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Award Number: W81XWH-13-2-0009

TITLE: Treating Intractable Post-Amputation Phantom Limb Pain with Ambulatory Continuous Peripheral Nerve Blocks

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Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES

14. ABSTRACT (brief – 200 words approx.) of most significant finding during the research period.

This is a randomized, double-masked, placebo-controlled clinical trial. The results will not be available until the completion of enrollment and unmasking of treatment groups. Therefore, there are no results/findings to report at this juncture as we are still completing enrollment.

The tasks of Funding Year 3 encompassed continued recruiting, enrollment and data collection:

- 52 subjects enrolled to date for all centers
- 21 subjects provided crossover treatment
- Expanded recruiting advertisements to multiple national publications and websites
- IRB-approved recruitment letters sent to prospective subjects
- Amputee support group outreach, prosthetics groups outreach, and clinic outreach conducted
- Data collection ongoing for all enrolled subjects
- Re-budgeted among enrolling sites due to uneven enrollment
- Completed the first interim analysis after 32 subjects (results remained masked for treatment group and revealed only to the DSMB, which recommended continuing with enrollment)

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT U	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	31	**19b. TELEPHONE NUMBER** *(include area code)*

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Introduction:

This project is a randomized, double-masked, placebo-controlled, simultaneous parallel and crossover, human-subjects clinical trial to determine if ambulatory continuous peripheral nerve block (CPNB) is an effective treatment for intractable phantom limb pain following a traumatic limb amputation. There is currently no reliable treatment for phantom limb pain, which resolves in only 16% of cases. This is a multicenter trial at five collaborating sites: Walter Reed National Military Medical Center, Naval Medical Center San Diego, Veterans Affairs Palo Alto, Cleveland Clinic, and the University of California, San Diego. Subjects will have an existing upper or lower amputation and experience phantom limb pain at least 3 times each week for the previous 8 weeks. They will be randomized to receive one of two study solutions in a double-masked manner: either a local anesthetic (ropivacaine 0.5%) or placebo (normal saline). Catheters will be removed after 6 days of at-home infusion. Although not required, each subject has the option to return for the alternative treatment 4-16 weeks later (crossover infusion). The primary endpoint will be the difference in average phantom pain intensity at baseline and 4 weeks following the initial infusion as measured with the Numeric Rating Scale between treatment groups for the initial infusion. Secondary endpoints will involve intra- and inter-subject comparisons of additional measures of pain and health-related quality-of-life. This trial has a strong potential to identify the first reliably effective treatment for intractable phantom limb pain following a traumatic limb amputation.

Body:

Revised SOW (accepted July 17, 2016):

Funding Year:	**2013**			**2014**	**2015**	**2016**	
Months (Within Year):	**1-4**	**5-8**	**9-12**			**1-10**	**11-12**
Register study on clinicaltrials.gov	x						
Progress to date: The study was registered on clinicaltrials.gov prior to the beginning of enrollment.							
Initiate DSMB meetings	x						
Progress to date: The DSMB charter was written and approved; and, DSMB meetings were begun prior to the beginning of enrollment.							
DSMB meetings (every 6 months)		x	x	x	x	x	x
Progress to date: The DSMB has met (by phone and/or SKYPE as the three members live in separate States) a total of two times since the previous annual report.							
Report to medical monitor (every month)		x	x	x	x	x	x
Progress to date: The Principal Investigator has provided a written report to the medical monitor Beverly							

Morris, RN (who is also the DSMB Chair), at the conclusion of each month; and, the medical monitor has confirmed receipt and approved the report each month. Information provided to the monitor monthly includes: the status of the study (new events such as how many institutions received IRB approval to send letters, interim analysis, personnel changes, etc); an enrollment update (currently enrolled, scheduled subjects for the following month, number left until next interim analysis); adverse events; unexpected adverse events; and protocol deviations.							
Finalize protocol and study forms	x						
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Hire/train research coordinators	x	x	x				
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Site visits and training by UCSD coordinator	x						
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Submit study to individual IRBs and USAMRMC	x	x					
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Site visits and training by Principal Investigator		x					
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Prepare data-entry platform at UCSD	x						
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Send database letters (following IRB approval)		x	x	x	x	x	
Progress to date: The following centers have received IRB approval to query their patient databases: Northwestern, MD Anderson, Hospital of Special Surgery, University of Utah, Mayo Clinic, University California San Francisco, and Rush University. All have been provided with stamped, sealed informational letters and all but the last two have sent these letters. The latter two institutions are in the process of sending their letters. There are five institutions with IRB approval and are currently compiling a list of possible patients from their database queries . There are four additional institutions which are working with their IRBs for approval and I anticipate will be granted approval within the next 6 months: Columbia University, Brooke Army Medical Center, Advocate Illinois Masonic Medical Center and the University of Chicago. An example of an IRB-approved letter is provided in the appendix.							
Educate clinic contacts for referrals		x	x				
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Order and prepare equipment	x	x					
Progress to date: Completed prior to enrollment in the first year of the grant period.							
Amputee support group outreach			x	x	x	x	
Progress to date: Completed prior to enrollment in the first year of the grant period. In addition, the							

research coordinator at the Cleveland clinic contacted two additional groups for referrals this past year; and, the Principal Investigator sent a representative to introduce the study to a large group of amputees at the Amputee Coalition National Conference in July 2015. All of these as well as the original contacts with enrolling institutions' pain clinics have yielded referrals.							
Advertising study in publications/websites			x	x	x	x	
Progress to date: Advertising continues in three publications with nation-wide dispersion: InMotion, The O&P Edge, and Amplitude. An example of the IRB-approved advertisement is included in the appendix.							
Patient enrollment (following IRB approval)			x	x	x	x	
Progress to date: We began enrollment at the very end of the 1st funding year (2013) after a year of regulatory work and setting up the study at each center. However, while the protocol worked very well, we enrolled relatively few subjects due to very tight enrollment criteria. In the middle of the first official year of enrollment (2014), the USAMRMC approved revisions to our enrollment, but it took nearly 3 additional months to clear all of the regulatory channels and then 2 additional months for our revised advertising to be published. Enrollment has picked up considerably since the changes were made, but we essentially "lost" that year of enrollment. Since we were anticipating enrolling in years 2014-2015, we will now need to enroll in the following year, 2016, which is still within the funding years of the original grant (2013-2016). Our enrollment stands at 52 of 142 total; but, the pace of enrollment has increased dramatically, and we anticipate will further increase with the arrival of the information letters to thousands of potential subjects. Therefore, we will continue enrollment through 2016. An enrollment table divided by enrolling institution is provided in the appendix. While enrollment has lagged original expectations to date, the letters sent from various institutions recently has yielded a plethora of scheduled subjects. For example, UC San Diego, the Cleveland Clinic, and Walter Reed Medical Center now have 3, 9, and 1 subjects scheduled for February alone. And, thousands additional letters will be sent out from other institutions within the next 6 months.							
Quality assurance			x	x	x	x	
Progress to date: The research coordinators at each enrolling site upload their CRFs to the RedCap database and fax these same forms to us at UC San Diego. There is an individual associated with the study (IRB approved) who then checks every value against what is in RedCap to catch any errors. To date, we have found not a single error, which is a testament to the enrolling center research coordinators.							
Interim analyses (at 25%, 50%, 75% enrollment)					x	x	
Progress to date: The first interim analysis was completed last year and the next will be done at 50% enrollment (72 evaluable subjects).							
Data collection & entry (Day 1 to Month 12)			x	x	x	x	x
Progress to date: Data collection is ongoing from the day of treatment and continuing for 1 calendar year, as per protocol.							
Data cleaning and final statistical analysis							x

Progress to date: This is a triple-masked randomized, controlled clinical trial. As such, the investigators will remain masked to treatment group until all data has been collected and the final statistical analysis completed. Therefore, there is no data to report currently. However, the statistician prepared the interim analysis for the DSMB and I requested from that statistician (Edward Mascha, PhD) that he provide Dr. Tilghman with the results. We have specific stopping rules, and the DSMB approved continuation of the trial. Therefore, the trial was not stopped due to futility or success, and enrollment continues.							
Abstract preparation							x
Progress to date: This will occur following study completion.							
Full-length manuscript preparation							x
Progress to date: This will occur following study completion.							
IRB closures at all enrolling centers							x
Progress to date: This will occur following study completion.							
Final report to USAMRMC							x
Progress to date: This will occur following study completion.							
Uploading results to ClinicalTrials.gov							x
Progress to date: This will occur following study completion.							
Results sent to all enrolled subjects							x
Progress to date: This will occur following study completion.							

DSMB: Data Safety Monitoring Board

UCSD: University of California San Diego

IRB: Institutional Review Board

USAMRMC: United States Army Medical Research and Materiel Command

Key Research Accomplishments:

- There are no study results to report at this time since this is a randomized, double-masked, placebo-controlled clinical trial; and, treatment group assignment will not be unmasked until the completion of enrollment.

Reportable Outcomes:

- There are no reportable outcomes available at this time since this is a randomized, double-masked, placebo-controlled clinical trial; and, treatment group assignment will not be unmasked until the completion of enrollment.

Conclusion:
This is a randomized, triple-masked, placebo-controlled clinical trial that will remain masked until enrollment is completed and the final value for the primary endpoint has been collected. We are continuing enrollment; and, therefore, no results are available at this time.

References:
Non-applicable

Appendices:
A sample informational letter, print advertisement, enrollment table by institution, and study questionnaires are included on the following pages.

Do you have phantom limb pain?

I am writing to you to let you know that there is a new study at the University of California at San Diego and the Cleveland Clinic involving a possible new treatment for phantom limb pain. If you are currently experiencing phantom limb pain, I thought you might be interested in participating in this new study.

Study Purpose: To determine if putting local anesthetic—or numbing medication—through one or two tiny tube(s) placed next to the nerves that go to an amputated limb will decrease phantom limb pain.

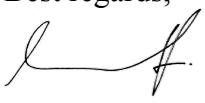
Study Intervention: To introduce the local anesthetic to the nerves that go to an amputated limb, the skin is numbed and a small needle inserted to area around the nerves. Then, a small tube—called a "catheter" and smaller than a piece of spaghetti—is placed through the needle next to the nerves. The needle is removed leaving the catheter in place, and local anesthetic is then infused through the catheter to continuously bathe the nerves in numbing medication. The catheter cannot be felt once placed—there is no unpleasant feeling (or any feeling of the catheter at all). A small, portable infusion pump is used to infuse the local anesthetic so that patients may receive the treatment in the comfort of their own homes. The catheter may be removed at home as well, so that patients do not need to return to the hospital after the catheter is initially placed.

Study Procedures: If you take part in this study, one (arm/hand) or two (leg/foot) catheters will be placed at either the Cleveland Clinic or the University of California at San Diego. You will initially receive either local anesthetic or sterile saline (like water) through the catheter—determined randomly, like a flip of a coin. For the following week you will continue to go about your normal routine, as the fluid will be infused using a small, portable infusion pump. You will be called daily so that we may check to see how you are doing, and you will have the phone and pager numbers of a physician who is available to you at all times. After 7 days, the catheter will be removed with instructions given over the telephone. We will call each week through the fourth week to see how you are doing. Four to sixteen weeks after the first catheter was inserted, you may have new catheter(s) placed, and you will receive the opposite treatment as the first infusion. So, if you initially received normal saline, the second infusion will be local anesthetic. In this way, ***every*** participant will receive the active treatment within the first four months after enrolling. However, if you decide that you do not want the second infusion, there is no obligation to receive it.

There is also no cost to participate in this study. However, you will be responsible for transportation to and from the center for the catheter insertion(s). To compensate you for your time and efforts, as well as help defray any travel expenses, $100 is provided following each catheter insertion; and, $50 for each day that you have your infusion running at home.

If you are interested in this study, please call the study coordinator at (858) 242-6017 (M-F, 9-5, Pacific) or email at phantompain@ucsd.edu and they will provide further study details and answer any questions for you.

Best regards,

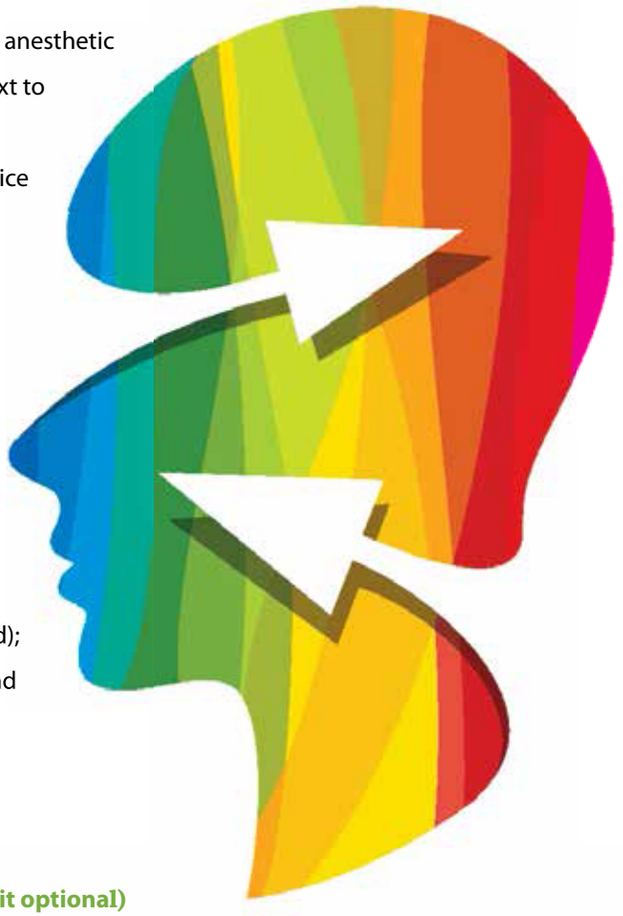


Stavros G. Memtsoudis, M.D.
Department of Anesthesiology
Hospital for Special Surgery

Do You Have Phantom Limb Pain?

If so, you might be eligible for a research study that aims to decrease and/or resolve phantom limb pain in people with an upper- or lower-limb amputation.

The purpose of this research study is to determine if putting local anesthetic (numbing medication) through one or two tiny tube(s) placed next to the nerve(s) that go to an amputated limb will decrease and/or resolve phantom limb and residual limb pain. The procedure, device and infusion are all FDA approved and have been used for over 20 years to decrease pain immediately after surgery.



Participants will receive $100 following each catheter insertion plus $50/day during the 6-day infusion(s), up to a maximum of $800/subject.

This study is being conducted at the University of California (San Diego, California); Cleveland Clinic (Cleveland, Ohio); Walter Reed National Military Medical Center (Bethesda, Maryland); Veterans Affairs Palo Alto Medical Center (Palo Alto, California); and Naval Medical Center (San Diego, California).

- **No surgery involved**
- **Either lower or upper limb amputations**
- **Only a single 2-4 hour visit to the treatment center (2nd visit optional)**

Human Research Protections Program
UC San Diego
Approved
Initial Approval: 04/04/2013
Current Approval: 04/23/2015
Protocol: 130341

For more information, please call or email:
858.242.6017 · phantompain@ucsd.edu

DoD Phantom Pain Study

	Year 1 (2013)				Year 2 (2014)				Year 3 (2015)				Year 4 (2016)				Total
Quarter	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
UC San Diego				1					8	1	3	*1*					14
Cleveland Clinic					3	1	8	3	2	5	6	*8*					36
Palo Alto VA										1		1					2
Walter Reed																	0
Naval Medical Center																	0
Quarterly Total	0	0	0	1	3	1	8	3	10	7	9	10	0	0	0	0	52
Yearly Total		1				15				36				0			52

Beck Depression Inventory

Randomization Number: ____ - ____ ____ ____ *[fill in following randomization]*

Subject Initials: ____ ____ ____

Time point: ☐ Initial ☐ Crossover ☐ 0 Days ☐ 28 Days ☐ 6 Months ☐ 1 Year

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:
- ☐ Subject could not be contacted
- ☐ Subject refusal
- ☐ Subject withdrew
- ☐ Other: _____

Circle the correct number for each question:

1) Sadness:
0 You do not feel sad.
1 You feel sad much of the time
2 You are sad all the time.
3 You are so sad or unhappy that you can't stand it

2) Pessimism:
0 You are not discouraged about your future.
1 You feel more discouraged about your future than you used to be.
2 You do not expect things to work out for yourself.
3 You feel your future is hopeless and will only get worse.

3) Past Failure:
0 You do not feel like a failure.
1 You have failed more than you should have
2 As you look back, you see a lot of failures.
3 You feel you are a total failure as a person.

4) Loss of Pleasure:
0 You get as much pleasure as you ever did from things you enjoy.
1 You don't enjoy things as much as you used to.
2 You get very little pleasure from the things you used to enjoy.
3 You can't get any pleasure from the things you used to enjoy.

[continued on next page]

5) Guilty Feelings:
0 You don't feel particularly guilty.
1 You feel guilty over many things you have done or should have done.
2 You feel quite guilty most of the time.
3 You feel guilty all the time.

6) Punishment Feelings:
0 You don't feel you are being punished.
1 You feel you may be punished.
2 You expect to be punished.
3 You feel you are being punished.

7) Self-Dislike:
0 You do not feel sad.
1 You feel sad much of the time.
2 You are sad all the time.
3 You are so sad or unhappy that you can't stand it.

8) Self-Criticalness:
0 You don't criticize or blame yourself more than usual.
1 You are more critical of yourself than you used to be.
2 You criticize yourself for all of your faults.
3 You blame yourself for everything bad that happens

9) Suicidal Thoughts or Wishes:
0 You don't have any thoughts of killing yourself.
1 You have thoughts of killing yourself, but you would not carry them out. *
2 You would like to kill yourself. *
3 You would kill yourself if you had the chance. *
*contact Site Director at end of questionnaire

10) Self-Dislike:

0 You don't cry any more than you used to.
1 You cry more than you used to.
2 You cry over every little thing.
3 You feel like crying, but you can't.

11) Agitation:

0 You are no more restless or wound up than usual.
1 You feel more restless or wound up than usual.
2 You are so restless or agitated that it's hard to stay still.
3 You are so restless or agitated that you have to keep moving or doing something.

12) Loss of Interest:

0 You have not lost interest in other people or activities.
1 You are less interested in other people or things than before.
2 You have lost most of your interest in other people or things.
3 It's hard to get interested in anything.

13) Indecisiveness:

0 You make decisions about as well as ever.
1 You find it more difficult to make decisions than usual.
2 You have much greater difficulty in making decisions than you used to.
3 You have trouble making any decisions.

14) Worthlessness:

0 You do not feel you are worthless.
1 You don't consider yourself as worthwhile and useful as you used to.
2 You feel more worthless as compared to other people.
3 You feel utterly worthless.

15) Loss of Energy:

0 You have as much energy as ever.
1 You have less energy than you used to have.
2 You don't have enough energy to do very much. 3 You don't have enough energy to do anything.

16) Changes in Sleeping Pattern:

0 You have not experienced any change in your sleeping pattern.
1a You sleep somewhat more than usual.
1b You sleep somewhat less than usual.
2a You sleep a lot more than usual.
2b You sleep a lot less than usual.
3a You sleep most of the day.
3b You wake up 1-2 hours early and can't get back to sleep.

17) Irritability:

0 You are no more irritable than usual.
1 You are more irritable than usual.
2 You are much more irritable than usual.
3 You are irritable all the time.

18) Changes in Appetite:

0 You have not experienced any change in appetite.
1a Your appetite is somewhat less than usual.
1b Your appetite is somewhat greater than usual.
2a Your appetite is much less than before.
2b Your appetite is much greater than usual.
3a You have no appetite at all.
3b You crave food all the time.

19) Concentration Difficulty:

0 You can concentrate as well as ever.
1 You can't concentrate as well as usual.
2 It's hard to keep your mind on anything for very long.
3 You find you can't concentrate on anything.

20) Tiredness of Fatigue:

0 You are no more tired or fatigued than usual.
1 You get more tired or fatigued more easily than usual.
2 You are too tired or fatigued to do a lot of the things you used to do.
3 You are too tired or fatigued to do most of the things you used to do.

21) Loss of Interest in Sex:

0 You have not noticed any recent change in your interest in sex.
1 You are less interested in sex than you used to be.
2 You are much less interested in sex now.
3 You have lost interest in sex completely

Enrollment CRF: Day 0
(Initial Treatment Only)

Randomization Number: ____ - ____ ____ ____ ***[fill in following randomization]***

Subject Initials: ____ ____ ____

Questionnaire administered by (initials): ___ ___

Day 0 date (initial catheter placement and/or date of questionnaire): ___ ___ / ___ ___ / 201 ___

Has subject signed HIPAA and informed consent form(s)? ☐ Yes ☐ No [STOP]

Last Name:	
First Name:	
Middle Name:	
Medical Record Number:	
Email:	
Phone Number:	(___ ___ ___) ___ ___ ___ - ___ ___ ___ ___
Backup Phone Number:	(___ ___ ___) ___ ___ ___ - ___ ___ ___ ___
Birth Date:	___ ___ / ___ ___ / ___ ___ ___ ___
Sex	☐ Female ☐ Male
Height	____ ____ ____ in *-or-* ____ ____ ____ cm
Weight	____ ____ ____ lbs *-or-* ____ ____ ____ kg
BMI [calculate]	____ ____ = [lbs / $(in)^2$] x 703 *-or-* ____ ____ = [kg / $(m)^2$]
Years of education completed	____ ____
Marital status	☐ Single (never married) ☐ Single (divorced) ☐ Married ☐ Separated ☐ Widowed
Military status	☐ Civilian (never in military) ☐ Veteran ☐ Reserves (inactive) ☐ Reserves (active) ☐ Active Duty
Address (#, street, city, state, zip code)	

Inclusion / Exclusion Criteria (check all that apply)

Inclusion Criteria:

☐ 18 years of age or older

☐ Upper or lower limb traumatic or surgical amputation **at least** 12 weeks prior to enrollment at or distal to the mid-humerus or hip (femoral head remaining), respectively; and including at least one metacarpal or metatarsal bone, respectively.

☐ Experiencing at least moderate phantom limb pain (defined as 2 or higher on the numeric rating scale, NRS 0-10), at least 3 times each week for the previous 8 weeks.

☐ Accepting of an ambulatory continuous peripheral nerve block for 6 days.

☐ Willing to avoid changes to their analgesic regimen from 4 weeks prior to and at least 4 weeks following the initial catheter placement (preferably 4 weeks following the second/crossover catheter insertion as well).

☐ Having a "caretaker" who will transport the subject home following the catheter insertion(s), and remain with the subject for the first night of the infusions.

Exclusion Criteria:

☐ Known renal insufficiency (creatinine > 1.5 mg/dL)

☐ Allergy to study medications

☐ Pregnancy

☐ Incarceration

☐ Inability to communicate with the investigators

☐ Morbid obesity (BMI greater than 40)

☐ Comorbidity that results in moderate-to-severe functional limitation (ASA greater than 2)

☐ Any contraindication to ambulatory perineural catheter placement or perineural local anesthetic infusion

☐ Other: _____

Disposition:

☐ Subject meets all inclusion and exclusion criteria **and enrolls** (CONTINUE collecting data on this form and fax to UCSD when complete)

☐ Subject meets all inclusion and exclusion criteria but does **not** choose to enroll (do NOT continue collecting data; but DO fax this form to UCSD: 858-683-2003)

☐ Subject does **not** meet all inclusion/exclusion criteria and therefore can**not** enroll (do NOT continue collecting data; but DO fax this form to UCSD: 858-683-2003)

[Continue on following page if subject meets all inclusion/exclusion criteria and chooses to enroll]

Study Limb Information

Initial Amputation Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Amputation extremity: ☐ Upper ☐ Lower

Side of amputation: ☐ Right ☐ Left

Level of original amputation (**distal to**…): ☐ wrist/ankle ☐ elbow/knee ☐ shoulder/hip

Initial Amputation Etiology (describe): _____

_____

_____

_____

Dates of **all** surgical revisions (month/year):

___ ___ / ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___

___ ___ / ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___ ___ ___ / ___ ___ ___ ___

Date *phantom* limb pain first occurred (month/year): ___ ___ / ___ ___ ___ ___

Phantom limb pain description (subject's own words): _____

_____

_____

History of *residual limb* or *stump* pain: ☐ Yes ☐ No

Current *residual limb* or *stump* pain: ☐ Yes ☐ No

Date *residual limb* or *stump* pain first occurred: ___ ___ / ___ ___ ___ ___ ☐ Not applicable

Current Prosthesis Use: ☐ Yes ☐ No

[Continued on following page]

NON-Study Limb(s) Information

Amputations in a limb OTHER than the study limb: ☐ Yes ☐ No [skip to next page]

Initial Amputation Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Amputation extremity: ☐ Upper ☐ Lower

Side of amputation: ☐ Right ☐ Left

Level of original amputation (distal to…): ☐ wrist/ankle ☐ elbow/knee ☐ shoulder/hip

Initial Amputation Etiology (describe briefly): _____

Surgical revision: ☐ Yes ☐ No

History of *phantom* limb pain: ☐ Yes ☐ No

Date *phantom* limb pain last occurred (month/year): ___ ___ / ___ ___ ___ ___

History of *residual limb* or *stump* pain: ☐ Yes ☐ No

Date *residual* limb pain last occurred (month/year): ___ ___ / ___ ___ ___ ___

Additional amputation(s): ☐ Yes ☐ No [skip to next page]

Initial Amputation Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Amputation extremity: ☐ Upper ☐ Lower

Side of amputation: ☐ Right ☐ Left

Level of original amputation (distal to…): ☐ wrist/ankle ☐ elbow/knee ☐ shoulder/hip

Initial Amputation Etiology (describe briefly): _____

Surgical revision: ☐ Yes ☐ No

History of *phantom* limb pain: ☐ Yes ☐ No

Date *phantom* limb pain last occurred (month/year): ___ ___ / ___ ___ ___ ___

History of *residual limb* or *stump* pain: ☐ Yes ☐ No

Date *residual* limb pain last occurred (month/year): ___ ___ / ___ ___ ___ ___

[Continued on following page]

Pain and Analgesic Regimen

Current **scheduled** analgesic medications (include dose):

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

Current **breakthrough (prn)** analgesic medications (include dose used in the past week)

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

Current analgesic **adjuvants** (e.g. acupuncture, biofeedback):

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

Day 0 CRF with Brief Pain Inventory completed prior to catheter insertion: ☐ Yes ☐ No [stop]

Beck's Depression Inventory completed prior to catheter insertion: ☐ Yes ☐ No [stop]

[Continued on following page]

Catheter Insertion(s)

Phantom limb pain (study extremity) *immediately prior* to premedication (NRS 0-10): ____ ____

Residual limb pain ("stump pain") *immediately prior* to premedication (NRS 0-10): ____ ____

Catheter Insertion Protocol:

Upper Limb (1 catheter): Curved array transducer; 17 g Tuohy (stimulation okay) needle tip between axillary artery and posterior brachial plexus cord. Normal saline (5-20 mL, less is better) injected *via* the needle to open the space. Flexible 19 g catheter 5 cm beyond needle tip. Needle removed over catheter, catheter tunneled subcutaneously, and catheter affixed using liquid adhesive, anchoring device, and occlusive dressings. Lidocaine 2% with epinephrine 2.5 µg/mL (30 mL) injected *via* the catheter.

Lower Limb (2 catheters): Linear array transducer; 17 g Tuohy (stimulation okay) needles. *Popliteal* first: sciatic nerve cephalad to sciatic bifurcation; *femoral* at inguinal crease. *For EACH catheter:* normal saline (5-20 mL, less is better) injected *via* the needle to open the space. Flexible 19 g catheter 5 cm beyond needle tip. Needle removed over catheter, catheter tunneled subcutaneously, and catheter affixed using liquid adhesive, anchoring device, and occlusive dressings. Lidocaine 2% with epinephrine 2.5 µg/mL (20 mL) injected *via* the catheter.

Catheter(s) inserted per protocol: ☐ Yes ☐ No

Phantom limb pain (study extremity) *20 min following* local anesthetic bolus[s] (NRS 0-10): ____ ____

Residual limb pain ("stump pain") *20 min following* local anesthetic bolus[s] (NRS 0-10): ____ ____

Decreased sensation of cold (alcohol) in appropriate sensory distributions: ☐ Yes ☐ No [replace or stop]

Subject randomized: ☐ Yes [insert randomization # on 1st page of this form] ☐ No [stop]

Infusion pump(s) running (femoral 2.5 mL/h; popliteal 5 mL/h; infraclavicular 7.5 mL/h): ☐ Yes ☐ No

Subject discharged home and forms **faxed** to UCSD (**858-683-2003**): ☐ Yes ☐ No [stop]

Coordinator: _____ ___ ___ / ___ ___ / 201 ___
Signature Date

Site Director: _____ ___ ___ / ___ ___ / 201 ___
Signature Date

Crossover Catheter Insertion: Day 0
(Crossover Treatment Only)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Questionnaire administered by (initials): ___ ___

Crossover catheter placement (Day 0): ___ ___ / ___ ___ / 201 ___

Did analgesic medications change since initial catheter insertion: ☐ Yes [fill-in below] ☐ No

Changes to **scheduled** analgesic medications (include dose):

1.	3.
2.	4.

Changes to **breakthrough (prn)** analgesic medications (include dose used in the past week)

1.	3.
2.	4.

Changes to analgesic **adjuvants** (e.g. acupuncture, biofeedback):

1.	3.
2.	4.

Day 0 CRF with Brief Pain Inventory completed prior to catheter insertion: ☐ Yes ☐ No [stop]

Beck's Depression Inventory completed prior to catheter insertion: ☐ Yes ☐ No [stop]

[Continued on following page]

Catheter Insertion(s)

Phantom limb pain (study extremity) *immediately prior* to premedication (NRS 0-10): ____ ____

Residual limb pain ("stump pain") *immediately prior* to premedication (NRS 0-10): ____ ____

Catheter Insertion Protocol:

Upper Limb (1 catheter): Curved array transducer; 17 g Tuohy (stimulation okay) needle tip between axillary artery and posterior brachial plexus cord. Normal saline (5-20 mL, less is better) injected *via* the needle to open the space. Flexible 19 g catheter 5 cm beyond needle tip. Needle removed over catheter, catheter tunneled subcutaneously, and catheter affixed using liquid adhesive, anchoring device, and occlusive dressings. Lidocaine 2% with epinephrine 2.5 µg/mL (30 mL) injected *via* the catheter.

Lower Limb (2 catheters): Linear array transducer; 17 g Tuohy (stimulation okay) needles. *Popliteal* first: sciatic nerve cephalad to sciatic bifurcation; *femoral* at inguinal crease. *For EACH catheter:* normal saline (5-20 mL, less is better) injected *via* the needle to open the space. Flexible 19 g catheter 5 cm beyond needle tip. Needle removed over catheter, catheter tunneled subcutaneously, and catheter affixed using liquid adhesive, anchoring device, and occlusive dressings. Lidocaine 2% with epinephrine 2.5 µg/mL (20 mL) injected *via* the catheter.

Catheter(s) inserted per protocol: ☐ Yes ☐ No

Phantom limb pain (study extremity) *20 min following* local anesthetic bolus[s] (NRS 0-10): ____ ____

Residual limb pain ("stump pain") *20 min following* local anesthetic bolus[s] (NRS 0-10): ____ ____

Decreased sensation of cold (alcohol) in appropriate sensory distributions: ☐ Yes ☐ No [replace or stop]

Infusion pump(s) running (femoral 2.5 mL/h; popliteal 5 mL/h; infraclavicular 7.5 mL/h): ☐ Yes ☐ No

Subject discharged home and forms **faxed** to UCSD (**858-683-2003**): ☐ Yes ☐ No [stop]

Coordinator: _____ ___ ___ / ___ ___ / 201 ___
Signature Date

Site Director: _____ ___ ___ / ___ ___ / 201 ___
Signature Date

Baseline Data Collection Form: Day 0

(Just prior to Initial *or* Crossover Treatment)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Treatment: ☐ Initial ☐ Crossover

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about any* ***phantom limb pain*** *you may be having.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST in the last three days? ____ ____

2a) How would you describe your phantom limb pain at its LEAST in the last three days? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE in the last three days? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST in the last three days? ____ ____

2b) How would you describe your stump pain at its LEAST in the last three days? ____ ____

3b) How would you describe your stump pain on AVERAGE in the last three days? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments or medications provided in the last three days? (enter 8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

In the last three days, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

Now, I am going to ask about the frequency and duration of different sensations [record "99" for continuous]**.**

13a) How many times in the last 3 days have you experienced **phantom limb** pain? ____ ____

14a) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

13c) How many times in the last 3 days have you experienced **non-painful phantom sensations** in the lost body part? ____ ____

14c) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

6b) How many times in the last 3 days have you experienced **stump** pain? ____ ____

7b) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

Data Collection Form: Day 1

(Initial or Crossover Treatment)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Treatment: ☐ Initial ☐ Crossover

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about* ***phantom limb pain****.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST since the catheters were inserted? ____ ____

2a) How would you describe your phantom limb pain at its LEAST since the catheters were inserted? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE since the catheters were inserted? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST since the catheters were inserted? ____ ____

2b) How would you describe your stump pain at its LEAST since the catheters were inserted? ____ ____

3b) How would you describe your stump pain on AVERAGE since the catheters were inserted? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments/medications provided since the catheters were inserted? (8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

Since the catheters were inserted, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

Patient Global Impression of Change Scale (PGIC)

How much improvement you have had in your phantom limb pain ***since the very first catheter was placed****:*

Very much worse			No change			Very much improved
1	2	3	4	5	6	7

Now, I am going to ask about the frequency and duration of phantom limb pain [record "99" for continuous]**.**

13a) How many times since the catheters were inserted have you experienced **phantom limb** pain? ____ ____

14a) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

13c) How many times since the catheters were inserted have you experienced **non-painful phantom sensations** in the lost body part? ____ ____

14c) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

6b) How many times since the catheters were inserted have you experienced **stump** pain? ____ ____

7b) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

Data Collection Form: Day 7

(Initial or Crossover Treatment)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Treatment: ☐ Initial ☐ Crossover

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about any* ***phantom limb pain*** *you may be having.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST since catheter removal? ____ ____

2a) How would you describe your phantom limb pain at its LEAST since catheter removal? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE since catheter removal? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST since catheter removal? ____ ____

2b) How would you describe your stump pain at its LEAST since catheter removal? ____ ____

3b) How would you describe your stump pain on AVERAGE since catheter removal? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

Data Collection Form: Days 14 and 21

(Initial or Crossover Treatment)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Treatment: ☐ Initial ☐ Crossover

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

Time point: ☐ Day 14 ☐ Day 21

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about any* ***phantom limb pain*** *you may be having.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST in the last three days? ____ ____

2a) How would you describe your phantom limb pain at its LEAST in the last three days? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE in the last three days? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST in the last three days? ____ ____

2b) How would you describe your stump pain at its LEAST in the last three days? ____ ____

3b) How would you describe your stump pain on AVERAGE in the last three days? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments or medications provided in the last three days? (enter 8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

In the last three days, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments or medications provided since catheter removal? (enter 8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

Since catheter removal, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

Patient Global Impression of Change Scale (PGIC)

How much improvement you have had in your phantom limb pain ***since the very first catheter was placed****:*

Very much worse			No change			Very much improved
1	2	3	4	5	6	7

Data Collection Form: Day 28
(Initial or Crossover Treatment)

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Treatment: ☐ Initial ☐ Crossover

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about* ***phantom limb pain****.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST in the last three days? ____ ____

2a) How would you describe your phantom limb pain at its LEAST in the last three days? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE in the last three days? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST in the last three days? ____ ____

2b) How would you describe your stump pain at its LEAST in the last three days? ____ ____

3b) How would you describe your stump pain on AVERAGE in the last three days? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments or medications provided in the last 3 days? (8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

In the last three days, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

Patient Global Impression of Change Scale (PGIC)

How much improvement you have had in your phantom limb pain ***since the very first catheter was placed****:*

Very much worse			No change			Very much improved
1	2	3	4	5	6	7

Now, I am going to ask about the frequency and duration of phantom limb pain [record "99" for continuous]**.**

13a) How many times in the last three days have you experienced **phantom limb** pain? ____ ____

14a) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

13c) How many times in the last three days have you experienced **non-painful phantom sensations** in the lost body part? ____ ____

14c) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

6b) How many times in the last three days have you experienced **stump** pain? ____ ____

7b) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

Which study fluid do you believe you received during your most-recent infusion:

☐ Definitely active ☐ Probably active ☐ Don't know ☐ Probably saline ☐ Definitely saline

Data Collection Form: Months 6 and 12

Randomization Number: ____ - ____ ____ ____

Subject Initials: ____ ____ ____

Time point: ☐ Month 6 ☐ Month 12

Administered by (initials): ___ ___

Questionnaire Date: ____ / ____ / 201 ____

If form not completed:

☐ Subject could not be contacted

☐ Subject refusal

☐ Subject withdrew

☐ Other: _____

Read aloud: *I am going to ask you some questions referring to pain in your limb being treated. Stump pain is defined as painful sensations located in the portion of the limb still physically present. Phantom limb pain is defined as painful sensations experienced where there is no longer a limb. First, I will ask you about* ***phantom limb pain****.*

On a scale from 0-10, with 0 equal to 'no pain' and 10 equal to 'worst imaginable pain':

1a) How would you describe your phantom limb pain at its WORST in the last three days? ____ ____

2a) How would you describe your phantom limb pain at its LEAST in the last three days? ____ ____

3a) How would you describe your phantom limb pain on AVERAGE in the last three days? ____ ____

4a) How would you describe how much phantom limb pain you have RIGHT NOW? ____ ____

The next questions use the same 0-10 scale, but now refer to your RESIDUAL LIMB or STUMP pain:

1b) How would you describe your stump pain at its WORST in the last three days? ____ ____

2b) How would you describe your stump pain at its LEAST in the last three days? ____ ____

3b) How would you describe your stump pain on AVERAGE in the last three days? ____ ____

4b) How would you describe how much stump pain you have RIGHT NOW? ____ ____

On a scale from 0%-100%, with 0% equal to 'no relief' and 100% equal to 'complete relief':

How much relief have pain treatments or medications provided in the last 3 days? (8888 if not applicable):

5a) PHANTOM LIMB pain? ____ ____ ____ %

5b) STUMP pain? ____ ____ ____ %

The next questions refer only to your phantom limb pain. On a scale from 0-10, with 0 equal to 'does not interfere' and 10 equal to 'completely interferes':

In the last three days, how has your *phantom limb pain* interfered with [must answer all]:

6a) General Activity ____ ____

7a) Mood ____ ____

8a) Walking ability ____ ____

9a) Normal work (includes both work outside the home and housework) ____ ____

10a) Relations with other people ____ ____

11a) Sleep ____ ____

12a) Enjoyment of life ____ ____

Patient Global Impression of Change Scale (PGIC)

How much improvement you have had in your phantom limb pain ***since the very first catheter was placed****:*

Very much worse			No change			Very much improved
1	2	3	4	5	6	7

Now, I am going to ask about the frequency and duration of phantom limb pain [record "99" for continuous]**.**

13a) How many times in the last three days have you experienced **phantom limb** pain? ____ ____

14a) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

13c) How many times in the last three days have you experienced **non-painful phantom sensations** in the lost body part? ____ ____

14c) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour

6b) How many times in the last three days have you experienced **stump** pain? ____ ____

7b) How many minutes/hours did each episode last, on average (circle m/h): ____ ____ min / hour