341

HUMAN SUBJECT RESEARCH – DETERMINATION FORM

This form should be completed and submitted to the UCHC IRB when an investigator proposes a project using human materials or human data that s/he does not believe constitutes human subject research. **The IRB Office is located in the Munson Building on the 2nd Floor. The interoffice mail code is 3926**. The investigator must provide adequate information for the IRB Chair to determine whether the project constitutes human subject research. If the Chair determines that a project is not human subject research the HSPO/IRB will have no on-going involvement with the project. If the project is deemed to meet the definition of human subject research, a complete IRB application will be required with the IRB providing guidance as to the type of review required. The IRB will also provide guidance on any HIPAA related issues.

Name of Investigator:	Martin Cherniack MD MPH
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E-mail:	Cherniack@uchc.edu Please contact Jeff Dussetschleger X1393 jdussetschleger@uchc.edu in regards to this request.

1. Provide a brief summary of the project.

See attached "Scope of Work"

2. Provide detailed description of all human material and/or data elements to be used in the project. (tabbing out of the bottom right cell will insert another row)

Human Materials	Data Set Elements/Fields	For IRB Use - Assigned Data Set #
Please see attached project grant pages 17-26		

3. Describe the source of the material / data. (e.g. existing samples in (give name of person's lab), purchased samples from (give company name), waste material gather from (describe accordingly), downloaded data from (describe data source) etc.)

The source material is health and lifestyle data that is collected during the routine business activities of Viridian Health Management

4. Place an **X after** any of the following HIPAA identifiers that will be contained in the data, or indicate that none of the identifiers in this list will be contained in the information, alternatively if no protected health information is being seen or collected indicate that HIPAA is not applicable.

Names		Unique identify #s, characteristics or codes		Geographic Subdivisions	
Phone		Serial #s		Health Plan Beneficiary	
Fax		Account #s		Vehicle Identifiers	
E-mail		Social Security #s		Biometric Identifiers	
URL		License #s		Device Identifiers	
IP Address		Medical Record #s		Dates (except year)	
None of the identifiers listed above will be included with the samples/data used for the study					**X**

The project does not involve the use of any protected health information, HIPAA is NA	

5. Describe how the material and/or data will be labeled/identified/coded at the time of receipt.

The data will be de-identified prior to our receiving the dataset. Each case will have an ID# but we will not have the key to link the data. The key will be kept by the provider of the data. We will be executing a "do not ask, do not provide" agreement between us and the data provider.

If data/samples are coded, answer the following questions:

6. Were the data / specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals? (If yes, and the data and/or specimens contain information about an individual, the project constitutes human subject research.)

7. Explain how the code is derived; if unknown to anyone on the research team, provide a statement to that effect.

8. Describe the access /ability / possibility for anyone involved with the project to, in any way, link a code to an individual.

It will not be possible for us to decoded the data as the key will be with the data collector/provider with and execute agreement stating that they will not share the key with us.

9. Place an X after the mechanism(s) in place to minimize the chance of the code being linked to an individual.

The key to decipher the code will be destroyed prior to initiation of the research.	
The investigator(s) and the key holder have entered into a written agreement prohibiting the release of the key while individuals are living (**attach for reference**).	
There are existing policies and operating procedures in place for a repository or data management center that have been approved by the IRB and that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased (**Provide IRB # of the approved registry/repository**).	
There are other legal requirements preventing the release of the key to the investigators (**describe accordingly on attached document**).	

Signature of Investigator **Date**

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FOR IRB USE ONLY:

1. Determine whether the proposed activity constitutes research according to either the Common Rule (45 CFR 46) or the FDA (21 CFR 50).

DHHS Definition of Research:	**Yes / No**

a. Is the activity a systematic investigation (including research development, testing and evaluation)?	yes
b. Is the activity designed to develop or contribute to generalizable knowledge?	yes
FDA Definition of Clinical Investigation:	
c. Any experiment that involves a test article and one or more human subjects that requires prior submission under 505(i) or 520(g) or for which the results are intended to be submitted later to or held for inspection by the FDA as part of an application for a research or marketing permit.	
Note: If yes to item a and to item b together and /or to item c alone, the activity is research under DHHS and/or FDA regulations. Proceed to question 2. If no to item a or b the activity is not research under DHHS regulations. If no to item c, the activity is not research under FDA regulation. If the activity is not research under either regulation, stop.	

2. Determine whether the activity involves human subjects.

DHHS Definition of Human Subject	**Yes / No**
a. Are data being obtained <u>about</u> one or more living individuals? (if yes proceed to item b, c and d, if no proceed to item d)	yes
b. Are the data collected through an intervention (physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes) or interaction (communication or interpersonal contact between investigator and subject) with the individual?	no
c. Is identifiable private information being obtained? Private identifiable information includes behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. medical record, being obtained?	no
FDA Definition of Human Subject:	
d. Does the project involve an individual (either a healthy human or a patient) who is or becomes a participant in research, either as a recipient of the test article or as a control?	no
e. Does the project involve an individual (in normal health or with a medical condition or disease) who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control?	no
Note: If no to a, the research does not involve human subjects under DHHS Regulations If yes to a, and also to b **and/or** c, the research does involve human subjects per DHHS regs If yes to a, and no to b **and** c – human subjects are not involved per DHHS regulations If no to d and e, the research does not involve human subjects under FDA regulations If yes to d and/or e, the research does involve human subjects per FDA regulations	

Note: Private information must be individually identifiable (i.e., the identity of the subject **is or may readily be** ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

IRB DETERMINATION – CHECK THE APPLICABLE CATEGORY(IES):

Human Subject Research Determination

Project is human subject research and will require an IRB submission.	
Project is not human subject research and IRB involvement is not required.	✓

HIPAA Determination

Project contains HIPAA defined identifiers and therefore HIPAA must be addressed.	
Project contains no HIPAA identifiers therefore HIPAA does not pertain.	✓

If the project is not Human Subject Research but HIPAA must be addressed, provide directions for the investigator to ensure HIPAA compliance:

Note to investigator: If the IRB has determined that a data set does not constitute human subject research, that data set may be used in other projects without additional determinations being made by the IRB. If additions/modifications are made to the data elements/field(s) noted above investigators are strongly encouraged to resubmit the revised information to the IRB for anther determination.

Judith M. Fulks 11/29/11

Signature of IRB reviewer making the determination Date