

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

Identifying information.

2. The work under consideration for publication.

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

Relationships not covered above.

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Definitions.

Dykens

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

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Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

1

administrative support, etc.



Section 1.	Identifying Information						
1. Given Name (First Name) Elisabeth		2. Surname (Last Name Dykens	23-March-2018				
4. Are you the corresponding author?		☐ Yes ✓ No	Corresponding Author's Name Michael Reidy				
5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome							
6. Manuscript Identifying Number (if you know it) 98333							
Section 2.	The Work Under C	onsideration for Pu	blication				
any aspect of the s statistical analysis,	ubmitted work (including	g but not limited to grants	om a third party (government, commercial, private foundation, etc.) for i, data monitoring board, study design, manuscript preparation,				
Section 3. Relevant financial activities outside the submitted work.							
of compensation clicking the "Add) with entities as descr	ibed in the instructions port relationships that	whether you have financial relationships (regardless of amount . Use one line for each entity; add as many lines as you need by were present during the 36 months prior to publication .				
	out the appropriate info						
Name of Entity		Grant? Personal Fees?	Non-Financial Other? Comments				
National Institutes of	Health	✓					
Foundation for Prade	er-Willi Research	✓					
	ı						
Section 4.	Intellectual Prope	rty Patents & Copy	yrights				
Do you have any	patents, whether plan	ned, pending or issued	, broadly relevant to the work? Yes V No				

Dykens 2



Section 5. Polationships not severed above
Relationships not covered above
Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?
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✓ No other relationships/conditions/circumstances that present a potential conflict of interest
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Section 6. Disclosure Statement
Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.
Dr. Dykens reports grants from National Institutes of Health, grants from Foundation for Prader-Willi Research, outside the submitted work; .

Evaluation and Feedback

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Dykens 3



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Miller 1



Section 1.	Identifying Inforn	nation				
Given Name (First Name) Jennifer		2. Surname (Last N Miller	3. Date 23-March-2018			
4. Are you the corresponding author?		Yes ✓ No	Corresponding Author's Name Michael Reidy			
5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome						
6. Manuscript Identifying Number (if you know it) 98333						
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any aspect of the s statistical analysis,	ubmitted work (including	g but not limited to gr	es from a third party (government, commercial, private foundation, etc.) for rants, data monitoring board, study design, manuscript preparation, No			
Section 3.	Relevant financial	activities outsid	e the submitted work.			
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication .						
	evant conflicts of inter		No			
If yes, please fill o	out the appropriate info	ormation below.				
Name of Entity		Grant? Persona	Non-Financial Other? Comments			
Ferring Pharmaceuticals		✓	research funding			
Zafgen		✓	research funding			
Rhythm Pharmaceuti	cals	✓	research funding			
Section 4.	Intellectual Prope	rty Patents & C	opyrights			
Daniel			., .			
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo						

Miller 2



Section 5.					
Section 5.	Relationships not covered above				
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Section 6.	Disclosure Statement				
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Dr. Miller reports the submitted w	grants from Ferring Pharmaceuticals, grants from Zafgen, grants from Rhythm Pharmaceuticals, outside ork; .				

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Angulo 1



Section 1. Identifying Inform	nation		
Given Name (First Name) Moris	2. Surname (Last Name) Angulo	3. Date 23-March-2018	
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Michael Reidy	
5. Manuscript Title Intranasal carbetocin reduces hyperph	agia in individuals with Pra	der-Willi syndrome	
6. Manuscript Identifying Number (if you k 98333	now it)		
Section 2. The Work Under C	Consideration for Public	cation	
	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,	
Section 3. Relevant financial	activities outside the s	submitted work.	
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Section 4. Intellectual Prope	utu. Datauta (Carrie	ula 6 a	
Intellectual Prope	rty Patents & Copyric	gnts	
Do you have any patents, whether plan	nned, pending or issued, br	oadly relevant to the work? Yes V No	

Angulo 2



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Dr. Angulo has nothing to disclose.					

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Roof 1



Section 1.	Identifying Inform	nation		
1. Given Name (First Name) Elizabeth		2. Surname (Last Name) Roof	3. Date 23-March-2018	
4. Are you the corresponding author?		Yes ✓ No	Corresponding Author's Name Michael Reidy	
5. Manuscript Title Intranasal carbet		agia in individuals with Pra	der-Willi syndrome	
6. Manuscript Ider 98333	ntifying Number (if you kr	now it)		
Section 2.	The Work Under Co	onsideration for Public	ation	
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Do you have any			oadly relevant to the work? Yes V No	

Roof 2



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Roof 3



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Reidy 1



Section 1. Identifying Inform	nation					
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4. Are you the corresponding author? ✓ Yes						
5. Manuscript Title Intranasal carbetocin reduces hyperpha	agia in individuals with Prade	er-Willi syndrome				
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Did you or your institution at any time rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of interes	g but not limited to grants, data	hird party (governmer				
If yes, please fill out the appropriate infe Excess rows can be removed by pressin		more than one entity	y press the "ADD" button to add a row.			
Name of Institution/Company	Grant	inancial Other?	Comments			
Ferring Pharmaceuticals, Inc.			salaried employee of study sponsor			
Section 3. Relevant financial	activities outside the sul	omitted work.				
Place a check in the appropriate boxes of compensation) with entities as descr clicking the "Add +" box. You should re Are there any relevant conflicts of interest.	ibed in the instructions. Use opert relationships that were p	one line for each ent	rity; add as many lines as you need by			
Section 4. Intellectual Proper	rty Patents & Copyrigh	ts				
Do you have any patents, whether plan If yes, please fill out the appropriate info Excess rows can be removed by pressin	ormation below. If you have i	•				

Reidy 2



Patent?	Pending?	Issued?	Licensed ?	Royalties?	Licensee?	Comments	
Method of treating prader-willi syndrome	✓						
Section 5. Relationshi	ps not cov	ered ab	ove				
Are there other relationships or potentially influencing, what yo				eive to have	influenced, or tha	at give the appearance of	
Yes, the following relationsh No other relationships/cond						st	
At the time of manuscript accep On occasion, journals may ask a	otance, journ	als will as	sk authors to	o confirm an	d, if necessary, up	date their disclosure stater	nents.
Section 6. Disclosure S	Statement						
Based on the above disclosures, below.	, this form wi	ill automa	atically gene	erate a disclo	sure statement, v	which will appear in the box	(
Dr. Reidy reports other from Fer patent Method of treating prad	-			g the condu	ct of the study; In	addition, Dr. Reidy has a	

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Royalties: Funds are coming in to you or your institution due to your patent

Hatoum 1



Section 1.	Identifying Inform	nation				
1. Given Name (First Name) Hind		2. Surname (Last Name Hatoum	e)	3. Date 23-March-2018		
4. Are you the corresponding author?		☐ Yes ✓ No		Corresponding Author's Name Michael Reidy		
5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome						
6. Manuscript Identifying Number (if you know it) 98333						
Section 2.	The Work Under Co	onsideration for Pu	blication			
any aspect of the s statistical analysis, Are there any rel If yes, please fill o	ubmitted work (including etc.)? evant conflicts of intere	s but not limited to grants est? Yes Normation below. If you	s, data monitoring bo	vernment, commercial, privat pard, study design, manuscrip ne entity press the "ADD" b	t preparation,	
Name of Institut			Non-Financial Support?	ther? Comments		
Ferring Pharmaceuticals				consulting arrangeme sponsor	ent with study	
Section 3.	Relevant financial	activities outside th	ne submitted wo	ork.		
of compensation clicking the "Adc Are there any rel	n) with entities as descri	ibed in the instructions port relationships that	s. Use one line for e were present duri	financial relationships (reg each entity; add as many lin ng the 36 months prior to	nes as you need by	
Section 4.	Intellectual Proper	ty Patents & Copy	yrights			
Do you have any	patents, whether plan	ned, pending or issued	l, broadly relevant	to the work? Yes	/ No	

Hatoum 2



Section 5. Polationships not severed above
Relationships not covered above
Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?
Yes, the following relationships/conditions/circumstances are present (explain below):
✓ No other relationships/conditions/circumstances that present a potential conflict of interest
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Section 6. Disclosure Statement
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Dr. Hatoum reports personal fees from Ferring Pharmaceuticals, during the conduct of the study; .

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Hatoum 3



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Willey 1



Section 1.	Identifying Inform	nation						
1. Given Name (Fi Richard	rst Name)	2. Surname (Last Name Willey	e)		Pate March-2018			
4. Are you the cor	responding author?	Yes ✓ No	•	Corresponding Author's Name Michael Reidy				
•	5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome							
6. Manuscript Ider 98333	ntifying Number (if you kn	now it)						
Section 2.	The Work Under Co	onsideration for Pu	blication					
Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)? Are there any relevant conflicts of interest? Yes No If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.								
Name of Institut	ion/Company	Grant? Personal Fees?	Non-Financial Support	Other Comme	nts			
erring Pharmaceution	als, Inc.			√ salaried en	nployee of study sponsor			
	l							
Section 3.	Relevant financial	activities outside th	ne submitted v	work.				
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication . Are there any relevant conflicts of interest? Yes Vo								
Section 4.	Intellectual Proper	ty Patents & Cop	yrights					
Do you have any	patents, whether plan	ned, pending or issuec	l, broadly relevar	nt to the work?	Yes 🗸 No			

Willey 2



Section 5. Relationships not sovered above
Relationships not covered above
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Dr. Willey reports other from Ferring Pharmaceuticals, Inc., during the conduct of the study; .

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Willey 3



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Bolton 1



Section 1.	Identifying Inform	nation						
1. Given Name (Fii Guy	rst Name)	2. Surname (Last Name) Bolton			3. Date 23-March-2018			
4. Are you the cor	responding author?	Yes ✓ No	•	Corresponding Author's Name Michael Reidy				
•	5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome							
6. Manuscript Ider 98333	ntifying Number (if you kn	now it)						
Section 2.	The Work Under Co	onsideration for Pu	blication					
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Name of Institut	ion/Company	Grant? Personal Fees?	Non-Financial Support?	Other Com	ments			
erring Pharmaceution	cals, Inc.			salaried	l employee of study sponsor			
	l							
Section 3.	Relevant financial	activities outside tl	ne submitted	work.				
Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to publication . Are there any relevant conflicts of interest? Yes Vo								
Section 4.	Intellectual Proper	rty Patents & Cop	yrights					
Do you have any	patents, whether plan	ned, pending or issuec	l, broadly releva	nt to the work?	Yes ✓ No			

Bolton 2



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Relationships not covered above						
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Dr. Bolton reports other from Ferring Pharmaceuticals, Inc., during the conduct of the study; .						

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Bolton 3



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Korner 1



Section 1. Identifying Inform	ation						
1. Given Name (First Name) Paul	2. Surname (Last Name) Korner	3. Date 23-March-2018					
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Michael Reidy					
5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome							
6. Manuscript Identifying Number (if you kn 98333	now it)						
Section 2. The Work Under Co	onsideration for Publi	cation					
	but not limited to grants, da	n a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,					
	ormation below. If you hav	ve more than one entity press the "ADD" button to add a row.					
Name of Institution/Company	Grant'	n-Financial Other? Comments					
Ferring Pharmaceuticals, Inc.		salaried employee of study sponsor					
Section 3. Polovant financial							
Relevant financial	activities outside the s	submitted work.					
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Section 4. Intellectual Proper	ity Datanta & Canyui	nhte					
intellectual Proper	ty Patents & Copyri	gnts					
Do you have any patents, whether plant If yes, please fill out the appropriate info Excess rows can be removed by pressing	ormation below. If you hav	roadly relevant to the work? Yes No No ve more than one entity press the "ADD" button to add a row.					

Korner 2



Patent?	Pending?	Issued?	Licensed ?	Royalties?	Licensee?	Comments		
Method of treating prader-willi syndrome	✓							
Section 5. Relationshi	ps not cov	ered abo	ove					
Are there other relationships or potentially influencing, what yo				eive to have	influenced, or tha	at give the appearance of		
_				e present (ex	plain below):			
	Yes, the following relationships/conditions/circumstances are present (explain below): No other relationships/conditions/circumstances that present a potential conflict of interest							
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Section 6. Disclosure S	tatement							
Based on the above disclosures, below.	this form wi	ill automa	atically gene	erate a disclo	sure statement, v	vhich will appear in the box	,	
Dr. Korner reports other from Fe patent Method of treating prad	-			ng the cond	uct of the study;	In addition, Dr. Korner has a	1	

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Korner 3



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Word limit for
			title precludes
			this
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3–4
ntroduction			
Background and	2a	Scientific background and explanation of rationale	5–9
objectives	2b	Specific objectives or hypotheses	9
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	17
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	_
Participants	4a	Eligibility criteria for participants	17
	4b	Settings and locations where the data were collected	17
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	
		actually administered	18–19
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
		were assessed	19–21
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	_21
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	17–18
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	17–18
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment		describing any steps taken to conceal the sequence until interventions were assigned	
mechanism			17–18
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	17–18

CONSORT 2010 checklist

Section/Topic	Item No	Checklist item	Reported on page No
•		interventions	1 5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	
		assessing outcomes) and how	17–18
	11b	If relevant, description of the similarity of interventions	_
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	21–22
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
diagram is strongly		were analysed for the primary outcome	10, 32 (Table 1)
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	10, 30 (Fig 1)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	17
	14b	Why the trial ended or was stopped	<u> </u>
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	32 (Table 1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10, 32 (Table 1)
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	10–12, 31 (Fig
estimation		precision (such as 95% confidence interval)	2), 33 (Table 2),
			35 (Table S1),
			36–39 (Figs
	17h	For himsey, sustaining a presentation of both absolute and relative offset since is recommended	S1-4)
Anaillant analyses	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	11–12, 34
			(Table 3)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14–15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13–14
Other information			

CONSORT 2010 checklist Page 2

Section/Topic	Item No	Checklist item	Reported on page No
Registration	23	Registration number and name of trial registry	4, 17
Protocol	24	Where the full trial protocol can be accessed, if available	4, 17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2, 4, 24

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 3