Research Participation & Data Governance Policy

Contents

REACHnet
Research Action for Health Network

I. Overview

A. Purpose: The purpose of this policy is to:

1. Inform investigators how to collaborate with the Research Action for Health Network (REACHnet) in the following capacities:
    - Requesting REACHnet resources and services for their own research initiatives;
    - Representing their health system as the site Investigator in another investigator's research initiatives; and/or
    - Representing the network as the local (i.e., REACHnet) Principal Investigator in a PCORnet study
2. Govern REACHnet's process for determining network and site participation in research projects
3. Govern approvals of data sharing pursuant to the terms of the REACHnet Master Data Sharing and Use Agreement, other applicable Data Sharing and Use Agreements, and IRB requirements

B. Scope: This policy applies to requests by the National Patient-Centered Clinical Research Network (PCORnet) and non-PCORnet Research Partners (institutions involved in the conduct of research as defined at 45 C.F.R. § 64.10 of the HIPAA Regulations), including REACHnet-affiliated and non-REACHnet-affiliated partners, to conduct research using REACHnet's infrastructure for:

1. Obtaining any data;
2. Conducting observational or interventional studies;
3. Collecting patient-reported/generated data; and/or
4. Accessing stakeholder engagement resources and services.

As set forth below, the research review process for PCORnet requests does not involve all of the steps required for non-PCORnet studies.

C. Decision-making: The REACHnet Coordinating Center facilitates the network's decision-making regarding research participation and the release of clinical and/or research data by working closely with the network leadership who represent each of REACHnet's partner institutions, including: Ochsner Health; Baylor Scott & White Health; Pennington Biomedical Research Center; Tulane University Schools of Medicine and Public Health/Tulane Medical Center [HCA]; LSU Health Sciences Center; University Medical Center New Orleans (LCMC Health); Partnership for Achieving Total Health (PATH) affiliated community-based clinics and hospitals; DHR Health Institute for Research and Development; and University of California San Francisco (UCSF) Medical Center. Hereafter, this decision-making body is referred to as "*Partner Health System Leadership*". Members of REACHnet's Partner Health System Leadership are listed in **Appendix A**.

The REACHnet Coordinating Center and Partner Health System Leadership govern the network's research participation and data sharing as follows:

1. First, the REACHnet Coordinating Center performs an administrative review of a given research request, data request, or service request to assess feasibility. Using guidelines approved by Partner Health System Leadership, the REACHnet Coordinating Center conducts this preliminary assessment to determine if the request for services and/or collaboration should be shared with leaders.
2. The REACHnet Coordinating Center communicates about research participation and data sharing opportunities with Partner Health System Leadership on a rolling basis. As research opportunities are shared, each leader acts as a liaison between REACHnet and their partner health system to determine system-level interest in participation and, if applicable, recruit system-level investigators and sites.

Decision-making for research participation is further discussed in the *Requesting Research Services* sections of this policy (sections II and III). Decision-making for the release of data is discussed in the *Data Governance* section of this policy (section V).

II. Requesting Research Services – Process for Investigators

A. Submission Procedures

Investigators who are interested in leveraging REACHnet resources and/or services are invited to submit the appropriate REACHnet Service Request Form(s) via REACHnet's online submission portal, Eco (https://eco.reachnet.org). Using Eco, investigators are able to organize all request-related forms in one project space and track the status of requests. REACHnet may also correspond with investigators via phone or email to discuss content of an application form before the form(s) is formally reviewed.

Investigators can find request forms and information about REACHnet services on REACHnet's website (http://www.reachnet.org/resources/forms/). Forms applicable to the research participation process include:

- *Prospective Research Request Form* (see Sections II.B. and V.A.)
- *Data Request Form* (i.e., for retrospective research; see Sections II.C. and V.B.)
- *Prep-to-research Query Request Form* (see Section V.C.)
- *Request for Engagement Services* (see Section VI)

Details for completing each form are described below.

B. Prospective Research Requests

Investigators who wish to access REACHnet services are invited to submit an application addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Target population
3. Description of intervention(s) and comparison groups or study cohort
4. Data needs, including clinical and patient-reported data collected by REACHnet
5. Proposed research sites (health systems), if applicable
6. Research team (by name and institution)
7. Funding details, if applicable
8. Use of REACHnet resources/services (note: services will require appropriate budget allotments)
9. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) will be engaged in the protocol development and project execution
10. Use of other CRN or HPRN resources/services
    - Investigators who are interested in engaging other PCORnet Health Plan Research Networks (HPRNs) or Clinical Research Networks (CRNs) to collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
    - If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures through the PCORnet Front Door
    - The use of other CRNs or HPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

The *REACHnet Prospective Research Request Form* reflects the above requirements. The request must be submitted, reviewed, and approved prior to receiving a letter of support from REACHnet for a funding application**. Please allow at least 30 days for the review process.**

C. <u>Retrospective Research Requests (i.e., data-only requests)</u>

Investigators who wish to obtain REACHnet partner data are invited to submit a *Data Request Form* addressing the following components of their proposed research project:

1. Specific Aims / Research Questions
2. Description of population of interest, including query parameters for inclusion/exclusion criteria
3. Engagement Plan detailing how patients, clinicians, and other stakeholders (as applicable) have been or will be engaged in generating the project idea or interpreting the results
4. Data needs, including specific clinical and patient-reported data elements collected by REACHnet
5. Funding details, if applicable
6. Use of other CRN or HPRN resources/services
    - Investigators who are interested in engaging other PCORnet Health Plan Research Networks (HPRNs) or Clinical Research Networks (CRNs) to collaborate on a study are encouraged to communicate with the REACHnet Coordinating Center about their research ideas and potential PCORnet collaboration
    - If deemed feasible, the REACHnet Coordinating Center will advise investigators through the additional application procedures that are outlined in the PCORnet Front Door Policy
    - The use of other CRNs or HPRNs for research purposes will require additional regulatory documentation beyond that required for REACHnet

D. <u>Review Process, Partner Health System Participation, and Communication of Decision</u>

1. The investigator will receive an email notification through Eco that the status of their project is “under review” or “needs action” within 10 working days of submission. The REACHnet Coordinating Center may communicate with the investigator during this time to clarify data needs and requested services. If necessary, the investigator will be responsible for revising the request form during this time.
2. The REACHnet Coordinating Center will review the submitted form and determine whether fulfilling the request is feasible.
3. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to REACHnet Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).
4. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leadership.
5. The REACHnet Coordinating Center will communicate a final decision about collaboraton within 30 working days after the Eco project was changed to “under review”. If the research request is approved, REACHnet will inform the investigator of the decision by changing the status of the Eco project to “approved”. If collaboration is deemed unfeasible during the formal review process, the Eco project status will be changed to ”rejected”. Investigators are invited to resubmit requests or contact the REACHnet Coordinating Center directly with questions about this decision.

III. Requesting Research Services – Process for PCORnet Research Opportunities

A. Opportunities to participate in studies initiated through PCORnet will be managed by the REACHnet Coordinating Center.
B. The REACHnet Coordinating Center will determine whether the research opportunity is feasible.
C. If deemed feasible, the REACHnet Coordinating Center will present the opportunity to the Partner Health System Leadership, and leaders will determine whether their respective health system is interested in participating. Leaders will identify co-investigators and sites from their respective health systems for interventional studies or determine if their respective health system will contribute requested data in response to data-only requests or prospective observational studies (for which co-investigators may also be recruited).
D. In response to both prospective and data-only research opportunities, the REACHnet Coordinating Center must receive express written consent to participate via email from Partner Health System Leaders.
E. The REACHnet Coordinating Center will communicate with PCORnet about whether the network (i.e., some combination of component health systems, but not necessarily all) will participate in a proposed study, based on the systems' willingness to participate.

IV. Regulatory Requirements

All approved research requests are subject to:

A. Applicable IRB approval requirements based on the type of study (see Table 2 for more information);
B. The terms of the REACHnet Master Data Sharing and Use Agreement, which sets forth any additional Data Sharing and Use Agreements that must be executed before data is shared; and
C. Partner Health System Leader approval for data sharing as set forth in the *Data Governance* section below.

V. Data Governance

REACHnet partner data is available to investigators to support prospective and data-only research projects. In addition, REACHnet partner data can support research preparation projects through prep-to-research queries and administrative queries geared toward ensuring data quality and readiness. Data governance differs based on the type of data requested. Data type definitions are aligned with those specified in the REACHnet Master Data Sharing and Use Agreement and PCORnet Data Sharing Agreement (DSA). They include:

1. Type 1: Administrative Queries (e.g., PCORnet Data Characterization)
2. Type 2: Analytic queries requiring return of de-identified aggregate data
3. Type 3: Analytic queries requiring return of de-identified individual level data
4. Type 4: Analytic queries requiring return of a limited data set (CDM[1] or CDM+[2])
5. Type 5: Analytic queries requiring return of identifiable individual level data
6. Type 6: Matching Assessment Queries (to monitor privacy preserving record linkage solution matching performance and troubleshoot any potential anomalies)

[1] The PCORnet Common Data Model (CDM) is a way of organizing clinical health data into a standard structure. Each PCORnet partner network maps data to the same consistent format (i.e., with the same variable name, attributes, and other metadata). For more information, visit https://pcornet.org/data-driven-common-model/.
[2] REACHnet has the capacity to assist investigators in acquiring data outside of the CDM from REACHnet partner health systems for research purposes.

REACHnet references these six data types throughout the *Data Governance* section of this policy. The sections below describe regulatory and administrative approval requirements for sharing the data types listed above. Table 1 provides an overview of these requirements.

A. Data to support prospective research

Data to support prospective research will take the form of data types 2-5. To receive data for prospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leaders' approval, as set forth in the *Requesting Research Services* sections (II and III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section (IV) above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health Systems Leadership.
3. Ongoing releases of data types 2-5 can occur without additional approval from participating Partner Health System Leadership.
4. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements fulfilled before data sharing can occur.
5. All data transfer will occur in a secure capacity.

B. Data to support retrospective research

Data to support retrospective research typically take the form of data types 3 and 4 (but could also include types 2 and 5). To receive data for retrospective research projects, the researcher must complete the steps described in the *Requesting Research Services* and *Regulatory Requirements* sections of this policy.

1. No data, regardless of type, will be released without Partner Health System Leaders' approval, as set forth in the *Requesting Research Services* sections (II and III) above and fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Once Partner Health System Leadership approves participation and applicable regulatory requirements are met, data types 2-5 can be released without additional review and/or approval from participating Partner Health System Leadership.
3. Additional data requests beyond those expressely defined in the applicable IRB, REACHnet Master Data Sharing and Use Agreement, and additional Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements fulfilled before data sharing can occur.
4. All data transfer will occur in a secure capacity.

C. Data to inform future research

Data to inform future research takes the form of a prep-to-research (PTR) or prep-to-analysis (PTA) query. Prep-to-research/analysis queries are data type 2. Prep-to-research queries assess the number of eligible patients meeting defined inclusion/exclusion criteria, while prep-to-analysis queries assess the frequency of outcomes among defined patient groups. Query requests are received locally via Eco as *Query Request*

Forms. REACHnet also receives prep-to-research queries through the PCORnet Distributed Research Network.

1. Approval from Partner Health System Leadership is not required prior to running a prep-to-research query, but pre-approval from Partner Health System Leadership is required prior to running a prep-to-analysis query.
2. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
3. Once prep-to-research/analysis queries are complete, results are sent to respective Partner Health System Leadership via email. For PCORnet queries, Partner Health System Leadership approval is not required to return results. For non-PCORnet prep-to-research queries, Partner Health System Leadership is allowed 72 hours (3 business days) to review their health system specific results and respond if they wish to opt out of sharing results with the requester. Active approval is not required to share results with the requester. For prep-to-analysis queries, approval from Partner Health System Leadership obtained via email is required to release results to the requester.
4. Prep-to-analysis query results cannot be released to requesting investigators without the approval of the Partner Health System Leadership.

To protect patient privacy, except in the case of PCORnet queries, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)." For PCORnet Queries in which Participant chooses to participate, Participant shall return low cell counts of Participant Data so that accurate counts of the availability of PCORnet's total results can be obtained. In the event that Participant returns cell counts <11, Data will be masked and aggregated with Data returned from other PCORnet participants before it is shared with a PCORnet Requestor.

D. Data to inform *potential* future research

Data to inform potential future research takes the form of a pre-prep-to-research query. Pre-prep-to-research queries are a data type 2; however, pre-prep-to-research queries only release aggregate results for a combination of two or more REACHnet partner systems and do not provide system-specific results.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the *Regulatory Requirements* section IV above.
2. Approval from Partner Health Systems Leadership is not required prior to running a pre-prep-to-research query or releasing the results to the requester.

To protect patient privacy, except in the case of PCORnet queries, REACHnet does not release query results where the cell count is between 1-10. If query results are between this range, they are marked as "LE 11" or "below threshold (BT)." For PCORnet Queries in which Participant chooses to participate, Participant shall return low cell counts of Participant Data so that accurate counts of the availability of PCORnet's total results can be obtained. In the event that Participant returns cell counts <11, Data will be masked and aggregated with Data returned from other PCORnet participants before it is shared with a PCORnet Requestor.

E. Data for administrative purposes

Data for administrative purposes are defined as data types 1 and 6.

1. No data, regardless of type, will be released without fulfillment of applicable regulatory requirements as summarized in the Regulatory Requirements section IV above.

2. Approval from participating health systems is not required prior to running data type 1 or 6 queries or releasing the results to PCORnet.

Table 1: Partner Health System Leadership Approval Requirements for Data Types

CATEGORY	REACHnet & PCORnet DSA data types	APPROVAL REQUIREMENT (for partner health system participation)	APPROVAL REQUIREMENT (before data release)
Prospective studies (e.g.,ongoing study with multiple data deliverables)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
Retrospective studies (e.g., data-only request associated with one single data deliverable)	Types 2-5	Approval to participate must be sent to REACHnet Coordinating Center via email	No approval necessary before data release
PTR queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results (72 hours/3 business days allowed for review and opt-out for non-PCORnet queries)
PTA queries (e.g., not yet associated with an active or proposed study)	Type 2	Approval required prior to query run	Approval is required prior to releasing results
Pre-PTR queries	Type 2	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results
Administrative queries	Type 1	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results
Matching assessment queries	Type 6	Approval is NOT required prior to query run	Approval is NOT required prior to releasing results

VI. Engagement Services

Engaging patients, clinicians, and community stakeholders during proposal development follows PCORI's suggested steps for engaging stakeholders throughout the entire research process. (More information about stakeholder engagement can be found in PCORI's Engagement Rubric.)

To help support investigators with project-specific engagement needs, REACHnet has developed an engagement infrastructure that includes services such as consultation on engagement plan development and resources such as access to REACHnet's *Health in Our Hands* patient network. Investigators who are interested in collaborating with REACHnet to fulfill their engagement needs are encouraged to submit a *Request for Engagement Services* form.

NOTE: Investigators who are requesting engagement services *in addition to other REACHnet services* as a component of prospective research do not need to complete a separate *Request for Engagement Services*

form. Instead, this request should be detailed in the section entitled "Stakeholder Engagement Services" of the *Prospective Research Request* form.

Given that many funding opportunities now require that proposals outline plans for engagement of patients and other stakeholders, (e.g. caretakers, community members, clinicians, etc.), it is strongly recommended that investigators complete this form *several months prior* to preparing their proposal.

A. Requirements for Engagement Services Requests

Investigators who wish to access REACHnet engagement services are invited to submit a request addressing the following components of their proposed research project:

1. Purpose of engagement within the project
2. Description of condition or community of interest
3. Description of project's engagement needs and goals
4. Description of research team's current resources and level of experience with engagement in research
5. Selection of specific REACHnet engagement services/resources
6. Engagement requirements set forth by funder, if applicable

B. Review Process & Communication of Decision

Requests for Engagement Services will be reviewed by the REACHnet Coordinating Center. Within 5 working days after the request is submitted via Eco, the investigator will receive an email notification that their project is "under review". If the engagement request is deemed feasible by the REACHnet Coordinating Center, the investigator will receive an email notification that their project is "approved". At this time, REACHnet engagement personnel will communicate directly with the investigator via Eco, phone, or email to more thoroughly discuss the investigator's request and collaborate on the development of a scope of work and budget for engagement services.

VII. IRB Requirements

REACHnet supports shared or ceded IRB review among network partners. REACHnet partners are members of two platforms that facilitate shared and ceded reviews: (1) IRBchoice (https://www.irbchoice.org/p/) and (2) SMART IRB (https://smartirb.org/).

Prior to IRB submission, investigators are encouraged to contact REACHnet personnel for guidance on IRB procedures using one of the two shared review platforms. PCORnet-designated and NIH-funded studies are required to use SMART IRB. Other studies may use SMART IRB or IRBchoice.

The IRB processes for various research scenarios are summarized in Table 2.

Table 2: IRB Process Guidance by Research Scenario

Research Design	Partnership Framework	IRB Framework
Deidentified data Observational No individual patient consent	Co-investigators at each data contributing institution	IRB Exemption(s) obtained; or lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB
	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; *IRBs for data*

		contributing institutions without investigators engaged in the research do not require review
Limited dataset Observational No individual patient consent	Co-investigators at each data contributing institution	Lead IRB identified; ceded or shared review by all data contributing institutions using IRB choice or SMART IRB
	Some data contributing institutions do not have an investigator engaged in the research	Lead IRB identified; ceded or shared review by data contributing institutions with investigators engaged using IRB choice or SMART IRB; IRBs for data contributing institutions without investigators engaged in the research do not require review
Health in Our Hands and/or survey data collection Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB
Interventional trial Prospective Patient recruitment/consent	Co-investigators at each participating institution	Lead IRB identified; ceded or shared review by all participating institutions using IRB choice or SMART IRB

VIII. Reporting Requirements

At the conclusion of the study, research findings must be reported to REACHnet. It is recommended that investigators assist in the summary and dissemination of results in a patient-friendly format, including through the Health in Our Hands patient network and on the REACHnet website.

Investigators are required to notify REACHnet of any manuscripts accepted for publication and abstracts or papers accepted for presentation within 15 days of acceptance. Authors/presenters are required to formally acknowledge REACHnet in all publications and presentations of research conducted using the network.

Please refer to REACHnet's Dissemination Policy for all manuscripts and conference presentations derived from research conducted via REACHnet.

1. **Acknowledgments section of manuscript or report:**
    a. It is required that the following language be included in the Acknowledgements Section of the manuscript or report to acknowledge collaboration with REACHnet: "*The research reported in this [work, publication, article, report, presentation, etc.] was conducted in partnership with Research Action for Health Network (REACHnet), funded by the People Centered Research Foundation (1274). REACHnet is a partner network in PCORnet®, the National Patient-Centered Clinical Research Network. PCORnet® has been developed with funding from the Patient Centered Outcomes Research Institute (PCORI). REACHnet's participation in PCORnet® has been funded through PCORI Award (CDRN 1306-04864). The*

content of this [work, publication, article, report, presentation, etc.] is solely the responsibility of the author(s) and does not necessarily represent the views of other organizations participating in, collaborating with, or funding REACHnet or PCORnet®, or of PCORI."

b. In addition to the funding acknowledgement, the following standardized acknowledgement of the REACHnet partnership will be used for ALL publications, presentations, and other dissemination-related activities, regardless of the authors listed: "*The authors acknowledge the participation of REACHnet partner health systems: [name all participating health systems, if permission is given to list*] in this project."*
**Data contributors may be listed if verification from the respective health system's REACHnet Co-PI is obtained. If the participating health systems wish to remain anonymous, their name(s) will not be listed here.*

2. **Citing a prep-to-research query or analysis using data from REACHnet's CDM Data Warehouse:** Investigators are required to cite all results acquired from REACHnet partner data that are presented in any format. The following language is recommended for citing prep-to-research or analysis results using data from REACHnet's CDM Data Warehouse: Research Action for Health Network, Louisiana Public Health Institute. Date dataset was created or updated. *Title or brief description of dataset, including time period, target patient population and health system(s) covered in the data if applicable* [Data file/Prep-to-research query]. New Orleans, Louisiana: Louisiana Public Health Institute.

Appendix A: REACHnet Partner Health System Leadership

REACHnet's decision-making is primarily governed by a group of representatives from REACHnet's partner health systems (i.e., data contributors) and institutions. The appointees' decision-making responsibilities vary by health system/institution depending on the extent of the system's data contribution. The table below lists the representatives from each partner health system/institution who are responsible for decision-making for REACHnet.

REACHnet Decision-Making: Partner Health Systems' & Institutions' Leadership	
Ochsner Health	**Eboni Price-Haywood, MD, MPH, FACP** *Director, Center for Outcomes and Health Service Research* Ochsner Health
Baylor, Scott & White Health	**Elisa Priest, DRPH, MPH** *Director, Research Suport Cores* Baylor Scott & White Research Institute
Pennington Biomedical Research Center (PBRC) NOTE: PBRC does not house clinical data and is therefore only responsible for sharing research opportunities with institutional investigators.	**Peter Katzmarzyk, PhD, FACSM, FAHA** *Associate Executive Director for Population and Public Health Sciences, Marie Edana Corcoran Endowed Chair in Pediatric Obesity and Diabetes* Pennington Biomedical Research Center
Tulane University Schools of Medicine and Public Health/Tulane Medical Center (HCA)	**Vivian Fonseca, MD, FRCP** *Tullis-Tulane Alumni Chair in Diabetes, Professor of Medicine, Chief – Section of Endocrinology* Tulane University School of Medicine
Partnership for Achieving Total Health (PATH)/Greater New Orleans Health Information Exchange (GNOHIE) NOTE: Approval for release of query results is given by the Executive Director, whereas approval to participate in prospective research is solicited at the clinic level.	**Thomas Carton, PhD, MS** *Executive Director of PATH* Louisiana Public Health Institute
University Medical Center New Orleans (LCMC Health)	**Jyotsna Fuloria, MD** *Vice President of Clinical Research* University Medical Center New Orleans
Louisiana State University Health Sciences Center	**Lucio Miele, MD, PhD** *Professor and Chair, Department of Genetics* LSU School of Medicine
DHR Health Institute for Research and Development	**Sohail Rao, MD, MA, DPhil** *President & CEO* DHR Health Institute for Research & Development
University of California San Francisco (UCSF) Medical Center	**Mark Pletcher, MD, MPH** *Professor, Epidemiology and Biostatistics* UCSF School of Medicine