

## ICMJE DISCLOSURE FORM

Date: 21<sup>st</sup> June 2021

Your Name: Andrew Cook

Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

Manuscript number (if known): NIHR129832

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
<b>Time frame: Since the initial planning of the work</b>			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) <b>No time limit for this item.</b>	___ None	
<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ NIHR	Various research contracts from the PHR, HTA, and i4i programmes. All payments made to my employer.
3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___ None	
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	Baptist Health, Florida, USA	Reimbursement for travel and provision of accommodation in March 2019 to attend a workshop on approaches to Pancreatic Surgery held in Miami, Florida, USA.
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Amsterdam University Medical Centre (The Netherlands) & Fondazione Poliambulanza Istituto Ospedaliero (Italy)	Member of the DMC of the DIPLOMA-2 study.
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___ None	
11	Stock or stock options	___ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___ None	
13	Other financial or non-financial interests	___ None	

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

## ICMJE DISCLOSURE FORM

Date: 26 June 2021

Your Name: Catherine Hewitt

Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

Manuscript number (if known): NIHR129832

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<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	__ X __ None	
3	Royalties or licenses	_ X _ None	
4	Consulting fees	__ X __ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	

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## ICMJE DISCLOSURE FORM

Date: 23 June 2021

Your Name: Dyfrig Hughes

Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

Manuscript number (if known): NIHR129832

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<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	__ X __ None	
3	Royalties or licenses	_ X _ None	
4	Consulting fees	__ X __ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
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10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	

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X  I certify that I have answered every question and have not altered the wording of any of the questions on this form.

## ICMJE DISCLOSURE FORM

**Date:** 1<sup>st</sup> September 2021

**Your Name:** Katie Biggs

**Manuscript Title:** Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

**Manuscript number (if known):** NIHR129832

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<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___ None	
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	___ None	
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	___ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___ None	
11	Stock or stock options	___ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___ None	
13	Other financial or non-financial interests	___ None	

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**X** I certify that I have answered every question and have not altered the wording of any of the questions on this form.

## ICMJE DISCLOSURE FORM

**Date:** 4<sup>th</sup> August 2021

**Your Name:** Nikki Totton

**Manuscript Title:** Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

**Manuscript number (if known):** NIHR129832

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<b>Time frame: Since the initial planning of the work</b>			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) <b>No time limit for this item.</b>	Medical Research Council	Payment made to my institution for the running of this project including time allocation, consumables for the workshop and conference dissemination
<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	

4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input type="checkbox"/> None	
13	Other financial or non-financial interests	<input type="checkbox"/> None	

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## ICMJE DISCLOSURE FORM

Date: 21Jun2021

Your Name: Jonathan Cook

Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

Manuscript number (if known): NIHR129832

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<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	

4	Consulting fees	<input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
6	Payment for expert testimony	<input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input type="checkbox"/> None	
8	Patents planned, issued or pending	<input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input type="checkbox"/> None	
11	Stock or stock options	<input type="checkbox"/> None	
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**X\_ I certify that I have answered every question and have not altered the wording of any of the questions on this form.**

## ICMJE DISCLOSURE FORM

**Date:** 21/06/2021  
**Your Name:** Dr Elizabeth Coates  
**Manuscript Title:** Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document  
**Manuscript number (if known):** NIHR129832

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<b>Time frame: past 36 months</b>			
2	Grants or contracts from any entity (if not indicated in item #1 above).	___ None	
3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___ None	
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	___ None	
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	___ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___ None	
11	Stock or stock options	___ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___ None	
13	Other financial or non-financial interests	___ None	

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  X   I certify that I have answered every question and have not altered the wording of any of the questions on this form.

## ICMJE DISCLOSURE FORM

Date: 21<sup>st</sup> June 2021  
 Your Name: Simon Day  
 Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document  
 Manuscript number (if known): NIHR129832

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<b>Time frame: past 36 months</b>			
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3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___ None	
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	___ None	
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	___ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___ None	
11	Stock or stock options	___ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___ None	
13	Other financial or non-financial interests	___ None	

Please place an "X" next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.

## ICMJE DISCLOSURE FORM

Date: 27 Aug 2021

Your Name: Steven A. Julious

Manuscript Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document

Manuscript number (if known): NIHR129832

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<b>Time frame: past 36 months</b>			
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3	Royalties or licenses	___ None	
4	Consulting fees	___ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input type="checkbox"/> None	
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