

#### **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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#### 3. Relevant financial activities outside the submitted work.

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## 4. Intellectual Property.

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

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Other: Anything not covered under the previous three boxes

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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

Freedberg 1



Section 1. Identifying Inform	ation				
Given Name (First Name)  Kenneth	2. Surna Freedbe	me (Last Name erg	<u>=</u> )		3. Date 15-February-2019
4. Are you the corresponding author?	Yes	<b>√</b> No	Correspon Caitlin M.	•	or's Name
<ul><li>5. Manuscript Title</li><li>Risks and Benefits of Dolutegravir- and E</li><li>Potential: A Modeling Study</li><li>6. Manuscript Identifying Number (if you known)</li></ul>		based Strate	gies for South <i>F</i>	African Wo	omen with HIV of Childbearing
M18-3358					
Section 2. The Work Under Co	nsidera	tion for Pu	blication		
Did you or your institution <b>at any time</b> receivany aspect of the submitted work (including statistical analysis, etc.)?	ve paymer	nt or services f	rom a third party		
Are there any relevant conflicts of intere	ــــــــــــــــــــــــــــــــــــــ	Yes N			
If yes, please fill out the appropriate info Excess rows can be removed by pressing			have more thar	n one enti	ity press the "ADD" button to add a row.
Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
NIH	<b>√</b>				None of these represent a COI
EGPAF	<b>✓</b>				
WHO/UNITAID	<b>✓</b>				
Section 3. Relevant financial a	activitie	s outside th	ne submitted	work.	
Place a check in the appropriate boxes in of compensation) with entities as described clicking the "Add +" box. You should rep	oed in the	instructions	. Use one line f	or each ei	ntity; add as many lines as you need by
Are there any relevant conflicts of intere		Yes N	-	-	
If yes, please fill out the appropriate info	rmation b	pelow.			
	2	Personal	Non-Financial		
Name of Entity	Grant •	Fees?	Support?	Other •	Comments
NIH	<b>√</b>				

Freedberg 2



Soutien A
Section 4. Intellectual Property Patents & Copyrights
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes V
Section 5. 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
At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.
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. Freedberg reports grants from NIH, grants from EGPAF, grants from WHO/UNITAID, during the conduct of the study; grants from NIH, outside the submitted work;.

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Freedberg 3



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Ciaranello 1



Section 1. Identifying Infor	mation								
1. Given Name (First Name) Andrea	2. Surname (Last Name) Ciaranello	3. Date 17-January-2019							
4. Are you the corresponding author?	Yes 🗸 No	Corresponding Author's Name							
5. Manuscript Title Dolutegravir for South African women with HIV of childbearing potential: Modeling the risks and benefits									
6. Manuscript Identifying Number (if you M18-3358	know it)	_							
Section 2. The Work Under	Consideration for Public	cation							
Did you or your institution <b>at any time</b> 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									
Section 3. Relevant financia	l activities outside the s	ubmitted 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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest? Yes Vo									
Section 4. Intellectual Prope	erty Patents & Copyrig	hts							
Do you have any patents, whether pla	nned, pending or issued, br	oadly relevant to the work? Yes V No							

Ciaranello 2



Section 5.	
Section 5.	Relationships not covered above
	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
Yes, the follo	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Ciaranello ha	as nothing to disclose.

### **Evaluation and Feedback**

Please visit <a href="http://www.icmje.org/cgi-bin/feedback">http://www.icmje.org/cgi-bin/feedback</a> to provide feedback on your experience with completing this form.

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Sax 1



Section 1.	Identifying Inform	ation								
1. Given Name (Fi Paul	rst Name)	2. Surnan Sax	ne (Last Nan	ne)		3. Date 17-January-2019				
4. Are you the cor	responding author?	Yes	✓ No	Correspond Caitlin Du	_	or's Name				
5. Manuscript Title Dolutegravir in pregnancy										
6. Manuscript Identifying Number (if you know it)										
Section 2.	The Work Under Co	nsiderat	ion for P	ublication						
Did you or your institution <b>at any time</b> 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										
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Name of Entity		Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments				
BMS				<b>✓</b>		Research project on atazanavir and heart disease.				
Gilead		<b>✓</b>	<b>✓</b>			Research grants to institution; fees for Scientific Advisory Board.				
lanssen			$\checkmark$			Scientific Advisory Board				
Merck			<b>✓</b>			Unfunded research projects; scientific Advisory Board.				
/iiV/GSK		<b>✓</b>	<b>✓</b>			Research grants to institution; fees for Scientific Advisory Board.				

Sax 2



Section 4. Intellectual Property Patents & Copyrights
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo
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Dr. Sax reports non-financial support from BMS, grants and personal fees from Gilead, personal fees from Janssen, personal fees from Merck, grants and personal fees from ViiV/GSK, outside the submitted work; .

#### **Evaluation and Feedback**

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Sax 3



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

Bekker 1



Section 1. Identifying Inform	ation	
Given Name (First Name) Linda-Gail	2. Surname (Last Name) Bekker	3. Date 21-January-2019
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Caitlin Dugdale
5. Manuscript Title Dolutegravir for South African women v	with HIV of childbearing p	otential: Modeling the risks and benefits.
6. Manuscript Identifying Number (if you kn M18-3358	now it)	
Section 2. The Work Under Co	onsideration for Public	cation
	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.
of compensation) with entities as descri clicking the "Add +" box. You should rep	bed in the instructions. Use port relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
Are there any relevant conflicts of intere		
If yes, please fill out the appropriate info	ormation below.	
Name of Entity	Grant? Personal Non	n-Financial other? Comments
Merck PTY LTD		
Gilead		Free drug for demonstration studies
Section 4. Intellectual Proper	ty Patents & Copyri	ghts
Do you have any patents, whether plan	ned, pending or issued, br	oadly relevant to the work? ☐ Yes ✓ No

Bekker 2



Section 5.	
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Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Bekker repor	ts personal fees from Merck PTY LTD, other from Gilead, outside the submitted work; .

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Wood 1



Section 1. Identifying Inform	nation							
1. Given Name (First Name) Robin	2. Surname (Last Name) Wood		3. Date 29-January-2019					
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Nar	me					
5. Manuscript Title Dolutegravir for South African women with HIV of childbearing potential: Modeling the risks and benefits.								
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Wood 2



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Dr. Wood has no	thing to disclose.

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Wood 3



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

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Section 1. Identifying Information	ation						
Given Name (First Name)  Rochelle	2. Surnar Walensk	ne (Last Nan Y	ne)		3. Date 17-January-2019		
4. Are you the corresponding author?	Yes ✓ No Corresponding Author's Name Caitlin Dugdale						
5. Manuscript Title Dolutegravir for South African women with HIV of childbearing potential: Modeling the risks and benefits							
6. Manuscript Identifying Number (if you known M18-3358	ow it)						
Section 2. The Work Under Co	nsidera	tion for P	ublication				
Did you or your institution <b>at any time</b> received any aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interest of the submitted work (including statistical analysis, etc.)?	but not limst? \( \sqrt{\sqrt{\gamma}} \) rmation b	nited to gran Yes	ts, data monitoring	board, st	udy design, manuscript preparation,		
Excess rows can be removed by pressing	the "X" b	utton.					
Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments		
National Institutes of Health	<b>✓</b>				1R37Al093269 Novel Methods to Inform HIV/TB Clinical Trial Development		
Steve and Deborah Gorlin MGH Research Scholar	<b>√</b>				Novel Approaches to Clinical Trial Design and Development		
Section 3. Relevant financial a	octivities	outside 1	the submitted	work.			
Place a check in the appropriate boxes ir of compensation) with entities as described clicking the "Add +" box. You should rep	oed in the	instruction	ns. Use one line fo	or each er	ntity; add as many lines as you need by		
•	Are there any relevant conflicts of interest?  Ves  No						
If yes, please fill out the appropriate info	If yes, please fill out the appropriate information below.						



Name of Entity	Grant?	Personal Fees	Non-Financial Support?	Other?	Comments		
National Institutes of Health	<b>✓</b>				1R37Al093269 Novel Methods to Inform HIV/TB Clinical Trial Development		
Steve and Deborah Gorlin MGH Research Scholar					Novel Approaches to Clinical Trial Design and Development		
Section 4. Intellectual Propert	y Pate	ents & Co <sub>l</sub>	pyrights				
Do you have any patents, whether plann	ed, pend	ing or issue	ed, broadly releva	nt to the	work? Yes V		
Section 5. Relationships not c	overed	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/cond	itions/cir	cumstance	es are present (exp	olain belo	pw):		
✓ No other relationships/conditions/circumstances that present a potential conflict of interest							
At the time of manuscript acceptance, jo On occasion, journals may ask authors to					•		
Section 6. Disclosure Statemen							
Disclosure Statemen	nt						
Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.							
Dr. Walensky reports grants from National Institutes of Health, grants from Steve and Deborah Gorlin MGH Research Scholar, during the conduct of the study; grants from National Institutes of Health, from Steve and Deborah Gorlin MGH Research Scholar, outside the submitted work; .							



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

abrams 1



Section 1. Identifying	Information					
Given Name (First Name) elaine	2. Surname (Last Name) abrams	3. Date 17-January-2019				
4. Are you the corresponding author	or? Yes 🗸 No	Corresponding Author's Name dugdale				
5. Manuscript Title Dolutegravir for South African w	omen with HIV of childbearing po	otential: Modeling the risks and benefits				
6. Manuscript Identifying Number ( M18-3358	if you know it)					
Section 2. The Work Ur	nder Consideration for Public	ation				
Did you or your institution <b>at any time</b> 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						
Section 3. Relevant fin	ancial activities outside the s	ubmitted 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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest?  Yes  No  If yes, please fill out the appropriate information below.						
Name of Entity	Grant? Personal Nor	o-Financial other? Comments				
/iiv pharmaceuticals		participated in pediatric ART advisory group				
Section 4. Intellectual	Property Patents & Copyric	phts				
Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes Vo						

abrams 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
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Dr. abrams reports personal fees from Viiv pharmaceuticals, outside the submitted work; .

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Myer 1



Section 1. Ide	ntifying Information					
1. Given Name (First Nan Landon	ne) 2. Surna Myer	nme (Last Name)		3. Date 18-July-2019		
4. Are you the correspon	ding author? Yes	Yes V No Corresponding Author's Name		ne		
5. Manuscript Title Dolutegravir for South	African women with HIV	of childbearing po	otential: Modeling the risks a	and benefits		
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Section 4.						
Inte	llectual Property Pat	ents & Copyrig	hts			
Do you have any pater	nts, whether planned, pend	ding or issued, bro	oadly relevant to the work?	☐ Yes ✓ No		

Myer 2



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Dr. Myer has nothing to disclose.					

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Stern 1



Section 1.	Identifying Inform	nation				
1. Given Name (Fi Madeline	rst Name)	2. Surname (Last Name) Stern		3. Date 18-January-2019		
4. Are you the cor	responding author?	Yes No Corresponding Author's Nat		ne		
5. Manuscript Title Dolutegravir for		with HIV of childbearing po	otential: Modeling the risks a	and benefits		
6. Manuscript Ider	ntifying Number (if you kr	now it)				
			_			
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Section 4.	Intellectual Proper	rty Patents & Copyri <u>c</u>	ghts			
Do you have any		.,	oadly relevant to the work?	☐ Yes ✓ No		

Stern 2



Section 5. Relationships not covered above				
helationships not covered above				
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Dugdale 1



Section 1. Identifying Inform	ation				
1. Given Name (First Name) Caitlin	2. Surname (Last Na Dugdale	ame)		3. Date 18-January-2019	
4. Are you the corresponding author?	✓ Yes No				
5. Manuscript Title Risks and Benefits of Dolutegravir- and E Potential: A Modeling Study		ategies for South <i>F</i>	\frican wo	men with HIV of Childbearing	
6. Manuscript Identifying Number (if you known M18-3358	ow it)				
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Did you or your institution <b>at any time</b> received any aspect of the submitted work (including statistical analysis, etc.)?  Are there any relevant conflicts of interest of the submitted work (including statistical analysis, etc.)?	but not limited to grass st? Yes  rmation below. If ye	ants, data monitorin	g board, sti	udy design, manuscript preparation,	
Name of Institution/Company	Grant? Persona	Non-Financial Support?	Other?	Comments	
National Institute of Allergy and Infectious Disease	<b>✓</b>			T32 Al007433	
Harvard University Center for AIDS Research	<b>✓</b>			Developmental grant under P30 Al060354	
Section 3. Polovant financial s					
Nelevalit Illialiciai a					
Place a check in the appropriate boxes ir of compensation) with entities as described clicking the "Add +" box. You should rep	oed in the instruction	ons. Use one line f	or each er	itity; add as many lines as you need	
Are there any relevant conflicts of interes		No			
If yes, please fill out the appropriate info	rmation below.				
Name of Entity	Grant? Persona	Non-Financial Support?	Other?	Comments	
National Institute of Mental Health	<b>✓</b>			R01 MH113478-01	
NIH/IMPAACT Network				DR808	

Dugdale 2



Name of Entity	Grant? Persona Fees?	Non-Financial Support?	Other? Comments		
National Institute of Mental Health	<b>✓</b>		R01 MH115793	3-01	
Section 4					
Section 4. Intellectual Propert	y Patents & Co	pyrights			
Do you have any patents, whether plann	ed, pending or issu	ed, broadly releva	nt to the work? Ye	es 🗸 No	
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Are there other relationships or activities potentially influencing, what you wrote i			nfluenced, or that give	the appearance of	
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Dr. Dugdale reports grants from Nationa for AIDS Research, during the conduct o IMPAACT Network, grants from National	f the study; grants	from National Inst	tute of Mental Health,	•	

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