CRF 01 – CONFIRMATION OF ELIGIBILITY AND STUDY ENTRY FORM

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

Please answer by ticking the appropriate box or filling in the required information.

1. INCLUSION CRITERIA: **If any of the below criteria is answered NO, the participant is NOT eligible for the trial.**		
Has the patient been recently referred (or re-referred) to palliative care service?	Yes ☐	No ☐
Has the patient locally advanced or metastatic, incurable* cancer? * Incurable means that the disease cannot be eradicated and the estimated survival is less than one year.	Yes ☐	No ☐
Is the patient aged 18 years or over?	Yes ☐	No ☐
Has the patient sufficient English language skills?	Yes ☐	No ☐
2. EXCLUSION CRITERION: **If the criterion below is answered YES, the participant is NOT eligible for the trial.**		
Currently receiving (or planned to receive) treatment with curative intent?	Yes ☐	No ☐
3. Capacity **If capacity is unclear then please complete a four point capacity test and document the answers on the Royal College of General Practitioners' MCA Toolkit worksheet at the end of this form.**		
Has the patient the capacity to consent to participate in the study?	Yes ☐	No ☐
4a. CONSENT **If patient has capacity, 'YES' in 3:**		
Has the patient provided written consent?	Yes ☐	No ☐
4b. CONSENT **If patient doesn't have capacity, 'NO' in 3:**		
Has a signed declaration form been received from a personal or nominated consultee?	Yes, personal consultee ☐ Yes, nominated consultee ☐	No ☐

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Completed on D D M M Y Y Y Y

5. DATE WRITTEN CONSENT was obtained:

D D M M Y Y Y Y

6. CONFIRMATION OF ELIGIBILITY:

Is the patient eligible to take part in the study?	Yes ☐	No ☐

7. Please write the name of the study site in the field below:

8. Date of assessment:

D D M M Y Y Y Y

9. Gender

- ☐ Male
- ☐ Female
- ☐ Don't want to tell

10. Age

__ __ __ years

11. Current location (Please tick one)

- ☐ Hospital Inpatient
- ☐ Hospice Inpatient
- ☐ At home
- ☐ In hospice day unit
- ☐ In hospital outpatients
- ☐ In hospice outpatients
- ☐ In care home
- ☐ Other residential care
- ☐ Other

Other , please specify:

12. Primary tumour (Please tick all that apply)

- ☐ Breast
- ☐ Lung
- ☐ Prostate
- ☐ Urological (bladder, testes)
- ☐ Haematological
- ☐ Upper GI tract
- ☐ Lower GI tract
- ☐ Head and Neck
- ☐ Gynaecological
- ☐ Neurological
- ☐ Rare Tumour Groups
- ☐ Other
- ☐ Unknown primary

13. Sites of metastases (Please tick all that apply).

- ☐ Liver
- ☐ Lung
- ☐ Bone
- ☐ Brain
- ☐ Skin
- ☐ Nodal
- ☐ Adrenal
- ☐ Renal
- ☐ Malignant ascites
- ☐ Malignant pleural effusion
- ☐ Other
- ☐ None
- ☐ Unknown

14. Is patient currently receiving tumour-directed therapy (or has stopped receiving such therapy within last four weeks)?

	Yes ☐	No ☐

15. If 'YES' in 14 please specify which type of treatment (Please tick all that apply).

- ☐ Chemotherapy
- ☐ Radiotherapy
- ☐ Hormone therapy
- ☐ Other tumour directed therapy (e.g. immunotherapy)

Principal Investigator's Signature Statement

I have reviewed the CRFs and confirm that, to the best of my knowledge, it accurately re'lects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

Once signed, no further changes can be made to this CRF without a signed data query form.

Record of Capacity Assessment Under Mental Capacity Act - CURB

Put a cross in boxes * ☐ if extra information and record on the back of this page.

1. Specify decision in question: *☐

   Who is asking that the decision should be made?

   Who is asking that capacity be assessed?

Assessment Question	Tick your assessment	Tick your assessment
2. Is there an impairment or disturbance in the functioning of mind or brain? (permanent or temporary).	YES ☐ impairment is present, record symptoms/behaviours, any relevant diagnosis. *☐	NO ☐ impairment is not present, record evidence.. If NO the person is deemed capable - assessment is complete . *☐
3. If yes:		
a) With all possible help given is the person able to understand (U) the information relevant to the decision ? Avoid questions inviting yes or no answers. Try "What do you think this decision means? How will this decision affect you? Why do you think this decision needs to be made? "	YES ☐ able to understand info. Record views/evidence to show they understood it. *☐	NO ☐ unable to understand info. Record steps taken to explain info and views/evidence why they did not understand it. *☐
b) Are they able to retain (R) the information long enough to make the decision? e.g. "Tell me what you understand by ...? " Remember they only need to retain long enough for you to be sure they have understood.	YES ☐ able to retain info, record evidence. *☐	NO ☐ unable to retain information, record any help given and evidence. *☐
c) Are they able to balance (B) or weigh the information as part of the decision making process? "What will happen if you make this decision? What will happen if you do not make this decision?	YES ☐ able to weigh information, record evidence. *☐	NO ☐ unable to weigh info record evidence. *☐
d) Are they able to communicate (C) the decision?	YES ☐ able to communicate, record evidence. *☐	NO ☐ unable to communicate, record evidence. *☐
Conclusion - If the answer to 2. is YES and the answer to any of 3. a) - d) is NO then the person lacks capacity under the Mental Capacity Act 2005.	Fluctuating Capacity: Always consider whether the person has fluctuating capacity and whether the decision can wait until capacity returns. If this is the case, explain and enter reassessment date in outcome below:	
	Outcome: *☐	
	Name, Role and Signatures of Assessor (s): Date: ___/___/_____ (DD/MM/YYYY)	

CRF 02 – PATIENT SYMPTOMS

PIPS2 Site ID: Area: Patient's Initials:

Patient ID: Patient's DoB: D D M M Y Y Y Y

If the patient has capacity ask the patient. Mark the answers by ticking the appropriate box or filling in the required information.

1. Abbreviated Mental Test Score

Once respondent has correctly answered 4 questions the assessment can stop.
If patient is unconscious or uncooperative score "0".

MENTAL TEST SCORE (MTS)	NAME: ADDRESS: HOSPITAL NO: D.O.B.						
Ten-point MENTAL TEST SCORE *Score one point for each correct answer* Date of assessment							
AGE must be correct							
TIME without looking at clock or watch, and correct to nearest hour							
42 WEST STREET give this (or similar) address twice, ask patient to repeat immediately (to check it has registered), and test recall at end of procedure							
RECOGNISE TWO PEOPLE point at nurse and other, ask: 'Who is that person? What does she/he do?							
YEAR Exact, except in January when previous year is OK							
NAME OF PLACE may ask type of place, or area of town							
DATE OF BIRTH exact							
START OF FIRST WORLD WAR Exact year							
NAME OF PRESENT MONARCH							
COUNT FROM 20 TO 1 backwards, may prompt With 30/29/28, no other prompts; patient may hesitate and self-correct but no other errors (tests concentration)							
CHECK RECALL of address and enter score above							
ADD comment if communication or mood abnormal, e.g. deaf, dysphasic, depressed – may effect MTS / TOTAL SCORE Out of 10							

Is the Abbreviated Mental Test Score…

- ☐ less than 4
- ☐ greater or equal 4

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Completed on: D D M M Y Y Y Y

2. Anorexia - "During the last week have you lost your appetite?"

If patient is unconscious then respond "No", if patient is receiving artificial nutrition respond "No", if patient is awake but does not request food or swallow food when offered then respond "Yes".

☐ Yes

☐ No

3. Dysphagia - "During the last week have you had difficulty swallowing?"

If patient is unconscious then "Yes". If patient has enteral feeding tube (NG, PEG or PEJ) then respond "Yes".

☐ Yes

☐ No

4. Dyspnoea at rest - "During the last week have you felt breathless at rest?"

If patient is unconscious but breathing appears labored or rapid then respond "Yes".

☐ Yes

☐ No

5. Fatigue – "During the last week have you felt fatigued?"

If patient is unconscious then respond "Yes". If the patient is more drowsy, tired or fatigued than usual respond "Yes".

☐ Yes

☐ No

6. Has the patient lost weight in the last month? – "During the last month have you lost weight?"

If the patient does not know or cannot answer and/or it is not possible to judge then answer "No".

☐ Yes

☐ No

Principal Investigator's Signature Statement

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Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

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CRF 03 - CLINICAL ASSESSMENT

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

Please tick the appropriate box or answer by entering the reading/ number as required.

1. Is clinically apparent ascites present?
Evidence from history, clinical examination or investigations

☐ Yes

☐ No

2. Is clinically apparent peripheral oedema present?
Shown by pitting oedema of dependent areas

☐ Yes

☐ No

3. Pulse:

— — — bpm

4a. Is the patient delirious? If in doubt, use CAM (see worksheet on page 2)

☐ Yes

☐ No

4b. If delirious ("Yes" in 4a.) is delirium considered to be caused by a single medication?

☐ Yes

☐ No

5. Oral intake: If patient has capacity ask: "During last week has your food intake been…"**

** If patients are receiving total parental nutrition they are categorized as "normal" oral intake, "moderately reduced" means reduced but more than mouthfuls; and "severely reduced" means mouthfuls or less.

☐ Normal

☐ Moderately reduced

☐ Severely reduced

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SHORT CONFUSION ASSESSMENT METHOD (SHORT CAM) WORKSHEET

Note: This worksheet can used as an alternative to the Short CAM Questionnaire. Testing of orientation and sustained attention is recommended prior to scoring, such as digit spans, days of week, or months of year backwards. This page can only be used to identify delirium cases. Please note it cannot be used to score severity using the CAM-S scoring system.

EVALUATOR: DATE:

I. ACUTE ONSET AND FLUCTUATING COURSE

a) Is there evidence of an acute change in mental status from the patient's baseline? No ____ Yes ____

b) Did the (abnormal) behavior fluctuate during the day, that is tend to come and go or increase and decrease in severity? No ____ Yes ____

II. INATTENTION

Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said? No ____ Yes ____

BOX 1

III. DISORGANIZED THINKING

Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject? No ____ Yes ____

IV. ALTERED LEVEL OF CONSCIOUSNESS

Overall, how would you rate the patient's level of consciousness?

-- Alert (normal)

-- Vigilant (hyperalert)

-- Lethargic (drowsy, easily aroused)

-- Stupor (difficult to arouse)

-- Coma (unarousable)

Do any checks appear in the box above? No ____ Yes ____

BOX 2

If Inattention and at least one other item in Box 1 are checked and at least one item in Box 2 is checked a diagnosis of delirium is suggested.

6. ECOG performance status - Please circle the appropriate grade

Grade	Definition
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g. light housework, office work)
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self-care, totally confined to bed or chair

7. How would you rate this patient's overall health during the past week? Please circle the appropriate grade

1 2 3 4 5 6 7

Very poor Excellent

8. Karnofsky Performance Scale (KPS) - Please circle the appropriate percentage

100%	Normal, no complaints, no signs of disease
90%	Capable of normal activity, few symptoms or signs of disease
80%	Normal activity with some difficulty, some symptoms or signs
70%	Caring for self, not capable of normal activity or work
60%	Requiring some help, can take care of most personal requirements
50%	Requires help often, requires frequent medical care
40%	Disabled, requires special care and help
30%	Severely disabled, hospital admission indicated but no risk of death
20%	Very ill, urgently requiring admission, requires supportive measures or treatment
10%	Moribund, rapidly progressive fatal disease processes
0%	Death

9. PPS – Please circle appropriate percentage in column PPS level

VICTORIA HOSPICE

Palliative Performance Scale (PPSv2)
version 2

PPS Level	Ambulation	Activity & Evidence of Disease	Self-Care	Intake	Conscious Level
100%	Full	Normal activity & work No evidence of disease	Full	Normal	Full
90%	Full	Normal activity & work Some evidence of disease	Full	Normal	Full
80%	Full	Normal activity *with* Effort Some evidence of disease	Full	Normal or reduced	Full
70%	Reduced	Unable Normal Job/Work Significant disease	Full	Normal or reduced	Full
60%	Reduced	Unable hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full or Confusion
50%	Mainly Sit/Lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or Confusion
40%	Mainly in Bed	Unable to do most activity Extensive disease	Mainly assistance	Normal or reduced	Full or Drowsy +/- Confusion
30%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Normal or reduced	Full or Drowsy +/- Confusion
20%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Minimal to sips	Full or Drowsy +/- Confusion
10%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Mouth care only	Drowsy or Coma +/- Confusion
0%	Death	-	-	-	-

Instructions for Use of PPS (see also definition of terms)

1. PPS scores are determined by reading horizontally at each level to find a 'best fit' for the patient which is then assigned as the PPS% score.
2. Begin at the left column and read downwards until the appropriate ambulation level is reached, then read across to the next column and downwards again until the activity/evidence of disease is located. These steps are repeated until all five columns are covered before assigning the actual PPS for that patient. In this way, 'leftward' columns (columns to the left of any specific column) are 'stronger' determinants and generally take precedence over others.

   Example 1: A patient who spends the majority of the day sitting or lying down due to fatigue from advanced disease and requires considerable assistance to walk even for short distances but who is otherwise fully conscious level with good intake would be scored at PPS 50%.

   Example 2: A patient who has become paralyzed and quadriplegic requiring total care would be PPS 30%. Although this patient may be placed in a wheelchair (and perhaps seem initially to be at 50%), the score is 30% because he or she would be otherwise totally bed bound due to the disease or complication if it were not for caregivers providing total care including lift/transfer. The patient may have normal intake and full conscious level.

   Example 3: However, if the patient in example 2 was paraplegic and bed bound but still able to do some self-care such as feed themselves, then the PPS would be higher at 40 or 50% since he or she is not 'total care.'
3. PPS scores are in 10% increments only. Sometimes, there are several columns easily placed at one level but one or two which seem better at a higher or lower level. One then needs to make a 'best fit' decision. Choosing a 'half-fit' value of PPS 45%, for example, is not correct. The combination of clinical judgment and 'leftward precedence' is used to determine whether 40% or 50% is the more accurate score for that patient.
4. PPS may be used for several purposes. First, it is an excellent communication tool for quickly describing a patient's current functional level. Second, it may have value in criteria for workload assessment or other measurements and comparisons. Finally, it appears to have prognostic value.

Definition of Terms for PPS

As noted below, some of the terms have similar meanings with the differences being more readily apparent as one reads horizontally across each row to find an overall 'best fit' using all five columns.

1. Ambulation
The items '**mainly sit/lie**,' '**mainly in bed**,' and '**totally bed bound**' are clearly similar. The subtle differences are related to items in the self-care column. For example, 'totally bed 'bound' at PPS 30% is due to either profound weakness or paralysis such that the patient not only can't get out of bed but is also unable to do any self-care. The difference between 'sit/lie' and 'bed' is proportionate to the amount of time the patient is able to sit up vs need to lie down.

'**Reduced ambulation**' is located at the PPS 70% and PPS 60% level. By using the adjacent column, the reduction of ambulation is tied to inability to carry out their normal job, work occupation or some hobbies or housework activities. The person is still able to walk and transfer on their own but at PPS 60% needs occasional assistance.

2. Activity & Extent of disease
'**Some**,' '**significant**,' and '**extensive**' disease refer to physical and investigative evidence which shows degrees of progression. For example in breast cancer, a local recurrence would imply 'some' disease, one or two metastases in the lung or bone would imply 'significant' disease, whereas multiple metastases in lung, bone, liver, brain, hypercalcemia or other major complications would be 'extensive' disease. The extent may also refer to progression of disease despite active treatments. Using PPS in AIDS, 'some' may mean the shift from HIV to AIDS, 'significant' implies progression in physical decline, new or difficult symptoms and laboratory findings with low counts. 'Extensive' refers to one or more serious complications with or without continuation of active antiretrovirals, antibiotics, etc.

The above extent of disease is also judged in context with the ability to maintain one's work and hobbies or activities. Decline in activity may mean the person still plays golf but reduces from playing 18 holes to 9 holes, or just a par 3, or to backyard putting. People who enjoy walking will gradually reduce the distance covered, although they may continue trying, sometimes even close to death (eg. trying to walk the halls).

3. Self-Care
'**Occasional assistance**' means that most of the time patients are able to transfer out of bed, walk, wash, toilet and eat by their own means, but that on occasion (perhaps once daily or a few times weekly) they require minor assistance.

'**Considerable assistance**' means that regularly every day the patient needs help, usually by one person, to do some of the activities noted above. For example, the person needs help to get to the bathroom but is then able to brush his or her teeth or wash at least hands and face. Food will often need to be cut into edible sizes but the patient is then able to eat of his or her own accord.

'**Mainly assistance**' is a further extension of 'considerable.' Using the above example, the patient now needs help getting up but also needs assistance washing his face and shaving, but can usually eat with minimal or no help. This may fluctuate according to fatigue during the day.

'**Total care**' means that the patient is completely unable to eat without help, toilet or do any self-care. Depending on the clinical situation, the patient may or may not be able to chew and swallow food once prepared and fed to him or her.

4. Intake
Changes in intake are quite obvious with '**normal intake**' referring to the person's usual eating habits while healthy. '**Reduced**' means any reduction from that and is highly variable according to the unique individual circumstances. '**Minimal**' refers to very small amounts, usually pureed or liquid, which are well below nutritional sustenance.

5. Conscious Level
'**Full consciousness**' implies full alertness and orientation with good cognitive abilities in various domains of thinking, memory, etc. '**Confusion**' is used to denote presence of either delirium or dementia and is a reduced level of consciousness. It may be mild, moderate or severe with multiple possible etiologies. '**Drowsiness**' implies either fatigue, drug side effects, delirium or closeness to death and is sometimes included in the term stupor. '**Coma**' in this context is the absence of response to verbal or physical stimuli; some reflexes may or may not remain. The depth of coma may fluctuate throughout a 24 hour period.

10. Time to terminal disease

Time between diagnosis of cancer and date at which cancer became incurable (to the nearest month).
The time at which the cancer became incurable is either the time at which it is deemed to be inoperable or becomes metastatic, whichever is the sooner.
If no information is available then please estimate the time to terminal disease by entering the median time between diagnosis and today's date.

10a. Please indicate if the "time to terminal disease" has been calculated:

i) based on discussion with patient, staff and/or from review of notes ☐

or

ii) by estimation only ☐

10b. Please record time to terminal disease (If incurable from diagnosis score 0, if time interval is less than one month then also score 0).

__ __ months

Principal Investigator's Signature Statement

I have reviewed the CRFs and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

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CRF 04 – BLOOD RESULTS

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

Blood results (from medical notes or electronic patient record)

For patients without capacity who have had a recent blood test (specimen still in lab) or are scheduled to have a blood test within 72 hours of study enrolment, these blood tests should be requested on the sample obtained as part of routine clinical care and the results recorded here.

For patients with capacity blood results must be recorded.

1. White blood count:

— — · — $\times 10^9$/L

2. Lymphocyte count (please enter as 10^9/L or if not available as %):

— — · — — $\times 10^9$/L

— — · — — %

3. Neutrophil count:

— — · — — $\times 10^9$/L

4. Platelet count:

— — — $\times 10^9$/L

5. Urea:

— — · — mmol/L

6. Albumin:

— — g/L

7. Alkaline phosphatase:

— — — U/L

8. Alanine transaminase

— — — U/L

9. C reactive protein

— — — · — mg/L

10. Lactate Dehydrogenase

— — — U/L

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Completed by | Print Name | Signature

Completed on D D M M Y Y Y Y

Principal Investigator's Signature Statement

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Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

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CRF 05 – DOCTOR PREDICTION OF SURVIVAL

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

To be filled in by the doctor

Please answer by ticking the appropriate box or filling in the required information.

1. Please enter the date when this form was completed/ the estimate obtained:

D D M M Y Y Y Y

2. What is your speciality?

- ☐ Palliative medicine
- ☐ Oncology
- ☐ Other

Other, please specify:

3. Please state your professional grade:

- ☐ Foundation
- ☐ Core Medical Trainee
- ☐ Specialist Trainee
- ☐ Consultant
- ☐ Other

Other, please specify:

4. How many years have you been working as a doctor since you qualified?

__ __ **years**

5. How many years have you been working in palliative care?

__ __ **years**

6. Please state your gender:

- ☐ Female
- ☐ Male
- ☐ Don't wish to answer

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7. How old are you?

__ __ years ☐ Don't wish to answer

8. How long have you had a relationship with the patient? (tick only one box)

- ☐ Less than one week
- ☐ Less than one month
- ☐ Less than three months
- ☐ Three months or more
- ☐ Never met patient

9. When did you last assess the patient? (tick only one box)

- ☐ Today
- ☐ Within the last three days
- ☐ Within the last week
- ☐ Within the last month
- ☐ Over one month ago
- ☐ Never met patient

10. What is your approximate estimate of the length of this patient's survival? (tick only one box)

- ☐ "Days" = 0 – 13 days
- ☐ "Weeks" = 14 – 55 days (2 – 7 weeks)
- ☐ "Months+" = 56 days or greater (i.e. 8 weeks or two months) or more

11. What is your more specific estimate of this patient's survival? (tick only one box)

- ☐ 1 week or less
- ☐ 2 weeks
- ☐ 3 weeks
- ☐ 4 weeks
- ☐ 5 weeks
- ☐ 6 weeks
- ☐ 7 - 8 weeks
- ☐ 9 - 10 weeks
- ☐ 11 - 12 weeks
- ☐ more than 12 weeks

12. Please state the estimated probability of this patient's survival for all of the time periods listed below.

100% probability means that you think the patient is certain to survive as long as the specified time period, 50% probability means that you think there is an equal probability that they may or may not survive, and 0% probability indicates that you are certain that they will not survive as long as the period specified.
The probability of survival should decrease or stay the same as one considers longer and longer time periods. Thus if, for example, you consider that the patient has a 70% chance of surviving for 1 day then their probability of surviving 3 , 7, 15, 30 or 60 days must be 70% or lower.

1 day	%
3 days	%
7 days	%
15 days	%
30 days	%
60 days	%

Principal Investigator's Signature Statement

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Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

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CRF 06 – NURSE PREDICTION OF SURVIVAL

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

To be filled in by the nurse

Please answer by ticking the appropriate box or filling in the required information.

1. Please enter the date when this form was completed/ the estimate obtained:

D D M M Y Y Y Y

2. What is your speciality?

- ☐ Palliative care
- ☐ Oncology
- ☐ Other

Other, please specify:

3. Please state your professional grade:

- ☐ Band 5
- ☐ Band 6
- ☐ Band 7
- ☐ Band 8
- ☐ Nurse consultant
- ☐ Other

Other, please specify:

4. How many years have you been working as a nurse since you qualified?

__ __ years

5. How many years have you been working in palliative care?

__ __ years

6. Please state your gender:

- ☐ Female
- ☐ Male
- ☐ Don't wish to answer

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Completed by

Print Name | Signature

Completed on D D M M Y Y Y Y

7. How old are you?

__ __ years ☐ Don't wish to answer

8. How long have you had a relationship with the patient? (tick only one box)

- ☐ Less than one week
- ☐ Less than one month
- ☐ Less than three months
- ☐ Three months or more
- ☐ Never met patient

9. When did you last assess the patient? (tick only one box)

- ☐ Today
- ☐ Within the last three days
- ☐ Within the last week
- ☐ Within the last month
- ☐ Over one month ago
- ☐ Never met patient

10. What is your approximate estimate of the length of this patient's survival? (tick only one box)

- ☐ "Days" = 0 – 13 days
- ☐ "Weeks" = 14 – 55 days (2 – 7 weeks)
- ☐ "Months+" = 56 days or greater (i. e. 8 weeks or two months or more)

11. What is your more specific estimate of this patient's survival? (tick only one box)

- ☐ 1 week or less
- ☐ 2 weeks
- ☐ 3 weeks
- ☐ 4 weeks
- ☐ 5 weeks
- ☐ 6 weeks
- ☐ 7 - 8 weeks
- ☐ 9 - 10 weeks
- ☐ 11 - 12 weeks
- ☐ more than 12 weeks

12. Please state the estimated probability of this patient's survival for all of the time periods listed below.

100% probability means that you think the patient is certain to survive as long as the specified time period, 50% probability means that you think there is an equal probability that they may or may not survive, and 0% probability indicates that you are certain that they will not survive as long as the period specified.
The probability of survival should decrease or stay the same as one considers longer and longer time periods. Thus if, for example, you consider that the patient has a 70% chance of surviving for 1 day then their probability of surviving 3 , 7, 15, 30 or 60 days must be 70% or lower.

1 day	%
3 days	%
7 days	%
15 days	%
30 days	%
60 days	%

Principal Investigator's Signature Statement

I have reviewed the CRFs and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

Once signed, no further changes can be made to this CRF without a signed data query form.

CRF 07 – MDT OF SURVIVAL

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

1. Have the doctor and the nurse independently given the same approximate length of survival?
Please check the answers to question 10 on CRF 05 and CRF 06

☐ Yes – go to 2.

☐ No – go to 3 and 3a.

2. If the answer to question 1 is "yes" (doctor and nurse independently agree on approximate length of survival), please tick below the agreed MDT estimate.

☐ "Days" = 0 – 13 days

☐ "Weeks" = 14 – 55 days (2 – 7 weeks)

☐ "Months+" = 56 days or greater (i. e. 8 weeks or two months or more)

3. If the answer to question 1 is "no" (doctor and nurse disagree on approximate length of survival), please ask them to confer and tick below the agreed MDT estimate.

☐ "Days" = 0 – 13 days

☐ "Weeks" = 14 – 55 days (2 – 7 weeks)

☐ "Months+" = 56 days or greater (i. e. 8 weeks or two months or more)

3a. Please enter the date when the agreed MDT estimate was obtained:

D D M M Y Y Y Y

Priment™ Clinical Trials Unit

Completed by

Print Name | Signature

Completed on D D M M Y Y Y Y

Principal Investigator's Signature Statement

I have reviewed the CRFs and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

Once signed, no further changes can be made to this CRF without a signed data query form.

Priment™ Clinical Trials Unit

Serious Adverse Event Reporting Form
Non-CTIMP studies

V1.0 12/02/2016

Trial Number: | | | | | | | | | | | Patient's Initials: | | | | | Date of birth: d d m m / y y y y

Site: | | | | | | | | | | | Responsible Clinician: .....

Country: UK

1. Type of report
☐ 1= First
2= Follow Up
If follow up specify number ☐

2. Trial Arm
N/A (Non-interventional)

3. Sex
☐ 1=Male
2=Female

4. Height | | | | cm

5. Weight | | | kg

6. Body Surface Area ☐ . ☐☐ m²

7. Why was the event serious?
☐ 1= Resulted in Death
2= Life-threatening
3= Required inpatient hospitalisation or Prolongation of existing hospitalisation
4= Persistent or significant disability/incapacity
5= Congenital anomaly/birth defect
6= Other

8. Where did SAE take place?
☐ 1= Hospital
2= Out-patient clinic
3= Home
4= Nursing Home
5= Other
If Other specify: .....

Details of SAE

9. Main diagnosis/symptom	10. Severity 1=Mild 2=Moderate 3=Severe	11. Date of onset dd/mm/yyyy	12. SAE Status 1= Resolved 2= Resolved with sequelae 3= Unresolved 4= Worsened 5= Fatal 6= Not assessable	13. Date resolved dd/mm/yyyy

Study Intervention (If your study is non-interventional, please move to 'Other treatments' below.

14.Intervention	15.Date of first administration of intervention dd/mm/yyyy	16.Actual dose given at most recent administration	17.Date of most recent administration of intervention dd/mm/yyyy	18.Causal relationship to SAE 1= Definitely 2= Probably 3= Possibly	19.was the event unexpected? 0=No 1=Yes	20.Action taken due to SAE 0=None 1=intervention stopped 2=Intervention delayed 3=Intervention amended 4= Other (please describe)
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Other treatments (Exclude any therapy given for management of SAE; include all concomitant medication. Continue on a separate sheet if necessary)

21.Treatment Give generic name	22.Total Daily Dose	23.Route 1= Oral 2= Intravenous 3= Subcutaneous 4= Other	24.Start Date dd/mm/yyyy	25.Ongoing 0=No 1=Yes	26.End Date dd/mm/yyyy	27.Causal relationship to SAE 1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6= No assessable	28.Action taken due to SAE 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

Signed by:

Printed Name:

Date Completed: d d m m y y y y

For office use only:
Date form entered onto database : dd - mm - yyyy

Initials of data enterer: | | | |

Priment™ Clinical Trials Unit

Serious Adverse Event Reporting Form
Non-CTIMP studies

V1.0 12/02/2016

Trial Number: | | | | | | | | | | | Patient's Initials: | | | | | Date of birth: d d m m y y y y

Site | | | | | | | | | | | Responsible Clinician: .....

Country: UK

29. Describe the serious adverse event (include manifestation & progression of event, any treatments given in response to the event and any relevant tests carried out e.g. WBC, neutrophil count. Continue on a separate sheet if necessary).

.....

.....

.....

.....

.....

Diagnostic Tests:

30. Test name					
31. Date					
32. Normal range					
33. Result (+ units)					

34. Date you became aware of this event d d m m y y y y

Signed by:

Printed Name:

Contact Telephone:

Date Completed: d d m m y y y y

Please email to primentsafetyreport@ucl.ac.uk with 24 hours of becoming aware of the event.

Priment Use ONLY

SUSAR:7 day ☐ **SUSAR:15 day** ☐

Event No | | | | | | | | |

Date sent to REC d d m m m y y y y

Form checked and Ready to file d d m m m y y y y

Priment Staff Signature

.....

For office use only:

Date form entered onto database : dd - mm - yyyy Initials of data enterer: | | | |

CRF 09 – WITHDRAWAL

PIPS2

Site ID: | Area: | Patient's Initials:

Patient ID: | Patient's DoB: D D M M Y Y Y Y

1. Has the patient withdrawn from the study?

☐ Yes – go to 2 and 3

☐ No

2. Please give reason why the patient has withdrawn from the study:

☐ Withdrawn consent

☐ Other, please specify:

3. Please give the date of withdrawal:

D D M M Y Y Y Y

Principal Investigator's Signature Statement

I have reviewed the CRFs and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by me or by a person under my supervision who has signed the Delegation and Signature Log.

Principal Investigator's Signature:	
Principal Investigator's Name:	Date of Signature:

Once signed, no further changes can be made to this CRF without a signed data query form.