I.

Title: **A Longitudinal, Case-Control Study to Collect Medical and Epidemiological Data and Blood Samples for Research Into the Causes of Multiple Sclerosis and Selected Demyelinating Diseases**

Protocol Number: **Protocol ACP- 001**

Date: **July 12, 2011**

Version: **3.0**

Sponsor:

Accelerated Cure Project for MS
300 Fifth Avenue
Waltham, MA 02451
781-487-0008

Approved by:

Hollie Schmidt Hollie Schmidt
(Vice President Scientific Operations)

II. Table of Contents

III. Glossary of Abbreviations and Definitions

ACP	Accelerated Cure Project for Multiple Sclerosis
ADEM	Acute Disseminated Encephalomyelitis
Case	Subject **with** the outcome of interest (at least one CNS demyelinating event characteristic of MS, TM, ADEM, NMO or ON)
CCS	Confidential Contact Sheet (Attachment II)
CNS	Central Nervous System
Control	Subject **without** the outcome of interest (no CNS demyelinating event characteristic of MS, TM, ADEM, NMO or ON)
CRF	Case Report Form
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonization
IRB	Institutional Review Board
MS	Multiple Sclerosis
NMO	Neuromyeltis Optica
OHRP	Office for Human Research Protections
ON	Optic Neuritis
PI	Principal Investigator
PUF	Participant Unit Form (Attachment I)
Subject	An individual who is or becomes a participant in clinical research, either as a case or as a control.
TM	Transverse Myelitis

1 ETHICS

1.1 Institutional Review Board (IRB)

The protocol and consent form for this study will be reviewed and approved by a duly constituted IRB before subjects are screened for entry into the study. The study may not start until written approval has been obtained and a copy has been provided to Accelerated Cure Project for Multiple Sclerosis (Sponsor). The Principal Investigator (PI) may not participate in the IRB's decision.

1.2 Principles of Good Clinical Practice (GCP)

This study will follow the general principles of Good Clinical Practice as outlined in the ICH Guidelines (1996) and in accordance with local and national guidelines.

1.3 Subject Information and Informed Consent

Each subject will be provided with oral and written information describing the nature and duration of the study in a language they can understand before signing and dating the consent form. If the subject is able to give only oral consent, a legally authorized representative for the subject who has witnessed the consent process will sign and date the consent form for the subject. The Site will retain the original signed consent form in a secure area. The subject will receive a copy of the signed and dated consent form prior to the conduct of any study related activities.

If the subject is a child under the age of 18, the child's parent will be provided with oral and written language describing the nature and duration of their child's participation in the study. The parent will be asked to sign and date a parental permission form prior to assent being sought from the child.

The child will be provided with oral and written language describing the nature and duration of the study in language appropriate to the child's age before signing and dating the assent form. If the pediatric subject is able to only give oral assent, a legally authorized representative for the subject who has witnessed the assent process will sign and date the assent form for the subject. The Site will retain the original signed permission form and the assent form in a secure area. The pediatric subject will receive a

copy of the signed and dated assent form prior to the conduct of any study related activities. The parent of the subject will receive a copy of the signed and dated permission form prior to the conduct of any study related activities.

1.4 Protocol Amendments

Amendments to the protocol will be subject to the same requirements as the original protocol. The PI will submit all periodic reports and updates as required by the IRB, including any final close out reports. The PI will inform the IRB and Sponsor of any reportable adverse events.

1.5 Subject Reimbursement

Subjects will be reimbursed a nominal amount for transportation costs and the time to participate in the study.

1.6 Confidentiality

In order to protect the privacy of each subject, materials collected from the subject (blood samples and data) will be anonymized of personally identifying information and will be identified only through a 5-digit randomly assigned barcode. The link between the barcode and the subject's identity will be maintained only by the Sponsor and will be held in a secure database.

Refer to sections 5.3 and 5.4 for additional information regarding confidentiality.

2 STUDY PERSONNEL

2.1 Sponsor

Accelerated Cure Project for Multiple Sclerosis
300 Fifth Avenue
Waltham, MA 02451
Phone: 781-487-0008
Fax: 781-487-0009

2.2 Contract Research Organization

Coordinating Center

Theorem Clinical Research, Inc.
630 Allendale Road
King Of Prussia, Pennsylvania 19406
Phone: 484-679-6714
Fax: 484-679-2410

2.3 Data Management

Document Solutions Group, Inc.
325 Technology Drive
Malvern, PA 19355
Phone: 484-913-0210
Fax: 494-913-0224

2.4 Central Laboratory

SeraCare BioServices
8425 Progress Drive
Frederick, MD 21701
Phone: 301-668-8100
Fax: 301-668-3416

3 INTRODUCTION AND STUDY RATIONALE

Multiple Sclerosis (MS) is a chronic disease of the Central Nervous System (CNS) in which demyelination occurs with varying degrees of inflammation and axonal injury. Irreversible disability in MS occurs as a consequence of neural conduction blockages due to the combined effects of segmental demyelination and axonal transection. MS is more common in women than men (~2:1), and the age of presentation follows a normal distribution with the majority of cases presenting in the 3rd and 4th decades of life. The disease affects an estimated 400,000 people in the US and 2 million people worldwide. The causes of MS are unknown but believed to be multifactorial. There is currently no cure, and treatments currently approved are minimally effective.

MS is a complex disease and the etiology has been difficult to address via traditional approaches. Two characteristics in particular make it difficult to determine the causes using traditional approaches:

1) MS is most likely a multifactorial disease involving multiple simultaneous underlying causes. While there is significant evidence to support a heritable genetic component, it does not appear to be sufficient to cause the disease. This is best demonstrated by comparing the concordance rate for identical twins (25-

30%) with that for non-identical siblings (2%) and the prevalence in the general population (0.1%).

It is, therefore, assumed that one or more susceptibility genes are necessary to cause MS. However, inherited genetic susceptibility is not sufficient to cause disease and additional factors are thought to be required. These factors may include somatic mutations, pathogens, toxic agents, nutritional deficits, trauma, and/or various combinations of the above.

As a consequence of the etiologic complexity of MS as well as the lack of a single defined etiologic factor (genetic or environmental), it is necessary to look for the causes of MS broadly in all etiologic categories. Since environmental and genetic factors are expected to be dependent rather than independent variables, it will be optimal to structure research within a discipline so that the results can be usefully combined with the results in another discipline.

2) MS in reality is a syndrome (a group of signs and symptoms that collectively characterize a disease). Like most syndromes, it is most likely not due to the same underlying causes for all people. While the end result of destruction of myelin and axons may be the same, the initial triggers may be different in different people. This heterogeneity of causes may explain the extremely wide variety of clinical courses seen in the people with the diagnosis, and the variability in treatment efficacy from individual to individual.

The possibility of etiologic heterogeneity hinders attempts to determine the causes of MS due to the current lack of sufficiently large study populations. Since a group of people diagnosed with MS may actually be a group of people with a number of different diseases, it is currently impossible to accurately determine the correct size for many studies.

It is necessary to obtain as large a collection of samples for study as can be made available in order to search for subpopulations with common characteristics that are of significant size. One of the major roadblocks to addressing these two issues is access to a large number of blood samples with associated medical and epidemiological data that is collected in anticipation of being used in multi-disciplinary studies.

Accelerated Cure Project for Multiple Sclerosis (Sponsor) is creating a large-scale multi-disciplinary blood and data repository. This repository will be developed through the collection of blood samples and epidemiological data from people with MS, Transverse Myelitis (TM), Acute Disseminated Encephalomyelitis (ADEM), Neuromyelitis Optica (NMO) or Optic Neuritis (ON), their relatives (with and without demyelinating diseases) and unrelated subjects without demyelinating diseases.

MS, TM, ADEM, NMO and ON are distinct diseases, each characterized by demyelination of the spinal cord, optic nerves, brain or some combination thereof. While distinct, there is a great deal of overlap in the symptoms presented with each disease and during the early stages of diagnosis, it is often difficult to distinguish among the diseases. As a result, a synergy exists in the collection and study of samples and data from subjects with each of these diseases, as knowledge gained through the study of one disease may provide insights into one or more of the others. In addition, subjects with each of these diseases provide very useful control samples for the others.

The repository developed through the collection of samples and data will be made available as a resource to researchers working on determining the causes of MS, TM, ADEM, NMO and/or ON.

4 OBJECTIVES

The purpose of this study is to establish a collection of blood samples and associated data from approximately 10,000 people who have experienced at least one CNS demyelinating event (characteristic of Multiple Sclerosis (MS), Transverse Myelitis (TM), Acute Disseminated Encephalomyelitis (ADEM), Neuromyelitis Optica (NMO) or Optic Neuritis (ON)) and control subjects, both related and unrelated to the case. These samples and data will be made available for use in multi-disciplinary research involving MS, TM, ADEM, NMO and/or ON.

The goals of this study are to enroll:

- Subjects who have experienced at least one CNS demyelinating event (characteristic of MS, TM, ADEM, NMO or ON)
- Blood relatives who have not experienced at least one CNS demyelinating event
- Blood relatives who have experienced at least one CNS demyelinating event
- Unrelated subjects who have not experienced at least one CNS demyelinating event and who are suitable controls for subjects with demyelinating diseases

Blood samples and corresponding medical and epidemiological data will be collected periodically from each subject over the course of their lifetime.

5 RESEARCH PLAN

5.1 Overall design and plan of the study

This is an open, multi-center, linked longitudinal, case-control study for the collection of blood samples and personal and medical information. Subjects will be followed periodically every one to two years (or more frequently, based on relapse events or interim MD appointments for events such as the prescription of new treatments) over their lifetime in order to monitor changes in lifestyle, environment and health status, as well as to collect additional blood samples as needed.

5.2 Selection of study population

Subjects will initially be enrolled at 5 or more study centers in the United States with an enrollment goal of 1000 total subjects enrolled per year in an ongoing fashion, up to 10,000 subjects. Additional US and Canadian sites may be added in the future. Subjects and their collected material (samples and data) will be identified by a 5 digit alpha-numeric, randomly assigned by the central laboratory.

5.2.1 CASE Inclusion criteria

1. Individuals with at least one CNS demyelinating event characteristic of MS, TM, ADEM, NMO or ON. A demyelinating event is defined as a symptom or constellation of symptoms referable to a disruption of the CNS white matter or myelin within gray matter. Characteristic syndromes include hemibody sensory or motor symptoms, mono-sensory symptoms, monoparesis, brainstem syndrome or cerebellar syndrome, lasting at least 24 hours and not acute in onset.

2. Individuals at least 18 years old and able to give informed consent or individuals younger than 18 years old, with parental permission, and able to give assent.

3. Individuals at least 18 years old willing and able to provide up to 110 ml blood via venipuncture or individuals younger than 18 years old willing and able to provide up to 50 ml blood via venipuncture.

5.2.2 CASE Exclusion criteria

1. Individuals with clinical or radiological evidence of stroke, meningitis, neoplastic, peripheral nervous system or primary muscle disease, or other

well characterized and defined diseases of the nervous system with the exception of MS, TM, ADEM, NMO, ON (to help eliminate related neurological signs/symptoms).

2. Individuals with a history of blood borne pathogens (e.g. viral hepatitis, HIV/AIDS) due to Laboratory restrictions.

3. Individuals with a history of allogeneic bone marrow transplant due to changes in genetic material.

4. Individuals who weigh less than 37 pounds due to limits on blood collection.

5.2.3 CONTROL Inclusion criteria

1. Related and unrelated individuals who have not experienced any CNS demyelinating events characteristic of MS, TM, ADEM, NMO or ON, and have not been diagnosed with any demyelinating disease.

2. Individuals at least 18 years old and able to give informed consent or individuals younger than 18 years old, with parental permission, and able to give assent.

3. Individuals at least 18 years old willing and able to provide up to 110 ml blood via venipuncture or individuals younger than 18 years old willing and able to provide up to 50 ml blood via venipuncture.

5.2.4 CONTROL Exclusion criteria

1. Individuals with clinical or radiological evidence of stroke, meningitis, neoplastic, peripheral nervous system or primary muscle disease, or other well characterized and defined diseases of the nervous system (to help eliminate related neurological signs/symptoms).

2. Individuals with a history of blood borne pathogens (e.g. viral hepatitis, HIV/AIDS) due to Laboratory restrictions.

3. Individuals with a history of allogeneic bone marrow transplant due to changes in genetic material.

4. Individuals who weigh less than 37 pounds due to limits on blood collection.

5.3 Study Procedures

5.3.1 Recruitment and Informed Consent

Subjects will be screened based on the protocol inclusion and exclusion criteria and approached in accordance with institutional IRB policies and HIPAA regulations related to research recruitment for clinical trials. Subjects who are identified as meeting eligibility criteria will be approached by either the Principal Investigator (PI) or trained study staff to determine their interest in participation. Subjects may also be identified through referrals to the PI. The Case Report Form (CRF) may be provided to the potential subject for their review. No information from the CRF will be collected from any potential subject prior to the consent process being conducted and written informed consent obtained, and in the case of minors, with assent.

Subjects will be asked to refer blood related family members with and without MS, TM, ADEM, NMO or ON, as well as unrelated controls, to the study. The relatives and unrelated controls will then have the option to contact the PI in order to be screened. In addition, the PI will screen and approach unrelated control subjects in accordance with institutional IRB policies and HIPAA regulations related to research recruitment for clinical trials. Advertisements may be used to recruit subjects and will be submitted with each site application.

The PI or study staff will conduct the consent process. All adult subjects will be informed about the study by the PI or study staff, who will provide verbal and written explanations about the study to the satisfaction of the subject. Written informed consent will be obtained from each subject. If the subject is able to give only oral consent, a legally authorized representative for the subject who has witnessed the consent process will sign and date the consent form for the subject. The PI will retain the original consent form. A copy of the signed and dated consent will be provided to the subject at the time of consent. No study-specific procedures will be conducted prior to obtaining consent. Written informed authorization explaining the subject's rights to the protection of private health information will also be obtained from each subject as written and approved by the institution governing the study site.

If the potential subject in question is a pediatric subject, the PI or study staff will first obtain the permission of the subject's parent for the subject to participate in the study. The subject's parent will be informed about the study by the PI or study staff, who will provide verbal and written explanations about the study to the satisfaction of the subject's parent. Written parental permission will be obtained from each pediatric subject's parent. If the subject's parent is able to give only oral permission, a legally authorized representative for the subject who has witnessed the permission process will sign and date the permission form for the subject's parent. The PI will retain the original permission form. A copy of

the signed and dated permission form will be provided to the subject's parents at the time of permission. The pediatric subject will not undergo the assent process nor will any study-specific procedures be conducted prior to obtaining parental permission. Written informed authorization explaining the subject's rights to the protection of private health information will also be obtained from each subject's parent as written and approved by the institution governing the study site.

If the potential subject in question is a pediatric subject, once parental permission has been obtained, the PI or study staff will conduct the assent process. All subjects will be informed about the study by the PI or study staff, who will provide verbal and written explanations about the study to the satisfaction of the subject. Written informed assent will be obtained from each pediatric subject. If the subject is able to give only oral assent, a legally authorized representative for the subject who has witnessed the assent process will sign and date the assent form for the subject. The PI will retain the original assent form. A copy of the signed and dated assent will be provided to the subject at the time of consent. No study-specific procedures will be conducted prior to obtaining assent.

5.3.2 Study Methodology

Once the subject is properly consented, the PI or study staff will interview the subject and complete a Case Report Form (CRF) which includes lifestyle, environmental, geographical, medical history and health status/history questions. Each subject will be assigned a unique alphanumeric barcode in order to link all data collected, including blood samples, to the subject. All supportive diagnostic reports submitted will have personally identifying information blackened out prior to submission in order to protect the identity of the subject. The blood samples will be forwarded to a Laboratory/repository for further processing and storage while the CRF data will be electronically stored at a centralized data management company. Both the Data storage facility and the Laboratory/repository will identify subjects solely by barcode and will not have access to the subject's identity.

In order to protect the privacy of each subject, material will be divided as such:

- The Sponsor will maintain the barcode and identity of the subject as well as the relationships of cases to referred cases and controls.
- The Laboratory will maintain the barcode and blood.
- The Data storage facility will maintain the barcode, CRF data, and the relationships of cases to referred cases and controls.
- The Site will maintain the consent form and no permanent link to the barcode.

This distribution of materials allows for subject protection by always maintaining the genotypic and phenotypic data separately and securely from any link to the subject.

When data and/or blood products are released from the Data storage facility or the Laboratory/repository to either the Sponsor or researchers, the data and blood products will be relabeled with new and different barcodes provided by the Laboratory/repository to ensure subject confidentiality. This second level or barcoding will provide an additional level of anonymity as represented by the following:

Subject identity → Initial barcode
(Sponsor is the one who maintains this link)

Initial barcode → Second level barcode
(Laboratory and Data storage vendor know **this** link, but not the link to the subject identity. Sponsor does **not** know this link.)

During the initial study visit, a venous blood sample will be drawn via venipuncture. This sample will not exceed 50 ml if the subject is younger than 18 years of age, and will not exceed110 ml if the subject is 18 years of age or older. Each tube of blood will be marked with only the date and time of the blood draw, as well as the assigned (initial) barcode. Blood samples will be processed, packaged and shipped to the Laboratory/repository according to sample processing and shipping instructions provided to the site by the Laboratory/repository. The samples will be further processed and stored by the Laboratory/repository until Sponsor authorizes the release of samples to qualified researchers.

In order to create a familial link to the subject, the assigned barcode will be entered on a Participant Unit Form (PUF) [Attachment 1] via the data management system. As family members and referred unrelated controls are enrolled, each unique barcode for each family member or control will be added to the PUF. If a family member meets the case inclusion criteria, the barcode will be entered on the original PUF and also on a new PUF. This new family member who has been enrolled as a case can then refer relatives and controls to the study and their barcodes will be entered on this PUF.

Each subject will complete a Confidential Contact Sheet (CCS) [Attachment 2] which will be forwarded to the Sponsor in order to facilitate periodic contact for longitudinal follow-up. The Sponsor will hold this link to the subject's identity in a separate protected, secure database. To facilitate the data query process, the Site will retain a copy of the CCS, which will allow the Site to maintain a temporary link connecting the barcode and the subject's name until all data queries are completed. The site will maintain a copy of the CCS form in their files until alerted by the sponsor to destroy it.

Subjects will be contacted by the PI to schedule a study visit approximately every 1-2 years (this visit may be scheduled at the same time as appointments with the physician). The purpose of the follow-up visits is to update significant changes in medical/health status, as well as ask new questions, such as questions about dietary habits. Additional blood samples may be obtained during follow-up visits. Subjects may also be asked to be interviewed or provide additional samples at the time of doctor's appointments for relapses, changes in medication, etc. A consent addendum, new CCS, and new CRF will be submitted for IRB approval prior to contacting subjects for additional study visits.

The Sponsor will send periodic mailings to all subjects to update contact information in order to keep track of them should they move or switch neurologists.

5.3.3 Initial Visit Summary

Once the subject is properly consented, the following steps take place during the initial visit:

1. Up to 110 ml of blood will be drawn from the subject if the subject is 18 years of age or older. If the subject is younger than 18 years of age, up to 50 ml of blood will be drawn. The blood tubes will be marked with the subject's unique barcode and date and time of blood draw.

2. The PI or other study staff will interview the subject. During this interview, the subject will be asked questions regarding their lifestyle, environmental, geographical and medical history and current status. This interview is expected to last approximately 1 ½ hours. The data gathered during the interview will be entered into an electronic data capture system. The data will only be identified by the subject's unique barcode.

3. The subject will be asked to refer blood relatives (with and without the aforementioned demyelinating diseases) and unrelated controls to the study.

4. The subject will fill out a confidential contact sheet (CCS) that will be forwarded to the Sponsor for storage in a secure location.

5. The subject is reimbursed a nominal amount for time, travel, etc.

   Steps 1 – 5 may occur in any order following proper consent.

6. The blood is packed and shipped to the storage facility according to sample processing and shipping instructions provided to the site by the Laboratory/repository.

7. The Study Coordinator will make a copy of CCS form. The Study Coordinator then faxes the CCS to the Sponsor and also mails the original to the Sponsor. The Study Coordinator will maintain the copy of the CCS form in their files until alerted by the Sponsor to destroy it.

5.3.4 Medical Supervision

Medical supervision is the responsibility of the PI. The PI may delegate day-to-day activities to trained study staff, but retains overall responsibility for ensuring that the study is conducted according to all applicable regulatory guidelines, sound medical practice, and in adherence to the principles of Good Clinical Practice.

5.4 Data Management and Analysis

5.4.1 Data Collection

All data collected via the CRF and supporting documents will be entered and stored in databases maintained by the Data management vendor. Offsite backups may be held by a third-party to guard against data loss. CRFs will be entered electronically at each Site. Additional forms (diagnostic reports, relevant medical records, images of MRIs, etc.) will be scanned and stored in an imaging system, which will provide image indexing and process workflow capabilities. The data will be checked for quality based on a defined set of data edit criteria.

The printed out CRF can act as its own source and the subject, or their legally authorized representative, is allowed to provide the information directly onto the form to be provided to site personnel. The forms can be completed either on-site at the time of the interview or prior to arrival. However, only site personnel will make the entries into the electronic CRF system from the printed CRF brought in by the subject or their legally authorized representative and only after proper consent is obtained. During the site personnel's interview with the consented subject, the data the subject has pre-filled on the paper copy of the CRF (if any) may be updated. It is assumed that the data entered into the electronic CRF is the most accurate and up to date.

5.4.2 Disclosure of Data

All subject information obtained as a result of this study is considered confidential and disclosure to parties other than those designated by the Sponsor or noted below is prohibited.

5.4.3 Data Analysis

The data will be queried and analyzed for sample selection based on the needs of each research plan accepted by the Sponsor.

5.4.4 Data Quality Assurance

Data generated as a result of this study are to be available for inspection on request by regulatory authorities or other government regulatory agency auditors, clinical monitors, Sponsor-designated independent auditor, the IRB, and any other regulatory agency permitted by law. Sites will be given sufficient notice to prepare for such an audit/inspection or monitoring visit and must be prepared to give the Sponsor or reviewing agency sufficient time to review source documents.

6 MANAGEMENT OF STUDY DOCUMENTS

Essential study documents for the conduct of this study will be maintained and filed according to ICH Guidelines for GCP. The Site will be instructed through information provided in the study binder at the initiation visit.

INVESTIGATOR SIGNATURE PAGE

I have read Protocol ACP-001 Amendment #2 dated July 12, 2011 and agree to:

- Conduct the study as outlined herein and in accordance with Good Clinical Practice.
- Maintain the confidentiality of all information reviewed in connection with this protocol.

In the opinion of the Sponsor, this protocol and safeguards described in this application are adequate to meet the standards of the Office of Human Research Protection (OHRP) with regard to the protection of human subjects involved in activities in which the subjects may be at risk.

The term “subject” refers to any individual who may be exposed to the possibility of physical, psychological, social or other harm as a consequence of any activities that goes beyond the application of those established and accepted methods necessary to meet his or her needs. The rights and welfare of individuals will be respected. The potential benefits outweigh any risks involved.

Name of Principal Investigator: (Please print)

_____

Signature of Principal Investigator

_____

Date of Signature:

_____

ATTACHMENT 1 – Participant Unit Form

Accelerated Cure Project

Participant Unit Form

ID of Participant

Place Bar Code Here	Date of Birth: __ __ / __ __ / __ __ __ __	Consent Date: __ __ / __ __ / __ __ __ __
	Initials: __ __ __ __	MS? YES ☐ NO ☐

ID of Relative or Unrelated Control

Specify Relationship to Participant

Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐
Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐
Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐
Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐
Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐
Place Bar Code Here	Father ☐	Son ☐	Brother ☐	Identical Tuplet ☐
	Mother ☐	Daughter ☐	Sister ☐	
	Other, related or non-related (describe below): ☐			MS? YES ☐ NO ☐

Site ID: __ __ __ __	Principal Investigator Last Name: __ __ __ __ __ __ __ __ __ __

ATTACHMENT 2 – Confidential Contact Sheet

Accelerated Cure Project

Confidential Contact Sheet

Place Bar Code Here

Provide the following personal information:

Date of Birth ___ / ___ / ____

Consent Date ___ / ___ / ____

Mother's Maiden Name

Provide the following contact information:

First Name

Middle Name

Last Name

Number and Street Address

City

State

Zip Code ____ - ____

Provide one or more of the following:

Preferred method (Check one):

Home Phone Number ___ - ___ - ____ ☐

Work Phone Number ___ - ___ - ____ EXT. ____ ☐

Cell Phone Number ___ - ___ - ____ ☐

E-mail Address ☐

Please provide information for an alternate contact (relative or friend):

First Name

Last Name

Number and Street Address

City

State

Zip Code ____ - ____

Phone Number ___ - ___ - ____

Specify your relationship to alternate contact:

Site ID: ____

Principal Investigator Last Name