

ICMJE Form for Disclosure of Potential Conflicts of Interest

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.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

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4. Intellectual Property.

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

5. Relationships not covered above.

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Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Mark

2. Surname (Last Name)
Geyer

3. Date
16-March-2019

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Renier J. Brentjens

5. Manuscript Title
Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

6. Manuscript Identifying Number (if you know it)
122627-INS-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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 Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution for the clinical trial described within the manuscript.
Lymphoma Research Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
American Society of Hematology	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
NIH/National Center for Advancing Translational Sciences	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Dava Oncology	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Honorarium for giving educational talk for which I controlled all content.

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

Section 5. Relationships not covered above

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Dr. Geyer reports other from Juno Therapeutics, grants from Lymphoma Research Foundation, grants from American Society of Hematology, grants from NIH/National Center for Advancing Translational Sciences, during the conduct of the study; personal fees from Dava Oncology, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Isabelle

2. Surname (Last Name) Rivière

3. Date 16-March-2019

4. Are you the corresponding author? Yes No Corresponding Author's Name Renier J. Brentjens

5. Manuscript Title Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

6. Manuscript Identifying Number (if you know it) 122627-INS-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution for the clinical trial described within the manuscript.
NIH/National Cancer Institute (P30-CA08748)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 3. Relevant financial activities outside the submitted work.

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Fate Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting fee; contracted research; ownership interest;

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
FloDesign Sonics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Contracted research; ownership interest
Juno Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Contracted research; consulting/ advisory role; royalty sharing agreement; stock ownership
Takeda	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Contracted research
Atara	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Contracted research

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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Dr. Rivière reports other from Juno Therapeutics, grants from NIH/National Cancer Institute (P30-CA08748), during the conduct of the study; other from Fate Therapeutics, other from FloDesign Sonics, other from Juno Therapeutics, other from Takeda, other from Atara, outside the submitted work; .

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Section 1. Identifying Information

1. Given Name (First Name) Brigitte 2. Surname (Last Name) Sénéchal 3. Date 16-March-2019

4. Are you the corresponding author? Yes No Corresponding Author's Name
Renier J. Brentjens

5. Manuscript Title
Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

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Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution (not to this individual) for the clinical trial described within the manuscript.

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Dr. Sénéchal reports other from Juno Therapeutics, during the conduct of the study; .

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Section 1. Identifying Information

1. Given Name (First Name) Xiuyan 2. Surname (Last Name) Wang 3. Date 16-March-2019

4. Are you the corresponding author? Yes No Corresponding Author's Name
Renier J. Brentjens

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Yongzeng

2. Surname (Last Name)
Wang

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Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Terence 2. Surname (Last Name) Purdon 3. Date 16-March-2019

4. Are you the corresponding author? Yes No Corresponding Author's Name
Renier J. Brentjens

5. Manuscript Title
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Section 1. Identifying Information

1. Given Name (First Name) Meier 2. Surname (Last Name) Hsu 3. Date 16-March-2019

4. Are you the corresponding author? Yes No Corresponding Author's Name
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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Sean

2. Surname (Last Name)
Devlin

3. Date
16-March-2019

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Renier J. Brentjens

5. Manuscript Title
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Section 1. Identifying Information

1. Given Name (First Name) M. Lia	2. Surname (Last Name) Palomba	3. Date 16-March-2019
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Renier J. Brentjens
5. Manuscript Title Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL		
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Elizabeth

2. Surname (Last Name)
Halton

3. Date
16-March-2019

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Renier J. Brentjens

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Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution (not to this individual) for the clinical trial described within the manuscript.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

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?

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Section 6. Disclosure Statement

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Dr. Halton reports other from Juno Therapeutics, during the conduct of the study; .

Evaluation and Feedback

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Yvette

2. Surname (Last Name) Bernal

3. Date 16-March-2019

4. Are you the corresponding author? Yes No

Corresponding Author's Name Renier J. Brentjens

5. Manuscript Title Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

6. Manuscript Identifying Number (if you know it) 122627-INS-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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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 Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution (not to this individual) for the clinical trial described within the manuscript.

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Bernal reports other from Juno Therapeutics, during the conduct of the study; .

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Michel

2. Surname (Last Name) Sadelain

3. Date 16-March-2019

4. Are you the corresponding author? Yes No

Corresponding Author's Name Dr. Renier Brentjens

5. Manuscript Title Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

6. Manuscript Identifying Number (if you know it) 122627-INS-CMED-RV-2

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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 Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution for the clinical trial described within the manuscript.

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Juno Therapeutics	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting, advising, royalty sharing agreement, stock ownership, and research funding

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Fate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Collaborative research agreement
Atara	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Collaborative research agreement
Takeda	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Collaborative research agreement; royalty
Berkeley Lights	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Scientific Advisory Board

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 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.

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Nucleic acids encoding chimeric T cell receptors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Juno Therapeutics	Relevant to the 19-28z CAR T-cell design used in the report herein.

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Dr. Sadelain reports other from Juno Therapeutics, during the conduct of the study; grants, personal fees and other from Juno Therapeutics, other from Fate, other from Atara, other from Takeda, other from Berkeley Lights , outside the submitted work; In addition, Dr. Sadelain has a patent Nucleic acids encoding chimeric T cell receptors with royalties paid to Juno Therapeutics.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Jae	2. Surname (Last Name) Park	3. Date 16-March-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Renier J. Brentjens
5. Manuscript Title Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL		
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Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution for the clinical trial described within the manuscript.
National Comprehensive Cancer Network Young Investigator Award	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
American Society of Hematology	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Geoffrey Beene Cancer Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Leukemia and Lymphoma Society	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Amgen	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting/advisory role
Juno Therapeutics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting/advisory role; research funding
Genentech/Roche	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Research funding
Novartis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting
GlaxoSmithKline	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting
Kite	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting
AstraZeneca	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting
Takeda	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consulting

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Park reports other from Juno Therapeutics, grants from National Comprehensive Cancer Network Young Investigator Award, grants from American Society of Hematology, grants from The Geoffrey Beene Cancer Foundation, grants from Leukemia and Lymphoma Society, during the conduct of the study; personal fees and other from Amgen, personal fees and other from Juno Therapeutics, other from Genentech/Roche, personal fees and other from Novartis, personal fees and other from GlaxoSmithKline, personal fees and other from Kite, personal fees and other from AstraZeneca, personal fees and other from Takeda, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Renier

2. Surname (Last Name)
Brentjens

3. Date
16-March-2019

4. Are you the corresponding author? Yes No

5. Manuscript Title
Safety and tolerability of conditioning chemotherapy followed by CD19-targeted CAR T-cells for relapsed/refractory CLL

6. Manuscript Identifying Number (if you know it)
122627-INS-CMED-RV-2

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Are there any relevant conflicts of interest? Yes No

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Damon Runyon Clinical Investigator Award	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Translational and Integrative Medicine Fund Research Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Annual Terry Fox Run for Cancer Research (New York, NY) organized by the Canada Club of New York	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Carson Family Charitable Trust	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Kate's Team	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Mr. William H. Goodwin and Mrs. Alice Goodwin and the Commonwealth Cancer Foundation for Research	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Experimental Therapeutics Center of MSKCC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Geoffrey Beene Cancer Foundation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The Bocina Cancer Research Fund	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Juno Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Financial support to institution for the clinical trial described within the manuscript.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 3. Relevant financial activities outside 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**.

Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Juno Therapeutics	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	consulting, advising, royalty sharing agreement, stock ownership, and research funding
Celgene	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	consulting

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? 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.

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Nucleic acids encoding chimeric T cell receptors.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Juno Therapeutics	Relevant to the 19-28z CAR T-cell design used in the report herein.

ICMJE Form for Disclosure of Potential Conflicts of Interest

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. Brentjens reports grants from Damon Runyon Clinical Investigator Award, grants from The Translational and Integrative Medicine Fund Research Grant, grants from The Annual Terry Fox Run for Cancer Research (New York, NY) organized by the Canada Club of New York, grants from Carson Family Charitable Trust, grants from Kate's Team, grants from Mr. William H. Goodwin and Mrs. Alice Goodwin and the Commonwealth Cancer Foundation for Research, grants from The Experimental Therapeutics Center of MSKCC, grants from The Geoffrey Beene Cancer Foundation, grants from The Bocina Cancer Research Fund, other from Juno Therapeutics, from null, during the conduct of the study; grants, personal fees and other from Juno Therapeutics, other from Celgene, outside the submitted work; In addition, Dr. Brentjens has a patent Nucleic acids encoding chimeric T cell receptors. with royalties paid to Juno Therapeutics.

Evaluation and Feedback

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

TREND Statement Checklist

Paper Section/ Topic	Item No	Descriptor	Reported?	
				Pg #
Title and Abstract				
Title and Abstract	1	• Information on how unit were allocated to interventions	✓	2; 14-18
		• Structured abstract recommended	✓	2
		• Information on target population or study sample	✓	2; 3-4
Introduction				
Background	2	• Scientific background and explanation of rationale	✓	3-4
		• Theories used in designing behavioral interventions	N/A	N/A
Methods				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	15; Table S6
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	15
		• Recruitment setting	✓	15
		• Settings and locations where the data were collected	✓	15
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	15-17
		○ Content: what was given?	✓	15-17
		○ Delivery method: how was the content given?	✓	15-16
		○ Unit of delivery: how were the subjects grouped during delivery?	✓	15-16
		○ Deliverer: who delivered the intervention?	✓	15-16
		○ Setting: where was the intervention delivered?	✓	15
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	15-16
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	15-16
		○ Activities to increase compliance or adherence (e.g., incentives)	N/A	N/A
Objectives	5	• Specific objectives and hypotheses	✓	16
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	16
		• Methods used to collect data and any methods used to enhance the quality of measurements	✓	16-17
		• Information on validated instruments such as psychometric and biometric properties	✓	16-17
Sample Size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	✓	17
Assignment Method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✓	15-16
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	✓	15-16
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	N/A	N/A

TREND Statement Checklist

Blinding (masking)	9	<ul style="list-style-type: none"> Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. 	✓	15
Unit of Analysis	10	<ul style="list-style-type: none"> Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) 	✓	17
		<ul style="list-style-type: none"> If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) 	N/A	N/A
Statistical Methods	11	<ul style="list-style-type: none"> Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data 	✓	17-18
		<ul style="list-style-type: none"> Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis 	✓	17-18
		<ul style="list-style-type: none"> Methods for imputing missing data, if used 	✓	17-18
		<ul style="list-style-type: none"> Statistical software or programs used 	✓	17-18
Results				
Participant flow	12	<ul style="list-style-type: none"> Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) 	✓	4; Figure 1
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study 	✓	4; Figure 1
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Assignment: the numbers of participants assigned to a study condition 	✓	4; Figure 1
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention 	✓	4-8; Figure 1
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition 	✓	4-10; Figure 1
		<ul style="list-style-type: none"> <ul style="list-style-type: none"> Analysis: the number of participants included in or excluded from the main analysis, by study condition 	✓	4-10; Figure 1
		<ul style="list-style-type: none"> Description of protocol deviations from study as planned, along with reasons 	N/A	N/A
Recruitment	13	<ul style="list-style-type: none"> Dates defining the periods of recruitment and follow-up 	✓	15
Baseline Data	14	<ul style="list-style-type: none"> Baseline demographic and clinical characteristics of participants in each study condition 	✓	4-5; Tables 1-2
		<ul style="list-style-type: none"> Baseline characteristics for each study condition relevant to specific disease prevention research 	✓	4-5; Tables 1-2
		<ul style="list-style-type: none"> Baseline comparisons of those lost to follow-up and those retained, overall and by study condition 	✓	8; Tables 1-2
		<ul style="list-style-type: none"> Comparison between study population at baseline and target population of interest 	✓	12
Baseline equivalence	15	<ul style="list-style-type: none"> Data on study group equivalence at baseline and statistical methods used to control for baseline differences 	N/A	N/A

TREND Statement Checklist

Numbers analyzed	16	<ul style="list-style-type: none"> Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible 	✓	4-10
		<ul style="list-style-type: none"> Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses 	✓	4-10; 13-14
Outcomes and estimation	17	<ul style="list-style-type: none"> For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision 	✓	4-10; Figure 4
		<ul style="list-style-type: none"> Inclusion of null and negative findings 	✓	4-10
		<ul style="list-style-type: none"> Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	N/A	N/A
Ancillary analyses	18	<ul style="list-style-type: none"> Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	✓	4-10 (w/ cited figs & tables)
Adverse events	19	<ul style="list-style-type: none"> Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	✓	6-7; Table 4; Figures S3-4
DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study 	✓	10-14
		<ul style="list-style-type: none"> Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations 	✓	10-14
		<ul style="list-style-type: none"> Discussion of the success of and barriers to implementing the intervention, fidelity of implementation 	✓	10-14
		<ul style="list-style-type: none"> Discussion of research, programmatic, or policy implications 	✓	10-14
Generalizability	21	<ul style="list-style-type: none"> Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues 	✓	10-14
Overall Evidence	22	<ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory 	✓	10-14

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>