### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

### **Specialist Adviser questionnaire**

Before completing this questionnaire, please read <u>Conflicts of Interest for Specialist</u> <u>Advisers</u>. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to:	tristan.mckenna@nice.org.uk

Procedure Name:	IP728/2 Infracoccygeal sacropexy using mesh for uterine prolapse repair
Name of Specialist Advisor:	Mr Moran
Specialist Society:	The British Society of Urogynaecology (BSUG)

#### 1 Do you have adequate knowledge of this procedure to provide advice?

- Yes.
- No please return the form/answer no more questions.

#### 1.1 Does the title used above describe the procedure adequately?

- Yes.
- $\boxtimes$  No. If no, please enter any other titles below.

#### Comments:

AS this is a mesh sling procedure rather mesh sheet, I would prefer ' IS using a mesh sling for vaginal vault prolapse'

#### 2 Your involvement in the procedure

- 2.1 Is this procedure relevant to your specialty?
- Yes.

- Is there any kind of inter-specialty controversy over the procedure?
- No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

#### Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

- 2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:
- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

#### Comments:

# WE did this procedure several years ago (>8 years) but have since stopped mainly due the infrequency of how often I would perform it and concerns relating to the type of mesh structure at the time.

### 2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

#### Comments:

I pick up the occasional patient who I feel may benefit and refer to a colleague in our local tertiary centre.

- 2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):
- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).

I have done clinical research on this procedure involving patients or healthy
volunteers.

- I have had no involvement in research on this procedure.
- Other (please comment)

#### Comments:

### 3 Status of the procedure

3.1	Which of the following	g best describes	the procedure	(choose one):
-----	------------------------	------------------	---------------	---------------

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

#### Comments:

## 3.2 What would be the comparator (standard practice) to this procedure? Either

1)vaginal procedure- sacrospinous fixation or posterior vaginal wall mesh sheet procedure with infracoccygeal fixation or sacrospinous fixation 2)Abdominal mesh sacrolpopexy

## 3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

#### Comments:

#### 4 Safety and efficacy

#### 4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

Risk of adverse event is realted to patient choice, training and experience of the surgeon. Overall rates of complications are between 5-10%

### 2. Anecdotal adverse events (known from experience)

Unable to comment – now a different procedure with different mesh

### 3. Theoretical adverse events

Mesh extrusion/erosion, Chronic pain, trauma to adjacent structures, painful sexual intercourse

### 4.2 What are the key efficacy outcomes for this procedure?

Patient satisfaction and comfort Secondary outcomes- objective prolapse assessment and complication; Long term prolapse recurrence risk

## 4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Long term issues of employing a vaginal mesh

#### 4.4 What training and facilities are needed to do this procedure safely?

Training in advanced pelvic surgery, supervised procedures and staged learning; Adequate case volume per year essential eg 10 or more cases per year or part of a trial.

### 4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

I am not aware

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list. Please note that NICE will do a literature search: we are only asking you

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please

do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

I am not aware of any recently.

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Not to my knowledge

#### 5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

I would suggest as a minimum completing the data pages on the BSUG database- this should collect all the relevant data you require in the short term. Long term follow up would be ideal – say up to 5 years but is highly impracticable.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

#### Refer BSUG database

5.2 Adverse outcomes (including potential early and late complications):

Utilise the IUGA/ICS mesh complications grading of complications and report to MHRA

#### 6 Trajectory of the procedure

## 6.1 In your opinion, how quickly do you think use of this procedure will spread?

Very slowly and may not increase above current levels.

## 6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

#### Comments:

## 6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

Moderate.

Minor.

Comments:

### 7 Other information

## 7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

I am not aware of any unless there is collected data from the national BSUG dataset already- you could request this data from BSUG

### 8 Data protection and conflicts of interest

### 8. Data protection, freedom of information and conflicts of interest

### 8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

✓ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

### 8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

<b>Consultancies or directorships</b> attracting regular or occasional payments in cash or kind		YES		
		NO		
Fee-paid work – any work commissioned by the healthcare industry – this includes income earned in the course of private practice				
			<b>Shareholdings</b> – any shareholding, or other beneficial interest, in shares	
of the healthcare industry	$\boxtimes$	NO		
<b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation,		YES		
meals and travel to attend meetings and conferences	$\square$	NO		
Investments – any funds that include investments in the healthcare				
industry		NO		
Do you have a <b>personal non-pecuniary</b> interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?		YES		
		NO		
Do you have a <b>non-personal</b> interest? The main examples are as follows:				
Fellowships endowed by the healthcare industry		YES		
	$\boxtimes$	NO		
Support by the healthcare industry or NICE that benefits his/her		YES		
position or department, eg grants, sponsorship of posts				
If you have answered YES to any of the above statements, please describe the				

### If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

#### Comments:

I have received travel bursuries, meeting sponsorship and lecturing income from Astellas within the past year.

Thank you very much for your help.

#### Dr Tom Clutton-Brock, Interventional

#### Professor Carole Longson, Director, Centre for Health Technology

<sup>&</sup>lt;sup>1</sup> 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Procedures Advisory Committee Chair Evaluation.

Jan 2016

### **Conflicts of Interest for Specialist Advisers**

#### 1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

- 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
- 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

#### 2 **Personal pecuniary interests**

- 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.
- 2.1.1 **Consultancies** any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
- 2.1.2 **Fee-paid work** any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
- 2.1.3 **Shareholdings** any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
- 2.1.4 **Expenses and hospitality** any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.
- 2.1.5 **Investments** any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 2.2 No personal interest exists in the case of:
- 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 2.2.2 accrued pension rights from earlier employment in the healthcare industry.

#### 3 **Personal family interest**

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

#### 4 **Personal non-pecuniary interests**

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

#### 5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific**,' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

- 5.1.1 **Fellowships** the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

#### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

#### **Specialist Adviser questionnaire**

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#### Please respond in the boxes provided.

Please complete and return to:

tristan.mckenna@nice.org.uk

#### Procedure Name:

IP268/2 Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair

Name of Specialist Advisor:

Mr Toozs-Hobson

Specialist Society:

The British Society of Urogynaecology (BSUG)

#### Do you have adequate knowledge of this procedure to provide advice? 1

- X Yes.
- No - please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

Yes.

X No. If no, please enter any other titles below.

TROCHAR

**Comments:** 

OR NON TROCHAR SYSTEM

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

X Yes. Is there any kind of inter-specialty controversy over the procedure?

No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

UROLOGY ARE BEGINNING TO Comments: MOVE INTO OR TOWNERS PROLARSE SURGOM

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

- 2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:
- l have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.
- Comments: THIS ADREA REMAINS A MINEFIELD THERE ARE 3 RECENT "EXPORT" REPORTS - NHSE, SCOTLANDD + SCENIHR, WE AWAIT THE

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.

I take part in patient selection or refer patients for this procedure regularly.

Comments:	VASC	MAJORITY	WITHIN	UROGYNAECOZOG	1
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- 2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):
- I have done bibliographic research on this procedure.
- I have done research on this procedure in laboratory settings (e.g. device-related research).
- I have done clinical research on this procedure involving patients or healthy volunteers.

X

ALSO HAVE BSUG DATABASE RESULTS

I have had no involvement in research on this procedure.

Other (please comment) SCE ABOVE X

BSUG DATABASC **Comments:** 

#### 3 Status of the procedure

- 3.1 Which of the following best describes the procedure (choose one):
- X Established practice and no longer new.
- -A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy,
- $\square$ Definitely novel and of uncertain safety and efficacy.
- П The first in a new class of procedure.

PROLIFT (J+J) + HUS PRODUCTS WITHDRHWN.

3.2 What would be the comparator (standard practice) to this procedure?

SALLOCOLPOPEXY (LAPAREOSCOPIC) OR SALPOSPINOUS FIXATION

- Please estimate the proportion of doctors in your specialty who are doing 3.3 this procedure (choose one):
- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- X Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments: NUMBERS LIVENTED DUE TO PRODUCTI BEING WITHORITON AND CONCERNS BASED ON REPORTS ABOVE + LIMITED OUTPUT DIATIG

#### Safety and efficacy 4

#### 4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

NHSET SCENIMR REPORTS SCE 3 PTD

VALINAR MESH REOCEDURES MANE 2520 RISCE OF EXTRUSION

ALL SURGEONS SMOULD REPORT THOM TO MARA BUT DONT - PATA FROM MARA?

2. Anecdotal adverse events (known from experience) SEC ABOVE. MHIRA MAY HAVE ADDITIONAL DATA

3. Theoretical adverse events

YES

VISCORAL INSLIEG MESH COMPLICATIONS -) CONTRACTURE (PAIN)

4.2 What are the key efficacy outcomes for this procedure?

GLOBHE IMPRESSIONS OF IMPROVEMENT OF PROTAPSE. CHANGE IN MCINIARY/BONE/SEXUA FUNCTION GOL.

- 4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?
- 4.4 What training and facilities are needed to do this procedure safely? CURRENTLY SUB SPECIALTY TRAINING
- 4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

NOT DIRECTLY ALTHOUGH SIMILAR IN VUE Study

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

WE ARE CURRENTLY REVIEWING BSNG DATABASE

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

YA

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

BSUG DATABASE CRITCRIA.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and guality-of-life measures):

5.2 Adverse outcomes (including potential early and late complications):

Trajectory of the procedure 6

In your opinion, how quickly do you think use of this procedure will 6.1 SLOWLY. THERE IS A CORTAIN AMOUNT spread? RELUCTANCE TO ENGLACE IN THIS CURRENTLY

TO THE WIDER MESH DOBNT C This procedure, if safe and efficacious, is likely to be carried out in 6.2

(choose one):

Most or all district general hospitals.

X A minority of hospitals, but at least 10 in the UK.

Fewer than 10 specialist centres in the UK.

 $\square$ Cannot predict at present.

SEE ABOVE Comments:

The potential impact of this procedure on the NHS, in terms of numbers 6.3 of patients eligible for treatment and use of resources, is:

Major.

Moderate.

X Minor.

Comments:

Other information 7

Is there any other information about this procedure that might assist 7.1 NICE in assessing the possible need to investigate its use?

IT WOULD BE HELPFUL FOR NICE TO "ADVISE" USING BSUG DATABATE AS STANDARD WHICH WILL ASSIST BSUG PROVIDING DATA TO NICE

#### 8 Data protection and conflicts of interest

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Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind		YES NO
Fee-paid work – any work commissioned by the healthcare industry –		YES
this includes income earned in the course of private practice		NO
Shareholdings – any shareholding, or other beneficial interest, in shares	X	YES
of the healthcare industry		NO

<sup>&</sup>lt;sup>1</sup> 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

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- 2.2.2 accrued pension rights from earlier employment in the healthcare industry.

Investments – any funds that include investments in the healthcare industry Do you have a <b>personal non-pecuniary</b> interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? Do you have a <b>non-personal</b> interest? The main examples are as follows: <b>Fellowships</b> endowed by the healthcare industry YE	<b>Expenses and hospitality</b> – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	$\times$	YES
industry       Image: Note that the industry of Nice that benefits his/her         Do you have a personal non-pecuniary interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?       Image: Nice that benefits his/her         Do you have a non-personal interest? The main examples are as follows:       Image: Nice that benefits his/her         Support by the healthcare industry or NICE that benefits his/her       Image: Nice that benefits his/her			NO
Do you have a personal non-pecuniary interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?       ✓	Investments – any funds that include investments in the healthcare		YES
<ul> <li>made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?</li> <li>Do you have a non-personal interest? The main examples are as follows:</li> <li>Fellowships endowed by the healthcare industry</li> <li>YE</li> <li>Support by the healthcare industry or NICE that benefits his/her</li> </ul>	industry		NO
topic?       Image: NC         Do you have a non-personal interest? The main examples are as follows:         Fellowships endowed by the healthcare industry       Image: YE         Image: NC         Support by the healthcare industry or NICE that benefits his/her       Image: YE	made a public statement about the topic or do you hold an office in a		YES
Fellowships endowed by the healthcare industry       Image: Second state industry       YE         Support by the healthcare industry or NICE that benefits his/her       Image: YE			NO
Support by the healthcare industry or NICE that benefits his/her	Do you have a <b>non-personal</b> interest? The main examples are as follows:		
Support by the healthcare industry or NICE that benefits his/her	Fellowships endowed by the healthcare industry		YES
		X	NO
NC NC			YES
	X	NO	

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

**Comments:** 

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair Centre for Health Technology

Professor Carole Longson, Director, Evaluation.

Jan 2016

I MANE RECIEVED PAYMENTS FOR LECTURES, CONSULTANCIOS ORTRAVEL IN THE LAST 2 YGARS PROM SEP, ASTOLIAS AND ALLERGAN A SHARE HOLDER IN P2PLED WHICH IS A MEDICHA DEVICE INNOVATION COMPANY I AM BUT NOT RELATED TO SURGERYS IWAVEA SECRETARY/TREASURER OF ULCY AND AM TREASURER OF BSNG. I UNDERTIKICE PRIVATE PRACTILE

#### 3 Personal family interest

- 3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.
- 3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- 3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.
- 3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- 3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- 3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
- 3.2 No personal family interest exists in the case of:
- 3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- 3.2.2 accrued pension rights from earlier employment in the healthcare industry.

#### 4 Personal non-pecuniary interests

These might include, but are not limited to:

- 4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- 4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

#### 5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as 'specific,' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as 'non-specific'. The main examples are as follows.

- 5.1.1 Fellowships the holding of a fellowship endowed by the healthcare industry.
- 5.1.2 **Support by the healthcare industry or NICE** any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:
- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.
- 5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.