

DUALITY OF INTEREST DISCLOSURE FORM

Preamble

TrialNet is a clinical research program sponsored by the NIDDK, the NICHD, and the NIAID involving basic and clinical scientists worldwide. All TrialNet supported investigators, members, associates, support staff and any key personnel on any studies, are required to abide by the TrialNet Duality of Interest Policies and Procedures and complete appropriate TrialNet Duality of Interest Disclosure forms. TrialNet's policy establishes a process through which dualities will be reduced, eliminated or managed as necessary for all participants in TrialNet. We urge you to read the policy and form carefully so that you understand your duties that arise out of your participation in TrialNet.

In addition to submitting the TrialNet Duality of Interest Disclosure Form, you will be expected to comply with all local and institutional requirements regarding duality of interest (or designated as "conflict of interest" by home institution) and disclosure. You must submit documentation to the Executive Committee of any institutional review and/or notification of a duality(ies) pertinent to TrialNet studies that are planned or in progress.

Note: you must sign and date each page of the disclosure form before returning it to the TrialNet Coordinating Center.

DUALITY OF INTEREST DISCLOSURE FORM***Disclaimer Agreement:***

Your signature on this form indicates that you have read and agree to comply with TrialNet's Duality of Interest Policy. Furthermore, in filing the TrialNet Duality of Interest Disclosure Form, you

- Certify that the information you have submitted on the TrialNet Duality of Interest Disclosure Form is complete and accurate to the best of your knowledge.
- Understand that if you have any doubt as to whether or not you fall into a particular category for disclosure, you will supply TrialNet with the necessary background information so it can assist you in resolving the ambiguity.
- Accept that you will be required to update the TrialNet Duality of Interest Disclosure Form at all attended Steering Committee Meetings. In addition, you will be required to complete forms when a study(ies)/protocol(s) is submitted for review.
- Understand that you must continue to update the TrialNet Duality of Interest Disclosure Form for the tenure of your involvement with TrialNet.
- Agree that in the event that the TrialNet evaluation of your disclosure statement requires additional information, you will comply with the review committee's request and supply them with more detailed information.
- Understand that failure to complete the TrialNet Duality of Interest Disclosure Form accurately as requested may result in disqualification from TrialNet activity.

TrialNet will use the information contained in this disclosure form solely for TrialNet related purposes. All disclosures are confidential and will be kept in restricted access for review. Personal identifiers will be removed wherever possible and legally permissible. TrialNet maintains records of all financial disclosures and all actions taken by TrialNet with respect to each documented duality of interest. These records must be kept for the duration of the contract and then will be transferred to NIDDK for further storage.

1. DEFINITIONS	
Research	A systematic investigation designed to develop or contribute to generalizable knowledge.
TrialNet Investigator	An investigator at a TrialNet site, TrialNet Coordinating Center, the Chairman's Office, the NIH, Clinical Centers, Central Laboratories and/or other Central Facilities.
TrialNet Member	An individual associated with TrialNet Affiliates or Satellites.
TrialNet Associate	An individual not affiliated with a TrialNet Central Facility, Center, Affiliate, or Satellite who serves on TrialNet committees or as a collaborator or as a consultant.
TrialNet Supporting Staff	Individuals engaged in research other than TrialNet investigators at a TrialNet site, TrialNet Coordinating Center, the Chairman's Office, the NIH, Clinical Centers, Central Laboratories and/or other Central Facilities.
TrialNet Research Personnel Subject to Dualities of Interest	Principal investigators, investigators, and any other persons (including supporting staff) whose objectivity could reasonably influence the design, conduct, review and/or reporting of TrialNet research activity.

Sign and date this page in the space below:

Please Print Name

Signature

Date

7/3/2003

TRIALNET: DUALITY OF INTEREST DISCLOSURE UPDATE FORM
For Change In Duality Status

This form should be used to indicate any new duality(ies) of interest since your last report. Also, if a duality(ies) previously reported no longer exists, please indicate.

1. DEFINITIONS	
Research	A systematic investigation designed to develop or contribute to generalizable knowledge.
TrialNet Investigator	An investigator at a TrialNet site, TrialNet Coordinating Center, the Chairman's Office, the NIH, Clinical Centers, Central Laboratories and/or other Central Facilities.
TrialNet Member	An individual associated with TrialNet Affiliates or Satellites.
TrialNet Associate	An individual not affiliated with a TrialNet Central Facility, Center, Affiliate, or Satellite who serves on TrialNet committees or is a collaborator or as a consultant.
TrialNet Supporting Staff	Individuals engaged in research other than TrialNet investigators at a TrialNet site, TrialNet Coordinating Center, the Chairman's Office, the NIH, Clinical Centers, Central Laboratories and/or other Central Facilities.
TrialNet Research Personnel Subject to Dualities of Interest	Principal investigators, investigators, and any other persons (including supporting staff) whose lack of objectivity could reasonably influence the design, conduct, review and/or reporting of TrialNet research activity.
Employment	Full or part time work.
Commercial Entity	Includes but is not limited to any company, business, firm, partnership or limited partnership. This also includes any TrialNet participants who have individual financial interest that are not covered by any of the above.
Personal Duality of Interest	Includes but not limited to personal associations or professional collaborations that could affect scientific objectivity or commitment to a research endeavor.
Affiliated Entity	One that owns, or is owned, or is subject to common ownership by any entity that is a participant in or is otherwise covered by TrialNet. For these purposes, ownership includes both direct and indirect ownership (ownership through intermediate entities).
Intellectual Property	Includes but not limited to copyrights, patents, trademarks, trade names, and trade secrets.
You	Refers to yourself, your spouse or dependents.

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

2. PERSONAL INFORMATION:	
Name:	
Institution:	
Address:	
E-mail Address:	
Title/Role in TrialNet	

TrialNet Role: Investigator Member Associate Support Staff Other

If Other, please indicate role or relationship:

3. EMPLOYMENT

Has there been any change in your duality of interest status regarding employment in a commercial entity (or its affiliated entities) having an interest in any medications, devices, or intellectual property (or any competing medications, devices or intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)?

YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Position</u>	<u>Protocol/Study</u>		
1.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
2.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
3.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

4. CONSULTANCIES/HONORARIA

Has there been any change in your duality of interest status as a consultant and/or sponsored speaker and received greater than \$10,000 per year from any single commercial entity (or its affiliated entities) having an interest in any medications, devices or intellectual property (or any competing medications, devices or intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)? YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Activity</u>	<u>Protocol/Study</u>		
1.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
2.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
3.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B

5. STOCK OWNERSHIP (Not publicly traded entity)

Has there been any change in duality of interest status regarding your ownership interests (including stock options), valued at greater than \$10,000 in a commercial entity (or its affiliated entities), the stock of which is not publicly traded and which has an interest in any medications, devices, or intellectual property (or any competing medications, devices or intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)? YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Type of Ownership</u>	<u>Protocol/Study</u>		
1.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
2.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
3.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

6. STOCK OWNERSHIP (Publicly traded entity)

Has there been any change in your duality of interest status regarding ownership interests (including stock options, but excluding indirect investments through mutual funds), valued at greater than \$10,000 in a publicly traded commercial entity (or its affiliated entities) having an interest in any medications, devices, or intellectual property (or any competing medications, devices or intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)?

YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Type of Ownership</u>	<u>Protocol/Study</u>		
1.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
2.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B
3.	_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
					A	B

7. INTELLECTUAL PROPERTY

Has there been any change in your duality status regarding patents, patents pending, or other forms of intellectual property (or any competing intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)? YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

	<u>Intellectual Property</u>	<u>Protocol/Study</u>		
1.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B
2.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B
3.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

8. BASIC SCIENCE RESEARCH AND CLINICAL TRIAL RESEARCH FUNDING

Has there been any change in your duality of interest status regarding basic or clinical research funding you have received totaling greater than \$30,000 over the last three years from a commercial entity (or its affiliated entities) having an interest in any medications, devices or intellectual property (or any competing medications, devices or intellectual property) that are utilized in a current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)? YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Position</u>	<u>Protocol/Study</u>		
1. _____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
				A	B
2. _____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
				A	B
3. _____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
				A	B

9. MEMBERSHIP ON BOARD OF DIRECTORS OR ADVISORY COMMITTEE

Has there been a change in your duality of interest status regarding Board of Directors or Advisory Committees on which you serve for a commercial entity (or its affiliated entities) having an interest in any- medications, devices, or intellectual property (or any competing medications, devices or intellectual property) that are utilized in current TrialNet study(ies) or protocol(s) or may be considered or proposed for future use in a TrialNet study(ies) or protocol(s)? YES NO

If yes, please provide the information requested below. If this is an addition to your list of duality(ies) please check A. If this is a duality that is no longer applicable, please check B. See separate page attached for additional disclosures.

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Protocol/Study</u>		
1. _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B
2. _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B
3. _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
			A	B

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

10. OTHER DUALITY(IES) OF INTEREST

Please indicate in the space below any personal interests, involvement with a non-commercial research organization and/or interests competing with TrialNet not indicated above that could be perceived as a duality of interest with regard to any of your TrialNet activities.

Sign and date this page in the space below:

Please Print Name

Signature

Date

ADDITIONAL DUALITIES

3. EMPLOYMENT

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Position</u>	<u>Protocol/Study</u>
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____

4. CONSULTANCIES/ HONORARIA

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Activity</u>	<u>Protocol/Study</u>
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____

5. STOCK OWNERSHIP (Not publicly traded entity)

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Type of Ownership</u>	<u>Protocol/Study</u>
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____

6. STOCK OWNERSHIP (Publicly traded entity)

<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Type of Ownership</u>	<u>Protocol/Study</u>
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____

Sign and date this page in the space below:

 Please Print Name

 Signature

 Date

7. INTELLECTUAL PROPERTY

	<u>Intellectual Property</u>	<u>Protocol/Study</u>
1.	_____	_____
2.	_____	_____
3.	_____	_____

8. BASIC SCIENCE RESEARCH AND CLINICAL TRIAL RESEARCH FUNDING

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Position</u>	<u>Protocol/Study</u>
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____

9. MEMBERSHIP ON BOARD OF DIRECTORS OR ADVISORY COMMITTEE

	<u>Commercial Entity</u>	<u>Medication/Device/Property</u>	<u>Protocol/Study</u>
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____

10. OTHER DUALITIES OF INTEREST

Please indicate in the space below any personal interests, involvement with a non-commercial research organization and/or interests competing with TrialNet not indicated above that could be perceived as a duality of interest with regard to any of your TrialNet activities.

Sign and date this page in the space below:

Please Print Name

Signature

Date

*DUALITY OF INTEREST FORM
For Assertion of No Change In Duality Status*

I assert that there has been no change in my duality of interest status since my last statement.

Name:	
Institution:	
Address:	
E-mail Address:	

TrialNet Role: Investigator Member Associate Support Staff Other

If Other, please indicate role or relationship:

Please sign and date this page in the space below:		
_____	_____	_____
Please Print Name	Signature	Date



To: All October 2004 Steering Committee Meeting Attendees
From: TrialNet Coordinating Center
Subject: Company Listing for updating Duality of Interest Status
Date: 9/15/2004

As noted by Jay Skyler, TrialNet Type 1 Diabetes Study Chairman, the following companies have products under consideration for TrialNet studies:

Amylin Pharmaceuticals and Eli Lilly & Co – Exenatide
Autoimmune and Eli Lilly & Co – Oral insulin
Bristol-Myers-Squibb - CTLA4-Ig
Chiron – IL-2
Genentech & IDEC Pharmaceuticals – (Anti-CD20) - Rituximab
Martek (formerly Omega Tech) – Omega 3 Fatty Acids
Mead- Johnson Nutritional – Enfamil and Lipil Infant Formulas
Neurocrine, Inc. - Insulin B9-23-APL
Peptor, Inc. and Aventis, Inc. - DiaPep277
Roche, Inc.- Mycophenolate mofetil (MMF)
Roche, Inc. and Protein Design Labs, Inc. (PDL) - Anti-CD25 (Daclizumab)
Wyeth – Rapamune (sirolimus)

This list is not to be construed as comprehensive, as other products may come up for review. Moreover, it is possible that a duality may arise by virtue of a relationship with a company that has a competitive product not currently under consideration for a TrialNet study.



TRIALNET: CONFIDENTIALITY AGREEMENT

Type 1 Diabetes TrialNet Study Group

This form must be signed by all TrialNet investigators, TrialNet Associates, TrialNet Members, and any others who would have access to any proprietary information related to any TrialNet study.

The undersigned is a participant in the Type 1 Diabetes TrialNet Study Group. The undersigned recognizes that in the course of evaluating potential interventions and conducting other TrialNet Study Group business, certain information of a confidential and/or proprietary nature will be provided, and that improper use of such information could damage an institution, a business, or another entity. The undersigned agrees not to disclose any such information to any third party or use it for any purpose except as indicated by the TrialNet Study Group. The undersigned agrees to take all precautions to avoid the unauthorized disclosure or use of such confidential information. The undersigned agrees that this applies to material provided in writing, orally, and to any notes taken. The undersigned will take all reasonable measures to protect the secrecy of the information and will notify the TrialNet Coordinating Center of any misuse or disclosure which comes to his/her attention.

The undersigned shall have no obligation of confidentiality or non-use with respect to any portion of information disclosed hereunder which (a) is or later becomes generally available to the public by use, publication or the like; (b) is obtained from a third party without restriction who had the legal right to disclose the same; (c) the undersigned already possesses, as evidenced by his/her written records, predating receipt thereof from TrialNet; or (d) is independently developed by the undersigned as conclusively evidenced by written records.

PERSONAL INFORMATION:	
Name:	
Institution:	
Address:	
E-mail Address:	
Title/Role in TrialNet	

TrialNet Role: Investigator Member Associate Support Staff Other

If Other, please indicate role:

Please keep copies of this form for completion by other TrialNet personnel at your site as needed, and forward to: TrialNet Coordinating Center, George Washington University, Biostatistics Center, 6110 Executive Blvd., Suite 750, Rockville, MD 20852.

Please sign and date this page in the space below and return it to the TrialNet Coordinating Center.

Please Print Name

Signature

Date