

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)	
Screening	FORM 01

Instructions:

This form does NOT need to be completed UNLESS a patient meets BOTH Phase I AND Phase II eligibility criteria. If the patient meets ALL of these criteria, please transfer the information to Page 2 of the form and proceed to the Phase III Eligibility Screening (patient interview) on Page 3.

The On-Site Study Coordinator (OSSC) should complete this form at the time each patient is screened for Phase III Eligibility. After the screening process is complete, the OSSC should return the form as soon as possible to the PoPCRN Office in one of the business reply envelopes supplied for the study.

If the screened patient was enrolled in the study, then please do the following:

- 1) Complete questions 5-17 by consulting medical records and/or staff
- 2) Ensure that all questions have been answered on each page or 'unavailable' has been written next to them
- 3) Remove the pink copies and retain them in the patient's file
- 4) Make copies of the Consent and HIPAA Authorization B Forms for the patient's file (recommended)
- 5) Mail the blue enrollment packet along with the original, signed copies of the Consent and HIPAA Authorization B Forms to the PoPCRN Office

If the screened patient was found to be ineligible for or decides not to enroll in the study, then please do the following:

- 1) Complete questions 4a-4e2 (based on where the patient interview ended) and questions 6, 7, 8, 9, 11 & 14 by consulting medical records and/or staff
- 2) Scribble out the patients initials on each page to ensure they are illegible (if applicable)
- 3) Remove the pink copies and retain them in the patient's file
- 4) Remove the form from the blue enrollment packet (if applicable)
- 5) Paper clip all pages of the form together
- 6) Mail the form to the PoPCRN Office

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Instructions: This form does **NOT** need to be completed **UNLESS** a patient meets **BOTH** Phase I **AND** Phase II eligibility criteria. If the patient meets **ALL** of these criteria, please transfer the information to Page 2 of the form and proceed to the Phase III Eligibility Screening (patient interview) on Page 3. The On-Site Study Coordinator (OSSC) should complete this form at the time each patient is screened for Phase III Eligibility. After the screening process is complete, the OSSC should return the form as soon as possible to the PoPCRN Office in one of the business reply envelopes supplied for the study.

Patient ID: 1-5 - [subject] Patient Initials: 6-8 Visit No: 9 0 [visit] Form No: 10-11 0 1 [form]

1. Date: 12-19 MM DD Year

2. **Phase I Eligibility Screening:** (Instructions - Please attempt to obtain this information from the medical records or medical staff first. If unable to do so, please ask the patient during the Phase III patient interview on Page 3. Please mark the answers to the questions below and on other pages of this form as indicated.)

	Yes	No
a. Adult age (≥ 18 years) [See Question 7 on Page 3]: [over18] _____ 20	<input type="text"/> 1	<input type="text"/> 0
b. English speaking: [english] _____ 21	<input type="text"/> 1	<input type="text"/> 0
c. Anticipated life expectancy of at least 3 weeks: [lifeExpectancy] _____ 22	<input type="text"/> 1	<input type="text"/> 0
d. Advanced cancer diagnosis [See Question 14 on Page 4]: _____ 23	<input type="text"/> 1	<input type="text"/> 0

If ALL of the answers to the criteria above are **YES**, please proceed.

If ANY of the answers are **NO**, the patient is ineligible for the study. Do not proceed to the Phase II or III Eligibility Screening. Please attempt to obtain information for Questions 6, 7, 8, 9, 11 & 14 on this form through medical records and/or staff. Please send the completed form as soon as possible to the PoPCRN Office in one of the business reply envelopes supplied for the study.
(Please refer to the instructions on Page 1 with regard to completing this form for ineligible patients.)

3. **Phase II Eligibility Screening:** (Instructions - Please attempt to obtain this information from the medical records or medical staff first. If unable to do so, please ask the patient during the Phase III patient interview on Page 3. Please mark the answers to the questions below and on other pages of this form as indicated.)

	Yes	No	Unavailable
a. Patient is receiving anticoagulant (blood thinning) therapy: [anticoag] _____ 24	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 8
b. Patient has a known platelet count of $<10,000$: [lowPlatelet] _____ 25	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 8
c. Patient has a known unstable spine: [unstableSpine] _____ 26	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 8

If ALL of the answers to the criteria above are **NO** or **UNAVAILABLE**, please proceed.

If ANY of the answers are **YES**, the patient is ineligible for the study. Do not proceed to Phase III Eligibility Screening. Please attempt to obtain information for Questions 6, 7, 8, 9, 11 & 14 on this form through medical records and/or staff. Please send the completed form as soon as possible to the PoPCRN Office in one of the business reply envelopes supplied for the study.
(Please refer to the instructions on Page 1 for completing this form for ineligible patients.)

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)	
Screening	FORM 01

		=			
--	--	---	--	--	--

6-8			
-----	--	--	--

0

0	1
---	---

32-39 MM DD Year

40 **1** Male **2** Female

Year	2000	2001	2002	2003
41-44				

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REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Patient ID: -

Patient Initials:

Visit No: [visit]

Form No: [form]

[subject]

8. Race and Ethnic Background:

Ethnicity: (Mark Yes or No for each)

[yesLatinx] a. Hispanic or Latino origin:

Yes No
1 0

[noLatinx] b. Not of Hispanic or Latino origin:

1 0

9. Race (Mark Yes or No for each)

a. White: [white]

b. Black or African American: [black]

c. Asian: [asian]

[pacific] d. Native Hawaiian or other Pacific Islander:

[aian] e. American Indian or Alaskan Native:

f. Other, please specify: _____

	Yes	No
47	1	0
48	1	0
49	1	0
50	1	0
51	1	0
52	1	0

[otherRace]

10. Marital Status: (Write Number in box)

53 1 = Married
2 = Committed Relationship
3 = Single, Never Married
4 = Divorced/Separated
5 = Widowed

[marital]

11. Patient location: (Write Number in box)

54 1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

[ploc]

12. Patient's primary payor/insurance source: (Write Number in box)

55 1 = Medicare
2 = Medicaid
3 = Commercial (private) insurance
4 = Own income, family support
5 = Medically indigent
6 = Other, specify: _____

[insurance]

13. Education - Highest Grade Completed: (Write Number in box)

56 0 = No Education
1 = Grammar School
2 = High School
3 = College
4 = Postgraduate

[education]

14. Primary Active Advanced Cancer Type: (Select from list below) [priCa]

57-58

- | | | |
|-----------------|---------------------------|--|
| 01 = Bladder | 11 = Multiple Myeloma | 21 = Unknown (ONLY if primary active type not known) |
| 02 = Brain | 12 = Oropharyngeal | |
| 03 = Breast | 13 = Ovary | |
| 04 = Colorectal | 14 = Pancreas | |
| 05 = Kidney | 15 = Prostate | |
| 06 = Leukemia | 16 = Skin (not melanoma) | |
| 07 = Liver | 17 = Stomach | |
| 08 = Lung | 18 = Uterus | |
| 09 = Lymphoma | 19 = Other specify: _____ | |
| 10 = Melanoma | 20 = Esophageal | |

15. Date of initial cancer diagnosis:

59-64 MM Year

Removed due to PHI, please see var [yearsCaDx] or [monthsCaDx] for time between diagnosis and org enrollment

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

SCREENING

(FORM 01)

Patient ID: - [subject] Patient Initials:

Visit No: 0 [visit] Form No: 0 1 [form]

16. Location of metastases (Mark all Yes or No):

	Yes	No
a. Bone: _____ 65	<input type="text"/> 1	<input type="text"/> 0 [boneMet]
b. Brain: _____ 66	<input type="text"/> 1	<input type="text"/> 0 [brainMet]
c. Liver: _____ 67	<input type="text"/> 1	<input type="text"/> 0 [liverMet]
d. Lung: _____ 68	<input type="text"/> 1	<input type="text"/> 0 [lungMet]
e. Spinal Cord: _____ 69	<input type="text"/> 1	<input type="text"/> 0 [spinalMet]
f. Other, specify: _____ 70	<input type="text"/> 1	<input type="text"/> 0 [otherMet]
g. None Known: _____ 71	<input type="text"/> 1	<input type="text"/> 0 [noMet]
h. Unknown: _____ 72	<input type="text"/> 1	<input type="text"/> 0 [unknownMet]

17. Other major diagnoses for this patient are: (Mark Yes or No for each): [From the medical records and/or patient interview]

	Yes	No
a. Arthritis: [arthritis] _____ 73	<input type="text"/> 1	<input type="text"/> 0
b. Additional Cancer diagnosis: [addCaDx] _____ 74	<input type="text"/> 1	<input type="text"/> 0
c. Deep venous thrombosis: [dvt] _____ 75	<input type="text"/> 1	<input type="text"/> 0
d. Delirium: [delirium] _____ 76	<input type="text"/> 1	<input type="text"/> 0
e. Dementia: [dementia] _____ 77	<input type="text"/> 1	<input type="text"/> 0
f. Depression: [depression] _____ 78	<input type="text"/> 1	<input type="text"/> 0
g. Diabetes: [diabetes] _____ 79	<input type="text"/> 1	<input type="text"/> 0
h. Global decline/frailty/failure to thrive: [globalDecline] _____ 80	<input type="text"/> 1	<input type="text"/> 0
[heartDz] i. Heart disease (e.g. congestive heart failure, coronary artery disease, atrial fibrillation): _____ 81	<input type="text"/> 1	<input type="text"/> 0
j. HIV/AIDS: [hiv] _____ 82	<input type="text"/> 1	<input type="text"/> 0
k. Hypertension: [htn] _____ 83	<input type="text"/> 1	<input type="text"/> 0
l. Infection (pneumonia, urinary tract infection, cellulitis): [infection] _____ 84	<input type="text"/> 1	<input type="text"/> 0
m. Kidney/renal disease: [renalDz] _____ 85	<input type="text"/> 1	<input type="text"/> 0
n. Liver disease: [liverDz] _____ 86	<input type="text"/> 1	<input type="text"/> 0
[lungDz] o. Lung disease (e.g. COPD, asthma, interstitial lung disease, pulmonary hypertension): _____ 87	<input type="text"/> 1	<input type="text"/> 0

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Patient ID: - [subject]

Patient Initials:

Visit No: 0 [visit]

Form No: 0 1 [form]

17. **CONTINUED** - Other major diagnoses for this patient are: (Mark Yes or No for each): [From the medical records and/or patient interview]

	Yes	No
p. Neurologic disease (e.g. Parkinson's, ALS, multiple sclerosis): [neuroDz]	<input type="text"/> 1	<input type="text"/> 0
q. Peripheral Vascular Disease: [pvd]	<input type="text"/> 1	<input type="text"/> 0
r. Pressure ulcers: [pressureUlcers]	<input type="text"/> 1	<input type="text"/> 0
s. Pulmonary embolus: [pe]	<input type="text"/> 1	<input type="text"/> 0
t. Stroke: [stroke]	<input type="text"/> 1	<input type="text"/> 0
u. Other (specify): [otherDz]	<input type="text"/> 1	<input type="text"/> 0

PATIENT INTERVIEW SECTION: (INSTRUCTIONS: PLEASE ASK THE PATIENT TO ANSWER THE FOLLOWING QUESTIONS. PROVIDE THE PATIENT WITH THE RESPONSE CARDS FOR REFERENCE DURING THE INTERVIEW.)

18a. Have you (the patient) ever received professional massage therapy? (Mark one) [pastMT]

Yes	No	Don't Know
<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 8

18b. If YES, when was your most recent professional massage therapy session? (Mark one) [recentMT]

- 1 Within the past 4 weeks
- 2 5 - 12 weeks ago
- 3 >12 weeks ago
- 4 Don't know
- 9 N/A

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Patient ID: - [subject]

Patient Initials:

Visit No: 0 [visit]

Form No: 0 1 [form]

19. PAIN SCREENING / ASSESSMENT TOOL

- a. Have you experienced pain, discomfort, or soreness at rest or with movement now or in the past week?
(Mark Yes or No) [painPastWk] 1 Yes 0 No

If the patient reports no pain, the interview is complete. PLEASE STOP HERE. The patient is NOT eligible for the study. If the patient reports pain, continue with the questions below.

CONTINUE ONLY IF PATIENT HAS PAIN

How strong is your pain? Because I can't feel your pain, I want you to use a scale (*show patient Pain Scale on Response Card #1 for this question*) to let me know how much pain you have. The numbers between 0 and 10 represent ALL the pain a person could have. Zero means "no pain" and 10 means "pain as bad as it could be." You can use ANY number between 0 and 10 to let me know how much pain you have. Call your pain a number between 0 and 10 so I will know the intensity of the pain you feel now.

Pain Intensity on Number Scale 0 - 10

(Record a number between 0-10 for each item, based on the patient's indication of his/her answer on the pain scale on Response Card #1.)

b. now [painNow]
97-98

c. worst over [painWorst24]
99-100 past 24-hours

d. least over [painLeast24]
101-102 past 24-hours

e. worst over
103-104 past week
[painWorstWk]

f. least over
105-106 past week
[painLeastWk]

g. number you would
107-108 like your pain to be
[painGoal]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Patient ID: - [subject]

Patient Initials:

Visit No: 0 [visit]

Form No: 0 1 [form]

20. How does your pain change with time? Which words would you use to describe the pattern of your pain?
(Mark all Yes or No):

- | | Yes | No | |
|---|------------------------|------------------------|----------------|
| a. Brief: _____ 109 | <input type="text"/> 1 | <input type="text"/> 0 | [painBrief] |
| b. Constant: _____ 110 | <input type="text"/> 1 | <input type="text"/> 0 | [painConstant] |
| c. Intermittent (comes and goes): _____ 111 | <input type="text"/> 1 | <input type="text"/> 0 | [painIntermit] |

21. On a 1 to 5 scale, where 1 is "not at all helpful" and 5 is "very helpful," how helpful do you believe message therapy would be for your pain? (Write answer in the box):

- 112 1 = not at all helpful
 2 = a little bit helpful [MEfficacy]
 3 = somewhat helpful
 4 = quite a bit helpful
 5 = very helpful

Instructions: Ask questions 1-10 in this list, record all answers and check either "correct" or "error." An answer must be entirely correct for a "correct" score (e.g., Date: if month and year are correct but day is wrong, the score is "error"). Ask question 4a ONLY if patient does not have a telephone. Record total number of errors based on ten questions at the bottom of this page. If the patient's number of errors is only one digit, please enter zero in the first box, e.g., one error should be entered as "01." Total number of errors determines whether or not to approach the patient for informed consent for study participation.

22a. Short Portable Mental Status Questionnaire (SPMSQ)

Correct	Error			
			1	What is the date today? _____ / _____ / _____ Month Day Year
			2	What day of the week is it? _____
			3	What is the name of this place? _____
			4	What is your telephone number? (____) - _____ - _____
			4a	What is your street address? _____ (Ask only if patient does not have a phone)
			5	How old are you: _____
			6	When were you born? _____
			7	Who is currently the President of the U.S.? _____
			8	Who was President just before him? _____
			9	What was your mother's maiden name? _____
			10	Subtract 3 from 20 and keep subtracting 3 from each new number, all the way down. (20, 17, 14, 11, 8, 5, 2)
[errorSPMSQ]				Total Number of Errors <input type="text"/> <input type="text"/> If total number of errors is ≥ 5, patient is ineligible for the study.

Instructions: Proceed to next page.

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Screening

FORM 01

Patient
ID:

[subject]

Patient
Initials:

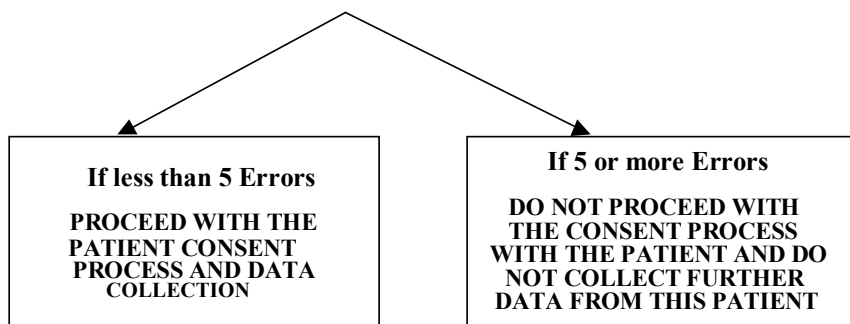
Visit
No:

[visit]

Form
No:

[form]

Total Number of Errors on the Mental Status Questionnaire (page 8):



22b. Is this patient eligible to consent for this study?

[eligible]

115 Yes No

If YES, please proceed with the consent and authorization process. The Consent Form and HIPAA Authorization Form B are included in blue enrollment packets.

Form Completed By: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Randomization Request

FORM 02

Instructions: The On-Site Study Coordinator (OSSC) should complete this form to request randomization to one of the treatment arms for each patient enrolled in the study. The OSSC should only complete the form **AFTER** the patient has signed the Consent and HIPAA Forms and the patient's signatures have been verified.

If the enrollment process took place via telephone interview, the OSSC or On-Site Data Collector (OSDC) **MUST** physically verify that the Consent and HIPAA Forms have been signed by the patient **BEFORE** a Randomization Request is made with this form or the Baseline Data Collection (Visit #1) is conducted.

Please fax this document to the PoPCRN Office using the toll-free number listed below.

Patient ID: 1-5 -

[subject]

Patient Initials: 6-8

Visit No: 9 0

Form No: 10-11 0 2

Instructions: Complete Questions 1-3 and fax the form to the PoPCRN Office at **1-866-301-7268**

1. Date of Randomization Request:

12-19 MM DD Year

Removed due to PHI, please see var [daysScreenRand] for number of days between screening and randomization or [daysOrgEnrollRand] for number of days between hospice organization enrollment and screening

Yes No

2. Patient met eligibility requirements for study?

20 1 2

3. Patient signed Consent Form and HIPAA Authorization Form B?

21 1 2

Instructions: Complete Question 4 after receiving randomization assignment from the PoPCRN Office

4. Record randomized treatment group for this patient [groupCode] based on email or phone call from PoPCRN Office.

Moving Touch Non-Moving Touch
22 1 2

Form Completed By: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Neuropathy Pain Scale (NPS)

FORM 03

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient ONLY at the Baseline Data Collection (Visit #1). The Baseline Data Collection can occur before Randomization Assignment OR within 3 working days of the Enrollment Date. If the Baseline Data Collection occurs after Randomization Assignment, then the the On-Site Study Coordinator (OSSC) will contact the OSDC regarding the Enrollment Date.

Patient ID: -
1-5 [subject]

Patient Initials:
6-8

Visit No: 1 [visit]
9

Form No: 0 3 [form]
10-11

1. Date:
12-19 MM DD Year

Removed due to PHI, please see var [daysRandNPS] for number of days between randomization and this form.

2. Patient location: [ploc]
(Write Number in box) 20

- 1 = Home
- 2 = Nursing Home/Skilled Nursing Facility
- 3 = Hospice Facility
- 4 = Other, specify: _____

Instructions: Please show the patient Response Card #2 and record the number indicated by the patient in the box beside each scale. If the patient's response is less than 2 digits, please place a zero in the first box.

3. Neuropathy Pain Scale:

- a. Please use the scale shown on the card to tell us how **intense** your pain is. Which number best describes the intensity of your pain.

0 1 2 3 4 5 6 7 8 9 10
No Pain The most intense pain sensation imaginable
21-22 [npsIntense]

- b. Please use the scale shown on the card to tell us how **sharp** your pain feels. Words used to describe "sharp" feelings include "like a knife", "like a spike", "jabbing" or "like jolts".

0 1 2 3 4 5 6 7 8 9 10
Not sharp The most sharp sensation imaginable ("like a knife")
23-24 [npsSharp]

- c. Please use the scale shown on the card to tell us how **hot** your pain feels. Words used to describe very hot pain include "burning" and "on fire".

0 1 2 3 4 5 6 7 8 9 10
Not hot The most hot sensation imaginable ("on fire")
25-26 [npsHot]

- d. Please use the scale shown on the card to tell us how **dull** your pain feels. Words used to describe very dull pain include "like a dull toothache", "dull pain", "aching" and "like a bruise".

0 1 2 3 4 5 6 7 8 9 10
Not dull The most dull sensation imaginable
27-28 [npsDull]

- e. Please use the scale shown on the card to tell us how **cold** your pain feels. Words used to describe very cold pain include "like ice" and "freezing".

0 1 2 3 4 5 6 7 8 9 10
Not cold The most cold sensation imaginable ("freezing")
29-30 [npsCold]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Neuropathy Pain Scale (NPS)

FORM 03

Patient
ID:

 -

[subject]

Patient
Initials:

Visit
No:

 1 [visit]

Form
No:

 0 3 [form]

- f. Please use the scale shown on the card to tell us how **sensitive** your skin is to light touch or clothing. Words used to describe sensitive skin include "like sunburned skin" and "raw skin".

0	1	2	3	4	5	6	7	8	9	10	31-32	<input type="text"/>	<input type="text"/>
										The most sensitive			
										sensation imaginable			
										("raw skin")			

[npsSens]

- g. Please use the scale shown on the card to tell us how **itchy** your pain feels. Words used to describe itchy pain include "like poison oak" and "like a mosquito bite".

0	1	2	3	4	5	6	7	8	9	10	33-34	<input type="text"/>	<input type="text"/>
										The most itchy			
										sensation imaginable			
										("like poison oak")			

[npsItch]

- h. Which of the following best describes the **time** quality of your pain? *Please complete only one answer:*

[npsTime]

- 1 = I feel a background pain all of the time and occasional flare-ups (breakthrough pain) some of the time.
 2 = I feel a single type of pain all of the time.
 3 = I feel a single type of pain only sometimes. Other times I am pain-free.

- i. Now that you have told us the different physical aspects of your pain, the different types of sensations, we want you to tell us overall how **unpleasant** your pain is to you. Words used to describe very unpleasant pain include "miserable" and "intolerable". Remember, pain can have a low intensity, but still feel extremely unpleasant, and some kinds of pain can have a high intensity but be very tolerable. With the scale shown on the card, please tell us how **unpleasant** your pain feels.

0	1	2	3	4	5	6	7	8	9	10	36-37	<input type="text"/>	<input type="text"/>
										The most unpleasant			
										sensation imaginable			
										("intolerable")			

[npsUnpleas]

Lastly, we want you to give us an estimate of the severity of your deep versus surface pain. We want you to rate each type of pain separately. We realize that it can be difficult to make these estimates, and most likely it will be a "best guess", but please give us your best estimate.

- j. How intense is your deep pain?

0	1	2	3	4	5	6	7	8	9	10	38-39	<input type="text"/>	<input type="text"/>
										The most intense			
										deep pain sensation			
										imaginable			

[npsDeep]

- k. How intense is your surface pain?

0	1	2	3	4	5	6	7	8	9	10	40-41	<input type="text"/>	<input type="text"/>
										The most intense			
										surface pain			
										sensation imaginable			

[npsSurface]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pain Evaluation

FORM 04

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals.

The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient ID:

1-5 -

[subject]

Patient Initials:

6-8

Visit No:

9

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit]

Form No:

10-11

[form]

1. Date:

12-19

MM

DD

Year

2. Patient location:

(Write Number in box)

20

1 = Home

2 = Nursing Home/Skilled Nursing Facility

3 = Hospice Facility

4 = Other, specify: _____

[ploc]

Removed due to PHI, please see var [daysRandPainEval] for number of days between randomization and this form's date

Instructions: Please ask the patient to indicate on the Body Diagram on Response Card #3 where he/she is experiencing pain. For those areas where the patient is experiencing pain, please ask him/her to indicate on the 0-10 scale how much pain he/she is experiencing [0 (no pain) to 10 (pain as bad as it could be)].

3. Where is your pain? (Mark Yes or No in the list where the patient has indicated areas of pain. For those areas where the patient is experiencing pain, record the level of pain 01-10.)

Please note: 'a' = Right side of the body; 'b' = Left side of the body

Body Section	YES	NO	If YES, level of pain (01-10)
1. Face [ynFace]	21 <input type="text"/> 1	<input type="text"/> 0	22-23 <input type="text"/> <input type="text"/> [lvFace]
2. Chest [ynChest]	24 <input type="text"/> 1	<input type="text"/> 0	25-26 <input type="text"/> <input type="text"/> [lvChest]
3a. Upper Arm - R (front & back) [ynArmUpR]	27 <input type="text"/> 1	<input type="text"/> 0	28-29 <input type="text"/> <input type="text"/> [lvArmUpR]
3b. Upper Arm - L (front & back) [ynArmUpL]	30 <input type="text"/> 1	<input type="text"/> 0	31-32 <input type="text"/> <input type="text"/> [lvArmUpL]
4a. Lower Arm - R (front & back) [ynArmLowR]	33 <input type="text"/> 1	<input type="text"/> 0	34-35 <input type="text"/> <input type="text"/> [lvArmLowR]
4b. Lower Arm - L (front & back) [ynArmLowL]	36 <input type="text"/> 1	<input type="text"/> 0	37-38 <input type="text"/> <input type="text"/> [lvArmLowL]
5a. Palm of Hand - R [ynPalmR]	39 <input type="text"/> 1	<input type="text"/> 0	40-41 <input type="text"/> <input type="text"/> [lvPalmR]
5b. Palm of Hand - L [ynPalmL]	42 <input type="text"/> 1	<input type="text"/> 0	43-44 <input type="text"/> <input type="text"/> [lvPalmL]
6. Abdomen [ynAbdomen]	45 <input type="text"/> 1	<input type="text"/> 0	46-47 <input type="text"/> <input type="text"/> [lvAbdomen]
7a. Front of Upper Leg - R [ynLegFrontUpR]	48 <input type="text"/> 1	<input type="text"/> 0	49-50 <input type="text"/> <input type="text"/> [lvLegFrontUpR]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pain Evaluation

FORM 04

Patient ID: - [subject]

Patient Initials:

Visit No:

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit] Form No: [form]

Body Section	YES	NO	If YES, level of pain (01-10)
7b. Front of Upper Leg - L [ynLegFrontUpL]	51 <input type="text"/> 1	<input type="text"/> 0	52-53 <input type="text"/> [lvLegFrontUpL]
8a. Front of Lower Leg - R [ynLegFrontLowR]	54 <input type="text"/> 1	<input type="text"/> 0	55-56 <input type="text"/> [lvLegFrontLowR]
8b. Front of Lower Leg - L [ynLegFrontLowL]	57 <input type="text"/> 1	<input type="text"/> 0	58-59 <input type="text"/> [lvLegFrontLowL]
9a. Top of Foot - R [ynFootTopR]	60 <input type="text"/> 1	<input type="text"/> 0	61-62 <input type="text"/> [lvFootTopR]
9b. Top of Foot - L [ynFootTopL]	63 <input type="text"/> 1	<input type="text"/> 0	64-65 <input type="text"/> [lvFootTopL]
10. Scalp (Back of Head) [ynScalp]	66 <input type="text"/> 1	<input type="text"/> 0	67-68 <input type="text"/> [lvScalp]
11. Posterior Cervical (Back of Neck) [ynPostCerv]	69 <input type="text"/> 1	<input type="text"/> 0	70-71 <input type="text"/> [lvPostCerv]
12. Shoulders / Upper Back [ynBackUp]	72 <input type="text"/> 1	<input type="text"/> 0	73-74 <input type="text"/> [lvBackUp]
13. Mid Back [ynBackMid]	75 <input type="text"/> 1	<input type="text"/> 0	76-77 <input type="text"/> [lvBackMid]
14. Lower Back [ynBackLow]	78 <input type="text"/> 1	<input type="text"/> 0	79-80 <input type="text"/> [lvBackLow]
15a. Back of Hand - R [ynHandBackR]	81 <input type="text"/> 1	<input type="text"/> 0	82-83 <input type="text"/> [lvHandBackR]
15b. Back of Hand - L [ynHandBackL]	84 <input type="text"/> 1	<input type="text"/> 0	85-86 <input type="text"/> [lvHandBackL]
16a. Gluteal (Buttocks) - R [ynGlutR]	87 <input type="text"/> 1	<input type="text"/> 0	88-89 <input type="text"/> [lvGlutR]
16b. Gluteal (Buttocks) - L [ynGlutL]	90 <input type="text"/> 1	<input type="text"/> 0	91-92 <input type="text"/> [lvGlutL]
17a. Back of Upper Leg - R [ynLegBackUpR]	93 <input type="text"/> 1	<input type="text"/> 0	94-95 <input type="text"/> [lvLegBackUpR]
17b. Back of Upper Leg - L [ynLegBackUpL]	96 <input type="text"/> 1	<input type="text"/> 0	97-98 <input type="text"/> [lvLegBackUpL]
18a. Back of Lower Leg - R [ynLegBackLowR]	99 <input type="text"/> 1	<input type="text"/> 0	100-101 <input type="text"/> [lvLegBackLowR]
18b. Back of Lower Leg - L [ynLegBackLowL]	102 <input type="text"/> 1	<input type="text"/> 0	103-104 <input type="text"/> [lvLegBackLowL]
19a. Bottom of Foot - R [ynFootBottomR]	105 <input type="text"/> 1	<input type="text"/> 0	106-107 <input type="text"/> [lvFootBottomR]
19b. Bottom of Foot - L [ynFootBottomL]	108 <input type="text"/> 1	<input type="text"/> 0	109-110 <input type="text"/> [lvFootBottomL]

Form Completed By: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Karnofsky Performance Scale

FORM 05

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals. The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient
ID:

[subject]

Patient
Initials:

Visit
No:

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit]

Form
No:

[form]

1. Date:

12-19

MM

DD

Year

2. Patient location:

(Write Number in box)

1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

[ploc]

Removed due to PHI, please see var [daysRandKPS] for number of days between randomization and date of form.

Instructions: Please complete this scale based on observation of the patient OR patient interview using Response Card #4. Please indicate below your best assessment of the patient's functional status.

DEFINITION	%	CRITERIA
Able to carry on normal activity and to work. No special care is needed.	100	Normal; no complaints; no evidence of disease
	90	Able to carry on normal activity; minor signs or symptoms of disease
	80	Normal activity with effort; some signs or symptoms of disease
Unable to work. Able to live at home, care for most personal needs. A varying amount of assistance is needed.	70	Cares for self. Unable to carry on normal activity or to do active work
	60	Requires occasional assistance, but is able to care for most of his/her needs
	50	Requires considerable assistance and frequent medical care
	40	Disabled; requires special care and assistance
Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	30	Severely disabled; hospitalization is indicated although death not imminent
	20	Very sick; hospitalization necessary, active supportive treatment necessary
	10	Moribund; fatal processes progressing rapidly
	0	Dead

Instructions: Please enter your best assessment of the patient's functional status in the boxes below. If the assessment rating is less than 3 digits, please place a zero in the first box.

3. ASSESSMENT RATING:

[kps]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Brief Pain Inventory (BPI)

FORM 06

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals. The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient ID: 1-5 - **[subject]**
Patient Initials: 6-8
Visit No: 9 1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3 **[visit]**
4 = Visit 4 (final)
Form No: 10-11 **0 6 [form]**

1. Date: ¹²⁻¹⁹
MM DD Year

2. Patient location: ²⁰
(Write Number in box)

1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

[ploc]

_____ due to PHI, please see var [daysRandBPI] for number of days
_____ in randomization and date of form.

Instructions: Please record the number indicated by the patient using Response Card #5 in the boxes beside each scale. If the patient's response is less than 2 digits, please place a zero in the first box.

3. Brief Pain Inventory:

a. Please rate your pain by indicating on the card the one number that best describes your pain at its **worst** in the last week:

0 1 2 3 4 5 6 7 8 9 10 21-22

No Pain as bad as you can imagine [bpiWorstWk]

b. Please rate your pain by indicating on the card the one number that best describes your pain at its **least** in the last week:

0	1	2	3	4	5	6	7	8	9	10	23-24		
No Pain										Pain as bad as you can imagine			

[bpiLeastWk]

c. Please rate your pain by indicating on the card the one number that best describes your pain on the **average**:

0 1 2 3 4 5 6 7 8 9 10 25-26

No Pain Pain as bad as you can imagine

[bpiAvg]

d. Please rate your pain by indicating on the card the one number that tells how much pain you have **right now**:

0 1 2 3 4 5 6 7 8 9 10 27-28

No Pain Pain as bad as you can imagine

[bpiNow]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Brief Pain Inventory (BPI)

FORM 06

Patient
ID:

 -

[subject]

Patient
Initials:

Visit
No:

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit]

Form
No:

[form]

3. CONTINUED:

e. Indicate on the card the one number that best describes how, during the past week, pain has interfered with your:

1) General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntGenAct]

2) Mood:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntMood]

3) Walking ability:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntWalk]

4) Normal work (includes both work outside the home and housework): *[This question may not apply to the patient. If this is the case, please write "not applicable" or "NA" next to it.]*

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntWork]

5) Relations with other people:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntRel]

6) Sleep:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntSleep]

7) Enjoyment of life:

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

[bpilntEnjoy]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Condensed Memorial Symptom Assessment Scale (MSAS)

FORM 07

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals. The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient ID: 1-5 - [subject] Patient Initials: 6-8 Visit No: 9 1 = Visit 1 (baseline)
2 = Visit 2 [visit] Form No: 10-11 0 7 [form]
3 = Visit 3
4 = Visit 4 (final)

1. Date: 12-19 MM DD Year 2. Patient location: 20 1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: [ploc]
Removed due to PHI, please see var [daysRandMSAS] for number of days between randomization and date of form.

Instructions: Please ask the patient if each symptom is present using Response Card #6 and indicate below. If present, then please mark one box to indicate how much each symptom bothers/distresses the patient. If not present, then please ONLY mark a response to the yes/no question; do NOT mark a response to the bother/distress question.

3. Condensed Memorial Symptom Assessment Scale (MSAS) [Modified]:

Symptom	Present		If present, how much did symptom bother or distress you in past 7 days?				
	Yes	No	Not at All	A little bit	Some-what	Quite a bit	Very much
	a. Lack of energy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b. Lack of appetite	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c. Pain	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d. Dry mouth	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. Weight loss	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. Feeling drowsy	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. Shortness of breath	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. Nausea	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. Constipation	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. Cough	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. Swelling of arms or legs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. Difficulty swallowing	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Condensed Memorial Symptom Assessment Scale (MSAS)

FORM 07

Patient ID: 1-5 -
[subject]

Patient Initials: 6-8

Visit No: 9

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit] Form No: 10-11 0 7 [form]

Symptom	Present		If present, how frequently did symptom bother or distress you in past 7 days?				
	Yes	No	Rarely	Occasionally	Frequently	Almost constantly	
m. Worrying	45 <input type="text"/> 1 <input type="text"/> 0	[msasWorry]	46 <input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	[msasWorryDstrs]
n. Feeling sad	47 <input type="text"/> 1 <input type="text"/> 0	[msasSad]	48 <input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	[msasSadDstrs]
o. Feeling nervous	49 <input type="text"/> 1 <input type="text"/> 0	[msasNerv]	50 <input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	[msasNervDstrs]
p. Feeling irritable	51 <input type="text"/> 1 <input type="text"/> 0	[msasIrrit]	52 <input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	[msasIrritDstrs]
q. Difficulty concentrating	53 <input type="text"/> 1 <input type="text"/> 0	[msasDiffConc]	54 <input type="text"/> 1	<input type="text"/> 2	<input type="text"/> 3	<input type="text"/> 4	[msasDiffConcDstrs]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

McGill Quality of Life Questionnaire (MQOL)

FORM 08

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals.

The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient

ID: 1-5

[subject]

Patient

Initials: 6-8

Visit

No: 9

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

Form

No: 10-11

0 8

[form]

Removed due to
PHI, please see var
[daysRandMQOL]
for number of days
between
randomization and
date of form

Date:

12-19

MM

DD

Year

2. Patient location:

(Write Number in box)

1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

[ploc]

Instructions: Please record the number indicated by the patient using Response Card #7 in the boxes beside each question. If the patient's response is less than 2 digits, please place a zero in the first box.

3. McGill Quality of Life Questionnaire (MQOL) [Modified]

Overall Quality of Life	
a. Considering all parts of my life-emotional, social, spiritual, and financial-over the past two days the quality of my life has been:	<div>very bad</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>excellent</div>
<div>21-22</div> <div></div>	
Begin each question with 'Over the past two days'.	
Physical Well-Being	
b. I have felt.....	<div>physically terrible</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>physically well</div>
<div>23-24</div> <div></div>	
Existential	
c. My life has been.....	<div>utterly meaningless and without purpose</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>very purposeful and meaningful</div>
<div>25-26</div> <div></div>	
d. When I thought about my whole life, I felt that in achieving life goals I have.....	<div>made no progress whatsoever</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>progressed to complete fulfillment</div>
<div>27-28</div> <div></div>	
e. When I thought about my whole life, I felt that my life to this point has been.....	<div>completely worthless</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>very worthwhile</div>
<div>29-30</div> <div></div>	
f. I have felt that I have.....	<div>no control over life</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>complete control over life</div>
<div>31-32</div> <div></div>	
g. I have felt good about myself as a person.....	<div>completely disagree</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>completely agree</div>
<div>33-34</div> <div></div>	
h. To me, the past two days were.....	<div>a burden</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>a gift</div>
<div>35-36</div> <div></div>	
Support	
i. The world has been.....	<div>an impersonal, unfeeling place</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>caring and responsive to my needs</div>
<div>37-38</div> <div></div>	
j. I have felt supported.....	<div>not at all</div> <div>0 1 2 3 4 5 6 7 8 9 10</div> <div>completely</div>
<div>39-40</div> <div></div>	

[mqolOverall]

[mqolPhys]

[mqolExtPurpose]

[mqolExtGoals]

[mqolExtWorth]

[mqolExtControl]

[mqolExtSelf]

[mqolExtGift]

[mqolSupWorld]

[mqolSupFelt]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pharmacologic Interventions

FORM 09

Instructions:

- Please complete this form at each scheduled Data Collection Visit.
- Record ALL medications used to decrease symptoms for this patient in the 24 hours prior to each Data Collection Visit.
- This information should be obtained from medical records, the patient/family/caregivers, and/or nursing staff. (An in-home medication log is available for voluntary use.)
- Place a check mark in the box to the left of each therapy used (with the appropriate route of administration if a narcotic), then indicate the dose and the total number of doses received in the prior 24 hours.

Narcotics & Average Dose:

If you are unable to complete the entire Form 09, then the most important medications to get information about are narcotics (Questions #3 and 4 on pages 2 and 3). Narcotics are listed by name and route of administration. Possible routes of administration include: intramuscular (IM), intrathecal (IT), intravenous (IV), oral, rectal, subcutaneous (SQ), and transdermal. A patient may be receiving a narcotic through one or more of these routes. Please mark the appropriate medication-route combination(s).

Narcotics are being converted to morphine equivalents for analysis purposes. Please calculate the average dose if a patient received a narcotic (or other medication) with:

Example #1: A range of doses (via the same route of administration for narcotics).

A patient received two different dose amounts of Morphine in the past 24 hours.

Patient Received: Morphine 3 mg x 2 doses AND Morphine 4 mg x 1 dose

To Enter Data on Form 09:

Add the total number of doses to use in the average dose calculation below and to put in the "Total # of Doses in the past 24 hours" column, e.g. 2 doses + 1 dose = 3 doses

Calculate the average dose of the medication to put in the "Dose" column

Total Amount = $(3 \text{ mg} \times 2) + (4 \text{ mg} \times 1) = 6 \text{ mg} + 4 \text{ mg} = 10 \text{ mg}$ = 3.3 mg/dose
 No of Doses 3 doses 3 doses 3 doses

Example #2: A dose via more than one route of administration, and two or more of the routes are listed together on Form 09 (only for narcotics).

A patient received Morphine both intravenously (IV) and subcutaneously (SQ) in the past 24 hours.

Patient Received: Morphine 10 mg IV x 4 doses AND Morphine 5 mg SQ x 1 dose

To Enter Data on Form 09:

Add the total number of doses to use in the average dose calculation below and to put in the "Total # of Doses in the past 24 hours" column, e.g. 4 doses + 1 dose = 5 doses

Calculate the average dose of the medication to put in the "Dose" column

Total Amount = $(10 \text{ mg} \times 4) + (5 \text{ mg} \times 1) = 40 \text{ mg} + 5 \text{ mg} = 45 \text{ mg}$ = 9 mg/dose
 No of Doses 5 doses 5 doses 5 doses

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pharmacologic Interventions

FORM 09

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals.

The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient
ID: 1-5

[subject]

Patient
Initials: 6-8

Visit
No: 9

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit]

Form
No: 10-11

0 9

[form]

1. Date:

12-19

MM

DD

Year

2. Patient location:

20

1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

(Write Number in box)

Removed due to PHI please see var [daysRandPharmInt]
for number of days between randomization and date of
form.

[ploc]

PHARMACOLOGIC INTERVENTIONS for SYMPTOMS

(Please see instructions on Page 1)

3. Narcotics:

Attach [-Dose] at end of base
variable name

Attach [DoseN] at end of
base variable name

Medication Name	Dose	Total # of Doses in past 24 hours
1a. ²¹ [] Codeine - Oral [narcCodePO]	1b. ²²⁻²⁴ [] mg	1c. ²⁵⁻²⁷ []
2a. ²⁸ [] Fentanyl, long-acting (Duragesic patch) - Transdermal [narcFentLATD]	2b. ²⁹⁻³¹ [] mcg	2c. ³²⁻³⁴ []
3a. ³⁵ [] Fentanyl, short-acting - IM, IT, IV [narcFentSAIVIM]	3b. ³⁶⁻³⁸ [] mcg	3c. ³⁹⁻⁴¹ []
4a. ⁴² [] Fentanyl, short-acting (Actiq) - Oral [narcFentSAPO]	4b. ⁴³⁻⁴⁵ [] mcg	4c. ⁴⁶⁻⁴⁸ []
5a. ⁴⁹ [] Hydromorphone (Dilaudid) - Oral, Rectal [narcHydrPOPR]	5b. ⁵⁰⁻⁵² [] mg	5c. ⁵³⁻⁵⁵ []
6a. ⁵⁶ [] Hydromorphone (Dilaudid) - IM, IT, IV, SQ [narcHydrIVIMSQ]	6b. ⁵⁷⁻⁵⁹ [] mg	6c. ⁶⁰⁻⁶² []
7a. ⁶³ [] Levorphanol (Levo-Dromoran) - Oral [narcLevoPO]	7b. ⁶⁴⁻⁶⁶ [] mg	7c. ⁶⁷⁻⁶⁹ []
8a. ⁷⁰ [] Meperidine (Demerol) - Oral [narcMepePO]	8b. ⁷¹⁻⁷³ [] mg	8c. ⁷⁴⁻⁷⁶ []
9a. ⁷⁷ [] Meperidine (Demerol) - IM, IT, IV, SQ [narcMepeIVIMSQ]	9b. ⁷⁸⁻⁸⁰ [] mg	9c. ⁸¹⁻⁸³ []
10a. ⁸⁴ [] Methadone - Oral [narcMethPO]	10b. ⁸⁵⁻⁸⁷ [] mg	10c. ⁸⁸⁻⁹⁰ []
11a. ⁹¹ [] Morphine, long-acting (e.g. MS Contin, Oramorph, Kadian, Avinza) - Oral, Rectal [narcMorpLAPOPR]	11b. ⁹²⁻⁹⁴ [] mg	11c. ⁹⁵⁻⁹⁷ []
12a. ⁹⁸ [] Morphine, short-acting (e.g. Roxanol, MSIR) - Oral, Rectal [narcMorpSAPOPR]	12b. ⁹⁹⁻¹⁰¹ [] mg	12c. ¹⁰²⁻¹⁰⁴ []
13a. ¹⁰⁵ [] Morphine, short-acting - IM, IT, IV, SQ [narcMorpSAIVIMSQ]	13b. ¹⁰⁶⁻¹⁰⁸ [] mg	13c. ¹⁰⁹⁻¹¹¹ []

IM = intramuscular
IT = intrathecal
IV = intravenous
SQ = subcutaneous

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pharmacologic Interventions

FORM 09

Patient ID: -

[subject]

Patient Initials:

Visit No:
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final)

[visit]

Form No:
 10-11

[form]

3. Narcotics - CONTINUED:

Attach [-Dose] at end of base variable name

Attach [DoseN] at end of base variable name

Medication Name	Dose	Total # of Doses in past 24 hours
14a. ¹¹² <input type="checkbox"/> Oxycodone, long-acting (Oxycontin) - Oral [narcOxycLAPO]	14b. ¹¹³⁻¹¹⁵ <input type="text"/> <input type="text"/> <input type="text"/> mg	14c. ¹¹⁶⁻¹¹⁸ <input type="text"/> <input type="text"/> <input type="text"/>
15a. ¹¹⁹ <input type="checkbox"/> Oxycodone, short-acting (Roxicodone) - Oral [narcOxycSAPO]	15b. ¹²⁰⁻¹²² <input type="text"/> <input type="text"/> <input type="text"/> mg	15c. ¹²³⁻¹²⁵ <input type="text"/> <input type="text"/> <input type="text"/>
16a. ¹²⁶ <input type="checkbox"/> Propoxyphene (e.g. Darvon, Darvon-N) - Oral [narcPropPO]	16b. ¹²⁷⁻¹²⁹ <input type="text"/> <input type="text"/> <input type="text"/> mg	16c. ¹³⁰⁻¹³² <input type="text"/> <input type="text"/> <input type="text"/>
17a. ¹³³ <input type="checkbox"/> Other: [narcOthrPOPR] - Oral, Rectal	17b. <input type="text"/> <input type="text"/> <input type="text"/> mg	17c. <input type="text"/> <input type="text"/> <input type="text"/>
18a. ¹³⁴ <input type="checkbox"/> Other: [narcOthrIVIMSQ] - IM, IT, IV, SQ	18b. <input type="text"/> <input type="text"/> <input type="text"/> mg	18c. <input type="text"/> <input type="text"/> <input type="text"/>

4. Narcotic Combinations:

Attach [-Dose] at end of base variable name

Attach [DoseN] at end of base variable name

Medication Name	Dose	Total # of Doses in past 24 hours
1. ¹³⁵ <input type="checkbox"/> Acetaminophen/Codeine [narcombAcetCode]	¹³⁶ <input type="checkbox"/> 1 = Tylenol #2 2 = Tylenol #3 3 = Tylenol #4	¹³⁷⁻¹³⁹ <input type="text"/> <input type="text"/> <input type="text"/>
2. ¹⁴⁰ <input type="checkbox"/> Acetaminophen/Hydrocodone (e.g. Vicoden, Lortab, Lorcet, Hyco-pap, Maxidone, Zydone) [narcombAcetHydr]	¹⁴¹ <input type="checkbox"/> 1 = 2.5 mg hydrocodone 2 = 5 mg hydrocodone 3 = 7.5 mg hydrocodone 4 = 10 mg hydrocodone	¹⁴²⁻¹⁴⁴ <input type="text"/> <input type="text"/> <input type="text"/>
3. ¹⁴⁵ <input type="checkbox"/> Acetaminophen/Oxycodone (e.g. Percocet, Endocet, Roxicet, Tylox) [narcombAcetOxyc]	¹⁴⁶ <input type="checkbox"/> 1 = 2.5 mg oxycodone 2 = 5 mg oxycodone 3 = 7.5 mg oxycodone 4 = 10 mg oxycodone	¹⁴⁷⁻¹⁴⁹ <input type="text"/> <input type="text"/> <input type="text"/>
4. ¹⁵⁰ <input type="checkbox"/> Acetaminophen/Propoxyphene [narcombAcetProp]	¹⁵¹ <input type="checkbox"/> 1 = Darvocet N-100 2 = Darvocet N-50	¹⁵²⁻¹⁵⁴ <input type="text"/> <input type="text"/> <input type="text"/>
5. ¹⁵⁵ <input type="checkbox"/> Aspirin (ASA)/Hydrocodone (Percodan) [narcombASAPerc]	¹⁵⁶ <input type="checkbox"/> 1 = 2.25 mg oxycodone 2 = 4.5 mg oxycodone	¹⁵⁷⁻¹⁵⁹ <input type="text"/> <input type="text"/> <input type="text"/>
6. ¹⁶⁰ <input type="checkbox"/> Fioricet [narcombFiot]	N/A	¹⁶¹⁻¹⁶³ <input type="text"/> <input type="text"/> <input type="text"/>
7. ¹⁶⁴ <input type="checkbox"/> Fiorinal [narcombFiol]	N/A	¹⁶⁵⁻¹⁶⁷ <input type="text"/> <input type="text"/> <input type="text"/>
8. ¹⁶⁸ <input type="checkbox"/> Ibuprofen/Hydrocodone (Vicoprofen) [narcombVico]	N/A	¹⁶⁹⁻¹⁷¹ <input type="text"/> <input type="text"/> <input type="text"/>
9. ¹⁷² <input type="checkbox"/> Other: [narcombOthr]	<input type="text"/> <input type="text"/> <input type="text"/> (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

IM = intramuscular
 IT = intrathecal
 IV = intravenous
 SQ = subcutaneous

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)	
Pharmacologic Interventions	FORM 09

FORM 09

Form No: 10-11

0	9
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 [form]

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

5. Non-Steroidal Anti-Inflammatory Medications (NSAIDs): Attach [-Dose] at end of base variable name Attach [Dosen] at end of base variable name

Medication Name	Dose	Total # of Doses in past 24 hours
1. ¹⁷³ <input type="checkbox"/> Celecoxib (Celebrex) [nsaidCele]	¹⁷⁴ <input type="checkbox"/> 1 = 100 mg 2 = 200 mg 3 = 400 mg	175-177 <input type="text"/> <input type="text"/> <input type="text"/>
2. ¹⁷⁸ <input type="checkbox"/> Diclofenac (e.g. Cataflam, Voltaren) [nsaidDicl]	¹⁷⁹ <input type="checkbox"/> 1 = 25 mg 2 = 50 mg 3 = 75 mg 4 = 100 mg	180-182 <input type="text"/> <input type="text"/> <input type="text"/>
3. ¹⁸³ <input type="checkbox"/> Diclofenac/Misoprostol (Arthrotec) [nsaidDiclMiso]	¹⁸⁴ <input type="checkbox"/> 1 = 50 mg diclofenac 2 = 75 mg diclofenac	185-187 <input type="text"/> <input type="text"/> <input type="text"/>
4. ¹⁸⁸ <input type="checkbox"/> Diflunisal (Dolobid) [nsaidDifl]	¹⁸⁹ <input type="checkbox"/> 1 = 250 mg 2 = 500 mg	190-192 <input type="text"/> <input type="text"/> <input type="text"/>
5. ¹⁹³ <input type="checkbox"/> Etodolac (Lodine) [nsaidEtod]	¹⁹⁴ <input type="checkbox"/> 1 = 200 mg 2 = 300 mg 3 = 400 mg 4 = 500 mg 5 = 600 mg	195-197 <input type="text"/> <input type="text"/> <input type="text"/>
6. ¹⁹⁸ <input type="checkbox"/> Flurbiprofen (Ansaid) [nsaidFlur]	¹⁹⁹ <input type="checkbox"/> 1 = 50 mg 2 = 100 mg	200-202 <input type="text"/> <input type="text"/> <input type="text"/>
7. ²⁰³ <input type="checkbox"/> Ibuprofen (e.g. Motrin, Advil) [nsaidIbup]	²⁰⁴ <input type="checkbox"/> 1 = 100 mg 2 = 200 mg 3 = 300 mg 4 = 400 mg 5 = 600 mg 6 = 800 mg	205-207 <input type="text"/> <input type="text"/> <input type="text"/>
8. ²⁰⁸ <input type="checkbox"/> Indomethacin (Indocin) [nsaidIndo]	²⁰⁹ <input type="checkbox"/> 1 = 25 mg 2 = 50 mg 3 = 75 mg	210-212 <input type="text"/> <input type="text"/> <input type="text"/>
9. ²¹³ <input type="checkbox"/> Ketoprofen (e.g. Orudis, Oruvail) [nsaidKetop]	²¹⁴ <input type="checkbox"/> 1 = 50 mg 2 = 75 mg 3 = 100 mg 4 = 150 mg 5 = 200 mg	215-217 <input type="text"/> <input type="text"/> <input type="text"/>
10. ²¹⁸ <input type="checkbox"/> Ketorolac (Toradol) [nsaidKetor]	²¹⁹ <input type="checkbox"/> 1 = 10 mg 2 = ____ mg	220-222 <input type="text"/> <input type="text"/> <input type="text"/>
11. ²²³ <input type="checkbox"/> Meloxicam (Mobic) [nsaidMelo]	²²⁴ <input type="checkbox"/> 1 = 7.5 mg 2 = 15 mg	225-227 <input type="text"/> <input type="text"/> <input type="text"/>
12. ²²⁸ <input type="checkbox"/> Nabumetone (Relafen) [nsaidNabu]	²²⁹ <input type="checkbox"/> 1 = 500 mg 2 = 750 mg	230-232 <input type="text"/> <input type="text"/> <input type="text"/>
13. ²³³ <input type="checkbox"/> Naproxen (e.g. Anaprox, Naprelan, Naprosyn) [nsaidNaprx]	²³⁴ <input type="checkbox"/> 1 = 250 mg 2 = 375 mg 3 = 500 mg 4 = 550 mg	235-237 <input type="text"/> <input type="text"/> <input type="text"/>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pharmacologic Interventions

FORM 09

Patient ID: - [subject]

Patient Initials:

Visit No: [visit]

Form No: 0 9 [form]

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

5. Non-Steroidal Anti-Inflammatory Medications (NSAIDs) - CONTINUED:

Attach [DoseN] at end of base variable name

Medication Name	Dose Attach [-Dose] at end of base variable name	Total # of Doses in past 24 hours
14. <input type="checkbox"/> Oxaprozin (Daypro) [nsaidOxap]	<input type="checkbox"/> 600 mg	<input type="text"/> <input type="text"/> <input type="text"/>
15. <input type="checkbox"/> Piroxicam (Feldene) [nsaidPiro]	<input type="checkbox"/> 1 = 10 mg 2 = 20 mg	<input type="text"/> <input type="text"/> <input type="text"/>
16. <input type="checkbox"/> Rofecoxib (Vioxx) [nsaidRofo]	<input type="checkbox"/> 1 = 12.5 mg 2 = 25 mg 3 = 50 mg	<input type="text"/> <input type="text"/> <input type="text"/>
17. <input type="checkbox"/> Sulindac (Clinoril) [nsaidSuli]	<input type="checkbox"/> 1 = 150 mg 2 = 200 mg	<input type="text"/> <input type="text"/> <input type="text"/>
18. <input type="checkbox"/> Tolmetin (Tolectin) [nsaidTolm]	<input type="checkbox"/> 1 = 200 mg 2 = 400 mg 3 = 600 mg	<input type="text"/> <input type="text"/> <input type="text"/>
19. <input type="checkbox"/> Valdecoxib (Bextra) [nsaidVald]	<input type="checkbox"/> 1 = 10 mg 2 = 20 mg	<input type="text"/> <input type="text"/> <input type="text"/>
20. <input type="checkbox"/> Other [nsaidOthr]	<input type="text"/> <input type="text"/> <input type="text"/> (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

6. Muscle Relaxants:

Attach [-Dose] at end of base variable name Attach [DoseN] at end of base variable name

1. <input type="checkbox"/> Baclofen [mrlxBacl]	<input type="checkbox"/> 1 = 10 mg 2 = 20 mg	<input type="text"/> <input type="text"/> <input type="text"/>
2. <input type="checkbox"/> Carisoprodol (Soma) [mrlxCari]	<input type="checkbox"/> 350 mg	<input type="text"/> <input type="text"/> <input type="text"/>
3. <input type="checkbox"/> Chlorzoxazone (Parafon Forte) [mrlxChlo]	<input type="checkbox"/> 500 mg	<input type="text"/> <input type="text"/> <input type="text"/>
4. <input type="checkbox"/> Cyclobenzaprine (Flexeril) [mrlxCycl]	<input type="checkbox"/> 10 mg	<input type="text"/> <input type="text"/> <input type="text"/>
5. <input type="checkbox"/> Metaxalone (Skelaxin) [mrlxMeta]	<input type="checkbox"/> 1 = 400 mg 2 = 800 mg	<input type="text"/> <input type="text"/> <input type="text"/>
6. <input type="checkbox"/> Methocarbamol (Robaxin) [mrlxMeth]	<input type="checkbox"/> 1 = 400 mg 2 = 750 mg	<input type="text"/> <input type="text"/> <input type="text"/>
7. <input type="checkbox"/> Orphenadrine (Norflex) [mrlxOrph]	<input type="checkbox"/> 1 = 50 mg 2 = 100 mg	<input type="text"/> <input type="text"/> <input type="text"/>
8. <input type="checkbox"/> Tizanidine (Zanaflex) [mrlxTiza]	<input type="checkbox"/> 1 = 2 mg 2 = 4 mg	<input type="text"/> <input type="text"/> <input type="text"/>
9. <input type="checkbox"/> Other: [mrlxOthr]	<input type="text"/> <input type="text"/> <input type="text"/> (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Pharmacologic Interventions

FORM 09

Patient ID: - [subject]

Patient Initials:

Visit No:

1 = Visit 1 (baseline)
2 = Visit 2
3 = Visit 3
4 = Visit 4 (final)

[visit]

Form No:

0 9

[form]

7. Other Analgesics:

Attach [-Dose] at end of base variable name

Attach [DoseN] at end of base variable name

Medication Name	Dose	Total # of Doses in past 24 hours
1. <input type="text"/> <input type="text"/> Acetaminophen (Tylenol) [analgAcet]	311 <input type="text"/> 1 = 325 mg 2 = 500 mg	312-314 <input type="text"/> <input type="text"/> <input type="text"/>
2. <input type="text"/> <input type="text"/> Tramadol (Ultram) [analgTram]	316 <input type="text"/> 50 mg	317-319 <input type="text"/> <input type="text"/> <input type="text"/>
3. <input type="text"/> <input type="text"/> Other: [analgOthr1]	<input type="text"/> <input type="text"/> <input type="text"/> (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
4. <input type="text"/> <input type="text"/> Other: [analgOthr2]	<input type="text"/> <input type="text"/> <input type="text"/> (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

8. Adjuvant Pain Medications:

Medication Name	Dose	Total # of Doses in past 24 hours
1. <input type="text"/> <input type="text"/> Amitriptyline (e.g. Elavil, Endep) [adjuAmit]	323 <input type="text"/> 1 = 10 mg 2 = 25 mg 3 = 50 mg 4 = 75 mg 5 = 100 mg 6 = 150 mg	324-326 <input type="text"/> <input type="text"/> <input type="text"/>
2. <input type="text"/> <input type="text"/> Carbamazepine (e.g. Carbatrol, Tegretol) [adjuCarb]	328 <input type="text"/> 1 = 100 mg 2 = 200 mg 3 = 300 mg	329-331 <input type="text"/> <input type="text"/> <input type="text"/>
3. <input type="text"/> <input type="text"/> Desipramine (Norpramin) [adjuDesi]	333 <input type="text"/> 1 = 10 mg 2 = 25 mg 3 = 50 mg 4 = 75 mg 5 = 100 mg 6 = 150 mg	334-336 <input type="text"/> <input type="text"/> <input type="text"/>
4. <input type="text"/> <input type="text"/> Dextroamphetamine (Dexedrine) [adjuDext]	338 <input type="text"/> 1 = 5 mg 2 = 10 mg 3 = 15 mg	339-341 <input type="text"/> <input type="text"/> <input type="text"/>
5. <input type="text"/> <input type="text"/> Doxepin (Sinequan) [adjuDoxe]	343 <input type="text"/> 1 = 10 mg 2 = 25 mg 3 = 50 mg 4 = 75 mg 5 = 100 mg 6 = 150 mg	344-346 <input type="text"/> <input type="text"/> <input type="text"/>
6. <input type="text"/> <input type="text"/> Gabapentin (Neurontin) [adjuGaba]	348 <input type="text"/> 1 = 100 mg 2 = 300 mg 3 = 400 mg 4 = 600 mg 5 = 800 mg	349-351 <input type="text"/> <input type="text"/> <input type="text"/>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)	
Pharmacologic Interventions	FORM 09

Form No: 10-11

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 [form]

8. Adjuvant Pain Medications - CONTINUED: Attach [-Dose] at end of base variable name Attach [Dosen] at end of base variable name

Medication Name		Dose	Total # of Doses in past 24 hours
352 7. <input type="checkbox"/> Imipramine (Tofranil)	[adjuMip]	353 <input type="checkbox"/> 1 = 10 mg 2 = 25 mg 3 = 50 mg 4 = 75 mg 5 = 100 mg 6 = 150 mg	354-356 <input type="text"/> <input type="text"/> <input type="text"/>
357 8. <input type="checkbox"/> Methylphenidate (e.g. Methylin, Metadate, Ritalin)	[adjuMeth]	358 <input type="checkbox"/> 1 = 5 mg 2 = 10 mg 3 = 20 mg	359-361 <input type="text"/> <input type="text"/> <input type="text"/>
362 9. <input type="checkbox"/> Nortriptyline (e.g. Pamelor, Aventyl)	[adjuNort]	363 <input type="checkbox"/> 1 = 10 mg 2 = 25 mg 3 = 50 mg 4 = 75 mg	364-366 <input type="text"/> <input type="text"/> <input type="text"/>
367 10. <input type="checkbox"/> Phenytoin (Dilantin)	[adjuPhen]	368 <input type="checkbox"/> 1 = 30 mg 2 = 100 mg	369-371 <input type="text"/> <input type="text"/> <input type="text"/>
372 11. <input type="checkbox"/> Tiagabine (Gabitril)	[adjuTiag]	373 <input type="checkbox"/> 1 = 2 mg 2 = 4 mg 3 = 12 mg 4 = 16 mg 5 = 20 mg	374-376 <input type="text"/> <input type="text"/> <input type="text"/>
377 12. <input type="checkbox"/> Valproate (e.g. Depakene, Depakote)	[adjuValp]	378 <input type="checkbox"/> 1 = 125 mg 2 = 250 mg 3 = 250 mg 4 = 500 mg	379-381 <input type="text"/> <input type="text"/> <input type="text"/>
382 13. <input type="checkbox"/> Other: _____	[adjuOthr]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

9. Anti-Anxiety Medications/Medications for Sleep:

383 1. <input type="text"/> Alprazolam (Xanax)	[anxiAlpr]	384 <input type="text"/> 1 = 0.25 mg 2 = 0.5 mg 3 = 1 mg 4 = 2 mg	385-387 <input type="text"/> <input type="text"/> <input type="text"/>
388 2. <input type="text"/> Chlordiazepoxide (Librium)	[anxiChlo]	389 <input type="text"/> 1 = 5 mg 2 = 10 mg 3 = 25 mg	390-392 <input type="text"/> <input type="text"/> <input type="text"/>
393 3. <input type="text"/> Clonazepam (Klonopin)	[anxiClon]	394 <input type="text"/> 1 = 0.5 mg 2 = 1 mg 3 = 2 mg	395-397 <input type="text"/> <input type="text"/> <input type="text"/>
398 4. <input type="text"/> Clorazepate (Tranxene)	[anxiClor]	399 <input type="text"/> 1 = 3.75 mg 2 = 7.5 mg 3 = 15 mg	400-402 <input type="text"/> <input type="text"/> <input type="text"/>
403 5. <input type="text"/> Diazepam (e.g. Dizac, Valium)	[anxiDiaz]	404 <input type="text"/> 1 = 2.7 mg 2 = 5 mg 3 = 10 mg	405-407 <input type="text"/> <input type="text"/> <input type="text"/>
408 6. <input type="text"/> Lorazepam (Ativan)	[anxiLora]	409 <input type="text"/> 1 = 0.5 mg 2 = 1 mg 3 = 2 mg	410-412 <input type="text"/> <input type="text"/> <input type="text"/>
413 7. <input type="text"/> Oxazepam (Serax)	[anxiOxaz]	414 <input type="text"/> 1 = 10 mg 2 = 15 mg 3 = 30 mg	415-417 <input type="text"/> <input type="text"/> <input type="text"/>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)	
Pharmacologic Interventions	FORM 09

Form No: 10-11

0	9
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 [form]

**Attach [DoseN] at end
of base variable name**

Medication Name	Dose Attach [-Dose] at end of base variable name	Total # of Doses in past 24 hours
8. ⁴¹⁸ <input type="text"/> Temazepam (Restoril) [anxiTema]	⁴¹⁹ <input type="text"/> 1 = 7.5 mg 2 = 15 mg 3 = 30 mg	⁴²⁰⁻⁴²² <input type="text"/> <input type="text"/> <input type="text"/>
9. ⁴²³ <input type="text"/> Triazolam (Halcion) [anxiTria]	⁴²⁴ <input type="text"/> 1 = 0.125 mg 2 = 0.25 mg	⁴²⁵⁻⁴²⁷ <input type="text"/> <input type="text"/> <input type="text"/>
10. ⁴²⁸ <input type="text"/> Other: [anxiOthr1] _____	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
11. ⁴²⁹ <input type="text"/> Other: [anxiOthr2] _____	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

10. Other Medications for Symptom Relief: [If more room is needed for additional medications, please write them under Question #11 and indicate that with an arrow, initials and date.]

Medication Name		Dose (including units, e.g. mg, mcg)	Total # of Doses in past 24 hours
1.	⁴³⁰ <input type="text"/> [sympOthrMed1]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
2.	⁴³¹ <input type="text"/> [sympOthrMed2]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
3.	⁴³² <input type="text"/> [sympOthrMed3]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
4.	⁴³³ <input type="text"/> [sympOthrMed4]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>

1. ⁴³⁴ <input type="text"/> Chemotherapy [sympOthrIntChemo]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
2. ⁴³⁵ <input type="text"/> Radiation therapy [sympOthrIntRadia]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
3. ⁴³⁶ <input type="text"/> Other: _____ [sympOthrInt	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg, mcg)	<input type="text"/> <input type="text"/> <input type="text"/>
4. ⁴³⁷ <input type="text"/> Zolpidem (Ambien) [sympOthrZolp]	<input type="text"/> <input type="text"/> <input type="text"/> _____ (mg)	<input type="text"/> <input type="text"/> <input type="text"/>

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REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Non-Pharmacologic Interventions

FORM 10

Instructions: The On-Site Data Collector (OSDC) should complete this form for each patient at approximately weekly intervals.

The Data Collection Visits should be scheduled as follows:

Baseline Data Collection (Visit #1)--Must occur within 3 working days of enrollment (signing of Consent and HIPAA Forms)

1st Weekly Visit (Visit #2)--Must occur approximately 5 working days from the Baseline Data Collection

2nd Weekly Visit (Visit #3)--Must occur approximately 5 working days from the 1st Weekly Visit (Visit #2)

Final Visit (Visit #4)--Must occur approximately 7 working days following the Final Treatment Visit [Note: For more information about the Final Visit, please refer to Section II, Part D (OSDC) or the instructions for Forms SC-3a-3e in Section III, Part A (OSSTM Forms) of the manual.]

Patient ID: 1-5 - **[subject]**

Patient Initials: 6-8

Visit No: 9
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final)

Form No: 10-11 **[form]**

1. Date: 12-19
 MM DD Year

2. Patient location: 20
 1 = Home
 2 = Nursing Home/Skilled Nursing Facility
 3 = Hospice Facility
 4 = Other, specify:
 [ploc]

Removed due to PHI please see var [daysRandNonPharmInt] for number of days between randomization and date of form.

3. **Non-Pharmacologic Interventions for Symptoms:** In the table below, please record *OTHER* strategies used to decrease the patient's symptoms over the past week. Please obtain this information through patient/caregiver interview, medical records, in-home sign-in sheets, and/or inter-disciplinary team (IDT) meetings. If a patient receives a non-study-related massage, please record that as "08 = Massage Therapy."

Strategy	Amount of time of each session (in minutes)	By Whom
<p>21-22 [strat1] (Select the appropriate answer from the list below and write the numbers in the boxes.)</p> <p>a1. <input type="text"/> <input type="text"/> <input type="text"/></p> <p>01 = Acupuncture or Acupressure</p> <p>02 = Aromatherapy</p> <p>03 = Art Therapy</p> <p>04 = Biofeedback, Hypnosis, Relaxation, or Guided Imagery</p> <p>05 = Chiropractice and/or Cranial-Sacral Therapy</p> <p>06 = Herbs, Supplements, or Homeopathic remedies</p> <p>07 = Magnetic Therapies</p> <p>08 = Massage Therapy</p> <p>09 = Music or Sound Therapy</p> <p>10 = Occupational Therapy</p> <p>11 = Pet Therapy</p> <p>12 = Physical Therapy or Exercise (e.g., Yoga, Tai Chi Chuan)</p> <p>13 = Psychotherapy or Counseling</p> <p>14 = Relaxation Therapy</p> <p>15 = Spiritual Counseling</p> <p>16 = Therapeutic or Healing Touch, Reiki, or Reflexology</p>	<p>23-25 [strat1Time] min. (Write the amount of minutes in the boxes. If less than 3 digits, please place zeros in the appropriate boxes.)</p> <p>a2. <input type="text"/> <input type="text"/> <input type="text"/></p>	<p>26 <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>a3. <input type="text"/> [strat1Whom]</p> <p>1 = Community Therapist</p> <p>2 = Faith Community</p> <p>3 = Family/Friend</p> <p>4 = Hospice Staff</p> <p>5 = Volunteer</p> <p>6 = Other (specify):</p>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Non-Pharmacologic Interventions

FORM 10

Patient ID: 1-5 - **[subject]**

Patient Initials: 6-8

Visit No: 9
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final)

[visit]

Form No: 10-11 **1 0**

[form]

3. Non-Pharmacologic Interventions for Symptoms - CONTINUED:

Strategy	Amount of time of each session (in minutes)	By Whom
<p>27-28 [strat2] (Select the appropriate answer from the list below and write the numbers in the boxes.)</p> <p>b1.</p> <p>01 = Acupuncture or Acupressure 02 = Aromatherapy 03 = Art Therapy 04 = Biofeedback, Hypnosis, Relaxation, or Guided Imagery 05 = Chiropractic and/or Cranial-Sacral Therapy 06 = Herbs, Supplements, or Homeopathic remedies 07 = Magnetic Therapies 08 = Massage Therapy 09 = Music or Sound Therapy 10 = Occupational Therapy 11 = Pet Therapy 12 = Physical Therapy or Exercise (e.g., Yoga, Tai Chi Chuan) 13 = Psychotherapy or Counseling 14 = Relaxation Therapy 15 = Spiritual Counseling 16 = Therapeutic or Healing Touch, Reiki, or Reflexology</p>	<p>29-31 [strat2Time] min. (Write the amount of minutes in the boxes. If less than 3 digits, please place zeros in the appropriate boxes.)</p> <p>b2.</p>	<p>32 <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>b3.</p> <p>[strat2Whom]</p> <p>1 = Community Therapist 2 = Faith Community 3 = Family/Friend 4 = Hospice Staff 5 = Volunteer 6 = Other (specify): _____</p>
<p>33-34 [strat3] (Select the appropriate answer from the list below and write the numbers in the boxes.)</p> <p>c1.</p> <p>01 = Acupuncture or Acupressure 02 = Aromatherapy 03 = Art Therapy 04 = Biofeedback, Hypnosis, Relaxation, or Guided Imagery 05 = Chiropractic and/or Cranial-Sacral Therapy 06 = Herbs, Supplements, or Homeopathic remedies 07 = Magnetic Therapies 08 = Massage Therapy 09 = Music or Sound Therapy 10 = Occupational Therapy 11 = Pet Therapy 12 = Physical Therapy or Exercise (e.g., Yoga, Tai Chi Chuan) 13 = Psychotherapy or Counseling 14 = Relaxation Therapy 15 = Spiritual Counseling 16 = Therapeutic or Healing Touch, Reiki, or Reflexology</p>	<p>35-37 [strat3Time] min. (Write the amount of minutes in the boxes. If less than 3 digits, please place zeros in the appropriate boxes.)</p> <p>c2.</p>	<p>38 <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>c3.</p> <p>[strat3Whom]</p> <p>1 = Community Therapist 2 = Faith Community 3 = Family/Friend 4 = Hospice Staff 5 = Volunteer 6 = Other (specify): _____</p>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Non-Pharmacologic Interventions

FORM 10

Patient ID: - **[subject]**

Patient Initials:

Visit No:
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final) **[visit]**

Form No: **[form]**
 1 0

3. Non-Pharmacologic Interventions for Symptoms - CONTINUED:

Strategy	Amount of time of each session (in minutes)	By Whom
<p>³⁹⁻⁴⁰ d1. <input type="text"/> <input type="text"/> [strat4] (Select the appropriate answer from the list below and write the numbers in the boxes.)</p> <p>01 = Acupuncture or Acupressure 02 = Aromatherapy 03 = Art Therapy 04 = Biofeedback, Hypnosis, Relaxation, or Guided Imagery 05 = Chiropractice and/or Cranial-Sacral Therapy 06 = Herbs, Supplements, or Homeopathic remedies 07 = Magnetic Therapies 08 = Massage Therapy 09 = Music or Sound Therapy 10 = Occupational Therapy 11 = Pet Therapy 12 = Physical Therapy or Exercise (e.g., Yoga, Tai Chi Chuan) 13 = Psychotherapy or Counseling 14 = Relaxation Therapy 15 = Spiritual Counseling 16 = Therapeutic or Healing Touch, Reiki, or Reflexology</p>	<p>⁴¹⁻⁴³ d2. <input type="text"/> <input type="text"/> <input type="text"/> [strat4Time] min. (Write the amount of minutes in the boxes. If less than 3 digits, please place zeros in the appropriate boxes.)</p>	<p>⁴⁴ d3. <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.) [strat4Whom] 1 = Community Therapist 2 = Faith Community 3 = Family/Friend 4 = Hospice Staff 5 = Volunteer 6 = Other (specify): _____</p>
<p>⁴⁵⁻⁴⁶ e1. <input type="text"/> <input type="text"/> [strat5] (Select the appropriate answer from the list below and write the numbers in the boxes.)</p> <p>01 = Acupuncture or Acupressure 02 = Aromatherapy 03 = Art Therapy 04 = Biofeedback, Hypnosis, Relaxation, or Guided Imagery 05 = Chiropractice and/or Cranial-Sacral Therapy 06 = Herbs, Supplements, or Homeopathic remedies 07 = Magnetic Therapies 08 = Massage Therapy 09 = Music or Sound Therapy 10 = Occupational Therapy 11 = Pet Therapy 12 = Physical Therapy or Exercise (e.g., Yoga, Tai Chi Chuan) 13 = Psychotherapy or Counseling 14 = Relaxation Therapy 15 = Spiritual Counseling 16 = Therapeutic or Healing Touch, Reiki, or Reflexology</p>	<p>⁴⁷⁻⁴⁹ e2. <input type="text"/> <input type="text"/> <input type="text"/> [strat5Time] min. (Write the amount of minutes in the boxes. If less than 3 digits, please place zeros in the appropriate boxes.)</p>	<p>⁵⁰ e3. <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.) [strat5Whom] 1 = Community Therapist 2 = Faith Community 3 = Family/Friend 4 = Hospice Staff 5 = Volunteer 6 = Other (specify): _____</p>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Non-Pharmacologic Interventions

FORM 10

Patient ID: - **[subject]**

Patient Initials:

Visit No:
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final) **[visit]**

Form No:
 10-11 **1 0 [form]**

4. **Documentation of "Usual Care":** In the table below, please record the type and length of contact for ALL visits with the patient over the past week. Please mark one type of visit per row. Please do NOT record study-related data collection or touch therapy visits.

Discipline	Length of time (minutes)
<p>a1. <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid/Certified Nurse Assistant 3 = Nurse (RN or LPN) 4 = Physician [hospiceVst1Who] 5 = Social Worker 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>a2. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst1Time]</p>
<p>b1. <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid 3 = Nurse 4 = Physician [hospiceVst2Who] 5 = Social Worker 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>b2. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst2Time]</p>
<p>c1. <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid 3 = Nurse 4 = Physician 5 = Social Worker [hospiceVst3Who] 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>c2. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst3Time]</p>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Non-Pharmacologic Interventions

FORM 10

Patient ID: - **[subject]**

Patient Initials:

Visit No:
 1 = Visit 1 (baseline)
 2 = Visit 2
 3 = Visit 3
 4 = Visit 4 (final)

Form No: **[form]**

[visit]

4. **Documentation of "Usual Care"- CONTINUED:** *In the table below, please record the type and length of contact for ALL visits with the patient over the past week. Please mark one type of visit per row. Please do NOT record study-related data collection or touch therapy visits.*

Discipline	Length of time (minutes)
<p>d1. ⁸¹ <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid 3 = Nurse 4 = Physician 5 = Social Worker [hospiceVst4Who] 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>d2. ⁸²⁻⁸⁶ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst4Time]</p>
<p>e1. ⁸⁷ <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid 3 = Nurse 4 = Physician 5 = Social Worker [hospiceVst5Who] 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>e2. ⁸⁸⁻⁹² <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst5Time]</p>
<p>f1. ⁹³ <input type="text"/> (Select the appropriate answer from the list below and write <u>one</u> number in the box.)</p> <p>1 = Chaplain 2 = Home Health Aid 3 = Nurse 4 = Physician 5 = Social Worker [hospiceVst6Who] 6 = Volunteer 7 = Other: _____ 8 = Nurse Practitioner or Physician's Assistant</p>	<p>f2. ⁹⁴⁻⁹⁸ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> min.</p> <p>(Write the length of time in box. If less than 5 digits, please place zeros in the appropriate boxes.)</p> <p>[hospiceVst6Time]</p>

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Treatment Form

(FORM 11)

Instructions: This form should be completed by the Moving Touch Therapist or Non-Moving Touch Volunteer for each randomized patient according to the following schedule:

Treatment Visit 1 within 3 working days of the Baseline Data Collection Visit Date or Randomization Assignment Date; Visits 2-6 within 2 work weeks (10 working days) of the 1st Treatment Visit. The On-Site Study Coordinator will be in touch with you to inform you which date to base your scheduling on.

Please inform the OSSC ASAP after the Last Treatment Visit has occurred.

If patient's level of consciousness is "Comatose" or "Somnolent", DO NOT PERFORM TREATMENT - fill out Form 13 Missed Visit Form.

Patient
ID:

1-5

[subject]

Patient
Initials:

6-8

Visit
No:

9

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

[visit]

Form
No:

10-11

[form]

1. Date of treatment:

12-19

MM

DD

Year

Removed due to PHI please see var [daysRandTreatment] for number of days between randomization and date of form.

2. Patient location:

1 = Home

2 = Nursing Home/Skilled Nursing Facility

3 = Hospice Facility

4 = Other, specify: _____

(Write Number in box)

[ploc]

3. Initial Assessment by Treatment Provider:

a. Patient's General Appearance (Describe - note any significant observations related to skin color, lesions, redness, dressings, ports, catheters, tubes, edema): _____

Not available in dataset

b. Patient Positioning (Describe the patient's ability to turn and his/her most comfortable position): _____

Not available in dataset

c. Significant Patient Comments prior to Therapy Session: (Note any comments related to areas of pain, discomfort, symptoms, ability to tolerate touch) _____

Not available in dataset

d. Did patient receive massage from someone else since last therapy session?

21

1

Yes

0

No

[outsideMT]

If "YES", date:

22-29

MM

DD

Year

Removed due to PHI please see var [daysOutsideMTTreat] for number of days between outside massage therapy and date of form.

30

****Complete the modified Memorial Pain Assessment Card (Form 12) prior to the therapy session and attach****

[mpacBefore]

e. Check box for each of the following that are completed:

☐

Explain treatment procedure

[prepExplain]

☐

Obtain assent for therapy

[prepAssent]

☐

Create quiet environment

[prepQuiet]

☐

Assemble supplies, if needed

[prepSupplies]

☐

Position for comfort and drape if needed

[prepPosition]

☐

Center self or begin mental distraction technique

[prepCenter]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Treatment Form

(FORM 11)

Patient ID: -

[subject]

Patient Initials:

Visit No:

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

[visit]

Form No:

[form]

f. Pulse immediately prior to hands-on portion of session (60 seconds):

37-39

[pulseBefore]

g. Respirations immediately prior to hands-on portion of session (60 seconds):

40-41

[respBefore]

h. Time beginning hands-on portion of session (24-hour clock):

42-45 :

[timeStart]

4. Final Assessment by Treatment Provider:

a. Time ending session (24-hour clock):

46-49 :

[timeEnd]

b. Pulse immediately after hands-on portion of session (60 seconds):

50-52

[pulseAfter]

c. Respirations immediately after hands-on portion of session (60 seconds):

53-54

[respAfter]

55

****Complete the modified Memorial Pain Assessment Card (Form 12) following the therapy session and attach**** [mpacAfter]

5. Describe Treatment Session:

a. The environment during the hands-on portion of the session was: (Write number in box)

56

1 = Very Quiet

2 = Somewhat Quiet

3 = Somewhat Noisy

4 = Very Noisy

[environment]

b. Sources of distraction during the hands-on portion of the session were (Mark YES or NO for each):

1) Ambient noise (e.g. overhead paging, alarms, etc.)

Yes
57

No

[distractNoise]

2) People (adults or children) present:

58

[distractPeople]

3) Pets present:

59

[distractPets]

4) Radio on - music:

60

[distractRadioMusic]

5) Radio on - talking:

61

[distractRadioTalk]

6) Television on:

62

[distractTV]

7) Other: _____

63

[distractOther]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Treatment Form

(FORM 11)

Patient ID: -

[subject]

Patient Initials:

Visit No:

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

[visit]

Form No:

[form]

5. CONTINUED - Describe Treatment Session:

- c. Patient's Attire: (Write the number of the category that best describes the patient's attire at time of the hands-on portion of the session):

- 64 1 = Fully clothed
2 = Hospital gown
3 = Light clothing (e.g. t-shirt, shorts)
4 = Pajamas or nightgown
5 = Underwear only
6 = Undressed

[attire]

- d. Patient's Position: (Indicate the positioning that is applicable to your session with the patient. For each position, indicate the approximate % of session time that the patient spent in that position):

Position	% of Session Time in this Position
Prone (Lying on front or face down)	65-67 <input type="text"/> <input type="text"/> <input type="text"/> [positionProne]
Seated	68-70 <input type="text"/> <input type="text"/> <input type="text"/> [positionSeated]
Side	71-73 <input type="text"/> <input type="text"/> <input type="text"/> [positionSide]
Supine (Lying on back or face upward)	74-76 <input type="text"/> <input type="text"/> <input type="text"/> [positionSupine]
Other: _____	77-79 <input type="text"/> <input type="text"/> <input type="text"/> [positionOther]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Treatment Form

(FORM 11)

Patient ID: 1-5 -

[subject]

Patient Initials: 6-8

Visit No: 10

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

[visit]

Form No: 11-12

[form]

6. Description of Treatment: (Examine the Body Diagram card included with your response card set to complete the questions below.)

- Areas of the body touched for moving touch or non-moving touch treatment (Mark YES or NO in the boxes below next to the list of body sections.)
- If you provided moving touch treatment, indicate the location and release of tender or trigger points. (Mark YES or NO in the boxes below next to the list of body sections to indicate if there was a release of tender or trigger points at that section.)
- If you provided non-moving touch treatment, indicate the approximate time in minutes that hands were held on each area (Mark time in boxes below next to the list of body sections. If you did not place hands on certain body sections, mark "00" for time in minutes at that section.)

Attach [Touch] at end of base variable name

Attach [MT] at end of base variable name

Attach [Time] at end of base variable name

Body Section #	Body Section Name	(6a - Touch)		(6b - MT)		(6c - NMT)
		YES	NO	YES	NO	Minutes
1	Face [face]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
2	Chest [chest]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
3a.	Upper Arm - R (front & back) [armUpR]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 2	<input type="text"/> <input type="text"/>
3b.	Upper Arm - L (front & back) [armUpL]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
4a.	Lower Arm - R (front & back) [armLowR]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
4b.	Lower Arm - L (front & back) [armLowL]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
5a.	Palm of Hand - R [palmR]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
5b.	Palm of Hand - L [palmL]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
6.	Abdomen [abdomen]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
7a.	Front of Upper Leg - R [legFrontUpR]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
7b.	Front of Upper Leg - L [legFrontUpL]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>
8a.	Front of Lower Leg - R [legFrontLowR]	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> 1	<input type="text"/> 0	<input type="text"/> <input type="text"/>

(FORM 11)

[form]

**Attach [Time] at end of
base variable name**

Version #9 (10/8/03) - Page 5 of 6

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Treatment Form

(FORM 11)

Patient ID: -

[subject]

Patient Initials:

Visit No:

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

[visit]

Form No:

[form]

7. If you provided moving touch treatment, indicate approximate *percent* of session time - Effleurage: %

[timeMTEff]

8. If you provided moving touch treatment, indicate approximate *percent* of session time - Petrissage: %

[timeMTPet]

9. Reason (if any) for early termination of treatment session: Not available in dataset

10. Significant observations or patient comments: Not available in dataset

11. Other comments observations (continue on other side and indicate with arrow, if needed): Not available in dataset

Form Completed By: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Memorial Pain Assessment Card (MPAC)

(FORM 12)

Instructions: This form should be completed by the Moving-Touch Therapist or Non-Moving Touch Volunteer for each randomized patient prior to and immediately following each moving-touch or non-moving touch session, as indicated on Form 11-Treatment Form.

Patient
ID:

1-5 -

[subject]

Patient
Initials:

6-8

Visit
No:

9

[visit]

1 = Visit 1
2 = Visit 2
3 = Visit 3
4 = Visit 4
5 = Visit 5
6 = Visit 6

Form
No:

10-11

[form]

12

1 = Pre-Session
2 = Post Session

[prePost]

1. Date:

13-20 MM DD Year

Removed due to PHI please see var [daysRandMPAC] for number of days between randomization and date of form.

Instructions: Please record the number indicated by the patient in the boxes beside each scale.

2. Please indicate on the card the number that best describes your **pain intensity** right now.

PAIN SCALE

0 1 2 3 4 5 6 7 8 9 10
LEAST POSSIBLE PAIN WORST POSSIBLE PAIN

21-22

[mpacPain]

3. Please indicate on the card the number that best describes your **mood** right now.

MOOD SCALE

0 1 2 3 4 5 6 7 8 9 10
WORST MOOD BEST MOOD

23-24

[mpacMood]

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Missed Visit or Therapy Form

(FORM 13)

Instructions: This form should be completed by the On-Site Data Collector, Moving Touch Therapist, or Non-Moving Touch Volunteer, for each randomized patient when a visit is missed. Please turn this form in to the On-Site Study Coordinator as soon as possible following a missed visit.

Patient ID: 1-5 - **[subject]**

Patient Initials: 6-8

Visit No: 9 **[visit]**

Form No: 10-11 **[form]**

1. Date: 12-19
MM DD Year

Removed due to PHI please see var [daysRandMiss] for number of days between randomization and date of form.

2. Patient location: 20 **[ploc]**
(Write Number in box)
1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____

3. Reason for missed visit or therapy session? (Write in one number)

- 21 ☐ 1 = Patient not in room or at home
[missReason] ☐ 2 = Patient refused
☐ 3 = Patient unable to participate in scheduled visit (e.g., too ill to participate, too tired to participate, comatose, somnolent, or too confused).
☐ 4 = Family refused to allow patient to participate in scheduled visit
☐ 5 = Patient died
☐ 6 = Other (please specify:) _____

4. a. Missed visit was for the following session: (Write in one number)

- [missType]** 22 ☐ 1 = Data collection by On-Site Data Collector
☐ 2 = Treatment session by Moving Touch Therapist or Non-Moving Touch Volunteer

If missed visit was for Baseline Data Collection, by the OSDC, the visit may be rescheduled within a maximum of 5 days beyond enrollment (the addition of 2 working days).

If for the Weekly Data Collection Visits, the visits may be rescheduled within a maximum of:

1st Weekly Visit = 7 working days beyond Baseline Data Collection

2nd Weekly Visit = 7 working days beyond 1st Weekly Visit

Final Data Collection Visit = 9 working days beyond Final Treatment Session.

If it is past that time period, do not reschedule visits and check box *4c.

If missed visit was for a Treatment Session, please reschedule ASAP if you are still within the 2 work week period (10 working days) from the first treatment session. If it is past that time period, do not reschedule visits and check box *4c.

b. Data collection or treatment session rescheduled:

23-30
MM DD Year

Removed due to PHI please see var [daysMissRsch] for number of days between missed visit date and rescheduled visit date.

*c. OSDC / MTT / NMTV : (Check box)

[noResched] 31 ☐ Unable to reschedule because it is past the time allowed for rescheduling.

Form Completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Serious Adverse Event (SAE)

FORM 14

Instructions:

The On-Site Study Coordinator (OSSC) should complete this form for each randomized patient who experiences a Serious Adverse Event (SAE), including death. Please complete a separate form for each SAE experienced by the patient.

Please call Dr. Jean Kutner at (303) 372-9086 within 24 hours of knowledge of the SAE. If she is not available, please leave a detailed message describing the incident.

Please complete and fax this form to the PoPCRN Office at 1-866-301-7268 within 48 hours of knowledge of the SAE.

The OSSC MUST report any Serious Adverse Events that are unexpected (Question 5 marked 2) and related (Question 7 marked 2-possibly, 3-probably, or 4-definitely) to one of the study treatments within the timelines and via the methods noted above if they occur during the patient's 3-to-4 week participation timeframe from the date of enrollment (signing of consent and HIPAA forms).

Events that are expected (except death) and unrelated to one of the study interventions do NOT need to be reported. These types of events are seen as part of the natural progression of the patient's disease.

All deaths, whether or not they are expected or related to the patient's participation in one of the study interventions, MUST be reported within the timelines and via the methods described above if they occur during the patient's 3-to-4 week participation timeframe from the date of enrollment (signing of consent and HIPAA forms). (This applies even if the patient has terminated from the study.)

For deaths involving actively enrolled patients and that lead to early termination of the patient from the study, please complete Form 15 (Study Termination & Mortality), in addition to Form 14. If the death occurs AFTER the patient's 3-to-4 week participation in the study, there is no need to fill out Form 14 or Form 15.

An SAE should only be categorized as a follow-up report (Question 3a marked 2 and 3b is the date of original SAE) if the current incident clearly relates to a previous incident. Otherwise, all SAEs are initial (Question 3a is 1).

- Example of Related SAEs: The first SAE was an embolism (Question 8 was marked 3) and the second SAE showed the cause of death (Questions 6d) as a pulmonary embolus (PE).
- Example of Unrelated SAEs: The first SAE was a skin tear (Question 8 was marked 7) and the second SAE showed the cause of death (Question 6d) as lung cancer.

If the SAE is categorized as a follow-up report, then it MUST be reported even if it occurs beyond the patient's anticipated 3-to-4 week participation timeframe.

Please do NOT mark the "Incident # for patient." This is for PoPCRN Office use only.

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Serious Adverse Event (SAE)

FORM 14

Instructions: The On-Site Study Coordinator (OSSC) should complete this form for each randomized patient who experiences a Serious Adverse Event (SAE), including death, while he/she is enrolled in the study. Please complete a separate form for each SAE experienced by the patient.

Please call Dr. Jean Kutner at (303) 372-9086 within 24 hours of knowledge of the SAE. If she is not available, please leave a detailed message describing the incident. Please complete and fax this form to the PoPCRN Office at 1-866-301-7268 within 48 hours of knowledge of the SAE.

Please do NOT mark the "Incident # for patient." This is for PoPCRN Office use only.

Patient ID: 1-5 - **[subject]**

Patient Initials: 6-8

Incident # for patient: 9 **[incNo]** Form No: 10-11 1 4 **[form]**

1. Date: 12-19 MM DD Year

Removed due to PHI please see var [daysRandSAE] for number of days between randomization and date of form.

2. Patient location: 20 1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____
[ploc]

3a. Initial or Follow-up Report: (Write number in box)

21 1 = Initial
2 = Follow-up - [Only if the current SAE clearly relates to a previously reported SAE] - Please answer Question 3b.

[reportType]

3b. Date of original SAE:

22-29 MM DD Year

Removed due to PHI please see var [daysSAEFU] for number of days between initial report and follow-up form (if this is a follow-up form).

4. Classification of SAE: (Write number in box)

30 1 = Hospitalization/prolonged hospitalization
2 = Disability
3 = Serious and/or unexpected reactions
4 = Death - [If death occurs during the study, then please complete Form 15]
5 = Congenital, anomaly or birth defect
6 = Life-threatening

[saeClass]

5. Expectedness: (Write number in box)

31 1 = Expected [If due to disease progression]
2 = Unexpected

[expectedness]

6a. Outcome: (Write number in box)

32 1 = Resolved - Please answer Question 6b.
2 = Ongoing
3 = Death - [If death occurs during the study, please complete Form 15] - Please answer Questions 6c and 6d.

[outcome]

b. If "Resolved", date resolved: 33-40 MM DD Year

Removed due to PHI please see var [daysUntilResolved] for number of days between initial report and SAE resolution.

c. If "Death", date of death: 41-48 MM DD Year

Removed due to PHI please see var [daysUntilDeath] for number of days between initial report and death.

d. Cause of death (Please specify exact cause): **[causeOfDeath]**

49-78

7. Relationship of SAE to Intervention: (Write number in box)

79 1 = Not related
2 = Possible
3 = Probable
4 = Definitely
[related]

8. Type of SAE: (Write number in box)

80 1 = Fracture
2 = Serious bruising
3 = Embolism
4 = Allergic reaction
5 = Dislodged catheter
6 = Dislocation of joints
7 = Skin tear
8 = Other, specify: _____
[saeType]

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Serious Adverse Event (SAE)

FORM 14

Patient ID: -

Patient Initials:

Incident # for patient:

Form No:

9. Attach all supporting documentation and list attachments here:

- a. _____
- b. _____
- c. _____
- d. _____

Form Completed By: _____

For PoPCRN OFFICE USE ONLY

10. If this is a death, is it possibly related to treatment and is more than 30 days after treatment?

If Yes, it must be reported to COMIRB. Report other deaths as required. 1 Yes 2 No

11. Has this type of event been reported to COMIRB before? 1 Yes 2 No

If YES, please list the number of times local: _____

If YES, please list the number of times off-site: _____

12. Is this SAE named in the consent form as a risk? 1 Yes 2 No

If NO, should it be? (Write number in box) 1 = Yes, (submit changes with an Alteration / Update Form)
2 = No, justify: _____

13. Do you recommend protocol changes? 1 Yes 2 No

If Yes, submit changes with a Protocol Amendment Form

14. Anticipated number of subjects to be enrolled across all sites:

15. Number of subjects enrolled across all sites:

As of date:
MM DD Year

REMINDER: If there is any new information contained in this report that might have an impact on issues of risk connected with this study, a revision must be made to the protocol and/or consent form.

Fill out the appropriate COMIRB SAE or Safety Update Form and report to COMIRB according to COMIRB rules.

At the PoPCRN Office, form completed by: _____

REDUCING END-of-LIFE SYMPTOMS WITH TOUCH (REST)

Study Termination & Mortality Form

(FORM 15)

Instructions: This form should be completed by the On-Site Study Coordinator whenever a randomized patient terminates participation in the study prematurely or dies. If the patient has suffered an adverse event or died, please notify the Project Manager at PoPCRN as soon as possible. Please complete Form 14-Serious Adverse Event Form.

Patient ID: 1-5 - [subject]

Patient Initials: 6-8

Form No: 9-10 1 5 [form]

1. Date: 11-18 MM DD Year

Removed due to PHI please see var [daysRandTerm] for number of days between randomization and form date.

2. Patient location: 19 1 = Home
2 = Nursing Home/Skilled Nursing Facility
3 = Hospice Facility
4 = Other, specify: _____
[ploc]

3. Patient terminates prematurely from study alive? a. 20 1 Yes 0 No (If NO, skip to Question 4)

If yes, reason for terminating prematurely from study: (Mark YES or NO)

YES	NO	[preTermAlive]
<input type="text"/> 1	<input type="text"/> 0	[ptRefuse]
<input type="text"/> 1	<input type="text"/> 0	[famRefuse]
<input type="text"/> 1	<input type="text"/> 0	[provRefuse]
<input type="text"/> 1	<input type="text"/> 0	[aeWithdrawal]
<input type="text"/> 1	<input type="text"/> 0	[cogImpair]
<input type="text"/> 1	<input type="text"/> 0	[dzProgress]
<input type="text"/> 1	<input type="text"/> 0	[dischAliveUnable]
<input type="text"/> 1	<input type="text"/> 0	[dischAliveUnwilling]
<input type="text"/> 1	<input type="text"/> 0	[reasonOther]

- b. Patient refuses to continue participation: _____ 21
- c. Patient's family requested withdrawal of patient from study: _____ 22
- d. Patient's physician/medical caregivers requested withdrawal of patient from study: _____ 23
- e. Adverse event requires withdrawal of patient from study: _____ 24
- f. Patient no longer able to participate due to cognitive impairment: _____ 25
- g. Patient no longer able to participate due to other symptoms or normal progression of disease: _____ 26
- h. Patient discharged alive and unable to continue participation: _____ 27
- i. Patient discharged alive and but unwilling to continue participation in the study: _____ 28
- j. Other (specify): _____ 29

4. Patient has died: a. 30 1 Yes 0 No [died]

b. If YES, date of death: 31-38 MM DD Year

Removed due to PHI please see var [daysRandDeath] for number of days between randomization and death date.

c. If YES, cause of death: [causeOfDeath]
39-68

If patient has died, please fill out Form 14 (Serious Adverse Event Form) immediately and follow it's instructions.

Form Completed by: _____