



## Screening Procedures Information Form

Sponsor \_\_\_\_\_

Sponsor Protocol No. \_\_\_\_\_

Principal Investigator:		
Mailing Address: (street, city, state/province, postal code, country)		
Phone: (     )	Fax: (     )	E-mail:

1.	<p>How is screening initiated?</p> <p><input type="checkbox"/> Incoming response to an ad or web site.</p> <p><input type="checkbox"/> Site or call center initiating a call to a patient whose name was obtained from a database or list.</p> <p>Please note: Provincial, state, or federal laws may prohibit unsolicited calls to people who have not given prior permission to be contacted.</p>
2.	<p>Will you be using a call center?</p> <p><input type="checkbox"/> Yes.</p> <p><input type="checkbox"/> No. If no, <b>go to question 9.</b></p>

**Questions about the call center's practices:**

3.	<p>How is information stored at the call center?</p> <p><input type="checkbox"/> In a database.</p> <p style="margin-left: 20px;">Describe the security measures in place: _____</p> <p style="margin-left: 20px;">_____</p> <p><input type="checkbox"/> On paper.</p> <p style="margin-left: 20px;">How and where is the paper stored? _____</p> <p style="margin-left: 20px;">_____</p> <p style="margin-left: 20px;">Who has access to the paper? _____</p> <p style="margin-left: 20px;">_____</p>
4.	<p>How long does the call center store information?</p>
5.	<p>How does the call center destroy information at the end of the designated storage time?</p>

## WIRB Screening Procedures Information Form (cont'd)

6.	Describe how and when the call center destroys <b>screening failure</b> records:		
7.	Does the call center sell or share the names of screened subjects to other entities? *If Yes, please explain:	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
8.	Does the call center forward subject information to the site? *If Yes, how is the subject information forwarded to the site? (for example, e-mail, fax)  _____	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

**Questions about the site's practices:**

9.	How is information stored at the site? <input type="checkbox"/> In a database. Describe the security measures in place: _____ <input type="checkbox"/> On paper. How and where is the paper stored? _____  Who has access to the paper? _____			
10.	How long is information stored at the site?			
11.	How does the site destroy information at the end of the designated storage time?			
12.	Does the site keep <b>screening failure</b> records with the other study records? *If No, please describe how and when they will be destroyed:	Yes <input type="checkbox"/>	*No <input type="checkbox"/>	
13.	Does the site sell or share the names of screened subjects to other entities? *If Yes, please explain:	*Yes <input type="checkbox"/>	No <input type="checkbox"/>	
14.	If the site receives subject information faxed from a call center, is the fax machine at the site accessible only to authorized study personnel? Comments:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>

# WIRB Screening Procedures Information Form (cont'd)

## WIRB Screening Requirements

(If you plan to screen in Canada, please call Client Services for more information about Canadian screening requirements.)

### *Introductory Statement:*

- The script must include an introductory statement that informs the subject of the purpose of the questions and that they do not have to answer any questions they do not want to answer.
- The script must not describe the type of questions that will be asked as “confidential;” i.e., rather than saying “we would like to ask you some *confidential* questions,” say “we would like to ask you some questions.” It is acceptable to say “personal questions” or “sensitive questions.” The purpose of this policy is to prevent any possible misunderstanding that the answers will be held in complete confidence.
- When appropriate, the script must include an introductory statement warning the subjects of the sensitive nature of the questions that might make the subject uncomfortable, and preferably include an example (for instance, “We are going to ask you about drug or alcohol use.”) This will generally be limited to questions about mental illness, substance abuse, and sexual abuse. For these types of screening scripts, it is preferable to not collect any identifying information until after the questions are asked (i.e., collect the name and other identifying information at the end of the conversation and the form).

Here is a sample introductory statement:

[Thank you for calling] (or) [We are returning your call] about a research study we will be doing. The purpose of the study is [briefly describe study - e.g., “. . . to evaluate the safety and effectiveness of an investigational drug for arthritis”].

Participation in this study would last about [number of days, weeks, etc.] and (if applicable) would require up to [number] of visits to our office.

To see if you might qualify for this study, I need to ask you some questions about your health history and present condition. Some of these questions may be sensitive, such as questions about [give examples - e.g., drug use, birth control, mental health, sexual activity, etc.] You do not have to answer any questions you do not want to answer. You may stop this interview at any time. If you do not qualify for this study, the information you give me will be [e.g., “destroyed immediately” or “stored (where and for how long)”]. Do I have your permission to proceed? "

### *Body of Screening Form*

- The Board expects to see the actual questions that will be asked, not just a general statement such as “inclusion/exclusion criteria addressed.”

### *Closing Statement*

- The script must include a closing statement informing the subject of whether or not they have met the preliminary screening requirements.
- The script must address in a closing statement whether the information received from the subject will be destroyed immediately, or whether it will be stored, and if so for how long and where.
- If the site would like to keep information for future contact for new studies, this must be described to the subject as well, and the subject must have an opportunity to decline.

### *Additional Issues*

- The screening script must be in language understandable by lay people. If complicated medical terms must be included in the screening script, please provide WIRB with an explanation of how they will be explained to the subjects.
- WIRB realizes that the script may not be followed verbatim, as subjects may ask additional questions or stray from the topic. This is acceptable, but WIRB expects that the interviewer will keep as closely as possible to the spirit and letter of the script.
- It is useful to WIRB if the investigator informs WIRB of the use of the recruitment screen; e.g., if it is going to be used with subjects calling in from advertisements, for calling patients listed in a database, or for conducting cold calls.