Date:	21 st June 2021	
Your Name:_	Andrew Cook	
Manuscript 1	Fitle: Utilising Benefit-Risl	Assessments within NIHR Clinical Trials - Guidance Document
Manuscript i	number (if known): NIHR	129832

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.

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		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)
		Time frame: Since the initial	planning of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	None	
		Time frame: past	36 months
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,	None	
	speakers bureaus,		
	manuscript writing or educational events		
6	Payment for expert testimony	None	
-	6 16 11 1:	D CALL III EL CL	
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		NI	
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	None	

X I certify that I have answered every question and have not altered the wording of any of the questions on this 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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1	All support for the present	ı	planning of the work
1	All support for the present manuscript (e.g., funding,	X None	
	provision of study materials,		
	medical writing, article		
	processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	X None	
	in item #1 above).		
	D 11: 1:	N N	
3	Royalties or licenses	_X None	
4	Consulting fees	X None	

		1	
5	Payment or honoraria for lectures, presentations,	X None	
	speakers bureaus,		
	manuscript writing or educational events		
6	Payment for expert testimony	X None	
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment, materials, drugs, medical	X None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	X None	

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

Date:23 J	June 2021
Your Name:	Dyfrig Hughes
Manuscript Tit	le: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document
Manuscript nui	mber (if known): NIHR129832

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		Time frame: past	36 months
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	

		1	
5	Payment or honoraria for lectures, presentations,	X None	
	speakers bureaus,		
	manuscript writing or educational events		
6	Payment for expert testimony	X None	
7	Support for attending meetings and/or travel	X None	
8	Patents planned, issued or pending	X None	
9	Participation on a Data Safety Monitoring Board or	X None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	X None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	X None	
12	Receipt of equipment, materials, drugs, medical	X None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	X None	

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

Date: 1st 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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1	All support for the present manuscript (e.g., funding, provision of study materials,	None	
	medical writing, article processing charges, etc.)		
	No time limit for this item.		
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	None	
	in item #1 above).		
3	Royalties or licenses	None	
4	Consulting fees	None	

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

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

Date: 4th 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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		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)
		Time frame: Since the initial	planning of the work
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	Medical Research Council	Payment made to my institution for the running of this project including time allocation, consumables for the workshop and conference dissemination
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	None None	
3	Royalties or licenses	None	

4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	None	

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Date:	_21Jun2021	
Your Name	e:Jonathan Cook	
Manuscrip	ot Title: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document	
Manuscrin	nt number (if known): NIHR129832	

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		Time frame: past	36 months
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3	Royalties or licenses	None	

4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
	group, paid or unpaid		
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	writing, gifts or other		
	services		
13	Other financial or non- financial interests	None	

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

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5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
	services		
13	Other financial or non- financial interests	None	

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

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	processing charges, etc.)		
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		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	None	
	in item #1 above).		
3	Royalties or licenses	None	
4	Consulting fees	None	

5	Payment or honoraria for lectures, presentations,	None	
	speakers bureaus,		
	manuscript writing or educational events		
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	None	
	Advisory Board		
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
	group, paid or unpaid		
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical	None	
	writing, gifts or other		
15	services		
13	Other financial or non- financial interests	None	

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

Date:	27 Aug 2021
Your Name:_	Steven A. Julious
Manuscript T	itle: Utilising Benefit-Risk Assessments within NIHR Clinical Trials - Guidance Document
Manuscript n	umber (if known): NIHR129832

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	processing charges, etc.)		
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		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated	None	
	in item #1 above).		
3	Royalties or licenses	None	
4	Consulting fees	None	

5	Payment or honoraria for lectures, presentations, speakers bureaus,	None	
	manuscript writing or educational events		
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	None	
	Advisory Board		
4.0			
10	Leadership or fiduciary role in other board, society,	None	
	committee or advocacy		
11	group, paid or unpaid	None	
11	Stock or stock options	None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other	None	
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