

New TrialNet Affiliate Packet Contents

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New TrialNet Affiliate Welcome Letter



Re: *Becoming a New Affiliate for the Type 1 Diabetes TrialNet Study Group*

Dear Investigator:

Thank you for your interest in becoming an affiliate member of the Type 1 Diabetes TrialNet Study Group. TrialNet is an international consortium of investigators in the United States, Canada, Europe, and Australia studying ways to prevent Type 1 Diabetes and preserve insulin secretion in individuals with newly diagnosed Type 1 Diabetes.

TrialNet Studies: The following is a list of the TrialNet studies that are currently active or soon to be active. These studies are at different phases of recruitment. Please contact the TNCC or reference the TrialNet public website at <http://www.diabetestrialnet.org/index.htm> for additional information on the current status of these studies.

TN01: Pathway to Prevention Study (Natural History) of the Development of Type 1 Diabetes

TN07: Oral Insulin for Prevention of Diabetes in Relatives at Risk of Type 1 Diabetes Mellitus

TN08: Effects of Recombinant Human Glutamic Acid Decarboxylase (rhGAD65) Formulated in Alum (GAD-alum) on the Progression of Type 1 Diabetes in New Onset Subjects

TN09: Effects of CTLA-4 Ig (Abatacept) On the Progression of Type 1 Diabetes In New Onset Subjects

TN10: Anti-CD3 (TEPLIZUMAB) for Prevention of Diabetes in Relatives At-Risk for Type 1 Diabetes Mellitus

TN11: Recombinant Human Glutamic Acid Decarboxylase (rhGAD65) Formulated in Alum (GAD- alum) for Prevention of Diabetes in Individuals At-Risk for Type 1 Diabetes

TN12: Effect of Metabolic Control at Onset of Diabetes on Progression of Type 1 Diabetes Metabolic Control

TN14: Effects of Anti IL-1Beta (Canakinumab) on the Progression of Type 1 Diabetes in New Onset Subjects

Enclosures: All of the enclosed forms must be completed and submitted to the TNCC. You have the option of printing and completing these forms manually and faxing, scanning, or mailing them to the TNCC. Some forms may be completed electronically, signed electronically, and submitted via email to the TNCC. Forms that can be completed electronically are indicated below with an asterisk (*). Others forms listed can be filled out electronically but require a manual signature and therefore will need to be printed by the site then faxed, mailed, or scanned and sent to the TNCC. For additional instructions on adding an electronic signature, click on the link below or contact the TNCC for assistance:

[20100423 Instructions on Adding an Electronic Signature to TN documents.pdf](#)

1. * *Fax Sheet and Checklist*: you can use this fax sheet and checklist as a guide/tally in order to keep track of all documents required to become a new affiliate.
2. * *Site Information Form*: please complete this informational form; please contact the USF TNCC with any questions on completing this form.
3. *W-9/W-8BEN*: please complete this document completely (W-8BEN is used for non-USA sites).

4. * *Site Delegation Log*: please complete this document completely. Make certain that anyone who will be working on TrialNet is listed and associated with the appropriate protocol(s) and role(s). This should be considered a running log. This should be signed by the site PI (electronic signatures are acceptable).
5. * *Confidentiality Form*: please read and complete this form (PI and Site Coordinator Only). These forms require a signature (electronic signatures are acceptable).
6. * *New User Form*: please complete this form for each individual listed on the site delegation log who will need access to the TrialNet website.
7. * *TN01 TrialNet IRB Checklist*: Please utilize this tool to ensure that your IRB submission contains all of the elements required by the TNCC.
8. *Clinical Center Contact List*: please refer to this document in order to identify your Clinical Center. You will need to provide the TNCC with a letter of support from your Clinical Center in order to become a TrialNet Affiliate. Please contact the USF TNCC for any additional questions about clinical centers in your region.
9. *USF TNCC Contact List*: please refer to this document if you need to contact the USF TNCC with any questions or concerns.

Affiliate Responsibilities: The main responsibilities of an affiliate are: to recruit and enroll research participants to TN01 Natural History Study as well as other TrialNet studies; initiate professional outreach by participating in grand rounds and assisting the Clinical Center with professional events; conduct independent participant outreach as well as assist the Clinical Center with recruitment events. Additionally, prior to initiating enrollment or research procedures on a TrialNet study, all affiliates must: obtain IRB approval for each study and send it to the USF TNCC, receive training from the USF TNCC for the study (including training on the USF TNCC web data capture and tracking systems), and send the USF TNCC study specific essential regulatory documents. For each study, once all site activation steps have been complete, the USF TNCC will send the affiliate a site activation letter; once a site activation letter is received for a specific study, the affiliate may then enroll to that particular protocol. Affiliates must also ensure their IRB approvals, staff contact information, and essential regulatory documents are up-to-date at the USF TNCC at all times.

Expected Timeline: Once a complete new affiliate packet is submitted to the USF TNCC by fax (813-910-5994) or e-mail (tncc@epi.usf.edu) and it is determined to be appropriate, it should take approximately 1 week for your site to receive access to the TrialNet internal website, details on steps to site activation for study protocols, and instructions regarding web site training.

Next Steps: In order to become an affiliate you will need to:

1. Obtain a letter of support from your Clinical Center. Please refer to the *Clinical Center Contact List* provided in this packet in order to identify your Clinical Center. The letter of support can be a formal letter or memo signed by the Clinical Center TrialNet Director or it can be an email from the Clinical Center TrialNet Director.
2. Complete the forms in this packet: 1. *Site Information Form*, 2. *W-9 or W-8BEN*, 3. *Confidentiality Forms*, 4. *Site Delegation Log*, 5. *New User Forms*

Note: All Forms can be completed electronically or may be printed out and manually completed by the sites

3. Both the site PI and Coordinator should complete an NIH approved human subjects educational course and obtain a certificate of completion; the certificate of completion must be sent to the USF TNCC. You can contact your local IRB for an approved course or take one online (e.g. the CITI online course: <http://www6.miami.edu/citireg/> or NIH online course: <http://phrp.nihtraining.com/users/login.php>)
4. The PI should sign and date a current copy of his/her Curriculum Vitae (CV) and include it in the final packet sent to the USF TNCC.
5. Fax (813-910-5994) or Email (tncc@epi.usf.edu) all documents (once complete) to the USF TNCC.
6. Once the USF TNCC has received a complete application from your site, you will receive an email from the USF TNCC letting you know the status of your application. You will also receive instructions from the TNCC on how to complete the required Duality of Interest forms once you receive access to the TrialNet web system.
7. After you submit the protocol to your IRB, send the TNCC your letter of approval and all IRB stamped Informed Consent/Assent documents. Please reference the *TN01 TrialNet IRB Checklist* to ensure that your IRB submission contains all of the elements required by the TNCC.
8. Contact the USF TNCC with any questions or concerns

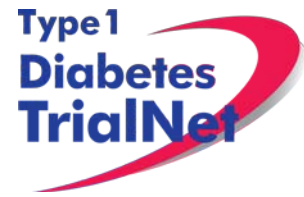
Again, we thank you for your interest in participating in the TrialNet Study Group.

Sincerely,

Jeffrey Krischer, Ph.D.

Director, TrialNet Coordinating Center

New TrialNet Affiliate Fax Sheet and Checklist



To: USF TNCC

From: _____

To Fax#: 813-910-5994

-And/OR-

To Email: TNCC@epi.usf.edu

Subject: New TrialNet Affiliate Forms and Documents

Completed documents attached:

- Site Information Form
- W-9/W-8
- Confidentiality form for PI
- Confidentiality form for Site Coordinator
- Site Delegation Log
- New User Forms (one for each staff member)
- Signed and recently dated CV of PI
- Human Subjects Education Certificate for PI
- Human Subjects Education Certificate for Site Coordinator
- Letter of support/Email from Clinical Center Director (please have emails sent to TNCC@epi.usf.edu)
- IRB Approval Letter & IRB Approved Informed Consent Documents

Name of person submitting packet

Date

Title

Phone

FAX

Email Address

New TrialNet Affiliate Site Information Form



Part A: Clinical Site Information

01. Site Name: _____

02. OHRP Assurance Number (FWA#): _____
If you do not have an OHRP number, please go to www.hhs.gov/ohrp/ for more information.

03. Site Mailing Address: _____

04. City: _____

05. Phone: _____ 06. Fax: _____

07. State/Province: _____

08. Zip or Postal Code: _____ 09. Country: _____

10. Projected Monthly Screening Numbers: _____

11. How did your site hear about becoming a TrialNet Affiliate: _____

Part B: Principal Investigator Information

12. Name: _____

13. Position: _____

14. Mailing Address: _____

15. City: _____

16. State/Province: _____

17. Zip or Postal Code: _____ 18. Country: _____

19. Phone: _____ 20. Fax: _____

21. Email: _____

New TrialNet Affiliate Site Information Form



Part C: Study Coordinator Information (Main Contact)

22. Check here if a study coordinator is not yet identified.

23. Name: _____

24. Mailing Address: _____

25. City: _____

26. State/Province: _____

27. Zip or Postal Code: _____ 28. Country: _____

29. Phone: _____ 30. Fax: _____

31. Email: _____

Part D: Payment/Reimbursement Information- *The following items must be completed in order to receive payments. (Insert "N/A" in fields that are not applicable):*

32. Federal Tax ID (FEID)#: _____

33. Payee (make reimbursement/payment in the name of): _____

Send Payment/Reimbursements to:

34. Name: _____

35. Mailing Address: _____

36. City: _____

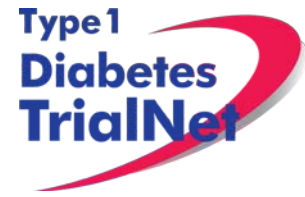
37. State/Province: _____

38. Zip or Postal Code: _____ 39. Country: _____

40. Phone: _____ 41. Fax: _____

42. Email: _____

New TrialNet Affiliate Site Information Form



43. Is this a Small, Minority or Women-Owned business?

Certified Yes No

Certified by State Yes No

Certified by Federal Yes No

Contact Person for Patient Care Payment/Reimbursements:

44. Check here if the contact person for patient care payment/reimbursements is the same as above (items #32 – 43).

45. Name: _____

46. Mailing Address: _____

47. City: _____

48. State/Province: _____

49. Zip or Postal Code: _____ 50. Country: _____

51. Phone: _____ 52. Fax: _____

53. Email: _____

Please Contact the USF TNCC with any questions or concerns

Fax: 813-910-5994

Email: tncc@epi.usf.edu

**University of South Florida
Purchasing & Property Services
Request for Taxpayer Identification and Certification
(Substitute for IRS Form W-9)**

Instructions:

1. Use this form only if you are a U.S. person (including U.S. resident aliens). If you are a foreign person, use the appropriate Form W-8.
2. Complete Part 1 by completing the one row of boxes that corresponds to your tax status.
3. Complete Part 2 by providing your Payment Remittance Address
4. Complete Part 3 if you are exempt from Form 1099 reporting.
5. Complete Part 4 by signing & dating form.

Part 1 – Tax Status: (complete only one row of boxes)

Individuals:
(Fill out this row)

Individual's Name: (first name, middle initial, last name) _____ - _____ - _____	Individual's Social Security Number _____ - _____ - _____
---	--

Sole Proprietor:
(Fill out this row)

A sole proprietorship may have a "doing business as" trade name, but the legal name is the name of the business owner.

Business Owner's Name: (REQUIRED) _____ (First Name) (Middle Initial) _____ (Last Name)	Business Owner's Social Security Number _____ - _____ - _____ or Employer ID Number _____ - _____ - _____	Business or Trade Name (OPTIONAL) _____ _____
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Partnership:
(Fill out this row)

Name of Partnership: _____ _____	Partnership's Employer ID Number _____ - _____ - _____	Partnership's Name on IRS records (see IRS mailing label) _____ _____
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Corporation, exempt charity or other entity:
(Fill out this row)

A corporation may use an abbreviated name or its initials, but its legal name is the name on the articles of incorporation.

Name of Corporation or Entity: _____ _____	Employer ID Number _____ - _____ - _____	Are you incorporated? YES NO <input type="checkbox"/> <input type="checkbox"/>	D.B.A. or T.A. companies? Attach all of the business names.
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Part 2 - Payment Remittance Address:

Part 3 – Exemption: If exempt from Form 1099 reporting, check here: AND check your qualifying exemption reason below:

1. Corporation Except there is no exemption for medical and healthcare payments or payments for legal services.	2. Tax Exempt Tax Exempt Charity under 501(a) (<i>includes</i> 501(c)(3)), or IRA	3. The United States or any of its agencies or instrumentalities	4. A state, the District of Columbia, a possession of the United States, or any of their political subdivisions.	5. A foreign government or any of its political subdivisions.
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Part 4 – Certification: Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding and
3. I am a U.S. person (including a U.S. resident alien).

Certification Instructions – You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return.

Name of Person completing this form: _____

Title of Person completing this form: _____

Signature: _____ Date: _____ Phone: (____) _____

Address: _____ City: _____ State: _____ ZIP: _____

E-Mail Address: _____

Certificate of Foreign Status of Beneficial Owner for United States Tax Withholding

OMB No. 1545-1621

▶ Section references are to the Internal Revenue Code. ▶ See separate instructions.
 ▶ Give this form to the withholding agent or payer. Do not send to the IRS.

Do not use this form for:

- A U.S. citizen or other U.S. person, including a resident alien individual W-9
- A person claiming that income is effectively connected with the conduct of a trade or business in the United States W-8ECI
- A foreign partnership, a foreign simple trust, or a foreign grantor trust (see instructions for exceptions) W-8ECI or W-8IMY
- A foreign government, international organization, foreign central bank of issue, foreign tax-exempt organization, foreign private foundation, or government of a U.S. possession that received effectively connected income or that is claiming the applicability of section(s) 115(2), 501(c), 892, 895, or 1443(b) (see instructions) W-8ECI or W-8EXP

Instead, use Form:

Note: These entities should use Form W-8BEN if they are claiming treaty benefits or are providing the form only to claim they are a foreign person exempt from backup withholding.

- A person acting as an intermediary W-8IMY

Note: See instructions for additional exceptions.

Part I Identification of Beneficial Owner (See instructions.)

1 Name of individual or organization that is the beneficial owner	2 Country of incorporation or organization
3 Type of beneficial owner: <input type="checkbox"/> Individual <input type="checkbox"/> Corporation <input type="checkbox"/> Disregarded entity <input type="checkbox"/> Partnership <input type="checkbox"/> Simple trust <input type="checkbox"/> Grantor trust <input type="checkbox"/> Complex trust <input type="checkbox"/> Estate <input type="checkbox"/> Government <input type="checkbox"/> International organization <input type="checkbox"/> Central bank of issue <input type="checkbox"/> Tax-exempt organization <input type="checkbox"/> Private foundation	
4 Permanent residence address (street, apt. or suite no., or rural route). Do not use a P.O. box or in-care-of address.	
City or town, state or province. Include postal code where appropriate.	Country (do not abbreviate)
5 Mailing address (if different from above)	
City or town, state or province. Include postal code where appropriate.	Country (do not abbreviate)
6 U.S. taxpayer identification number, if required (see instructions) <input type="checkbox"/> SSN or ITIN <input type="checkbox"/> EIN	7 Foreign tax identifying number, if any (optional)
8 Reference number(s) (see instructions)	

Part II Claim of Tax Treaty Benefits (if applicable)

9 I certify that (check all that apply):

a The beneficial owner is a resident of _____ within the meaning of the income tax treaty between the United States and that country.

b If required, the U.S. taxpayer identification number is stated on line 6 (see instructions).

c The beneficial owner is not an individual, derives the item (or items) of income for which the treaty benefits are claimed, and, if applicable, meets the requirements of the treaty provision dealing with limitation on benefits (see instructions).

d The beneficial owner is not an individual, is claiming treaty benefits for dividends received from a foreign corporation or interest from a U.S. trade or business of a foreign corporation, and meets qualified resident status (see instructions).

e The beneficial owner is related to the person obligated to pay the income within the meaning of section 267(b) or 707(b), and will file Form 8833 if the amount subject to withholding received during a calendar year exceeds, in the aggregate, \$500,000.

10 Special rates and conditions (if applicable—see instructions): The beneficial owner is claiming the provisions of Article _____ of the treaty identified on line 9a above to claim a _____ % rate of withholding on (specify type of income): _____
 Explain the reasons the beneficial owner meets the terms of the treaty article: _____

Part III Notional Principal Contracts

11 I have provided or will provide a statement that identifies those notional principal contracts from which the income is **not** effectively connected with the conduct of a trade or business in the United States. I agree to update this statement as required.

Part IV Certification

Under penalties of perjury, I declare that I have examined the information on this form and to the best of my knowledge and belief it is true, correct, and complete. I further certify under penalties of perjury that:

- 1** I am the beneficial owner (or am authorized to sign for the beneficial owner) of all the income to which this form relates,
- 2** The beneficial owner is not a U.S. person,
- 3** The income to which this form relates is (a) not effectively connected with the conduct of a trade or business in the United States, (b) effectively connected but is not subject to tax under an income tax treaty, or (c) the partner's share of a partnership's effectively connected income, **and**
- 4** For broker transactions or barter exchanges, the beneficial owner is an exempt foreign person as defined in the instructions.

Furthermore, I authorize this form to be provided to any withholding agent that has control, receipt, or custody of the income of which I am the beneficial owner or any withholding agent that can disburse or make payments of the income of which I am the beneficial owner.

Sign Here ▶

Signature of beneficial owner (or individual authorized to sign for beneficial owner) Date (MM-DD-YYYY) Capacity in which acting



**TRIALNET: CONFIDENTIALITY AGREEMENT
TYPE 1 DIABETES TRIALNET STUDY GROUP**

Site/Organization Name: _____

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 the development, design, conduct and analysis of TrialNet studies, 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 understands that all material related to TrialNet, whether distributed electronically or on paper, conveyed verbally, or as notes taken, is to be considered confidential and should not be disclosed to any other party unless the material is already in the public domain. The latter is defined as "any material that can be accessed by the general public." Unless the material is already in the public domain, the undersigned agrees not to disclose any TrialNet information to any third party or use if 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 will take all reasonable measures to protect the confidentiality 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 possess, as evidence by his/her written records, predating receipt thereof from TrialNet; (d) is independently developed by the undersigned as conclusively evidenced by written records or (e) is required to be disclosed pursuant to law or court order.

This confidentiality policy is not intended to apply to policies regarding the publication of scientific results, which per the terms of the prime award from NIDDK are determined by the TrialNet Steering Committee. Specifically, the terms of the prime award state that "Manuscripts and presentations will be written and reviewed according to the policies and procedures set forth by the DPT-1 and TrialNet Steering Committee."

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:

Please keep copies of this form for completion by other TrialNet personnel at your site as needed, and forward to : TrialNet Coordinating Center, University of South Florida, Pediatrics Epidemiology Center 3650 Spectrum Blvd., Suite 100 Tampa, FL 33612; Fax: (813) 910-5994; Email: [q &&@epi.usf.edu](mailto:q&&@epi.usf.edu)

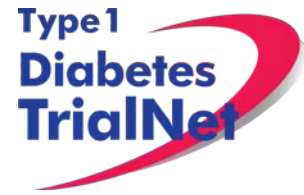
Please sign and date this page in the space below and return to TrialNet Coordinating Center.

Please Print Name

Signature

Date

Current TrialNet Site New User/Contact Correction Form



New User/Contact Correction/Remove User: *please complete a new form for each staff member who needs to be added, have contact information corrected, or removed from the website.*

01. Site Number (or name): _____

02. New TrialNet Member

Current TrialNet Member, Contact Information Correction *(if you select this option then only complete name and contact information fields which are incorrect on the web site and need to be updated- e.g. provide only your updated email address).*

Remove/Make Inactive Previous TrialNet Member *(if you select this option then only member's name is needed).*

03. Name: _____

04. Title: _____

05. Mailing Address: _____

06. City: _____

07. State/Province: _____

08. Zip or Postal Code: _____ **09. Country:** _____

10. Phone: _____ **11. Fax:** _____

12. Email: _____

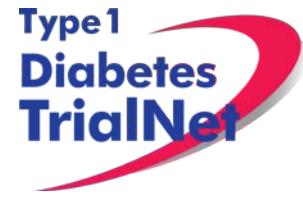
Please Contact the USF TNCC with any questions or concerns:

Phone: 813-396-9560

Fax: 813-910-5994

Email: tncc@epi.usf.edu

New TrialNet Affiliate Clinical Center Contacts



Barbara Davis Center [7]

Barbara Davis Center for Childhood Diabetes [7]

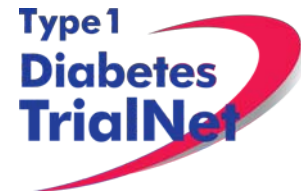
University of Colorado Health Sciences Center
1775 N. Aurora Ct.
Aurora, CO 80045 USA
Ph: (303) 724-6745
Fax: (303) 724-7503

Site Type: Clinical Center

Peter Gottlieb, MD [*Principal Investigator*]
Associate Professor of Pediatrics and Medicine
University of Colorado
Health Science Center Barbara Davis Center for Childhood Diabetes
1775 Aurora Ct.
Aurora, CO 80045-6511 USA
Ph: (303) 724-6714
Fax: (303) 724-6707 or 303-724-6784
Email: Peter.Gottlieb@uchsc.edu

Vicky Gage [*Trial Coordinator*]
University of Colorado
Health Science Center Barbara Davis Center for Childhood Diabetes
1775 Aurora Ct.
Aurora, CO 80045-6511 USA
Ph: (303) 724-6766
Fax: (303) 724-7503
Email: victoria.gage@ucdenver.edu

New TrialNet Affiliate Clinical Center Contacts



Benaroya Research Institute 10]

Benaroya Research Institute [10]

1201 9th Avenue
Seattle, WA 98101 USA
Ph: (206) 515-5233
Fax: (206) 515-5239

Site Type: Clinical Center

Carla Greenbaum, MD [Principal Investigator]

Director, Diabetes Research Program
Benaroya Research Institute
1201 Ninth Ave
P.O. Box 358285
Seattle, WA 98101 USA
Ph: (206) 515-5232 (ass't Marilyn Reeve)
Ph: (206) 515-5231
Fax: (206) 515-5239
Email: cjgreen@benaroyaresearch.org
Email2: mreeve@benaroyaresearch.org

Marli McCulloch-Olson [Site Coordinator]

Trial Coordinator
Benaroya Research Institute
Diabetes Clinical Research Unit
1201 Ninth Ave.
Seattle, WA 98101-2795 USA
Ph: (206) 515-5233
Fax: (206) 515-5239
Email: Marli@benaroyaresearch.org

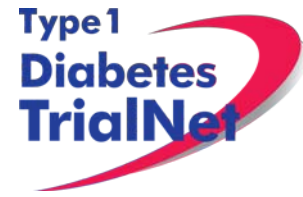
Mary Ramey, MS, RD, CDE [Site Coordinator]

Benaroya Research Institute
1201 9th Avenue
Seattle, WA 98101 USA
Ph: (206) 223-6842
Fax: (206) 515-5239
Email: mramey@benaroyaresearch.org

Christine Webber [Recruitment Coordinator]

Clinical Research Coordinator/Recruiter
Benaroya Research Institute
1201 9th Ave
Seattle, WA 98101 USA
Ph: (206) 515-5237
Fax: (206) 515-5239
Email: cwebber@benaroyaresearch.org

New TrialNet Affiliate Clinical Center Contacts



Children's Hospital of Pittsburgh [14]

University of Pittsburgh [14]

Children's Hospital of Pittsburgh, Dept/Pediatric Endocrinology
3705 5th Avenue
Pittsburgh, PA 15213 USA
Fax: (412) 692-6449

Site Type: Clinical Center

Dorothy Becker, MD [*Principal Investigator*]

Chief of Endocrinology & Diabetes/Director of Diabetes Program

University of Pittsburgh

Children's Hospital of Pittsburgh Department of Pediatric Endocrinology

3705 5th Avenue

Pittsburgh, PA 15213 USA

Ph: (412) 692-5179

Fax: (412) 692-5834

Email: dorothy.becker@chp.edu

Karen Riley, RN [*Site Coordinator*]

Trial Coordinator

Children's Hospital of Pittsburgh

Rangos Research Center

3460 5th Ave.

Room # 5115

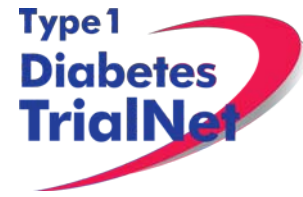
Pittsburgh, PA 15213 USA

Ph: (412) 692-5210

Fax: (412) 692-6449

Email: karen.riley@chp.edu

New TrialNet Affiliate Clinical Center Contacts



Columbia University [15]

Columbia University [15]

Naomi Berrie Diabetes Center
1150 St. Nicholas Ave.
Second Floor
New York, NY 10032 USA
Fax: (212) 851-5460

Site Type: Clinical Center

Robin S. Goland, MD *[Principal Investigator]*
Associate Professor of Medicine and Co-Director
Naomi Berrie Diabetes Center
Columbia University Medical Center
1150 St. Nicholas Avenue
New York, NY 10032 USA
Ph: (212) 851-5492
Fax: (212) 851-5460
Email: rsg2@columbia.edu

Ellen Greenberg, MS *[Site Coordinator]*
Trial Coordinator
Columbia University
Naomi Berrie Diabetes Center
1150 St. Nicholas Ave.
Second Floor
New York, NY 10032 USA
Ph: 212-851-5425
Fax: 212-851-5460
Email: emg25@columbia.edu

New TrialNet Affiliate Clinical Center Contacts



Indiana University – Riley Hospital for Children [16]

Indiana University – Riley Hospital For Children [16]

Indianapolis, IN 46202 USA

Ph: (317) 948-8879

Fax: (317) 944-2579

Site Type: Clinical Center

Linda DiMeglio, MD *[Clinical Center Director]*

Indiana University Riley Hospital for Children

700 Barnhill Drive RI-5960 Indianapolis, IN 46202 USA

Ph: (317) 274-7595

Fax: (317) 274-3882

Email: dimeglio@iupui.edu

Maria Nicholson Spall, RN, CCRP *[Site Coordinator]*

Study Coordinator Indiana University -Riley Hospital for Children

702 Barnhill Drive, Suite 5960

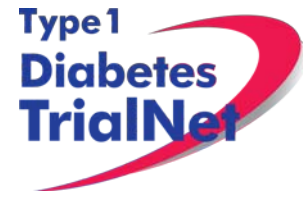
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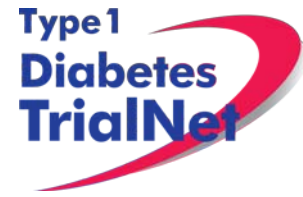
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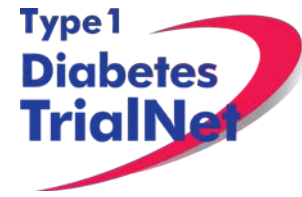
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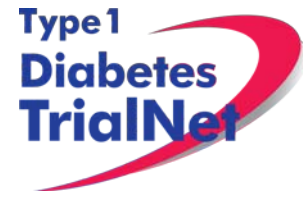
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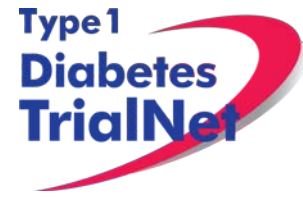
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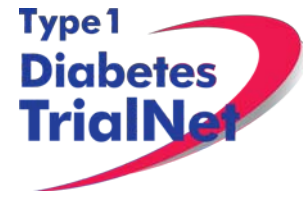
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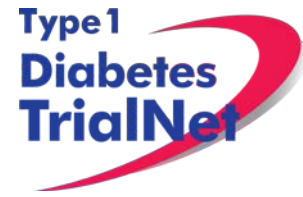
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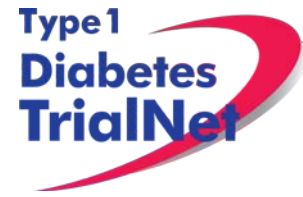
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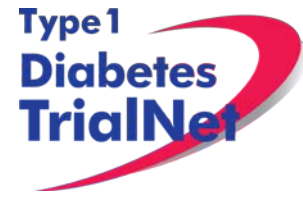
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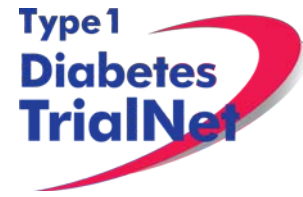
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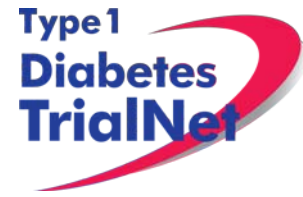
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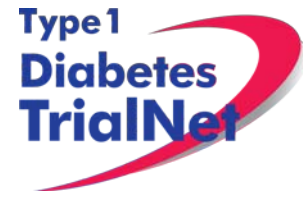
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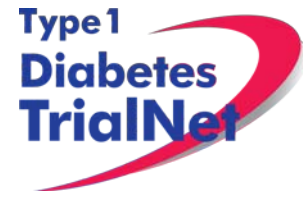
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TN01 TrialNet IRB Checklist



Please ensure the following documents are included in your site's submission to your local IRB or WIRB. All of these documents or templates for these documents are available on the TrialNet Members' website or by contacting the TrialNet Coordinating Center.

Most Recent TrialNet TN01 - Pathway to Prevention (Natural History) Protocol Version 15August2011

Screening Informed Consent and Assent

Monitoring Informed Consent and Assent

TrialNet promotional materials (brochures/posters/etc.)

Other participant materials (Participant Handbook, Negative and Rescreen letter templates, etc.)

Note: Protocol specific documents are located under their respective protocol in the TrialNet Members' website under Document Navigation in the *Protocol Documents* folder. Promotional materials are located under the TrialNet main page of the Members' website under Document Navigation in the *Promotional Materials and Handouts* folder. If your IRB requests any additional documents, please contact the TNCC.

Your IRB Approval Should Include (Initial/Amendment/Modification Submissions Only):

An actual letter or correspondence from the IRB indicating that the project was/is approved

The date of the approval letter/correspondence

The correct protocol title and protocol date listed in the approval letter

Explicit reference to the version date of the protocol, version date of the Informed Consents/Assents and any additional study documents that were approved

Approval letter should be signed by the IRB chair or their designee

Explicit reference to what the IRB is approving (the type of submission- initial, modification, etc.)

IRB approved Consents and Assents should be stamped by the IRB. (If the IRB does not stamp documents then your site should supply the TNCC with IRB policy describing their quality control/document version control procedures)

IRB approved Consents and Assents should indicate the valid from and through dates

Please submit these documents to the TrialNet Coordinating Center:

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Email: Regulatory@epi.usf.edu