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Site Contributions Work Group
White Paper for CNS Summit 2015: Improving the Subject Screening Process

Preamble

The Site Contributions Workgroup is made up of site investigators, staff members and their allies. We are dedicated to site action and advocacy in shaping the future of clinical research.

At the 2014 CNS Summit, our presentation focused on the Subject screening process. This is an area in which sites have the opportunity to challenge commonly-accepted methods and formalize a streamlined and flexible process. We discussed several “best practices” for a screening process, including:

- A fully consented, IRB-approved pre-screen intake for potential Subjects;
- The use of a clinician-to-clinician contact form to request pertinent information from a potential study participant’s primary care clinicians;
- Developing a flexible screening process, including two-visit screens to accommodate Subjects who would be overly burdened by the number of screening procedures required by some protocols.

Since the Summit, the group has been working to come up with a body of non-proprietary documents (attached) designed to aid sites in improving the screening process. This includes:

- A rationale for each practice;
- A suggested procedure for implementation of each practice;
- Any forms that may be useful for sites in implementation of these practices.

We have collected these documents into this white paper, and made them freely available online at http://tinyurl.com/cns2015scwg

We are currently seeking IRB approval for these documents, where appropriate. As such, this material remains subject to change.

Accessibility is an important principle in our work. These materials do not represent a model ideal of a high-tech, high-budget site, but rather low-cost solutions that can be implemented by most sites. We anticipate and welcome a near future in which technology and advanced industry practice will render many of these concerns obsolete.

The members of the Site Contributions Work Group are experienced leaders in the industry, and hope to use our acumen to the betterment of the industry as a whole.
Rationale for the Establishment of a Standard Pre-Screen Process for Clinical Research

In the conduct of clinical research, many sites precede their screening visits with a pre-screen, medical intake or “core” screen visit to gather essential information on a potential Subject. This process is often an ad hoc response to the challenges stemming from a screening process that places a high burden on both Subjects and clinicians. This intake process should be standardized and held to the same standard of quality as any intake performed by any medical practice in the country. The elements of a clinical intake may vary based on pertinent study protocols and the needs of individual sites, but may include:

- Collecting essential information such as demographics, vital signs, and BMI;
- Urinalysis to screen for substance use;
- A urine pregnancy test (where applicable) and determination as to the Subject’s reproductive status;
- An overview of the Subject’s chief complaint, as well as medical and psychiatric treatment history;
- A listing of the Subject’s current and most recent medication use.

The Subject shall sign a concise and legible informed consent document before any of these procedures are undertaken.

The use of a pre-screen visit is an expedient measure, and a highly utile one, especially for “standalone” sites not affiliated with a hospital or practice. Performing a pre-screen can help startup sites build a patient database that can aid patient recruitment across multiple protocols, as well as reducing the fiscal burden of uncompensated screen fails. A pre-screen also reduces the time burden placed on Subjects, and provides the public health benefit of a no-cost medical evaluation. Additionally, a standardized clinical intake will assist in exposing duplicate (i.e. “professionalized”) patients.

The protocol-specific consent process often uses complex and legalistic language; protocol-specific consent documents can fail in their stated purpose of informing Subjects and obtaining their consent. The burden of informing Subjects of their rights and responsibilities falls upon investigators; a medical intake process, with a short and legible consent document, provides an opportunity for real information and real consent. Simplifying the informed consent process, to a point where a Subject can genuinely understand it, will help to educate the public as to the vital role that clinical research plays in their lives, and will aid in study recruitment.
Procedure for a Standard Pre-Screen Process for Clinical Research

This procedure outlines a method for a fully consensual, safe, and non-intrusive pre-screen or clinical intake visit.

1.0: Purpose and Responsibilities

1.1 Policy:
- A pre-screen visit, whether or not it is held in connection with a particular protocol, must be conducted with the same clinical and ethical rigor as any other study visit conducted at the site.

1.2 Responsibilities:
- It is the responsibility of the clinical management either to conduct, or to appropriately delegate and review the conduct of, a pre-screen visit.
- All sites are different. Not every item in this procedure may apply to each site. The clinical management at each site may alter these procedures according to their own needs and circumstances.
- It is the duty of site management and regulatory staff to ensure that all site-specific procedures adhere to the highest ethical standards of clinical practice.

2.0: Procedures

2.1 Elements of Consent
- The Subject must review and sign a concise, legible consent document before the clinical staff perform any procedures or make any medical inquiries.
- The Subject must be given an opportunity to discuss the content of the consent document with the clinical staff, who will answer any questions and define any words the Subject does not understand.
- The document will inform the Subject that the pre-screen visit is intended for assessment of the Subject’s health status and will not determine eligibility in a study.
- The document will clearly specify the procedures to be undertaken during the pre-screen visit.
- The document will clearly state the Subject’s rights and responsibilities as a Subject, and emphasize that study participation does not abridge these rights.
- If a potential study protocol may require the Subject to fast or washout for research screening, such that consent for fasting/washout must be obtained prior to the screening visit, the Subject may consent to fasting/washout at this time.
- The document will not be used prior to IRB approval.
2.2 Elements of the Pre-Screening Visit

- A pre-screening visit should include only the essential elements of a medical intake necessary to determine the Subject’s general health status, and to scan for basic exclusion/inclusion criteria for study eligibility.
- The Subject’s basic information should be taken, and may be cross-referenced with other Subject data in order to ensure that he is not a duplicate (i.e. “professional”) patient.
- A Subject’s vital signs and BMI may be determined through non-invasive procedures.
- A urinalysis to scan for pregnancy and substance use is appropriate, pending the Subject’s informed consent.
- Study staff will conduct an interview determining the Subject’s chief complaint, symptoms, medical history, and treatment history.
- If deemed appropriate, a medical intake form may be altered or tailored to different study indications. For sites conducting multiple studies involving a single indication, this may help investigators determine which study might be suitable for the Subject. The pre-screen, however, is not intended as a replacement for a protocol-specific screen.
- Study staff should follow up with the Subject as promptly as possible to inform him whether or not he is eligible for a protocol-specific screening visit.

3.0: Attached Documents

3.1 Declaration of Agreement to Participate...

- The Declaration of Agreement to Participate in a Health Status Assessment is a proposed, non-proprietary model for a pre-screen informed consent form.
- The Subject is to read it over with site staff on hand to explain anything that they do not understand.
- The Subject is to sign the document before beginning the intake process.

3.2 Medical Intake

- This medical intake is to be completed by the site staff and the Subject together during the screening visit.
- Sections A, B, and C are not specific to any indication and should be completed with all Subjects.
- Section D is provided as an example of an indication-specific addendum that can be used where applicable.
DECLARATION OF AGREEMENT TO PARTICIPATE IN A HEALTH STATUS ASSESSMENT

SiteName: [[Site name]]
Medical Director: [[Director name]]
24 Hour Emergency Number: [[Emergency #]]

This consent form may contain words that you do not understand. Please ask the staff to explain anything that you do not clearly understand.

[[Site name]] conducts clinical studies of experimental treatments. Generally, Subjects at [[Site name]] are seen because of their intent to take part in experimental studies. [[Site name]] does not provide medical care and does not replace medical care.

PURPOSE OF THIS AGREEMENT
This agreement describes the Health Status Assessment process. [[Site name]] uses this assessment to help determine whether someone is a good candidate for a study.

If you agree to undergo this assessment, you may be asked about your personal, medical, social, family, and in some cases psychiatric history. You may also undergo standard, non-intrusive medical tests, such as:

- Height and weight measurements;
- A blood pressure reading;
- An ElectroCardioGram (ECG);
- Urine collection, which may be used to screen for illegal substances or, if appropriate, for pregnancy.

Based upon the results of this assessment, the staff may decide that you are a good candidate for a study. If so, the next step is a detailed Informed Consent Document explaining a specific study. You will have time to read document carefully and to ask the study staff any questions you want before making a decision as to whether to participate. [[Site name]] will not take any further tests or procedures unless you sign the Informed Consent Document.

Your health information will be kept private and secure. If you choose to take part in a specific research study and sign the study-specific Informed Consent Document, the information gathered here may be shared with the Sponsor of the study.
**BENEFITS, RISKS AND DISCOMFORTS**
You will not necessarily directly benefit from this Health Status Assessment. You may receive health information such as a current blood pressure reading, or a pregnancy test result; you may also benefit from a general discussion of your health.

The risks from taking part in this assessment are minimal. The tests performed and questions asked may make you feel embarrassed and uncomfortable. It is important to answer these questions honestly. If this discomfort is too much for you, you may choose to end the assessment at any time.

**COSTS AND PAYMENT**
You will be neither paid nor charged for participating in the assessment process. [[Site name]] will pay for all tests and procedures performed. [[Site name]] provides these services voluntarily and for Health Status Assessment purposes only. [[Site name]] does assume financial responsibility for your ongoing medical care or needs.

**PARTICIPATION INFORMATION**
Your participation in this process is completely voluntary. You can choose not to take part in this process or to end it at any time.

In either case, you will not be penalized. If you decide not to take part in further assessments, you should tell the [[Site name]] staff immediately. If you do not finish the assessment, you will not be considered for any specific research study at this time. This will not exclude you from possibly participating in future studies. If you decide to participate in the future, you may be asked to go through the same Health Status Assessment process at that time. If you decide not to participate, but do wish to be considered for future studies, [[Site name]] will hold your completed documents in a secure and confidential file for up to one year.

You may ask [[Site name]] to destroy any forms you have filled out at any time.
CONSENT

I, ____________________________(your printed name), hereby give my consent and authorization to be interviewed by the study staff of [[Site name]]. This interview will be used to determine by eligibility for participation in a clinical research study. I understand that only the [[Site name]] staff can determine my eligibility. My agreement to be interviewed and participate in the Health Status Assessment does not mean that I will necessarily be accepted into a research study.

I voluntarily agree to participate in the Health Status Assessment process.

I understand I have not given up any of my legal rights by signing this informed consent.

I will receive a signed and dated copy of this form.

______________________________
Printed name of Participant

______________________________  ________________/______/______
Signature of Participant        Date of Signature (dd/mm/yyyy)

______________________________
Printed name of person conducting consent process

______________________________  ________________/______/______
Signature of person conducting consent process  Date of signature (dd/mm/yyyy)
[Site name]
Medical Intake
Section A (demographic information)

Patient Name:
First, Middle Initial, Last

Chief complaint/area of interest:

Could Subject commit to fifteen weeks of clinical trial participation?
☐ Yes ☐ No ☐ Unsure

Has Subject participated in clinical research in the past?
If yes, when? For what condition?

Race/ethnicity: [DOB: MM/DD/YYYY]
Born/raised in:

Sex/gender expression:

Sexual Orientation:

Capable of bearing children?
If not, why not?
If yes, is double-barrier protection okay during study?
☐ Yes ☐ No

Marital status:

Prior spouses?
Any children?

Education:

Gender, age of each

Currently breastfeeding?
☐ Yes ☐ No

Donated blood?

Work status:

Unemployed? Retired?
Occupation?
Full or part time?

Military service?

Current or past

Legal troubles?

Current or past

Substance Use:

Past and present

Substance
Caffeine
Nicotine
Alcohol
Marijuana
Cocaine
Amphetamines
Heroin
Methadone
Pain meds
Hallucinogens
Synthetic drugs

Time period
Start date
End date or Ongoing

Notes
Frequency?
Context of use?
Sought treatment?
### Medications:
Past and present

<table>
<thead>
<tr>
<th>Medication</th>
<th>Time period</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pills</td>
<td></td>
<td>For what condition?</td>
</tr>
<tr>
<td>Herbal</td>
<td></td>
<td>Hospitalized?</td>
</tr>
<tr>
<td>Ingested</td>
<td>Start date</td>
<td>Allergic reactions?</td>
</tr>
<tr>
<td>Inhalers</td>
<td>End date or</td>
<td>Side effects?</td>
</tr>
<tr>
<td>Injected</td>
<td>Ongoing</td>
<td>Why discontinued?</td>
</tr>
</tbody>
</table>

### Medical conditions:
Past and present

<table>
<thead>
<tr>
<th>Condition</th>
<th>Time Period</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric</td>
<td></td>
<td>Severity?</td>
</tr>
<tr>
<td>Personality disorder</td>
<td></td>
<td>Symptoms?</td>
</tr>
<tr>
<td>Neurological</td>
<td></td>
<td>Hospitalized?</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
<td>Treatment?</td>
</tr>
<tr>
<td>Hematological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocrine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metabolic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skeletomuscular</td>
<td>Start date</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>End date or</td>
<td></td>
</tr>
<tr>
<td>STDs</td>
<td>Ongoing</td>
<td></td>
</tr>
</tbody>
</table>

### Surgeries/Procedures:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental?</td>
<td></td>
<td>Was it successful?</td>
</tr>
<tr>
<td>Cosmetic?</td>
<td></td>
<td>Complications?</td>
</tr>
<tr>
<td>Appendectomy?</td>
<td></td>
<td>Hospital stay? Duration?</td>
</tr>
<tr>
<td>Tonsillectomy?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
[Site name]
Medical Intake
Section C (procedures and notes)

Height: Ft.‘ in.”
Weight: Lbs.

Pregnancy result:
☐ Pos. ☐ Neg.

Drug screen result:
☐ Pos. ☐ Neg.

Blood pressure: mm Hg
(Diastolic)
(Systolic)

Substances indicated?

Apparent Behavior:

Miscellaneous Notes:

Clinician signature

Date
Is Subject currently undergoing a depressed episode?
☐ Yes   ☐ No   ☐ Unsure

**Symptoms:**  
In the current episode

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sadness</td>
<td></td>
</tr>
<tr>
<td>Irritability</td>
<td></td>
</tr>
<tr>
<td>Anxiousness</td>
<td></td>
</tr>
<tr>
<td>Hopelessness</td>
<td></td>
</tr>
<tr>
<td>Decreased energy</td>
<td></td>
</tr>
<tr>
<td>Hyperactivity</td>
<td></td>
</tr>
<tr>
<td>Grandiosity</td>
<td></td>
</tr>
<tr>
<td>Overspending</td>
<td></td>
</tr>
<tr>
<td>Hallucinations</td>
<td></td>
</tr>
<tr>
<td>Suicidal thoughts</td>
<td></td>
</tr>
<tr>
<td>Change in sleep/Appetite/Weight/ Libido/Interests/</td>
<td>Severity?</td>
</tr>
<tr>
<td>Self-image/Concentration/Memory/Cognition</td>
<td>Affected by treatment? Occurred in prior episodes? Any relevant details</td>
</tr>
</tbody>
</table>

**Prior episodes:**  
If any, starting with the first

<table>
<thead>
<tr>
<th>Starting</th>
<th>Ending</th>
<th>Treatment and Response</th>
</tr>
</thead>
</table>

**Suicide Attempts:**  
If any, starting with the first

<table>
<thead>
<tr>
<th>Date</th>
<th>Method</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hospitalized?</td>
</tr>
</tbody>
</table>
Rationale for the Establishment of a Standard Clinician-to-Clinician Contact Form to be Used by Clinical Research Sites

Patient medical records are the backbone of medical information and are crucial to the conduct of research. These documents, however, are currently very burdensome for clinicians to release and for research sites to obtain. This difficulty can interfere with the timely conduct of research.

This time and labor burden is not the result of any particular regulation or requirement, but of inefficient methods of communication between the medical and research communities. As these communities are mutually interdependent, they must be able to communicate promptly when needed. Barriers to health information portability should not exceed those required by three priorities:

- Protecting the health of patients;
- Protecting the patients’ right to privacy and informed consent;
- Compliance with all pertinent regulatory guidelines.

The transfer of medical information should entail a hierarchy of good-faith efforts. Where official medical records cannot be promptly received, many research sites (with patient consent) contact clinicians directly to request the pertinent information. This is an appropriate measure to reduce the burden of record transfer and encourage collegiality between institutions of research and patient care. A standard, IRB-approved form should be introduced and standardized to allow a clinician to quickly provide the most pertinent information to site staff.

Because many doctors’ offices (and sites) rely on obsolete communications technology, this form should be answerable via fax and mail as well as digital transfer. The form will mainly comprise of a series of simple questions answerable by “yes/no” checkboxes. These can probe as to common exclusion criteria such as substance abuse, autoimmune disorders, and other chronic illnesses. The form can also be used to confirm diagnosis of the condition pertinent to the study, and give a brief overview of the patient’s treatment history. The clinician will be given opportunity to voice any concerns about the potential Subject’s study participation. Otherwise, this brief overview should suffice until the transfer of official medical records can process.

Advancing the dialogue between patient care and research will lead to more research participation and help take medicine into the future.
Procedure for the Retrieval of Patient Records for Research Purposes

This procedure establishes a hierarchy of procedures for a clinical study staff to contact and engage with the clinicians holding a study Subject’s medical records.

1.0: Purpose and Responsibilities

1.1 Policy:
- A direct, communicative relationship with a Subject’s primary care physician (or other medical care professional, where applicable) is essential to clinical conduct and patient safety.
- The full retrieval of patient medical records often places an unnecessary burden on both the medical and research communities, and should not be the only route towards obtaining a Subject’s past medical information.
- A patient is the owner of his own medical records and should be the primary arbiter of when, and to whom, they are shared or released.

1.2 Responsibilities:
- It is the duty of the site management to obtain the needed medical information. Medical clinicians follow their own prerogatives and are not responsible for a site’s failure to comply.
- All sites are different. Not every item in this procedure may apply to each site. The clinical management at each site may alter these procedures according to their own needs and circumstances.
- It is the duty of site management and regulatory staff to ensure that all site-specific procedures adhere to the highest ethical standards of clinical practice.
2.0: Procedures

2.1: Initiating Contact
- The site staff should ask that a prospective Subject name his current medical caretaker(s) at the earliest opportunity, such as during a phone interview or pre-screen intake visit.
- A prospective Subject must consent to have his medical information shared with the site before contact is established.
- Clinician-to-clinician contact should be initiated as early as possible after the Subject has consented. Direct contact (e.g. a telephone conversation) between the PI and the Subject’s physician is optimal.

2.2: Release of Medical Information
- The site should request a full transfer of medical records.
- The site may also use an IRB-approved clinician-to-clinician contact form to gain a sense of the Subject’s qualifications for participation.
- A contact form could include a quick checklist of yes-or-no questions scanning for common exclusion criteria, but must also include a space for the medical clinician to comment and list any concerns that he may have related to participation in a trial.

3.0: Attached Documents

3.1: Clinician-to-Clinician Contact Form
- The included clinician-to-clinician contact form takes the form of a letter and may be mailed, faxed, or emailed to another clinician.
- It is to be sent attached to the Authorization to Release or Otherwise Obtain Medical Records.
- It is considered best practice to contact the receiving clinician directly and let them know that this document is being sent.
- The content of this document is made to be modular. It can ask for any indications considered appropriate based on the Subject, the Study, and the receiving clinician.

3.2: Authorization to Release or Otherwise Obtain...
- This consent form is to be signed by the Subject and attached to the clinician-to-clinician contact form.
- If the site is using a pre-screen, this form should be signed and reviewed during a pre-screen visit.
Dear [[physician name]]:

I represent [[Site name]], a research site currently running a [[Phase]] clinical trial for [[condition]]. Your patient, [[Subject name]], is being considered for participation. [[Subject's first name]] has signed the attached consent form authorizing the release of medical information. In the interest of better understanding your patient’s medical status, we request that you send us a copy of their medical records for the past year. Should the patient end up volunteering for the study, we will send lab results to your office.

To expedite this exchange for information, it would be an enormous help to us if you could complete this form and return it to us at your convenience.

Do you have any concerns as to your patient’s participation in this study?  
[ ] Yes  [ ] No

Please use this space for any comments you might have:

______________________________

Please indicate your knowledge as to whether your patient has any of the following medical conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune disorders?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes Mellitus?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recent suicide attempt?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance abuse?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other psychiatric disorders?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any other conditions that you believe might be relevant to the study?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please use this space if you’d like to comment on any of the above conditions:

______________________________

I appreciate this opportunity to work with you and your patient. Thank you for your help and for the care you provide.

Cordially,

[[PI name]]
Authorization to Release or Otherwise Obtain Medical Information and Records

Name (print): ________________________________________________

Date of Birth: _______________________________________________

Agency/Institution (if applicable): _______________________________

This Authorization will be used by [[Site name]] for clinical reasons related to my participation in clinical research studies.

This document will authorize [[Site name]] to release or otherwise obtain medical and psychiatric information from my medical records in accordance with federal regulations (42 CFR Part 2). This includes the release of any information concerning Human Immunodeficiency Virus and related illnesses, as well as test results, counseling, and prior treatment.

I understand that my records have a privileged and confidential status, protected by federal regulations and state statutes. I agree to waive that status for the purposes authorized by this document.

I understand that I have the right to refuse this authorization. I further understand that I am authorizing the release of information from privileged and confidential records. This authorization is for a continuing disclosure which remains valid for the duration of my participation in a clinical trial, and, if required, for up to one year following.

This authorization may be revoked at any time with my written request.

Signature of the Patient: __________________________ Date: __________

Signature of Witness: ______________________________ Date: __________
(if applicable)
Rationale for the Establishment of a Standard Screening Visit Division to be Used by Clinical Research Sites

For many clinical study protocols, completing a full screening visit can take many hours and is taxing on both sites and patients. Many sites agree that the screening process for certain protocols would be greatly improved if “split” into two visits. This is specifically true:

- In studies of child or adolescent populations;
- In studies of certain geriatric disorders, such as Alzheimer’s Disease;
- For certain disease indications requiring the use of many time-consuming evaluation scales.

By splitting screening visits, sites can use their time more effectively by:

- Diminishing fatigue among subjects and site staff;
- Increasing the quality of screening data;
- Limiting unnecessary procedures in subjects who ultimately will not qualify for study participation.

It should be the site’s decision whether to split a screening visit, based on the study and the subject in question. In some cases, it will be more effective and convenient for both the site and the subject to complete a screen in one visit. No two sites have the same needs. For some sites, there is a large difference in time burden between a known patient, a subject who has completed an on-site pre-screen, and a new patient who has completed only a brief phone questionnaire. Others may weigh the burden of a one-visit screen based on the age and the mental and physical health of the patient.

Two key principles should inform the division of procedures and assessments:

- The integrity of data should be preserved at all times;
- Subjects should be asked to complete less invasive procedures first, and move on to potentially more invasive procedures as they develop a rapport with the study staff.

Psychiatric assessments and diseases scales can be performed on the first visit, without the patient being required to fast. The Subject will then return on a second visit, having fasted (if necessary), and complete the labwork and more invasive procedures at that time.
Procedure for the Division of a Screening Visit

1.0: Purposes and Responsibilities

1.1 Policy:

- Sites should have the option of conducting a screening visit over two visits where this would be beneficial to the Subject, the Site, or both.
- A two-visit screen must be administered in adherence with the Study Protocol and the highest standard of clinical practice.
- Elements of a screen should be administered from the least to the most invasive, when it is sensible to do so.

1.2 Responsibilities:

- The Site will contact the Sponsor to ensure that a divided screening visit does not constitute a protocol deviation.
- The Site staff will inform prospective Subjects of their options, that a prospective Subject may make an informed decision as to how to format their screening visits.
- The Subject will be given the option to complete the visit over one or two visits.

2.0: Division of Procedures

2.1 First Visit:

- Site staff will perform the Informed Consent process.
- In accordance with Study Protocol, all psychiatric structured interviews and disease scales, including cognitive assessments, should be completed in the order specified.
- The Investigator then determines whether the Subject is excluded from the study, based on these evaluations.
- If not excluded, Subject will be instructed to fast for Protocol-specified period of time, if indicated in the Protocol, prior to the next visit.

2.2 Second Visit:

- The Subject will return to the Site after fasting, if indicated in the Study Protocol.
- The Investigator will perform any remaining scales, as defined in the Protocol, that pertain to a Subject’s physical state, such as movement scales.
- The Subject will undergo remaining assessments in a logistically sensible order, unless this order is contraindicated by the Protocol.