

Non-Government Application for Massachusetts All-Payer Claims Data [Exhibit A]

I. INSTRUCTIONS

This form is required for all Applicants, except Government Agencies as defined in [957 CMR 5.02](#), requesting protected health information. All Applicants must also complete the [Data Management Plan](#), attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the Organization. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's [Data Use Agreement](#). Applicants may wish to review that document prior to submitting this Application.

Before completing this Application, please review the data request information on CHIA's website:

- [Data Availability](#)
- [Fee Schedule](#)
- [Data Request Process](#)

After reviewing the information on the website and this Application, please contact CHIA at apcd.data@state.ma.us if you have additional questions about how to complete this form.

All attachments must be uploaded to IRBNet with your Application. All Application documents can be found on the [CHIA website](#) in Word and in PDF format or on [IRBNet](#) in Word format. If you submit a PDF document, please also include a Word version in order to facilitate edits that may be needed.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is submitted. A [Fee Remittance Form](#) with instructions for submitting the application fee is available on the CHIA website and IRBNet. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet.

II. FEE INFORMATION

1. Consult the most current [Fee Schedule](#) for All-Payer Claims Database data.
2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.data@state.ma.us.
3. If you believe that you qualify for a fee waiver, complete and submit the [Fee Remittance Form](#) and attach it and all required supporting documentation with your application. Refer to the [Fee Schedule](#) (effective Feb 1, 2017) for fee waiver criteria.
4. Applications will not be reviewed until the application fee is received.
5. Data for approved Applications will not be released until the payment for the Data is received.

III. ORGANIZATION & INVESTIGATOR INFORMATION

Project Title:	Urban-rural disparities in healthcare for children with medical complexity
IRBNet Number:	
Organization Requesting Data (Recipient):	Dartmouth College
Organization Website:	http://tdi.dartmouth.edu/
Authorized Signatory for Organization:	Jill Mortali
Title:	Director, Sponsored Projects
E-Mail Address:	Jill.M.Mortali@dartmouth.edu
Address, City/Town, State, Zip Code:	Dartmouth College, Office of Sponsored Projects, 11 Rope Ferry Road, Hanover, NH, 03755
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Dr. David Goodman
Title:	Professor, Department of Pediatrics & The Dartmouth Institute for Health Policy & Clinical Practice
E-Mail Address:	David.C.Goodman@dartmouth.edu
Telephone Number:	603-650-5000
Address, City/Town, State, Zip Code:	TDI, Williamson Translational Research Building, Dartmouth Hitchcock Medical Center, 1 Medical Center Drive, Lebanon, NH, 03766
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Dr. JoAnna Leyenaar
Title:	Associate Professor of Pediatrics & The Dartmouth Institute for Health Policy & Clinical Practice
E-Mail Address:	JoAnna.K.Leyenaar@hitchcock.org
Telephone Number:	603-653-0855
Names of Co-Investigators:	Dr. David Goodman, MD Dr. James O'Malley, PhD Ms. Megan Murphy, MS Ms. Devin Parker, MPH Dr. Erika Moen, PhD Dr. Andrew Schaefer, PhD
E-Mail Addresses of Co-Investigators:	David.C.Goodman@dartmouth.edu James.OMalley@dartmouth.edu Megan.A.Murphy@dartmouth.edu Devin.M.Parker@dartmouth.edu Erika.L.Moen@dartmouth.edu Andrew.P.Schaefer@dartmouth.edu

IV. PROJECT INFORMATION

1. What will be the use of the CHIA Data requested? [Check all that apply]

- | | | |
|---|--|--|
| <input type="checkbox"/> Epidemiological | <input type="checkbox"/> Health planning/resource allocation | <input type="checkbox"/> Cost trends |
| <input type="checkbox"/> Longitudinal Research | <input type="checkbox"/> Quality of care assessment | <input type="checkbox"/> Rate setting |
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> X Research studies | <input type="checkbox"/> Severity index tool |
| <input type="checkbox"/> Surveillance | <input checked="" type="checkbox"/> X Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> Other (describe in box below) | |

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

One-in-five American children live in rural areas, and one-quarter of these children – 2.95 million - have chronic health conditions. Survey data have documented several urban-rural disparities in healthcare quality: rural-residing children are more likely to report unmet healthcare needs and less likely to receive preventive healthcare than children who live in urban areas. In a study of hospitalizations at freestanding children’s hospitals, rural-residing children had a higher prevalence of complex chronic conditions, higher inpatient costs, and greater risk of readmission than their urban-residing peers. However, at a population level we have extremely limited knowledge about the magnitude and determinants of urban-rural disparities in healthcare utilization and quality; this knowledge is essential to develop effective interventions that reach children at greatest risk of adverse health outcomes. The overall objective of this proposal is to comprehensively evaluate urban-rural disparities in healthcare utilization and quality for children and adolescents up to 18 years of age with social risk factors and chronic illnesses, including cancers, progressive and multisystem illnesses, and mental and behavioural health conditions. We will conduct a retrospective cohort analysis of healthcare claims data (commercial and Medicaid) to achieve the following Specific Aims: 1) Develop cohorts of urban- and rural-residing children with social risk factors and chronic illnesses using established ICD-9/10 based algorithms, and determine how urban- and rural- residing children differ with respect to clinical and demographic characteristics; 2) identify disparities in home health, ambulatory and inpatient healthcare use between children who reside in urban and rural settings, 3) Identify disparities in healthcare quality for children and identify individual-, family-, community- and health-system factors associated with these disparities, 4) Construct patient-sharing networks among physicians who care for children and determine whether network characteristics of physicians are associated with disparities in quality of care.

3. Has an Institutional Review Board (IRB) reviewed your Project?

- X **Yes** [If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.]
- No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology:** Applicants must provide either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V. PUBLIC INTEREST

1. Briefly explain why completing your Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health,*

health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.

Disparities in healthcare quality for children may have substantial downstream impacts – for example, poor quality of care in ambulatory care settings may result in increased healthcare costs in the form of hospitalizations or chronic disease complications. Our research may ultimately lower healthcare costs by identifying risk factors for poor healthcare quality among children in MA. Our primary goal is to characterize urban-rural disparities in healthcare quality for children and to ultimately improve child health by identifying factors at the level of the child, the family, the health system and the community that may be associated with disparities in healthcare quality. These factors may then be addressed in clinical care and/or healthcare policy to improve the health of children in MA. We have identified several established measures of quality of care that can be operationalized using claims data. By characterizing disparities in healthcare quality for urban and rural residing children, as well as community and health system factors associated with these disparities, we will provide foundational data from which clinicians, administrators and policy makers can work to improve healthcare quality.

VI. DATA REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. Data requests will be fulfilled using the most current Release Version. For more information about the most current APCD Release Version, including available years of data and a full list of elements in the release please refer to release layouts, data dictionaries and similar documentation included on [CHIA's website](#).

Data requests are typically fulfilled on a one time basis, however; certain Projects may require future years of data that will become available in a subsequent release. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial Release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. List years of data requested (only list years available in the [current Release Version](#)): 2013-2017

2. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

X **One-Time Request** OR Subscription

3. Specify below the data files requested for this Project, and provide your justification for requesting each file.

X **Medical Claims**

Describe how your research objectives require Medical Claims data: We will use medical claims data to identify our cohort of children with chronic illnesses and disabilities using established ICD-9 and ICD-10 based algorithms. We will also use this data to identify healthcare encounters along the care continuum from home care to ambulatory and hospital-based care. Finally, we will use medical claims to develop our quality measures (for example, emergency department visits for ambulatory care sensitive conditions) and measures of aggregate health system utilization (based on cumulative RVUs). We require NPI to determine the type of provider for each medical claim (e.g., family practice, pediatric cardiology) based on linkage of NPI with the CMS NPI file

(linking taxonomy code with NPI).

Pharmacy Claims

Describe how your research objectives require Pharmacy Claims data:

Dental Claims

Describe how your research objectives require Dental Claims data:

X Member Eligibility

Describe how your research objectives require Member Eligibility data: We will use Member Eligibility data to determine the primary payor for each child in our cohort (Medicaid or commercial payer), and to determine duration of enrollment.

Provider

Describe how your research objectives require Provider data:

Product

Describe how your research objectives require Product data:

VII. DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of Data to the minimum amount of data needed to accomplish a specific Project objective.

All-Payer Claims Database data is released in Limited Data Sets (LDS). All applicants receive the “Core” LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the core elements and additional elements), please refer to [release layouts](#), [data dictionaries](#) and similar documentation included on CHIA’s website.

1. Specify below which enhancements you are requesting in addition to the “Core” LDS, provide your justification for requesting each enhancement.

Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select one of the following options.

<input type="checkbox"/> 3-Digit Zip Code (standard)	<input checked="" type="checkbox"/> X 5-Digit Zip Code***
<p>*** If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: The primary aim of this research will be to determine urban-rural disparities; we require 5-digit zip code to determine the urban- or rural-residence of children using Rural-Urban Commuting Area codes. In addition, we require 5-digit zip code to calculate travel times from individuals’ home zip code centroid to the place of healthcare delivery (e.g., emergency department).</p>	

Date Resolution

Select one option from the following options.

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> X Day (YYYYMMDD) *** [for selected data elements only]
<p>*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: We are requesting day to understand the temporality between visits (for example, 7-day readmissions following hospital admission versus 30- or 365-day readmissions, timing of follow-up following hospital discharge), number of ambulatory care visits per date, number of dates in which the children engage with the healthcare system, and to ensure that we do not have duplicate counts of clinical encounters (e.g., to limit hospital days to one per date).</p>		

National Provider Identifier (NPI)

Select one of the following options.

<input type="checkbox"/> Encrypted National Provider Identifier(s) (standard)	<input checked="" type="checkbox"/> X Decrypted National Provider Identifier(s)***
<p>*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: We require decrypted NPIs to determine the taxonomy of each provider (i.e. pediatric cardiology), which we will determine by linking NPI to the CMS taxonomy codes.</p>	

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

- X Yes
 No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program.* Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

Our goal in conducting this research is to provide information that will directly support clinical care, Medicaid and commercial insurance program administration, and other health policy for children. While urban-rural disparities in healthcare quality have been the focus on national survey research, surveys are subject to recall bias and low response rates, and may not reach populations at greatest risk. Using these data, we will identify disparities in healthcare access and outcomes among children in MA who live in urban and rural regions, and will determine factors associated with these disparities. These findings can then be used by healthcare providers, administrators and policymakers to improve healthcare quality for children at risk of poor outcomes. As a result, we anticipate that this project will provide valuable data for MassHealth regarding disparities in healthcare access and quality experienced by their beneficiaries. This is particularly relevant for children with chronic illness, many of whom receive MassHealth benefits.

IX. DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?

- X Yes
 No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]

- Individual Patient Level Data (e.g. disease registries, death data) - THIS IS UNCHECKED
 X Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
 X Individual Facility Level Data (e.g., American Hospital Association data)
 X Aggregate Data (e.g., Census data)
 Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

- 1) 5-digit ZIP code will be linked to the Rural Urban Commuting Area codes to characterize children and urban and rural-residing. We will also use 5-digit ZIP code to link with American Community Survey characteristics to describe community-level characteristics (i.e. % children living in childhood poverty by ZIP code)
- 2) At the provider level, we will link NPI with CMS taxonomy files to determine provider taxonomy/specialty (e.g., family medicine, pediatric cardiology).
- 3) At the facility level, hospital name will be linked to the American Hospital Association data to categorize hospitals according to size and provision of pediatric services (e.g., freestanding children's hospital, hospital with pediatric services)

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

We will use the variables within the APCD listed above to link directly with the datasources provided. There will be no probabilistic linkages.

5. If yes, attach or provide below a complete listing of the variables from all sources to be included in the final linked analytic file.

- 1) From the 5-digit zipcode linkage with Rural Urban Community Area codes, we will characterize each individual as (i) urban-residing or (ii) rural residing;
- 2) From the 5-digit zipcode linkage with the American Community Survey we will develop the following community-level characteristics: (i) median household income for zip-code; (ii) % children living in poverty for zip-code; (iii) parental educational level for zip-code;
- 3) From the linkage of NPI with the CMS taxonomy files we will categorize each provider as a (i) general pediatrician, (ii) nurse practitioner or physician's assistant; (iii) family physician; (iv) other generalist, (v) pediatric specialist; (vi) non-pediatric specialist
- 4) For the linkage of hospital name with the American Hospital Association file we will characterize the closest hospital of the child as a: (i) children's hospital, (ii) non-children's hospital

Note: We will not be linking MA data to APCD from other states. We will conduct each state's data analysis separately. In all tables and results presentations, we will abide by cell suppression requirements. We will not be linking any individual-level data.

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

All of these variables will be reported in aggregate only; we will abide by all cell-suppression policies. None of the variables listed above could result in identification of individual patients or providers.

X. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications **will not disclose a cell less than 11**, and percentages or other mathematical formulas that result in the display of a cell less than 11.

Results of this research will be published in peer reviewed scientific journals, and via abstracts and presentations at professional society meetings. We will ensure that all publications will not disclose a cell less than 11, and no percentage or mathematical formula will allow for the calculation of cell size numbers less than 11. The PI, Dr. Leyenaar, will review all abstracts, papers and presentations to ensure adherence to this policy.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

We do not anticipate dissemination of results internally, except within the research team to review interim results and to discuss next steps.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

We will use 5-digit zip codes for the purpose of categorizing individuals as urban or rural residing according to the Rural-Urban Commuting Areas (RUCA) categorization. The lowest level of analysis that will be presented will be the RUCA tiers of urban or rural. We will not be presenting maps or region-specific data.

4. Will you be using CHIA Data for consulting purposes?

- Yes
 No

5. Will you be selling standard report products using CHIA Data?

- Yes
 No

6. Will you be selling a software product using CHIA Data?

- Yes
 No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index tool, risk adjustment tool, reference tool, etc.)

- Yes
 No

8. Will you be reselling CHIA Data in any format not noted above?

- Yes
 No

If yes, in what format will you be reselling CHIA Data?

9. If you have answered “yes” to questions 5, 6, 7 or 8, please describe the types of products, software, services, or tools.

10. If you have answered “yes” to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

XII. APPLICANT QUALIFICATIONS

1. Describe your previous experience using claims data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

The Dartmouth Institute has longstanding experience using claims data for research purposes. Drs. Leyenaar, Goodman and O’Malley, and research assistant Ms. Parker are currently using Colorado all payer claims data to complete an analogous evaluation to that presented here in that state. Dr. Goodman previously used APCD from VT, NH and ME to create *The Dartmouth Atlas of Children’s Health Care in Northern New England* to characterize population-level resource utilization for children in these states. In addition, Dr. Goodman and colleagues used the APCD from these three states to focus specifically on children with chronic illnesses, examining regional variation in health system use. Drs. O’Malley, Goodman and Moen also have extensive experience using Medicare claims data for research purposes.

Most significantly, Dr. Goodman has received MA APCD for an analysis of variation in newborn care in MA. We will utilize the same data storage and management infrastructure as previously approved by CHIA.

2. **Resumes/CVs:** When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Agency must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without

prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.*]

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	
Company Website	
Contact Person:	
Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

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2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

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3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

- Yes
 No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	
Company Website:	
Contact Person:	

Title:	
E-mail Address:	
Address, City/Town, State, Zip Code:	
Telephone Number:	
Term of Contract:	

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

3. Will the agent or contractor have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

Yes

No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

IVX. ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access,

disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Applicants approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) that the requested Data is the minimum necessary to accomplish the purposes described herein; (3) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (4) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	
Printed Name:	Jill Mortali
Title:	Director, Office of Sponsored Projects

Attachments

A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:

- X 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
- X 2. Data Management Plan; including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database
- X 3. CVs of Investigators (upload to IRBnet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.

[INSERT IRB approval letter and protocol, or research methodology]