

Study Title
Protocol # XXX
IDE # XXXXXXXX

Company Name
Version: Draft
Page X of XX

Study Site ID

Patient ID

Date of Visit

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

M D Y

Inclusion/Exclusion

Inclusion criteria, check (✓) appropriate box below.

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Yes No

<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP
<input type="checkbox"/>	STOP

Exclusion criteria, check (✓) appropriate box below.

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Yes No

STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>

Patient signed and dated informed consent form on:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

M D Y

For data entry
use only:

E	V
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Data are accurate to the best of my knowledge:

Principal Investigator's Initials

Date

Study Site ID

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M		D		Y	

Patient Demographics

If possible, the patient should complete questions 3 and 4.

1. Gender Male Female

2. Date of birth.....

M		D		Y	

3. Ethnicity Hispanic Non-Hispanic

4. Race..... Caucasian..... Asian.....
African American..... Pacific Rim.....
Native American..... Other.....

5. ETC.....

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M

D

Y

Medical History

HAVE YOU EVER HAD OR DO YOU NOW HAVE ANY OF THE FOLLOWING CONDITIONS:

	YES	NO
a. Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>
b. Lived with someone with Tuberculosis	<input type="checkbox"/>	<input type="checkbox"/>
c. Asthma or breathing problems related to exercise, pollen, etc.	<input type="checkbox"/>	<input type="checkbox"/>
d. Been prescribed or use an inhaler	<input type="checkbox"/>	<input type="checkbox"/>
e. Loss of vision in either eye	<input type="checkbox"/>	<input type="checkbox"/>
f. Loss of hearing or wear a hearing aid	<input type="checkbox"/>	<input type="checkbox"/>
g. Impaired use of arms, legs, hands, feet	<input type="checkbox"/>	<input type="checkbox"/>
h. Knee problems	<input type="checkbox"/>	<input type="checkbox"/>
i. Broken bones(s) (cracked or fractured)	<input type="checkbox"/>	<input type="checkbox"/>
j. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
k. Anemia (including sickle cell)	<input type="checkbox"/>	<input type="checkbox"/>
l. Dizziness or fainting spells (including after exercise)	<input type="checkbox"/>	<input type="checkbox"/>
m. Frequent or sever headaches	<input type="checkbox"/>	<input type="checkbox"/>
n. Head injury, memory loss, or amnesia	<input type="checkbox"/>	<input type="checkbox"/>
o. Seizures, convulsions, epilepsy, or fits	<input type="checkbox"/>	<input type="checkbox"/>
p. Car, train, sea, and/or air sickness	<input type="checkbox"/>	<input type="checkbox"/>
q. A period of unconsciousness	<input type="checkbox"/>	<input type="checkbox"/>
r. Heart trouble or murmur	<input type="checkbox"/>	<input type="checkbox"/>
s. Received counseling for emotional or behavior disorder	<input type="checkbox"/>	<input type="checkbox"/>
t. Eating disorder (bulimia, anorexia)	<input type="checkbox"/>	<input type="checkbox"/>
u. Sleepwalking	<input type="checkbox"/>	<input type="checkbox"/>
v. Bedwetting	<input type="checkbox"/>	<input type="checkbox"/>
w. Been hospitalized	<input type="checkbox"/>	<input type="checkbox"/>

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M D Y

Baseline Assessment

Measurement #1.....

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Measurement #2.....

--	--	--	--

Measurement #3.....

--	--	--	--

Measurement #4.....

--	--	--	--

ETC.....

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Date

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Date of Visit

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Intervention

Measurement #1.....

--	--	--	--

Measurement #2.....

--	--	--	--

Measurement #3.....

--	--	--	--

Measurement #4.....

--	--	--	--

ETC.....

--	--	--	--

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M D Y

Post-Intervention

Measurement #1.....

--	--	--	--

Measurement #2.....

--	--	--	--

Measurement #3.....

--	--	--	--

Measurement #4.....

--	--	--	--

ETC.....

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Study Site ID	Patient ID	Date of Visit												
<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; height: 20px;"><input type="text"/></td> <td style="width: 20%; height: 20px;"><input type="text"/></td> <td style="width: 20%; height: 20px;"><input type="text"/></td> <td style="width: 20%; height: 20px;"><input type="text"/></td> <td style="width: 20%; height: 20px;"><input type="text"/></td> <td style="width: 20%; height: 20px;"><input type="text"/></td> </tr> <tr> <td style="text-align: center;">M</td> <td></td> <td style="text-align: center;">D</td> <td></td> <td style="text-align: center;">Y</td> <td></td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	M		D		Y	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>									
M		D		Y										

Adverse Event

Investigator: Enter one adverse event per form, where an adverse event is an undesirable change in the patient's baseline, an adverse effect is a device related event, and a serious adverse device effect is on that is related to the device and results in hospitalization, prolongation of hospitalization, is life-threatening, or results in permanent disability or death. Document and record all adverse events in source files. Report all serious adverse events or device related effects to sponsor and IRB.

Sponsor: Document and record all graft-related adverse events and unanticipated or serious adverse events (whether graft-related or not), and report them to other investigators within 10 days and FDA.

Description of Event

<p>Onset Date.....<input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; width: 100%;"> M D Y </div></p> <p>Cessation Date.....<input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/><input style="width: 20px; height: 20px;" type="text"/> <div style="display: flex; justify-content: space-around; width: 100%;"> M D Y </div></p>	<p>Relationship to Device</p> <table style="width: 100%;"> <tr> <td style="width: 80%;">unrelated</td> <td style="width: 20%; text-align: center;"><input type="text"/></td> </tr> <tr> <td>probably not</td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>possibly</td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>probably</td> <td style="text-align: center;"><input type="text"/></td> </tr> <tr> <td>definitely</td> <td style="text-align: center;"><input type="text"/></td> </tr> </table>	unrelated	<input type="text"/>	probably not	<input type="text"/>	possibly	<input type="text"/>	probably	<input type="text"/>	definitely	<input type="text"/>
unrelated	<input type="text"/>										
probably not	<input type="text"/>										
possibly	<input type="text"/>										
probably	<input type="text"/>										
definitely	<input type="text"/>										
<p>Intensity..... mild <input style="width: 20px; height: 20px;" type="text"/></p> <p style="padding-left: 100px;">moderate <input style="width: 20px; height: 20px;" type="text"/></p> <p style="padding-left: 100px;">severe <input style="width: 20px; height: 20px;" type="text"/></p>	<p>Unanticipated yes <input style="width: 20px; height: 20px;" type="text"/></p> <p style="padding-left: 100px;">no* <input style="width: 20px; height: 20px;" type="text"/></p> <p>*event was described in informed consent form</p>										

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Principal Investigator's Initials Date

Study Site ID

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Patient ID

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Date of Visit

M D Y

Study Exit

Exit Date:

M D Y

Reason for study exit:

Expired

Withdrew

Other

(explain)

Date of death:

M D Y

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Principal Investigator's Initials

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Date

Study Site ID

--	--

Patient ID

--	--	--

Date of Visit

M D Y

Patient Medications

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

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Medication: _____

Dose: _____

Medication: _____

Dose: _____

Medication: _____

Dose: _____

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