

## ANNEX 1 – DOCUMENT TEMPLATES

University for the Common Good



22<sup>nd</sup> February 2021

By Email

**Invitation from the moderator to participate in the Transvaginal Mesh Case Record Review**

Following on from the Cabinet Secretary for Health and Sport's letter of 10<sup>th</sup> February 2021, this is a personal invitation to ask you whether you would like to take part in the Review. With this invitation, I have included a form which provides some further detail on what the Review will involve and how it will be progressed.

The Review aims to provide clarity on individual case records and the mesh removal procedure performed by providing an opportunity for you to set out your concerns, to have your records reviewed and to allow for discussion, explanation and mutual understanding.

If you choose to participate, a consent sheet is also included at the end of the form which I would be obliged if you would return to the review administrator, Irene Brown. Irene's email is [Irene.Brown@gcu.ac.uk](mailto:Irene.Brown@gcu.ac.uk). Your participation in the Review is entirely voluntary and if you do not want to take part then you need to do nothing further.

Further information about the Review can also be found on the website- <https://tmcr.scot> Please note that we are currently revising the '*structure and process*' section of the Terms of Reference and I will keep all participants advised on this progress personally and through the '*updates*' tab of the website. I am grateful to all of those who have shared their comments or been in touch with me.

If you would like to participate in the Review and once we have received your completed consent form, I will write to you again to invite you to an initial meeting with me to discuss the review process and to address any questions that you may

have. It is important that you feel supported and comfortable during these meetings you are therefore welcome to bring someone of your choice to accompany you.

Due to our current circumstances, this will need to take place virtually. Please let us know if you have any concerns about using technology for this stage of the process.

Finally, I wish to express my thanks to you in advance and promise that if you decide to participate in the Review, I will listen and, along with the members of the Review Panel, we will aim to provide clarity and answers.

Yours sincerely

A handwritten signature in cursive script that reads "Alison Britton". The signature is written in black ink and is positioned above the printed name and title.

**Alison Britton**

**Moderator Transvaginal Mesh Case Record Review**

Professor of Healthcare and Medical law, Glasgow Caledonian University

## Transvaginal Mesh Case Record Review

### Participant letter and consent form



#### **Why have I received this?**

You have received this letter because you attended a meeting with the First Minister in November 2019. You are now being invited to take part in the Transvaginal Mesh Case Record Review.

#### **Why has this review been set up?**

The Scottish Government has arranged this review following the meetings with the First Minister in November 2019. During the meetings, women raised concerns that entries in their case records may not accurately reflect the treatment they had received.

#### **What will the review look at?**

The Review Panel will look at your concerns about information in your case records and how the entries in your records have been reported to you, specifically about whether your mesh was fully or partially removed.

You will be given a participant form to fill in to provide your concerns in advance, and those concerns will provide the basis for your review.

The review will involve an open discussion, where your case records will be explained and considered.

#### **What won't the review look at?**

This is not intended as a review of your overall experience and full medical history. It will focus on your concerns about the full or partial removal of mesh and how this has been recorded in your case records.

If you are concerned about any other part of your care or treatment, you should contact your health board. The Review Panel administrator can give you details of how to do this. Taking part in this review does not affect your rights to raise a complaint with your health board or start any legal proceedings.

The Review Panel will not make any specific recommendations for further treatment. You should continue to see your GP and other healthcare professionals to make sure you receive appropriate care.

### **Do I have to take part?**

No. The review is voluntary and it is up to you to decide whether or not you think this would be helpful to you. If you want to take part in the review, fill in and return the consent form enclosed with this letter. If you do not want to take part, you do not need to take any action.

### **Who will be on the Review Panel?**

The Review Panel will be made up of the following people.

- **Moderator**  
Alison Britton, Professor of Healthcare and Medical Law, Glasgow School for Business and Society, Glasgow Caledonian University
  
- **Administrator**  
Irene Brown, Administrator, Directorate of School Professional Services, Glasgow Caledonian University
  
- **Clinicians**  
Professor Anthony Smith, Professor of Urogynaecology (Manchester Academic Health Sciences Centre), consultant gynaecologist (retired)  
  
Mr Ian Currie, Consultant Obstetrician & Gynaecologist, Buckinghamshire Hospitals NHS Trust  
  
Dr Carey Lunan, GP, Scotland

### **How have the Panel members been chosen?**

The Review Panel members have been chosen based on their individual qualities, expertise, knowledge, authority and standing.

### **What will the review involve?**

If you return your consent form to confirm that you want to be part of the review, you will be sent a participant form to fill in. That form will ask you to set out your main concerns and the evidence you would like reviewed.

It is important that you feel supported throughout this process. The Scottish Independent Advocacy Alliance can provide support, and we encourage you to use their service if you need help with any part of the review process. An advocate from the Scottish Independent Advocacy Alliance will be able to support you in expressing your concerns and filling in the participant form. If you would like to use this service, please let the administrator know.

### **What happens after I fill in and return the consent form?**

You will be invited to a 'virtual meeting' with the moderator to discuss the review process. Please tell the administrator if you have any concerns about using technology for this stage of the process.

The virtual meeting will be held online.

After the virtual meetings, the moderator will ask the relevant health boards to provide the evidence the Review Panel needs to look into your concerns. The healthcare professional responsible for your case records will be asked whether they would like to give their own opinion and address your concerns. All information that identifies you will be removed by the health boards.

The moderator will then invite you to join in another virtual meeting, to make sure that the Panel have the relevant case record entries from the health boards. Once you have confirmed this, the records will be passed to the Review Panel. Each clinician on the Review Panel will check the records separately and fill in a form to set out their understanding of the records.

The full Review Panel will then meet to discuss the records and reach a decision about how accurate your records are.

After the decision is reached, you and anyone supporting you will meet with the moderator, the administrator and one clinical member of the Review Panel so the decision can be explained to you and the records can be discussed. It is expected that this will also be a virtual meeting.

The findings of the review will also be clearly set out in a report that will be sent to you and the health board. You will have the opportunity to comment on this report after you have carefully considered it.

Finally, the moderator will write to you to ask you for feedback on the review process. Your feedback will help influence future reviews.

### **What information will not be shown in my case records?**

Any information which identifies you or others, such as names, addresses and dates of birth, will be removed from your records. So the Review Panel will not know whose case records they are looking at (until you meet with them) or who the healthcare professional responsible for the records is.

Your CHI number (which is your unique identification number for the NHS) will be left on your records to make sure that the moderator and administrator can link your records with your participant form.

### **Can I bring someone with me?**

Yes, you are encouraged to bring someone with you for support. An advocate from the Scottish Independent Advocacy Alliance can also support you. If you would like support from an advocate, please let the administrator know.

Making sure that you have the support you need is an important part of the review process.

### **Can I change my mind about taking part?**

Of course. The review is entirely voluntary and you can stop taking part in it at any time.

### **What will happen if the Review Panel thinks my case records are not accurate?**

If the Review Panel thinks that your case records do not accurately reflect the treatment you received, they will send their report on the review to your health board for them to consider. The entry relating to your case records will be flagged so that those involved in your future care can see that you have been involved in the review. In all cases, the report will be added to your medical records.

### **Who will have access to my case records?**

The five members of the Review Panel will have access to your records during the review.

Confidentiality is a priority, and your details will be kept private. There are arrangements in place to make sure that there is no unauthorised access to your information.

If you ask to see the personal information we hold about you, another authorised member of staff within Scottish Government may need access to your information.

More information about how your personal information can be used is given in our privacy notice. This is on our website at <http://tmcrr.scot> or you can ask us for a copy.

### **What happens if I'm not happy with the review?**

You will have an opportunity to raise any comments and questions about the review with the Review Panel. If you are not happy with the Panel's final response to your comments and questions, you can make a complaint to Scottish Public Services Ombudsman (SPSO).

If you have any other complaints about your case records, or about the care and treatment you have received, you should contact your health board. The administrator will give you the information you need to do this. If you are unhappy with your health board's response, you can ask the SPSO to consider your complaint.

**Can I speak to the media about the case record review?**

You are asked not to speak to the media about this review until the entire process has ended. This is to make sure that media coverage does not harm the review for other participants.



### Consent form

#### Your details

Full name:		
Address:		
Date of birth:		

By signing below and returning this form you are confirming that you want to take part in the Transvaginal Mesh Case Record Review.

Your signature:	
Date:	

#### Permission to release information to a third party

To carry out a comprehensive review, the Review Panel will need to see your medical records. The Panel members have a legal duty to keep your information confidential.

By signing below you are:

- giving NHS [BOARD NAME: ] permission to pass your medical records to the Review Panel so they can carry out the Transvaginal Mesh Case Record Review; and
- confirming that you do not object to the Review Panel seeing your confidential medical records.

Your signature:	
Date:	

## Transvaginal Mesh Case Record Review

### Participant form



Name:

CHI number:

Your health board:

By returning your consent form, you confirmed that you want to take part in the Transvaginal Mesh Case Record Review. This review is entirely voluntary. If you have changed your mind about taking part, you do not need to fill in and return this form.

This form is for you to set out your concerns and the evidence the Review Panel need for the review. It is important to remember that the review is not intended to look into your overall experience and full medical history. It will look into your concerns about the full or partial mesh removal and how this has been recorded in your case records.

If any concerns you have about your mesh removal are not covered by the questions in this form, please write these concerns in the section provided for this on page 3.

The information you provide in this form will be given to the Review Panel. The Review Panel will do their best to answer the concerns you raise and will explain the

entries in your case records. The Review Panel will focus on what has been reported in your case records about your mesh removal, and any further information which makes you think that your records are inaccurate.

It is important that you feel supported while taking part in the review. The Scottish Independent Advocacy Alliance can support you throughout the review process. If you would like their support when filling in this form, the administrator can put you in touch with them.

**Your concerns**

Where did you have mesh removal surgery and when?  
(Give all dates if you have had surgery more than once.)

What are your concerns about your mesh removal?

What information makes you think that your case records, or correspondence about your mesh removal, are incorrect?

What evidence do you think the Review Panel needs to see?  
(Please be as specific as possible. If you can provide dates – accurate or approximate – this will help the Review Panel get the correct information from your health board.)

**Further information**

If you have any other concerns about your mesh removal that have not been covered in the questions above, please give details below.

**Your signature**

Sign below to confirm that you understand that the information in this form will be used for the review and the relevant health boards will be asked to provide the relevant entries in your medical records.

Signature:.....

Date:.....

Thank you for taking the time to fill in this form.

When the review has ended, we would like your feedback on your experience of the review. The feedback will influence future reviews.

Are you are happy for us to contact you for feedback?

Yes           No

A report on the overall process will be published. In this report we would like to include references to the concerns raised by participants. **All the information in the report will be completely anonymous.**

Are you are happy for anonymous information about your concerns to be included in the final report?

Yes           No

Answering no to the questions above will not affect your participation in the review.

Please return this form to Irene Brown, at (EMAIL ADDRESS), by [DATE].

## ADVOCACY TEMPLATE

***‘Advocacy means getting support from another person to help you express your views and wishes, and help you stand up for your rights. Someone who helps you in this way is called your advocate.’***

<https://www.mind.org.uk/information-support/guides-to-support-and-services/advocacy/what-is-advocacy/>

***‘The role of an advocate is to offer independent support to those who feel they are not being heard and to ensure they are taken seriously and that their rights are respected. An advocate will ensure a person has the tools to make an informed decision; it is not about making the decision for the person.’***

<https://www.ageuk.org.uk/wp-assets/globalassets/leeds/original-blocks/get-involved/volunteer/the-role-of-an-advocate-1.pdf>

### Introduction

Advocacy is part of everyday life. It is an ordinary activity. Many of us will at some point in our lives look to the support of someone we trust to help us speak up for ourselves to get our voice heard about decisions or actions that affect our lives. Even the most confident and articulate among us can feel less able to cope when we are ill or feeling under pressure. In these circumstances it can be difficult to ask questions about our concerns. It is at these times that the support of an advocate can make all the difference to someone's quality of life.

Having an advocate can help someone feel more supported and confident in being able to share their story with us, based on their own wishes and views.

On behalf of the panel and all of those involved in the Case Record Review, we would like to express our thanks to you for supporting the participant that has asked you to be their advocate.

It can be helpful to discuss the main issues of concern with the participant beforehand so that that you both feel clear about what the priorities are for the participant. Any questions that the participant would like answered can also be listed, as this can be a useful *aide memoire* on the day.

### ***Conflicts of interest***

As we have said, advocacy plays an important role in supporting people to express their views and in providing a source of support which gives them the confidence to speak out. Advocacy is vital in nurturing trust and effectively supporting people to ensure their views are considered and that they are heard. It should also provide an environment in which they can confidently raise any concerns they may have with their advocate in the knowledge that there are no conflicts of interest. As part of the Case Record Review process, during the first interview, we will routinely ask the participant if they would also like the opportunity to speak to us in private (ie without the advocate present) as this is considered good practice.

One of the most important elements of performing an advocacy role is that you are as independent and impartial as possible from the situation. As a Panel we regularly review and declare any potential conflicts of interest as part of this process. We are keen to follow the same principles for those in the important role of advocate, and we would be grateful if you could consider the following questions and share any potential conflicts of interest at the start of the process. This helps us to ensure that we are all acting in a way that is open and transparent, and in the best interests of the participant.

1. Is your relationship to the participant professional or personal?
2. Are you gaining any financial benefit from undertaking this role as the participant's Advocate or receiving income that could reasonably raise an expectation of a conflict of interest with your duties of independence and impartiality as an advocate?
3. Have you personally received any form of medical treatment which forms the subject of this Review (i.e. transvaginal mesh surgery) that could reasonably raise an expectation of conflict of interest with your duties as an independence and impartiality as an Advocate?<sup>311</sup>

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<sup>311</sup> See: <https://www.mind.org.uk/information-support/guides-to-support-and-services/advocacy/what-is-advocacy/#:~:text=Advocacy%20means%20getting%20support%20from,way%20is%20called%20you%20advocate> [Accessed May 13 2021]



# Transvaginal Mesh Case Record Review

## Consenting to your case records being disclosed – some questions answered

### Why do my case records need to be disclosed?

Your case records contain personal, sensitive information. They can only be disclosed (shared with others) with your permission. If you decide to take part in the case record review, your records are an essential part of the review as they contain evidence of your medical treatment and your experience with transvaginal mesh.

### How will my case records be shared?

Your case records are held by the healthcare provider responsible for your treatment – whether that is your GP or the hospital. They will send your records to a professional case records consultancy, Clinco, for them to turn into a standard format for the review. You can find out more about Clinco from their website at [www.clinco.co.uk](http://www.clinco.co.uk).

### What measures are in place for the records to be kept safely?

Clinco is accredited to ISO27001, which is an international standard in data protection. Your records will be processed in line with an information-security system.

### Will the case records be made anonymous before being reviewed?

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See: <https://www.ageuk.org.uk/bp-assets/globalassets/leeds/original-blocks/get-involved/volunteer/the-role-of-an-advocate-1.pdf> [Accessed May 13 2021]

The Health Board will try to remove names and identifying information from the case records, but these appear many hundreds or thousands of times in a set of records and are often handwritten.

### Who will be able to read my case records?

Clinco and all three clinicians on the Review Panel will read the records for the purpose of preparing your individual report. The Moderator and Administrator may need to read all or part of the records to get a clearer understanding of the issues which will arise in the course of the review.

### Who will be able to read any reports or other documents arising from or referring to my case records?

The Review Panel will keep any comments, background information or feedback you provide confidential. Your specific concerns, in your own words, will be made available to Clinco.

The written report on your case will be made available to you. You will then discuss it with the Moderator, Administrator and one clinician on the Review Panel. Once the report has been finalised, to take account of your discussions, a copy will be placed with your case notes (if appropriate).

### What happens to my case records once the review is over?

Printed copies will be securely shredded and digital copies will be permanently deleted.

### I think I'd like to take part – what happens next?

Ask any further questions, to make yourself sure that you'd like to take part in the review. You can ask the administrator or moderator by email at [irene.brown@casrecordreview.scot](mailto:irene.brown@casrecordreview.scot). If and when you feel ready, you can also email [this mailbox](#). to confirm you want to take part. After this, you will be sent a form for you to provide information about your case. You will be asked to say where you received transvaginal mesh treatment, and the specific issues which arose in connection with that treatment.

Once you have returned the filled-in form to the Administrator, you will receive a letter asking you to agree to Clinco getting your case records.

**Can I change my mind and withdraw my consent?**

You can withdraw your consent at any time by emailing [irene.brown@caserecordreview.scot](mailto:irene.brown@caserecordreview.scot). Your case records will then be shredded.



# Transvaginal Mesh Case Record Review

## Consent for GP to disclose case records

To (address of GP surgery):

.....  
.....  
.....

Patient details	
Name	
Date of birth	
Address and postcode	

Dear Dr.....,

I agree to you sending copies of my full case records, including all consultation records, out-of-hours records, test results and other correspondence, to Clinco at:

**Clinco**  
**Innovation House**  
**Discovery Park**  
**Sandwich**  
**Kent**  
**CT13 9ND.**

If you prefer, you can email the records to [sharonphilpott@clinco.co.uk](mailto:sharonphilpott@clinco.co.uk).

I confirm that I am giving my permission for you to release my health records and that I know how they will be used.

Thank you for your help.

Signature: .....

Date: .....



# Transvaginal Mesh Case Record Review

## Consent for hospital to disclose case records

To (hospital address):

.....

.....

.....

Patient details	
Name	
Date of birth	
Address and postcode	
Hospital number	

I agree to you sending copies of my full case records, including all clinical, nursing and surgical records, test results, imaging, correspondence and internal investigation records, to Clinco at:

**Clinco**

**Innovation House**

**Discovery Park**

**Sandwich**

**Kent**

**CT13 9ND.**

If you prefer, you can email the records to [sharonphilpott@clinco.co.uk](mailto:sharonphilpott@clinco.co.uk).

I confirm that I am giving you permission to release my health records and that I know how these will be processed.

Thank you for your help.

Signature: .....

Date: .....







# Transvaginal Mesh Case Record Review

## Your information and specific concerns

Your personal details	
Name	
Date of birth	
Address and postcode	

Details of your GP	
GP's name	
GP practice address and postcode	

Details of the hospital where you underwent transvaginal mesh treatment	
Hospital name	
Hospital address and postcode	
Your hospital number	
Period of treatment	From: To:

Details of any other hospital where you received transvaginal mesh treatment or aftercare	
Hospital name	
Hospital address and postcode	
Your hospital number	

Period of treatment	From: To:
Brief details of treatment	

In the boxes below, briefly summarise any issues you had with the following.

**Before treatment**

The information provided by healthcare professionals	
The process of giving consent	
Any other issue	

<b>The treatment</b>	
The type of mesh implant used	
The choice of surgery	
The standard of surgical care	
Any other issue	
<b>After treatment</b>	
The standard of aftercare	
The information provided by healthcare professionals	
Any other issue	
<b>Mesh removal or other remedial treatment</b>	
The extent of the removal	
The standard of surgical care	
Any other issue	
<b>Any other comments about your treatment</b>	

In the boxes below, please summarise any concerns you have about the following.

**The completeness of your case records**

**The accuracy of your case records**

**Any other aspect of your case records**

# CLINICAL PROFORMA

Participant CHI:

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Panel Member:

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Date:

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What are the concern(s) raised by the participant – summary?

- The completeness of the case records
- The accuracy of the case records
- Any other aspect of the case records

What evidence does the participant want the Panel to review?

**Before treatment –**

- The information provided by Healthcare professionals
- The process of giving consent
- Any other issue

**The treatment –**

- The type of mesh implant used
- Options regarding treatment
- The standard of surgical care
- Any other issue

**After treatment –**

- The standard of aftercare
- The information provided by Healthcare professionals
- Any other issue

**Mesh removal or other remedial treatment –**

- The extent of the removal
- The standard of surgical care
- Any other issue

What are your findings based on the case records?

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Are the concern(s) raised supported by the evidence?

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**Declaration of Interests Form**

Transvaginal Mesh Case Record Review

Please ensure that this form is completed with all interests that may be relevant, regardless of timescales.

I, [FULL NAME], as a member of the Transvaginal Mesh Case Record Review Panel, hereby declare my private and business interests as at (date) \_\_\_\_\_ are as follows:

Potential Conflict of Interest	Yes/No	If Yes, Please Provide Details
<p>Sources of Income:</p> <p>Do you receive income from outside your employer and Scottish Government that could reasonably raise an expectation of a conflict of interest with your duties of independence and impartiality as part of the review Panel?</p>		
<p>Office Holder:</p> <p>Do you hold office in a public or private organisation that reasonably raises an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Trusteeships:</p> <p>Are you a Trustee or a Director of any trustee company in which a member of your family is a beneficiary that could reasonably raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Agreements:</p> <p>Are you, or a member of your immediate family, party to any contract, agreement or understanding that gives rise to an obligation or an expectation of reward that could reasonably raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		

Transvaginal Mesh Case Record Review

<p>Other Interests:</p> <p>Do you, or any member of your immediate family, hold any other substantial financial or other interest that could raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		
<p>Director's Duties:</p> <p>Have you ever been disqualified from acting as a Director, or acting in the management of a company?</p>		
<p>Medical Interests:</p> <p>Have you, or any member of your immediate family, been subject to any form of medical treatment which forms the subject of this review which could raise an expectation of a conflict of interest with your duties as part of the review Panel?</p>		

I, [FULL NAME], hereby declare that to the best of my knowledge and belief the information I have provided above is true and correct.

I undertake to advise fellow members of the review Panel in writing if a conflict or potential conflict of interest arises during the course of this review and, if it is considered appropriate by the Panel, to thereafter stand down in any decision making process in which I may be compromised.

I understand that this information will be published on the Case Record Review website.

Signature:

Date:

### Evaluation and Feedback for the Case Record Review

Please mark **X** in the box for the response that best applies for Q1-8. Q9-10 are for your own words. Please answer all questions if you can.

At your first meeting, how good was the Moderator at:	Poor	Fair	Good	Very Good	Excellent
Q1 <b>Making you feel at ease</b> (introducing herself, explaining her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)					
Q2 <b>Letting you tell your "story"</b> (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)					
Q.3 <b>Really listening</b> (paying close attention to what you were saying)					
Q.4 <b>Being interested in you as a whole person</b> (asking/knowing relevant details about your life, your situation; not treating you as "just a number")					
Q.5 <b>Fully understanding your concerns</b> (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)					
Q6 <b>Showing care and compassion</b> (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")					
Q.7. <b>Being positive</b> (having a positive approach and a positive attitude; being honest but not negative about your problems)					

Q8. <b>Explaining things clearly</b> (fully answering your questions; explaining clearly, giving you adequate information; not being vague)					
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Q.9 What have you found **most valuable** about this process?

Q.10 What do you think **could be improved** about this process?

**Thank you for taking the time to complete this evaluation.**