

Pediatric PittNet



Welcome to our network

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CTSI Pediatric PittNet

University of Pittsburgh Clinical and Translational Science Institute

Practice-Based Research Network

Welcome to [Pediatric PittNet](#), the University of Pittsburgh's CTSI practice-based research network. Becoming a member of [Pediatric PittNet](#) allows you to take advantage of the many approaches we offer to help recruit prospective participants for your research study. Recruitment support includes posting on our website, in our practices, and various eBlasts to the community, Children's Community Pediatrics, and Primary Care Centers. On-site enrollment is also offered in selected practices via experienced [Pediatric PittNet](#) research nurses.

Who is Pediatric PittNet?

[Pediatric PittNet](#) is a practice-based research network that is working collaboratively with the community, Children's Community Pediatric practices and Children's Hospital Primary Care Centers to improve the health of children.

In 2007 the University of Pittsburgh Clinical and Translational Science Institute (NIH/NCRR/CTSA Grant UL1 RR024153) created [Pediatric PittNet](#) to facilitate the translation of pediatric research discoveries into practice in order to improve the health of the region's children. [Pediatric PittNet](#) consolidates and builds on previous physical and mental health research networks that have successfully supported federal- and industry-funded clinical research studies based in pediatric primary care over the past decade. To meet the goal of effective translation, [Pediatric PittNet](#) promotes collaboration between pediatric clinical investigators and practitioners.

[Pediatric PittNet](#) currently includes many research protocols covering a range of common childhood behavioral health and physical health concerns.

Where is Pediatric PittNet?

[Pediatric PittNet](#) is present in participating community practices, Children's Community Pediatrics practices and Children's Hospital of Pittsburgh Primary Care Centers in and around Pittsburgh.

Together, there are 21 practices including 37 office sites in 6 counties in Western Pennsylvania. We have over 190 [Pediatric PittNet](#) providers serving over 200,000 privately and publicly insured patients, aged birth to 21 years, in urban, suburban and rural settings.

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GETTING STARTED

Approval:

Please find attached to this packet, your Pediatric PittNet approval letter for your research study.

One Page Study Summary:

Please complete the attached one page summary for Pediatric PittNet to reference when/where applicable.

Be sure to include the following points:

1. At least 3 inclusion and exclusion criteria
2. Important study specifics (briefly summarized) e.g. no braces for fMRI scans; treatment study; etc.
3. Name and number for **docs** to contact in regards to recruitment and for **patients** to contact (*if different*)

Recruitment Support:

Please note: this section is intended for informative purposes. Reference the check list at the end of this packet for a complete list of action items.

- **Pediatric PittNet Website**

Your study information will be posted to our network website at www.pedspittnet.pitt.edu. Here you can find information about the network, active research studies, and other useful links and resources.

Your study will be included on the electronic Active Studies List and Virtual Research Binder. If your research study has a website, please provide the link and this will also be included.

- **Quarterly Newsletter: The Paw**

Each issue of *The Paw* includes a current list of active studies, two study articles, and other news and announcements. If selected to be featured in the newsletter, your study will be contacted to obtain a draft article to be printed in the coming issue.

Director's Note:
Hi, everyone! As you can see from this issue, we are very busy with a number of new research studies, especially the AOM and Flu vaccine effectiveness studies. We appreciate all of your support in launching these new projects. Congratulations to the practices in Dr. Zimmerman's practice improvement study. Your increased Flu vaccination rates surpassed all goals! Thank you to all of you who completed the anonymous Retrospective Clinic Survey from our PBRN colleagues at Wash. St. Louis. With 64 respondents we had more than St. Louis, Cincinnati, Dayton & Chicago! Thank you, too, for helping us to plan new studies. Stay tuned for upcoming teleconferences on ADHD management for college students and on teen driving safety. Finally, remember to send us your topic ideas for a "Clinical Pearl" video.

RESEARCH NEWS

RIVUR and CUTIE
Two of Dr. Hoberman's UTI Studies (RIVUR and CUTIE) have completed enrollment and are finishing up on follow up visits. 106 participants received careful evaluation and monitoring of their recurrent UTIs and renal scarring during these studies. Thank you to all of the practices that referred patients and to those who have welcomed our Pediatric PittNet Research Nurses into your sites to enroll!

AOM Study
With the close of some studies comes the start of new ones! Dr. Hoberman's study of 5 vs. 10 days of antibiotics for AOM started enrolling in CCP Armstrong, CCP Bass Wolfson-Cranberry, CCP Gil-East Side, CCP MPA, and PCC Oakland. The study is also accepting referrals from PCC Turtle Creek and Children's at Mercy.

Flu Study
Dr. Zimmerman's CDC-funded Flu Vaccine Effectiveness study began enrolling in January. This study will provide participating practices with information about the local influenza attack rate and vaccine effectiveness estimates by age group. Please refer any patient 6 months or older with respiratory symptoms.

Please contact your on-site PittNet nurse to make referrals to these or other PittNet studies:

Research Nurse	Location	Number
Tracy Balentine	Kensington/ Nazareth Heights	412 316 6403
Kris Daw	North	412 304 9706
Kristy Maslin	City	412 302 0655
Nancy Weichler	East	412 328 4714

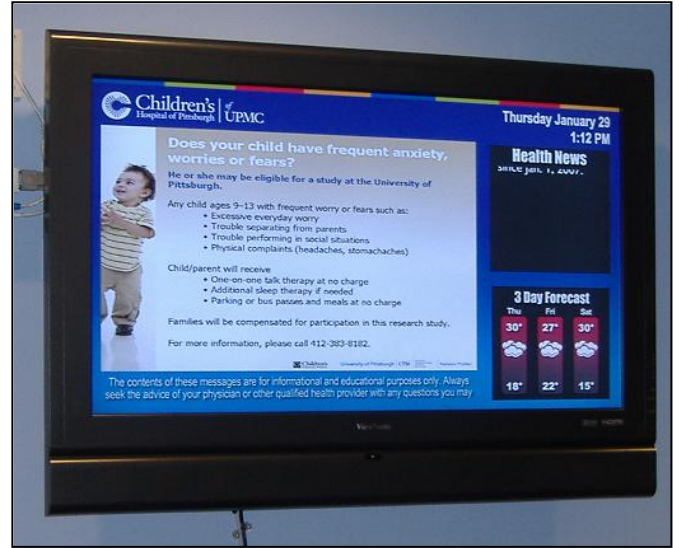
Clinical Pearls from Pediatric PittNet
Dr. Dorothy Becker filmed our network's first Clinical Pearl video on Type 1 Diabetes. You can access the video on our website at www.pedspittnet.pitt.edu click on Clinical Pearls from PittNet. Dr. Alessandro Hoberman and Nader Shaikh also filmed a Clinical Pearl on the new AAB UTI guidelines and research studies.

• **eMessage Boards**

Pediatric PittNet has 42 inch flat screen televisions, also known as eMessage Boards, in most of our Pediatric PittNet practices. The eMessage boards show slides of research studies and patient educational information for families to view while waiting for their appointments.

Please complete **one** of the attached templates with your study information. (A sample eMessage Board slide is included for your reference) Pediatric PittNet will submit the slide to the IRB via a specialized mechanism that has been developed with the IRB for approval.

Please be advised that we update our eMessage board slides and themes on a quarterly basis. As a result, your study slide may not run year round. We have developed this strategy focusing on seasonal topics to maximize exposure to families in the waiting areas.




FEATURED PEDIATRIC PITNET RESEARCH STUDY OF THE MONTH

Emotion Regulation in Youth at High Risk of Bipolar Disorder


PI: Cecile Ladouceur, Ph.D

Background:
Bipolar Disorder (BD) is characterized by difficulties processing and regulating emotions. BD is significantly greater in children whose parents have BD. Attention deficit hyperactivity disorder (ADHD) is one of the most frequent co-morbid psychiatric disorders in pediatric BD and is highly prevalent in offspring of individuals with BD.

Study objective:
The goal of this research project is to use functional magnetic resonance imaging (fMRI) to examine whether offspring with ADHD of parents with BD will show distinct patterns of brain activity on tasks that involve processing and regulating emotions compared to offspring with ADHD of parents who have not been affected with a mood disorder.



Methods:
Parents and their children will first be screened by phone to determine initial eligibility for the study. If criteria are met, the family will then be invited to our office to participate in a diagnostic evaluation to determine final eligibility into our study. If final criteria are met, the family will be invited back for a second visit, which includes the fMRI brain scan, some computer games and questionnaires.



Inclusion criteria:

- Children with a diagnosis of ADHD
- between 8-17 years

Exclusion criteria:

- Children with parents who have a past or current mood disorder
- Braces or metal implants
- Pregnancy
- Substance abuse in the past 6 months

Benefits to participants: Comprehensive diagnostic evaluation and treatment referrals when appropriate. Compensation provided.

Benefits to referring doctors: Advancing knowledge about the development of Bipolar Disorder in children and adolescents as well as inform early diagnosis and treatment of the disorder. Upon participant request, doctors may also receive a copy of the diagnostic evaluation.

Contact Information:
Claire Dempsey
412-383-8135
dempseycm@upmc.edu

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• **Study of the Month**

Every month a new research study is featured. If selected, the one page summary provided by your research staff will be used to generate a flyer announcement that is distributed to all of our network providers and posted to our website.

Visit our website and navigate to the [Study of the Month](#) section to view past announcements.

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Other Resources:

- ***REDCap***

REDCap is a secure, web-based application used for constructing and maintaining online surveys, data forms, and databases. Projects are created through an Online Designer or offline via a “data dictionary” template in Excel which can be uploaded to REDCap later.



REDCap also offers automated export procedures for data downloads to Excel and other common statistical packages. REDCap has a built-in project calendar, scheduling module, and ad hoc report tools. Advanced features are available including branching logic, file uploading, and calculated fields.

Please note: REDCAP is intended for IRB approved research projects and is not to be used for clinical use. Appropriate IRB approval is required to store research data in the system. Identifiable information is not permitted.

To learn more about REDCap and how it can benefit yours tudy, watch this [brief summary video](#) (4 min)

- ***University Marketing Communications***

The University Marketing Communications (UMC) department is dedicated to devising the best approach for research study teams to engage in to reach their target audience.

Services include print pieces, advertising, mass mailing, and letters of support. Contact UMC today to see what they can do for your study!



Contact Information:

Bill Young
Publications and Marketing
Senior Director
412-624-4209
wky@pitt.edu

- ***CTSI Pediatric Research Participant Registry***

The University of Pittsburgh CTSI Registry is a voluntary system to connect patients with research studies relevant to their health history. Registered parents receive information about research studies matched to their selected health topics. Research studies are encouraged to sign-up with the Registry to take advantage of this recruitment method. Visit their website at www.researchregistry.pitt.edu

Contact Information:

Kerri Jacksons
jacksonk@pitt.edu

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CHECK LIST

Provided by Pediatric PittNet:

- Approval Letter
- Research Study Summary - template
- eMessage board slide - template options
- eMessage board slide - sample

Once completed, please return the following items electronically to Pediatric PittNet:

- Research Study Summary
- Research Study flyer - electronic copy for website posting
- Research study website address - link to from PittNet website (*if applicable*)
- eMessage board slide

To:

abby.trainer@chp.edu

Pediatric PittNet Administrative Research Coordinator

****Please be sure to notify [Pediatric PittNet](#) of any changes to your research study that affect the services provided by our network to ensure that accurate information is distributed to the community. (i.e. study contact name or number change, study flyer update, recruitment inclusion/exclusion criteria change, etc.)**

*****Please remember to refer to CTSI in all publications that were helped by this grant with the following citation: *The project described was supported by the National Institutes of Health through Grant Number UL1TR000005***

On behalf of [Pediatric PittNet](#), we look forward to working with your research study.
Thank you in advance for contributing to our network mission of improving children's health through research.

Please direct all questions to:

Abby Trainer

Pediatric PittNet Administrative Research Coordinator

abby.trainer@chp.edu

412 692 5900

For more information about [Pediatric PittNet](#), visit our website at www.pedspittnet.pitt.edu

Pediatric PittNet



On-Site Research Study Start-Up

For Research Study Coordinators (non-Pediatric PittNet staff)

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Welcome to [Pediatric PittNet](#), the University of Pittsburgh’s CTSI practice-based research network. We are thrilled to have your study contribute to our network mission of improving children’s health through research and look forward to working with you.

Before you are able to begin on-site activity, there are a few items to review. We’ve developed the following information packet to help new studies begin recruitment in our network practices as smoothly as possible. We’ve taken into consideration not only the safety of our patients but also research ethics and execution of a thorough review process to verify that all materials being used have been approved by the IRB and are appropriate for a pediatric setting.

Please take a minute to review the information in this packet and complete each item as directed. If you have any questions please contact Carrie Fascetti at christopherc@upmc.edu.

Pediatric PittNet *Specifications*

Contact Information

Please identify the appropriate contact information for your study team using the table below. We will need to reach these contacts at any time during the course of your research study for various reasons so it is important that we always have the most up-to-date information on file.

On-site recruiting should occur during the practice hours of operation. During these hours, please provide a person to contact that will be available should a consult be necessary. It is extremely important that we know who is immediately accessible since we are recruiting in a clinical setting and need to have questions answered about recruiting in a timely manner (i.e. while the family is still being seen by the physician). Indicate below whom the first, second, and third person to contact should be.

Protocol Title:				
	Name	Phone	E-mail	Phone Tree #1 is the person we should contact first
PI				
Co-PI				
Co-I				
Research Coordinator				
Regulatory Coordinator				
Research Team Members				

Study Nickname

Pediatric PittNet recommends that your study team develop a nickname for practice providers and nurses to use when referring to your research study. Some type of abbreviation, short title, or moniker is helpful when referencing your study. Pediatric PittNet would like to suggest the following options (please select one or make another suggestion):

- Option #1
- Option #2
- Option #3
- Other: _____

Practice Specific Information

This table helps to organize important information about the pediatric practice your study will be enrolling patients from. Some of this information has been provided to you by Pediatric PittNet. Any missing information should be collected by your study team.

Practice name and address	
Practice Hours	
Best days of the week for Research Staff to be in the practice	
Lead physician	
Lead Pediatric PittNet physician	
Office manager	
Lead nurse	
Contact working with research staff to coordinate study (lead physician or manager)	
Pediatric PittNet research nurse if applicable	
Current Pediatric PittNet research nurse studies recruiting for if applicable	

Pre-Implementation

Most on-site research coordinators require at least a small amount of space to conduct study procedures in the practices. Please consider the items listed below and address any that need resolved prior to beginning study activity.

- **Workspace requirements** (e.g. confidential space)
- **Computer** (device or connectivity)
- **Phone**
- **Storage** for research materials/supplies (locked or unlocked)
- **Refrigerator**

Meetings

There are a number of meetings that should take place prior to implementing a study. Here is a list of suggested meetings and their description.

Meeting	Description
PI Practice Talk	Principal Investigator (PI) visits the practice to explain the research study. This will be coordinated through Pediatric PittNet . *Please see the outline below for more details.
Meet and Greet	Meet the practice doctors and staff and introduce the study.
MA In-Service	Explain to the medical assistants (MA) what the study is about. Script how the MA should offer the study to the family. Emphasize to them how important it is to obtain permission from the family before the research staff may discuss their participation. Explain what “dot phrase” is in the electronic medical record.

*This PI Practice Talk Outline identifies the main points to include in study talks to the practices:

- **Purpose:** To educate community providers on the research study available to their patients. Any and all questions and concerns should be addressed to clarify procedures, methods, and expectations.
- **Length:** Presentation should be **15- 20 minutes** with 10 minutes of questions/discussion
- **Format:**
 - **Brief overview** of the research study
 - **Benefit** to families and physicians
 - **Design** in a simplified format
 - **Inclusion/exclusion** in a simplified format
 - **Method** of recruitment
 - PittNet Administrator (PA) and PittNet Nurse (PN) will assist in explaining the methods of recruitment (i.e. screening)
 - **Contact** information for the PI
 - Please plan to hand out cards with ways to contact the PI

Practice Implementation

Once the research staff arrives on-site, [Pediatric PittNet](#) will host implementation on an as needed basis depending on the study including but not limited to the following:

- **Introduction to staff:**
 - Manager
 - Pediatric Providers (MD, PA, CRNP, Psychiatrist MD)
 - Medical Assistants (MA)
 - Behavioral Health Therapists
- **Review of Office Flow:**
 - The **front desk** is responsible for checking in patients and scheduling future appointments. The front desk can also assist with MedSpeed pickup arrangements.
 - The **schedulers** take calls for and schedule outgoing patients.
 - **Nurses** serve as patient advocates. They receive phone calls and assist providers with their patient resource needs.

- **MA**s usually room patients for their visit (as well as other responsibilities). Be sure to ask the MA to explain the stages of the patient visit after being placed in a room including the colored flag schedule.
- The **Research Nurse** coordinates the active study with office providers and staff. They explain the study, how screening will be done, and how the practice will be involved in the screening and study procedures.

Important Reminders and Information

Before starting a study in the practice, be sure to do the following:

- **PROVIDERS**
 - Obtain/create a list of all the practice providers
 - Make a copy of the office schedule or provider schedule
 - Identify the best way to communicate with each provider (face to face, email, phone)
 - Make sure to remind the providers about the study especially if it has been awhile since the PI Practice talk.
 - Explain the provider role in the study (give a brief study description and obtain permission for the research staff to approach the parent to discuss study participation)
 - Discuss with the provider how to tell if a subject is appropriate for the study. (if applicable)
- **MA**s
 - Explain the MA's role in the study (give a brief study description and obtain permission for the research staff to discuss study participation)
 - Remind them to "dot phrase" in the computer that they had given permission for the research team to speak with the parent about participation.
- **MISC.**
 - Always remember to obtain permission before entering a patient room. Research staff should never enter an exam room without permission from the practice staff or physician first.
 - Speak with the [Pediatric PittNet](#) Administrator prior to implementing any changes to recruitment strategies.
 - IRB approval must be obtained for all implementation or study procedure modifications.
- **EPIC NOTES**
 - The research nurse must always put a brief note in the EPIC record for any patient that enrolls in a study. The note is one sentence and follows this general format: *After consent process, patient enrolled in ____ study.* It is best practice to only fill in the short name of the study.
 - This is note seen as a communication tool. It prevents nurses from re-enrolling the same children into studies. It also helps some studies communicate if certain medications are not to be given per protocol.

Start-Up Checklist

[Pediatric PittNet](#) has created the following research study coordinator checklist to make sure that all necessary steps are taken and completed before on-site recruitment begins in the locations highlighted at the beginning of this packet. Please work through each task, check the box when it is complete, insert the date of completion, and use the comments column for any additional notes. Once this checklist is complete, sign and date at the bottom and return to abby.trainer@chp.edu Carrie Fascetti, PittNet Administrator, will contact you to schedule a meeting for review of this list in its entirety. If you have any questions prior to the meeting, please contact Carrie at christophere@upmc.edu

Version: 12/12/2013

Pediatric PittNet

Research Study Coordinator Checklist

Study Title:	
Study Coordinator:	
Locations:	

Activity	Complete	Date (mm/dd/yyyy)	Comments
Training with Pediatric PittNet	<input type="checkbox"/>		
Approval – IRB	<input type="checkbox"/>		
Approval - Pediatric PittNet Exec Comm.	<input type="checkbox"/>		
PittNet review committee modifications complete - study team check list signed	<input type="checkbox"/>		
Individual review - IRB approved forms (prior to preliminary meeting)	<input type="checkbox"/>		
Individual review - Cross check electronic to hard copies (prior to preliminary meeting; following all modifications; and on a monthly basis)	<input type="checkbox"/>		
Computer program testing – if applicable	<input type="checkbox"/>		
Research Nurse access – added to all study systems, databases, WePay, etc.	<input type="checkbox"/>		
Study Materials	<input type="checkbox"/>		
Study Supplies	<input type="checkbox"/>		
Practice visit - with PI	<input type="checkbox"/>		
Practice visit – meet and greet	<input type="checkbox"/>		
Practice approved	<input type="checkbox"/>		

By signing, I hereby certify that the above activities have been completed in their entirety in preparation for the research study listed above to begin activity in the designated practice location(s).

Signature:

Date:

Please note: When an IRB modification is made, you will be asked to complete a form verifying that all of the changes approved by the IRB have also been changed in the forms or computer programs given to families.

Thank you

We thank you in advance for your cooperation and will be attentive to any questions, comments, or concerns you may have. Our goal is to ensure that research activity is conducted professionally and appropriately in all of network practices so as to protect the safety of our children. We look forward to working with you!!

