Vale of York
Clinical Commissioning Group

Individual Funding Request Policy and Procedure
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The on-line version is the only version that is maintained. Any printed copies should, therefore, be viewed as 'uncontrolled' and as such may not necessarily contain the latest updates and amendments.

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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
1	VoYCCG	Approved Policy		
2	NECS IFR team	Review of policy and update of organisation name following transfer of provider		
3				
4				
5				

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CONTENTS

1 INTRODUCTION

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 (DH, March 2013) (Ref 12.3). Two rights relate specifically to the availability of medicines and other treatments:

    1) You have the right to drugs and treatments that have been recommended by NICE for use in the NHS if your doctor says they are clinically appropriate for you.
    2) You have the right to expect local decision 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 2014/15 (Department of Health, December 2011) (Ref 12.6).
- NHS Vale of York CCG Operational Plan.

NHS Vale of York 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).

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

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 Executive Committee and the Council of Clinical Representatives.

3. IMPACT ANALYSES

3.1 Equality

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.

To ensure the above, this Policy and Procedure has been Equality Impact Assessed. Details of this assessment are attached at Appendix 6. As a result of the Equality Impact Assessment (EIA) there are no additional identified risks or related actions required other than training of Panel members.

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.

3.2 Sustainability

There are no sustainability impacts through this policy. Completed Sustainability Impact included in Appendix 7. Commissioning policies are agreed against clinical and cost effectiveness considerations.

3.3 Bribery Act 2010

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 pace 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.

Further information of the Bribery Act can be found at www.opsi.gov.uk/acts. Further advice may be sought from the NECS Corporate Governance department.

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.
  AND
- 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.

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.

Any panel member is requested to identify any conflict of interest in any funding requests from patients that are known to them, this must be declared at the onset of any panel meetings.

4. SCOPE

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 of England Commissioning Support (NECS) 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.
- All referring clinicians within primary, secondary and tertiary care.
- Those treatments and services which are subject to CCG commissioning but are not routinely funded by the CCG and funding needs to be considered on an individual basis. This might include:
  - Interventions not supported by NICE

- Requests to continue funding for patients previously treated by self-funding or through funding from the device manufacturer or pharmaceutical industry, provider trusts treating at their own risk, on compassionate grounds
- through a decision made by another CCG commissioner where the patient has become the commissioning responsibility of a CCG covered by the terms of this policy
- Requests for referral to a service not commissioned locally and not listed on the national menu (including applications for overseas treatment)

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 & AIMS

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. NB – the term ‘healthcare interventions’ includes the use of drugs, interventions and therapies

6. DEFINITIONS

6.1 Cost effectiveness

The cost effectiveness of a treatment or intervention is the ration 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.

6.2 Clinical effectiveness

The clinical effectiveness of a treatment or intervention is best measured using published randomised controlled trials comparing it with "usual"/ control (or no) treatment. Evidence of a lower standard is often used and a "hierarchy" exists to indicate how robust it might be (see Appendix 1).

6.3 An Individual Funding Request

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.
Individual Funding Requests are not the same as:

- Decisions that are related to care packages for patient 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 community based service).

Individual Funding Requests generally arise in one of four circumstances:

- The patient has a rare condition and the clinician 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 unproved, 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.

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

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.

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.

6.4 Exceptionality

Exceptionality is difficult to define, therefore pragmatism and flexibility are necessary. However it may be summed up 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).

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.

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.

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.

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 a population based commissioning decision, these factors will equally not be considered for Individual Funding Requests.

6.5 Request for cross-border treatment and treatment outside the European Economic Area (EEA)

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

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.

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.

7. ROLES AND RESPONSIBILITIES

The Individual Funding Request function of the CCG is supported by NHS North of England Commissioning Support (NECS) and details of the full process are provided in the appendices in the form of a Standard Operating Procedure.

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

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

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

NECS will hold patient level information on behalf of the CCGs to support the IFR process. All patient information will be handled in confidence and stored in accordance with the Information Governance Framework relating to person identifiable information.

IFR panel members will take into account the need for confidentiality and operate under the Caldicott guidelines. All patient specific electronic communication will be via a secure nhs.net connection.

NECS will on behalf of CCGs, keep a full set of information electronically under a single record number. Telephone calls relating to IFR enquiries will be logged and notes kept with the case file, where appropriate. Relevant email communication and hard copy documents will be stored with the electronic file.

Electronic records and IFR panel minutes will be saved securely and access will be available to authorised staff only. Panel member hard copy records must be disposed of as confidential waste.

NECS IFR processes will comply at all times with information privacy, confidentiality and security legal and regulatory requirements and best practice. NECs will fully respect patient confidentiality and ensure that patient information is not collected, processed or shared without valid patient consent or other legal basis.

8. IMPLEMENTATION

8.1 Development of General Policies for Interventions

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.

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.

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.

All Individual Funding Requests are considered 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.

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/rss/

8.2 Health Care Interventions that the CCG will not Commission Routinely

There are a number of health 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.

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.

Commissioners, general practitioners, service providers and clinical staff considering treating patients from 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.

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 National Institute for Health and Care Excellence (NICE) , has published a Medtech innovation briefing (MIB), 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.

This policy will be published on the CCG website and all staff will be made aware of its publication through communications and team meetings.

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.

9. TRAINING AND AWARENESS

The IFR Policy will be made available on the CCG's Intranet and Internet.
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.

10. MONITORING AND AUDIT

There will be an annual report from the Individual Funding Request Team 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.

11. POLICY REVIEW

General commissioning policies and the Individual Funding Request Policy will be reviewed by the author at least every two years (unless otherwise required by national guidance or other imperatives) and approved by the Executive Committee.

Minor amendments (such as changes in the title) may be made prior to the formal review, details of which will be monitored and approved by the CCG's Corporate Manager.

12. REFERENCES

"Priority Setting: managing individual funding requests". The NHS Confederation, 2008. NHS Institute for Innovation and Improvement. Available at http://www.nhsconfed.org/~/media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf

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Appendix 1 - THE INDIVIDUAL FUNDING REQUEST STANDARD OPERATING PROCEDURE

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 will only be accepted when submitted via the NECS Electronic IT System.

In accordance with the CCG and NECS Information Governance policies, the IFR team cannot process applications submitted without evidence that the patient has given consent for their personal information to be shared. Clinicians should therefore submit IFR applications using the eIFR system, using the tick box to indicate that they have discussed the Information Governance Statement with their patient. Applications will not be accepted or processed without evidence of patient consent to share information, and will be returned to the applicant explaining the reasons why.

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. Only clinical photographs will be accepted.

Where the GP can reasonably be expected to know the intervention requires IFR, it is expected that they will apply for funding prior to referral. Where the treatment required can only be identified by a Consultant, the Consultant should apply for IFR funding. The Consultant cannot delegate their responsibility back to the GP.

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.

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 syntheses. 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.

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).

In order to direct requests along the appropriate decision making pathway, the IFR team will clinical triage all requests before providing a recommended outcome for the IFR Panel to ratify. Clinical triage must be undertaken by two members of staff, one of whom must be a clinical 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.

<u>The role of Clinical Triage</u>:

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

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

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

- The request has not been submitted by a healthcare professional
- Relevant clinical information has been omitted
- The request does not need to go through the IFR process as it meets the threshold criteria for that intervention

- The request can be dealt with under another existing contract

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

- There is no clinical case
- The request does not meet criteria outlined in an agreed commissioning policy and for which no case has been made for exceptionality
- That treatment can be commissioned because they meet pre-agreed exceptions (some of which are set through precedent)
- The request raises a major policy issue and needs further discussion and work

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

- IFR Clinical Triage Support Officer
- IFR Case Assistant
- Two CCG GPs/clinical decision makers (one to be the Chair)

The following attendees will be available, as and when required, in an advisory capacity but are not decision-making members of the Panel:

- Learning Disability & Mental Health Specialist or representative
- Medicines Management Lead or representative
- Secondary Care Consultant
- NECS IFR Team representative

Patients and their referring clinician will **not** be invited to attend the Panel at which their request is being considered.

Administrative support to the Panel will be provided by the NECS Individual Funding Request team.

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.

To ensure effective, fair and transparent decision making the Panel must be quorate to agree decisions. Two medically qualified members of the IFR Panel and a case manager will be present to ensure the meeting is quorate.

All Individual Funding Requests received by the CCG will be given a case reference number within a secure electronic system maintained by the NECS 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 NECS IFR team and members of the Panel.

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 5 working days 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 4 weeks, the case will be considered closed. Should the requested information be received after this point then the referring clinician will need to make a new referral.

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.

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 - £23,000 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 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–fund treatment (except for equipment funding requests, which in some cases may be paid for jointly with the local authority)
- Fund elective treatment requested retrospectively
- Fund equipment ordered prior to Panel approval
- Recommend alternative treatments for a particular condition or patient.

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 ratification. A decision record and outcome will be maintained by the NECS Electronic IFR IT System for each request the Panel considers.

Decisions made by the Panel will be communicated on behalf of the IFR Panel by the NECS IFR team to the requesting clinician within 10 working days of the date of the Panel at which the request was considered.

Urgent Requests

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 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 Should there be uncertainty as to the clinical rationale for the urgency of the request, the NECS IFR team can request supporting rationale from the referring clinician before confirming the status of the request as urgent.

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.

Where a provider chooses to go 'at risk' in the event of an IFR decision not being made in time, the onus for cost of the intervention, the continuation of treatment and/or financial impact rests entirely with the provider.

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 advanced of a Panel meeting will be communicated to the referring clinician within 2 working days of the date of the decision.

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,

The CCG 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 on the Vale of York CCG website to explain the Individual Funding Request and Appeal processes.

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).

The Process for Appeals

The requesting clinician may appeal against the decision of the IFR Panel not to support their request for a procedure or intervention, and must trigger the appeal using the eIFR system 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 meet monthly (where there are cases to be considered) and its business and decisions will be fully recorded. 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).

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.

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, 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

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 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.

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

Appendix 2 – TERMS OF REFERENCE

VALE OF YORK CCG
INDIVIDUAL FUNDING REQUEST PANEL

1 General

The Individual Funding Request Panel is a Committee of the Vale of York Clinical Commissioning Group Governing Body (thereafter known as CCG).

2 Role and Purpose

The Individual Funding Request Panel will be a confidential forum. The Individual Funding Request Panel will have a nominated Panel Chair and Vice Chair. The Panel will consider funding requests from NHS clinicians in respect of health care interventions for individuals where NHS Vale of York CCG general policy is not to fund that intervention or where there is no specific policy/national guidance.

The Panel will be quorate if it consists of a Chair and a minimum of one CCG clinical decision makers are present.

3 Remit

The Individual Funding Request Panel works with key managers and clinicians within NHS Vale of York CCG to consider individual requests for procedures/treatment where NHS Vale of York CCG's general policy is not to fund that intervention. This will include those procedures/treatments/drugs classified as low priority, specific contract exclusions or treatments not covered by specific policy/national guidance.

The Individual Funding Request Panel will also consider requests for approval for treatment/procedures which have been classified as low priority or where the patient does not meet specified eligibility criteria for a specific financial year where the requesting clinician claims that there are clinically exceptional circumstances in line with the Individual Funding Request Policy.

The financial limit per case will be a maximum of £250,000. Requests for treatment over this limit will be referred to the Clinical Commissioning Governing Body.

The Individual Funding Request Panel will receive requests from the IFR team, including those which have been clinically triaged. A unique case number will be applied to each case by the IFR team. Decisions made will be noted by the IFR team member taking the minutes of the meeting. Minutes will be detailed and include the clinical evidence considered, any evidence disregarded and the reasons for the decision

The Individual Funding Request Panel will not make policy decisions on behalf of the Clinical Commissioning Group Governing Body but will confine its decision making to individual treatment funding requests. If any individual case requires consideration of an extant policy, this will be referred to the Clinical Commissioning Group Governing Body.

Where a policy does not currently exist, but where it is likely that a service development requires consideration, the clinician(s) concerned will be directed to the appropriate person/committee within the CCG for the business case to receive appropriate consideration.

The Individual Funding Request Panel will take into account relevant clinical evidence, NICE guidance/recommendations, other regional/national policy and any other specific guidance relating to the requested treatment/procedure when considering the request.

Where necessary, clinical advice will be sought from appropriate specialists e.g. NHS England, national treatment networks, to assist the decision making process.

All cases will be retained within a secure electronic system and electronic filing system which conform to the highest standards of Information Governance, with copies of all email communication to and from the Panel including the final decisions stored electronically. All correspondence relating to specific cases should be sent via secure N3 connection using nhs.net email.

4 Decisions for clinically urgent cases

Occasionally, there may be need to consider a case outside the usual panel arrangements where the referring clinician has indicated the need for *clinical* urgency (risk of death or serious disability). In the event of a request citing clinical urgency, panel members will be contacted directly by the IFR team, along with appropriate evidence to assist the decision making, and will be able to provide their individual decision by the same means. Where possible, these requests will be responded to within 2 working days. In the event of Individual Funding Request Panel members being unable to agree, the nominated Panel Chair will make the final funding decision.

5 Composition of the Individual Funding Request Panel

Membership of the Individual Funding Request Panel will comprise of:

- IFR Clinical Triage Support Officer
- IFR Case Assistant
- Two CCG GPs/clinical decision makers (one to be the Chair)

The following attendees will be available, as and when required, in an advisory capacity but are not decision-making members of the Panel:

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

In the event that a GP member has a conflict of interest with an individual request they will not take part in the decision making to ensure that a robust process is maintained.

6 Format of Cases

Funding requests will be forwarded to the Individual Funding Request Panel in electronic format using the NECS IFR IT System. Each request will be recorded as an individual case with an assigned case number and will indicate very clearly whether a very urgent decision is required based on the clinical urgency of the case.

7 Relationship and Reporting to the Clinical Commissioning Group Governing Body

The Individual Funding Request Panel will be directly accountable to the Clinical Commissioning Governing Body.

Regular quarterly reports will be required by Clinical Commissioning Group on the range of cases considered and the cost implications of decisions made.

The Panel will provide an anonymised Annual Report (compiled by the NECS IFR Team) to the CCG Board, summarising the decision for the previous year.

Administrative support: Provided by the NECS Individual Funding Request team.

Quorum: To ensure effective, fair and transparent decision making they must consist of a Chair and a minimum of one CCG clinical decision makers.

Meeting Frequency: The panel will meet monthly as a minimum.

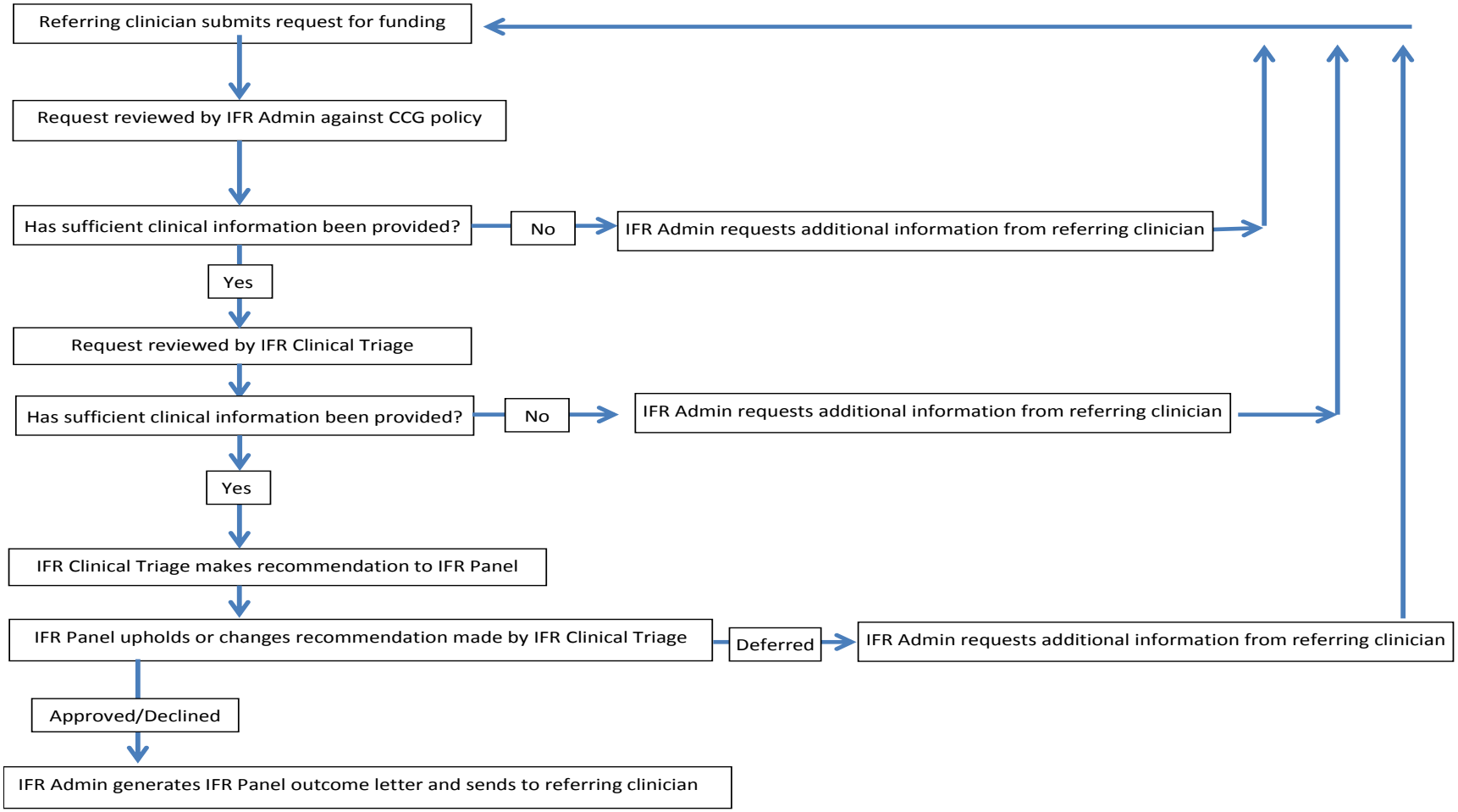
Reporting: Every Panel meeting will produce a ‘decision record’ so as to maintain accurate documentation of the whole decision making process. A decision record and outcome will be maintained by the NECS IFR team within a secure electronic system for each request the Panel considers.

Decisions made by the Panel will be communicated by the Individual Funding Request team to the requesting clinician 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 NECS Individual Funding Request team in accordance with the Vale of York 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).

Vale of York
Clinical Commissioning Group

APPENDIX 3: IFR Panel Process Map



APPENDIX 4

Terms of Reference

Vale of York CCG
IFR Appeals Panel

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 triggering an appeal using the eIFR system within three months of the date of the decision letter from the IFR Panel.

The CCG will establish a separate Appeals Panel to consider appeals against decision 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 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
- 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, they will either:

  a) Reject the appeal and support the original decision of the IFR Panel
  b) 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 patients or their clinician(s) 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 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 NECS IFR team on behalf of the Chair or other clinical representative to the requesting clinician within 10 working days of the date of the appeal decision.
- The Appeal 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):

- Senior CCG Representative (Chair)
- Two CCG GPs/clinical decision makers who were not involved in considering the case at the Individual Funding Request Panel
- IFR Case Assistant.

Administrative Support: Provided by the NECS IFR Team.

Legal support: Provided by the CCG's Legal and Governance Team

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

- 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)

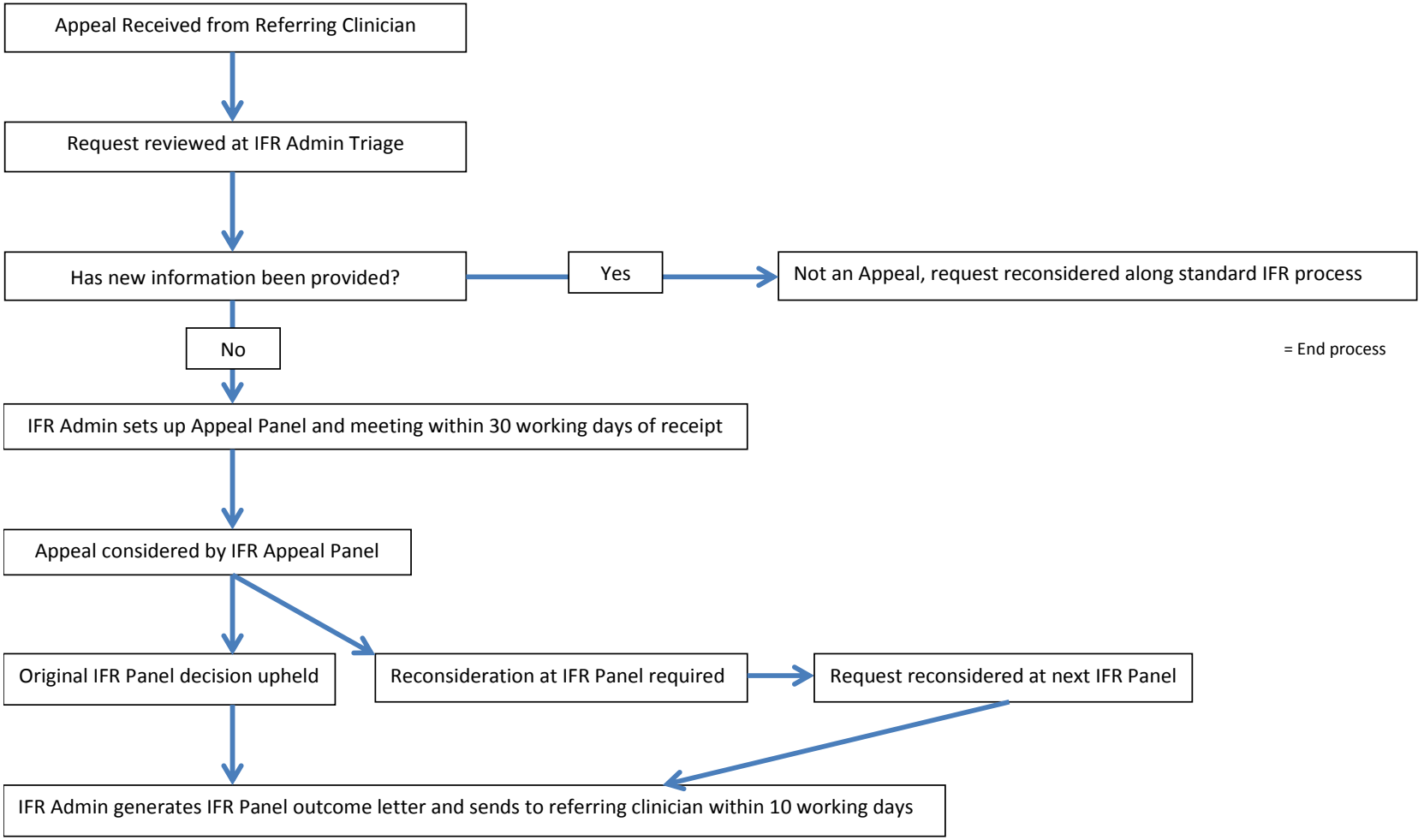
Meeting Frequency: The Appeals Panel will meet as required (where there are cases to be considered).

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

The appeals panel reports to the Clinical Commissioning Group Governing Body.

Vale of York
Clinical Commissioning Group

APPENDIX 5: IFR Appeal Panel Process Map



Equality Impact Assessment Strategy Policies

General Information	
Policy:	IFR Policy
Date of Analysis:	02 March 2018
Policy Lead: **(Name, job title and department)**	Catherine Lightfoot Clinical Triage Lead North of England Commissioning Support
What are the aims and intended effects of this policy?	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	
Are there any significant changes to previous policy likely to have an impact on staff, patients or other stakeholder groups?	None identified	
Please list any other policies that are related to or referred to as part of this analysis	NICE Guidance National EIA Census 2011	
Who is likely to be affected by this policy?	General Public	
	Service Users	✔
	Staff	
What engagement / consultation has been done, or is planned for this policy and the equality impact assessment?	Variations of this policy have been considered and approved by a number of other CCGs across the North Yorkshire and Humber locality. Prior to going to the CCG's Governing Body, it has also been considered by the Executive Committee and the Council of Representatives.	
Promoting Inclusivity and NHS Vale of York CCG's Equality Objectives. How does the project, service or function contribute towards our aims of eliminating discrimination and promoting equality and diversity within our organisation? How does the policy promote our equality objectives	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.	

Equality Data

Needs and issues: What do you currently know about the needs or issues affecting people from different protected	**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%

characteristic groups, relevant to your policy?	**Disability**	15.8% of people within the Vale of York CCG population are living with a limiting long term illness or disability.
	Gender / Sex	The gender split in the Vale of York CCG area is 48.7% male and 51.3% female (Joint Strategic Needs Assessment).
	Gender identity (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.
	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 or 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'.
	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).
	Pregnancy and maternity	North Yorkshire has a lower than national average rate of infant mortality and low birth rate.
	Marriage or 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.
	Socio-economically disadvantage	There are no figures available relating to socio-economically disadvantaged groups.
Do you have gaps in understanding about the needs of different groups, and how will you fill these?		The ethos of the Individual Funding Request panel ensures that decisions are made based on clinical grounds and that people are not disadvantaged because of a protected characteristic.
Communication and Engagement How are you going to engage with different groups and communities and show that their feedback informs your service review?		

Assessing Impact

Is this policy (or the implementation of this policy) likely to have a particular impact on any of the protected characteristic groups?
(Based on analysis of the data / insights gathered through engagement, or your knowledge of the substance of this policy)

Protected Characteristic:	No Impact:	Positive Impact:	Negative Impact:	Evidence of impact and, if applicable, justification where a *Genuine Determining Reason*[1] exists (see footnote below – seek further advice in this case)
Gender	✔			
Age	✔			
Race / ethnicity / nationality	✔			
Disability	✔			
Religion or Belief	✔			
Sexual Orientation	✔			
Pregnancy and Maternity	✔			
Transgender / Gender reassignment	✔			
Marriage or civil partnership	✔			

What measures have been put in place to mitigate any potential impact?

1. [1] *The action is proportionate to the legitimate aims of the organisation (please seek further advice)*

Action Planning:

As a result of performing this analysis, what actions are proposed to remove or reduce any risks of adverse impact or strengthen the promotion of equality?

Identified Risk:	Recommended Actions:	Responsible Lead:	Completion Date:	Review Date:
There are no identified risks				

Sign-off

All EIAs must be signed off by a member of SMT
I agree / disagree with this assessment / action plan
If *disagree*, state action/s required, reasons and details of who is to carry them out with timescales:
Signed off by (Name/Job Title)
Signed:
Date:

Appendix 7 – SIA

SUSTAINABILITY IMPACT ASSESSMENT

Staff preparing a policy, Governing Body (or Sub-Committee) report, service development plan 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	Policy Name: Individual Funding Request Policy and Standard Operating Procedure
What is the main purpose of the document	The purpose of this SIA is to record any positive or negative impacts that this is likely to have on sustainability.
Date completed	21/06/18
Completed by	Louise Horsfield

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?	n/a		
	Will it support more efficient use of cars (car sharing, low emission vehicles, environmentally friendly fuels and technologies)?	n/a		
	Will it reduce 'care miles' (telecare, care closer) to home?	n/a		
	Will it promote active travel (cycling, walking)?	n/a		
	Will it improve access to opportunities and facilities for all groups?	n/a		

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?
	Will it specify social, economic and environmental outcomes to be accounted for in procurement and delivery?	n/a		
Procurement	Will it stimulate innovation among providers of services related to the delivery of the organisations' social, economic and environmental objectives?	n/a		
	Will it promote ethical purchasing of goods or services?	n/a		
	Will it promote greater efficiency of resource use?	1	Where possible treatments will be collaboratively commissioned seeking to maximise clinical and cost effective services.	
	Will it obtain maximum value from pharmaceuticals and technologies (medicines management, prescribing, and supply chain)?	1	Where possible treatments will be collaboratively commissioned seeking to maximise clinical and cost effective services.	
	Will it support local or regional supply chains?	n/a		
	Will it promote access to local services (care closer to home)?	n/a		

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?
	Will it make current activities more efficient or alter service delivery models	0	No impact	
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?	n/a		
	Will it promote or support equal employment opportunities?	n/a		
	Will it promote healthy working lives (including health and safety at work, work-life/home-life balance and family friendly policies)?	n/a		
	Will it offer employment opportunities to disadvantaged groups?	n/a		
Community Engagement	Will it promote health and sustainable development?	n/a		
	Have you sought the views of our communities in relation to the impact on sustainable development for this activity?	n/a		

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?
Buildings	Will it improve the resource efficiency of new or refurbished buildings (water, energy, density, use of existing buildings, designing for a longer lifespan)?	n/a		
	Will it increase safety and security in new buildings and developments?	n/a		
	Will it reduce greenhouse gas emissions from transport (choice of mode of transport, reducing need to travel)?	n/a		
	Will it provide sympathetic and appropriate landscaping around new development?	n/a		
	Will it improve access to the built environment?	n/a		
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 minimise 'care miles' making better use of new technologies such as telecare and telehealth, delivering care in settings closer to people's homes?	n/a		

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?
	Will it promote prevention and self-management?	n/a		
	Will it provide evidence-based, personalised care that achieves the best possible outcomes with the resources available?	1	Commissioning policies are evidence based and where appropriate supported by clinical network structures and processes. They will also support the introduction of new technologies as appropriate.	
	Will it deliver integrated care, that co-ordinate different elements of care more effectively and remove duplication and redundancy from care pathways?	n/a		

Appendix 8 – Bribery Act 2010 Guidance

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.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
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.	
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.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
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.	
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.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
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.	
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.	

Areas for action	Expected Action	Evidence of Compliance/Assurance
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.	