the analysis, it is evident that a risk of discrimination exists (direct, indirect, unintentional or otherwise) to one or more of the nine groups of people who share *Protected Characteristics.* However, a genuine determining reason exists which justifies the use of this policy and further professional advice. ***[Insert what the discrimination is and the justification of the discrimination plus any actions which could help what reduce the risk]***

Equality Impact Findings (continued):			
		Actions	Wording for Policy / Project / Function
Amber **Adjust the Policy**	As a result of performing the analysis, it is evident that a risk of discrimination (as described above) exists and this risk may be removed or reduced by implementing the actions detailed within the *Action Planning s*ection of this document.	**The policy can be published with the EIA** The policy can still be published but the Action Plan must be monitored to ensure that work is being carried out to remove or reduce the discrimination. Any changes identified and made to the service/policy/ strategy etc. should be included in the policy. Another EIA must be completed if the policy is changed, reviewed or if further discrimination is identified at a later date.	As a result of performing the analysis, it is evident that a risk of discrimination (as described above) exists and this risk may be removed or reduced by implementing the actions detailed within the *Action Planning s*ection of this document. ***[Insert what the discrimination is and what work will be carried out to reduce/eliminate the risk]***
Green **No major change**	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.	**The policy can be published with the EIA** Another EIA must be completed if the policy is changed, reviewed or if any discrimination is identified at a later date	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.

Brief Summary/Further comments	

Approved By		
Job Title:	Name:	Date:

2 APPENDIX 2: Sustainability Impact Assessment

Staff preparing a policy, Governing Body (or Sub-Committee) report, service development or project are required to complete a Sustainability Impact Assessment (SIA). The purpose of this SIA is to record any positive or negative impacts that this is likely to have on sustainability.

Title of the document	**Individual Funding Request Policy and Procedure**
What is the main purpose of the document	**To demonstrate a clear process for decision making**
Date completed	
Completed by	

Domain	**Objectives**	**Impact of activity** Negative = -1 Neutral = 0 Positive = 1 Unknown = ? Not applicable = n/a	**Brief description of impact**	**If negative, how can it be mitigated?** **If positive, how can it be enhanced?**
Travel	Will it provide / improve / promote alternatives to car based transport? Will it support more efficient use of cars (car sharing, low emission vehicles, environmentally friendly fuels and technologies)? Will it reduce 'care miles' (telecare, care closer) to home? Will it promote active travel (cycling, walking)? Will it improve access to opportunities and facilities for all groups?	0	Patients will be required to travel to providers of healthcare to receive their treatment.	
Procurement	Will it specify social, economic and environmental outcomes to be accounted for in procurement and delivery? Will it stimulate innovation among providers of services related to the delivery of the organisations' social, economic and	1	Where possible treatments will be collaboratively commissioned seeking to maximise clinical and cost	

	environmental objectives? Will it promote ethical purchasing of goods or services? Will it promote greater efficiency of resource use? Will it obtain maximum value from pharmaceuticals and technologies (medicines management, prescribing, and supply chain)? Will it support local or regional supply chains? Will it promote access to local services (care closer to home)? Will it make current activities more efficient or alter service delivery models		effective services.	
Facilities Management	Will it reduce the amount of waste produced or increase the amount of waste recycled? Will it reduce water consumption?	N/A		
Workforce	Will it provide employment opportunities for local people? Will it promote or support equal employment opportunities? Will it promote healthy working lives (including health and safety at work, work-life/home-life balance and family friendly policies)? Will it offer employment opportunities to disadvantaged groups?	N/A		
Community Engagement	Will it promote health and sustainable development? Have you sought the views of our communities in relation to the impact on sustainable development for this activity?	N/A		
Buildings	Will it improve the resource efficiency of new or refurbished buildings (water, energy, density, use of existing buildings, designing for a longer lifespan)? Will it increase safety and security in new buildings and developments? Will it reduce greenhouse gas emissions from transport (choice of mode of transport, reducing	N/A		

	need to travel)? Will it provide sympathetic and appropriate landscaping around new development? Will it improve access to the built environment?			
Adaptation to Climate Change	Will it support the plan for the likely effects of climate change (e.g. identifying vulnerable groups; contingency planning for flood, heat wave and other weather extremes)?	N/A		
Models of Care	Will it minimising 'care miles' making better use of new technologies such as telecare and telehealth, delivering care in settings closer to people's homes? Will it promote prevention and self-management? Will it provide evidence-based, personalised care that achieves the best possible outcomes with the resources available? Will it deliver integrated care, that co-ordinate different elements of care more effectively and remove duplication and redundancy from care pathways?	1		

3 APPENDIX 3: Bribery Act 2010 Guidance

Introduction

On July 2011 the Bribery Act 2010 came into force, making it a criminal offence to give, promise, or offer a bribe and to request, agree or receive a bribe. It increased the maximum penalty for bribery to 10 years' imprisonment, with an unlimited fine. Furthermore the act introduces a 'corporate offence' of failing to prevent bribery by the organisation not having adequate preventative procedures in place. An organisation may avoid conviction if it can show that it had such procedures and protocols in place to prevent bribery.

The Ministry of Justice in its consultation and guidance set out six broad management principles whereby an organisation can demonstrate an effective defence by showing that it had effective bribery prevention measures in place.

Risk Assessment – this is about knowing and keeping up to date with the bribery risks you face in your sector and market;

Top level commitment – this concerns establishing a culture across the organisation in which bribery is unacceptable. If your business is small or medium sized this may not require much sophistication but the theme is making the message clear, unambiguous and regularly made to all staff and business partners;

Due diligence – this is about knowing who you do business with; knowing why, when and to whom you are releasing funds and seeking reciprocal anti-bribery agreements ; and being in a position to feel confident that business relationships are transparent and ethical;

Clear, Practical and Accessible Policies and Procedures – this concerns applying them to everyone you employ and business partners under your effective control and covering all relevant risks such as political and charitable contributions, gifts and hospitality, promotional expenses, and responding to demands for facilitation demands or when an allegation of bribery comes to light.

Effective implementation – this is about going beyond 'paper compliance' to embedding anti-bribery in your organisation's internal controls, recruitment and remuneration policies, operations, communications and training on practical business issues.

Monitoring and review – this relates to auditing and financial controls that are sensitive to bribery and are transparent, considering how regularly you need to review your policies and procedures, and whether external verification would help.

Relevance to the NHS

NHS organisations are included in the Bribery Act's definition of a "relevant commercial organisation". Any senior manager or executive who consents to or connives in any active or passive bribery offence will, together with the organisation, be liable for the corporate offence under the act.
Any individual associated with an organisation who commits acts or omissions forming part of a bribery offence may be liable for a primary bribery offence under the act or for conspiracy to commit the offence with others – including, for example, their employer.

Risks in breaching the Bribery Act

There are a number of risks entailed in breaching the Bribery Act. These include:

- Criminal sanctions against directors, board members and other senior staff as a corporate offence – Section 7 of the Act.
- Convictions of bribery or corruption may also lead to the organisation being precluded from future public sector procurement contracts.
- Damage to the organisation's reputation and negative impact on patient/stakeholder perceptions.
- Potential diversion and/or loss of resources.

What do NHS organisation's need to do?

There are a number of steps NHS organisations can take:

- The Board needs to understand its responsibility in respect of the act.
- Be clear that, as NHS organisations, you are covered by corporate liability for bribery on the part of their employees, contractors and agents.
- Take steps to make your employees, contractors and agents aware of the standards of behaviour that are expected of them: this may include training for employees who might be affected – for example, employees with responsibility for procurement.
- Review existing governance, procedures, decisions-making processes and financial controls, introduce them if not already in place and, where necessary, provide appropriate training for staff.
- Record the fact that these steps have been taken, as they provide the defence against corporate liability under the act.

Areas for Action

Once risks have been assessed the organisation must put in place procedures that are *proportionate* to bribery risks that are identified.

The checklist below provides details of areas for actions to assist in ensuring proportionate steps to ensure prevention and defence against corporate liability under the act. The checklist is based on best practice guidance documents issued by NHS Protect in May 2011, Ministry of Justice and other anti-bribery and corruption NGOs.

Internal Audit and Counter Fraud Teams will provide support to the organisation to help ensure that assurance can be given against the points in the following checklist during 2012/13.

Bribery Act 2010 Guidance and Bribery Prevention Checklist

	Areas for action	Expected Action	Evidence of Compliance/Assurance
	1. Governance and Top Level Commitment	The Chief Executive should make a statement in support of the anti-bribery initiative and this should be published on the organisation's website. The board of directors should take overall responsibility for the effective design, implementation and operation of the anti-bribery initiatives. The Board should ensure that senior management is aware of and accepts the initiatives and that it is embedded in the corporate culture.	
	2. Due Diligence	This is a key element of good corporate governance and involves making an assessment of new business partners prior to engaging them in business. Due diligence procedures are in themselves a form of bribery risk assessment and also a means of mitigating that risk. It is recommended that at the outset of any business dealings, all new business partners should be made aware in writing of the organisation's anti-corruption and bribery policies and code of conduct.	
3. Code of conduct		The organisation should either have an anti-bribery code of conduct or a general code of conduct for staff with an anti-bribery and corruption element. The organisation should revise the Standards of Business Conduct Policy (or equivalent) and Declaration of Interests guidance (see point 4 below) to reflect the introduction of the Bribery Act.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
4. Declaration of Interests/Hospitality	The organisation should have in place a declaration of business interests/gifts and hospitality policy which clearly sets out acceptable limits and also a mechanism to monitor implementation.	
5. Employee employment procedures	Employees should go through the appropriate propriety checks e.g. CRB (Criminal Records Bureau) and/or a combination of other checks before they are employed to ascertain, as far as is reasonable, that they are likely to comply with the organisation's anti-bribery policies.	
6. Detection procedures	The organisation should ensure Internal Audit/Counter Fraud check projects, contracts, procurement processes and any other appropriate systems where there is a risk that acts of bribery could potentially occur.	
7. Internal reporting procedures	The organisation should have internal procedures for staff to report suspicious activities including bribery.	
8. Investigation of Bribery allegations	The organisation should have procedures for staff to report suspicions of bribery to NHS Protect (previously NHS Counter Fraud and Security Management Service) and the organisation's Local Counter Fraud Specialist for investigation/referral to the appropriate authorities.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
9. Risk assessment	MoJ (Ministry of Justice) guidance states"…organisations should adopt a risk-based approach to managing bribery risks…[and] an initial assessment of risk across the organisation is therefore a necessary first step". The organisation should, on a regular basis, assess the risk of bribery and corruption in its business and assess whether its procedures and controls are adequate to minimise those risks.	
10. Record keeping	The organisation should keep reasonably detailed records of its anti-fraud and corruption initiatives, including training given, hospitality given and received and other relevant information.	
11. Internal review	The organisation should carry out an annual internal review of the anti-bribery and corruption programme.	
12. Independent assessment and certification	Proportionate to risks identified, the organisation should commission, at least every three years, an independent assessment and certification of its anti-bribery programme.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
13.Internal and External communications	The organisation should publicise the NHS Fraud and Corruption Reporting Line (FCRL) and on-line fraud reporting facility. The organisation should publicise the Security Management role (theft and general security issues) and reporting arrangements. The organisation should work with its stakeholders in the public and private sector to help reduce bribery and corruption in the health industry.	
14.Awareness and training	The organisation should provide appropriate anti-bribery and corruption awareness sessions and training on a regular basis to all relevant employees.	
15. Monitoring: • Overall Responsibility • Financial/Commercial Controls	• A senior manager should be made responsible for ensuring that the organisation has a proportionate and adequate programme of anti-fraud, corruption and bribery initiatives. • The organisation should ensure that its financial controls minimise the risk of the organisation committing a corrupt act. • The organisation should ensure that its commercial controls minimise the risk of the organisation committing a corrupt act. These controls would include appropriate procurement and supply chain management, and the monitoring of contract execution.	

4 APPENDIX 4: IFR Application Forms

Exceptional Circumstances Submission Form
(GP referrals)

On completion please post to:

Individual Funding Request Panel
North Yorkshire and Humber Commissioning Support Unit
Unit 1, Triune Court
Monks Cross North
York
YO32 9GZ

Email: yhcs.exceptions@nhs.net
Safe haven fax: 01904 694 702

CONTACT INFORMATION

1. Referring Clinician	**GP/Consultant Name:**	
	GP Name (if different to referring clinician):	
	Practice/Hospital name and address:	
	Tel:	
	Fax:	
	Email:	
	Provider referred to:	
2. Patient Details	**NHS Number:**	
	Responsible CCG:	
	UBRN number:	
	Date of referral to exception panel:	

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

3. Patient Diagnosis	
4. Intervention Requested	
5. Significant clinical history e.g. duration of symptoms, co-morbidities, etc.	
6. Give details of relevant treatment/management/ investigations carried out in primary/secondary care (in accordance with the relevant clinical thresholds	
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 from this intervention 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 on mobility, self-care, pain/discomfort, anxiety/depression?	
10. Patient has given consent to share information (please tick box to confirm)	

Please ensure that you enclose a copy of the referral letter with this form. The referral cannot be considered unless all relevant information is included. Where this is omitted, the requesting clinician may be asked to provide it before the case can be taken to the Individual Funding Request Panel.

EXCLUDED DRUGS AND DEVICES
EXCEPTIONAL CIRCUMSTANCES FORM
(for completion by hospital consultant)

On completion, please post to:

Individual Funding Request Panel
North Yorkshire and Humber Commissioning Support Unit
Triune Court
Unit 1
Monks Cross North
York
YO32 9GZ

Email: yhcs.exceptions@nhs.net
Safe haven fax: 01904 694702

CONTACT INFORMATION

1.Trust Name and Address		
2. Applicant Details	**Name:**	
	Designation:	
	Tel:	
	Email (NHS.net if possible):	
3. Patient Details	**Hospital ID number:**	
	NHS No:	
	Registered Consultant:	
	Registered GP name:	
	Registered GP address:	
	Responsible Commissioner (CCG):	
	Referred by (other than GP):	
	Date of referral:	
4. Application reviewed by Chief Pharmacist or nominated deputy (in the case of a drug intervention)	**Name:**	
	Signature or email confirmation:	

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

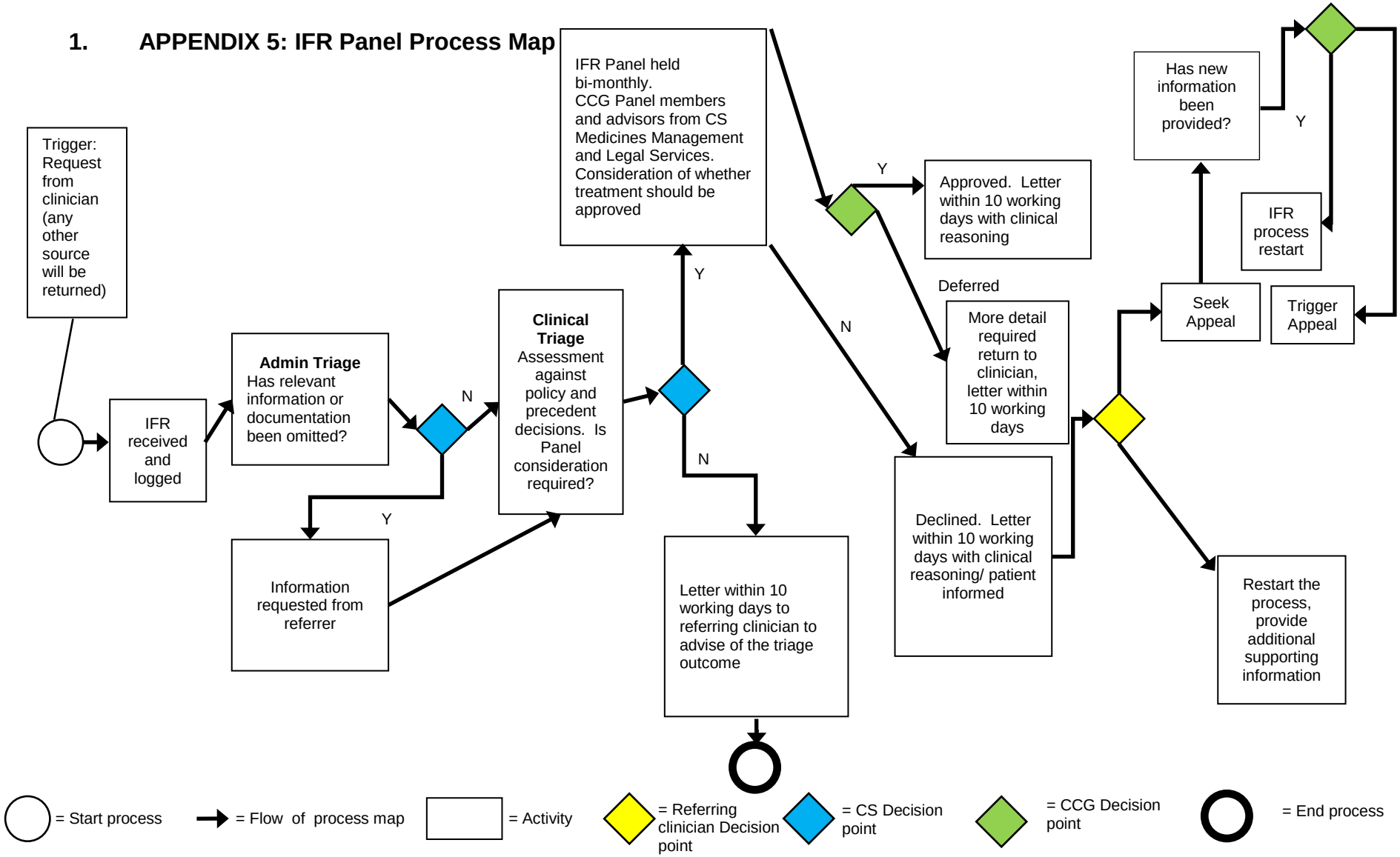
5. Patient Diagnosis (for which intervention is requested)			
6. Details of intervention (for which funding is requested)	**Name of intervention:**		
	Dose and frequency:		
	Planned duration of intervention:		
	Route of administration:		
	Anticipated cost (inc. VAT) – seek advice from pharmacy:		
7. 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?)		
8. (a) What would be the standard intervention at this stage?			
(b) What are the exceptional circumstances that make the standard intervention inappropriate (N.B: please refer to the CCG definition for clinical exceptionality, non-clinical factors cannot be taken into account).			
9. What is the patient's clinical severity? (Where possible use standard scoring systems e.g. WHO, DAS scores, walk test, cardiac index, etc.)			
10. 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	**Dates**	**Intervention (e.g. drug/ surgery)**	**Reason for stopping* /Response achieved**

tolerated			
11. Anticipated start date	Please state if request is CLINICALLY URGENT and if so, why		

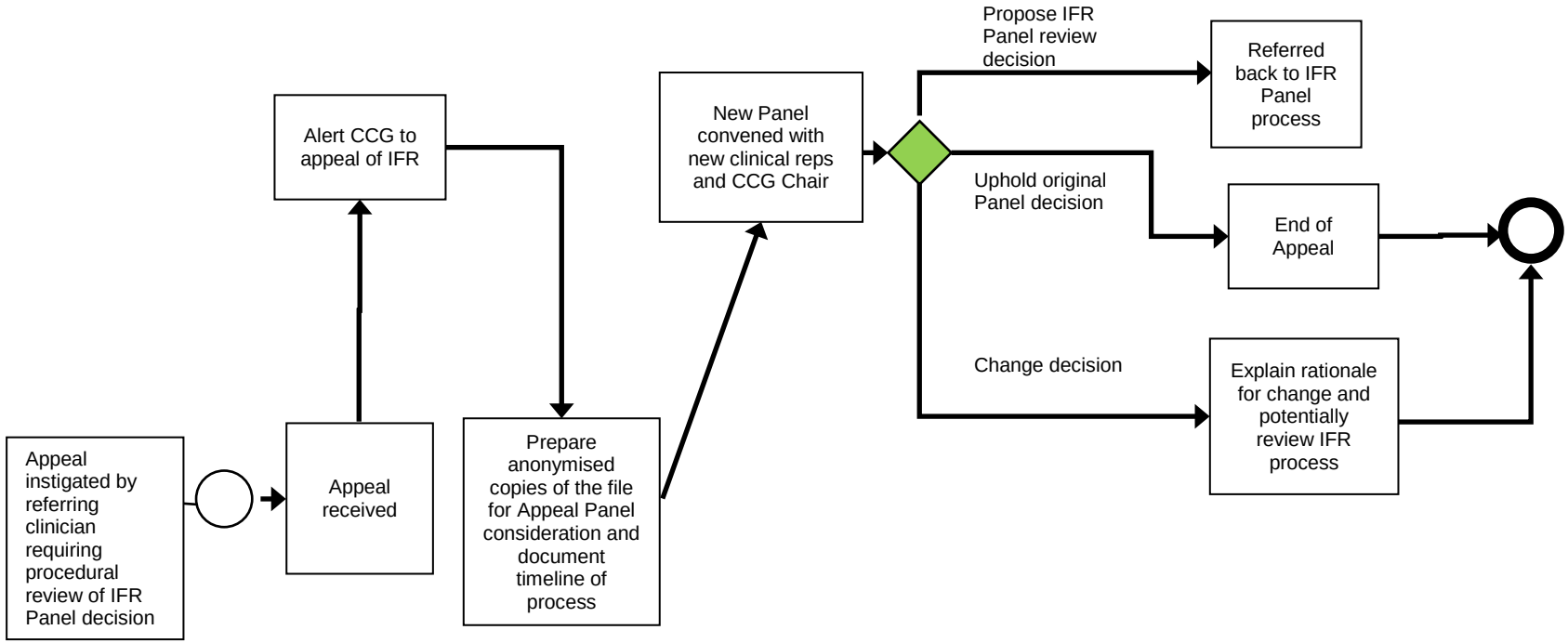
CLINICAL EVIDENCE

12. Is requested intervention licensed for use in the requested indication in the UK?	Delete as appropriate: **NO** / **YES** (refer to pharmacy if required)
13. 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:
14. 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)**
15. (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?	
16. What is the anticipated toxicity of the intervention for this patient?	
17. Are there any other clinical patient factors that need to be considered?	Delete as appropriate: **YES / NO** If **Yes**, please give details:
18. Date form completed	
19. Patient has given consent to share information (please tick box)	

1. APPENDIX 5: IFR Panel Process Map



2. APPENDIX 6: Appeal Panel Process Map



Key

= Start process

= Flow of process map

= Activity

= CCG Decision point

= End process