

<Name of GP>
<Address1>
<Address2>
<City>
<County>
<Postcode>

<Date>

Dear <Name of GP>

Re: <Patient's name>, NHS number: <NHS number>, RAIN Study number: <RAIN number>

As I'm sure you are aware, five months ago, <name> spent time in intensive care following an acute traumatic brain injury. In two weeks time, we intend to write to them to invite them to participate in the above research study. RAIN aims to better understand recovery from head injury to inform care for future patients (NHS Research Ethics Committee Reference Number: 09/MRE09/10). Patient participation is entirely voluntary.

Naturally, to avoid the distress of receiving a letter addressed to a recently deceased family member, we would be very grateful if you would inform us as to whether your records indicate if <Patient's name> is alive or not and if alive confirm that <Patient name> is currently residing at the address shown on the attached form. We will not contact them until we hear back from you.

There are four possible ways to inform us, please either:

- enter these data onto the web based form (<web address>), using the confidential RAIN Study number <RAIN number> assigned to <Patient name>, or
- post the form to the above address; or
- fax the completed form to 020 7388 3759; or
- telephone Dr Gita Prabhu, RAIN Study Coordinator on 020 7554 9770.

<Patient name> (or their carer) will be asked to complete a health survey questionnaire (incorporating the Extended Glasgow Outcome Score and the EQ-5D) so we can assess their recovery and use of health services.

If you have any questions about the RAIN Study, then please do not hesitate to contact us on 020 7554 9770.

Thank you for your time.

Yours sincerely

Dr Gita Prabhu (RAIN Study Coordinator)
Dr David Harrison (Chief Investigator)
Intensive Care National Audit & Research Centre (ICNARC)

Understanding recovery from head injury to inform care

NHS Research Ethics Committee (Reference Number: 09/MRE09/10)

Chief Investigator: Dr David Harrison, RAIN Study Coordinator: Dr Gita Prabhu

We would be very grateful if you would provide the following information.

Our records indicate that <Name of patient> (<ref number>) is:

Alive

Dead

If alive, our records indicate that this patient is currently residing at:

<Address1>

<Address2>

<City>

<County> <Postcode>

Yes

No

If no please provide the patient's current address below:

Date form was completed: / /

Completed by : _____

On behalf of <Name of GP>

<Address1>

<Address2>

<City>

<County> <Postcode>

Please either:

- enter these data onto the secure web based form (<web address>); or
- post the form to the above address; or
- fax the completed form to 020 7388 3759; or
- telephone Dr Gita Prabhu, RAIN Study Coordinator on 020 7554 9770.

Thank you for your time

<Name of participant>
<Address1>
<Address2>
<City>
<County>
<Postcode>

<Date>

Dear <Name of participant>

I am <Name of Local Investigator>, <job title> and I was involved in your care when you were admitted to our intensive care unit six months ago at <Name of hospital>. Our intensive care unit is participating, with other units, in a research study aiming to better understand recovery from head injury to inform care for future patients. As part of this study, we would like to know about your recovery. All we need you to do is to answer the enclosed, two, short questionnaires.

If you do not wish to take part, then please return the uncompleted questionnaires in the FREEPOST envelope and you will receive no further contact about the Study. Please note: your current and future care will not be affected whether you decide to, or not to, participate in this Study.

If you are the carer for the person to whom this letter is addressed and they are unable to read it, we would be very grateful if you would take the time to look through this letter and Information Sheet on their behalf. If you feel that they would like to participate, then please complete the questionnaires on their behalf. By better understanding the recovery of the person you care for, we hope to improve the care for future patients with head injuries.

The RAIN Study is being conducted by a health research charity called ICNARC (the Intensive Care National Audit & Research Centre). The aim of the Study is to investigate why some patients make a better recovery than others. To do this, we need to know about your recovery. We will compare the information you provide us in these questionnaires to information about your head injury and treatment that was collected by staff from the critical care unit during your stay in intensive care. I have included an Information Sheet with this letter. This will give you more detailed information about the Study. The Study has been approved by an NHS Research Ethics Committee (Reference Number: 09/MRE09/10).

- If you agree to participate, please sign the Consent Form (yellow sheet) and then we would be grateful if you would complete the enclosed questionnaires (blue and green sheets); this should only take around 15 minutes. Please return all of these in the FREEPOST envelope.
- If you are unable to complete the questionnaires on your own, then please ask one of your relatives/carers/friends to help you. Please return all of these in the FREEPOST envelope.

<date>

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- If you do not wish to take part then please return the uncompleted questionnaires in the FREEPOST envelope and you will receive no further contact about the Study.

If you have any questions regarding the RAIN Study, then please do not hesitate to contact Dr Gita Prabhu, the RAIN Study Co-ordinator, on 020 7554 9770.

Finally, if you would like some information about head injuries or support in your recovery, Headway is a charity that provides this help and support to people and to those who care for them. Headway can be contacted on this freephone number: 0808 800 2244 or by email to helpline@headway.org.uk. Alternatively, your local rehabilitation unit may be able to offer advice (<tel: >).

Thank you very much for your time.

Yours sincerely

<Name of Principal/Local Investigator>

<Job title>, <hospital>

On behalf of the RAIN Study group.

Enclosed:

- Information Sheet
- Consent Form (yellow sheet)
- Your Health - Questionnaire (blue sheets)
- Health Services Questionnaire (green sheets)
- FREEPOST envelope
- Pen

INFORMATION SHEET

Understanding recovery from head injury to inform care

NHS Research Ethics Committee (09/MRE09/10)

Chief Investigator: Dr David Harrison, RAIN Study Coordinator: Dr Gita Prabhu

We would like to invite you to take part in a research study to help improve the care of patients who have suffered a traumatic brain injury (TBI). To do this we need you to fill out two short health questionnaires. The information below explains why we are doing this research and what it involves. Please read this information carefully so you can make an informed decision. If you have any questions please contact the RAIN Study team who will be more than happy to help. **Please note: your current and future care will not be affected whether you decide to, or not to, participate in this study.**

What is Traumatic Brain Injury?

Traumatic brain injury (TBI) is when a strike or knock to the head affects the normal functioning of the brain. There are many causes of TBI, such as a fall or a road traffic accident. The symptoms can vary from feeling sick or dizzy, to a brief loss of consciousness, to coma. Recovery after TBI is also varied. Some patients make a full recovery but others are left with a disability. If you would like some information about head injuries or support in your recovery, Headway is a charity that provides this help and support to people and to those who care for them. Headway can be contacted on this freephone number: 0808 800 2244 or by email to helpline@headway.org.uk. Alternatively, your local rehabilitation unit may be able to offer advice (<tel: >)

How will RAIN help TBI patients?

The overall aim of the Risk Adjustment In Neurocritical care (RAIN) Study is to improve the outcome and care given to patients who had a TBI. We are looking at patients who were admitted to critical care units to find why some people make a better recovery than others.

Many factors contribute to whether a person makes a good recovery. These include the type of injury, the health and age of the patient, where they were cared for and the medical treatment given. As every patient is different it can be difficult to know when/if a patient should be moved to another critical care unit, or when to start a particular treatment. We need to analyse data from thousands of patients to find what links the patients who have a positive outcome. The information that you provide us is vital for us to help improve the care for patients who have a TBI.

What would I have to do to take part in the study?

1. You would need to sign the Consent Form (yellow sheet).
This allows us to use information collected during your stay in hospital. This includes the type of injury you had, the treatments you received for that injury and which hospital(s) you stayed in.

2. You would need to fill out the health questionnaires (blue and green sheets).
This will help us understand how well you are since your injury. This should only take about 15 minutes to complete.

Enclosed is a pen to fill out the forms and a FREEPOST envelope to return the Consent Form and questionnaires to us.

Do I have to take part?

No. It is up to you whether or not you take part.

- If you agree to participate, then please sign the Consent Form (yellow sheet) and then we would be grateful if you would complete the enclosed questionnaires (blue and green sheets); this should only take around 15 minutes.
- If you do not wish to take part then please return the uncompleted questionnaires in the FREEPOST envelope and you will receive no further contact about the Study.

How safe is my information?

The information collected is sent to a health research charity called ICNARC (the Intensive Care National Audit & Research Centre) for analysis. ICNARC has a secure computer system and a strict information security policy (approved by the Department of Health). All ICNARC staff sign a contract agreeing to keep data secure and confidential. It is forbidden to remove patient data from the premises. ICNARC is registered under the Data Protection Act (Reg. No.: Z6289325). Anonymised data collected as part of this study will be stored securely for five years following the end of the study.

What will happen to the results of the study?

The results may help improve the care of TBI patients in critical care. We hope these data will answer questions such as: When are treatments effective? When should TBI patients be moved to another critical care unit? How do the patient's initial symptoms relate to their outcome? The Study should be completed in February 2012. If you would like to be sent a copy of the results please contact the RAIN Study team.

Who do I contact about the study?

If you have any questions, concerns or complaints, please contact the RAIN Study Coordinator, Dr Gita Prabhu (address and telephone number overleaf).

IF THE PERSON YOU CARE FOR IS UNABLE TO GIVE INFORMED CONSENT

We would like the person you care for to take part in a research study. This study will help future patients who suffer a traumatic brain injury. If the person you care for is not well enough to decide for himself/herself whether or not to participate, we ask if you could read through this sheet carefully. We would like you to give your opinion as to whether or not you think your relative/friend/partner would object to taking part in this research.

If you feel that the person you are caring for would agree to take part in this research, please could you sign the yellow Consent Form and state your name and relationship to the patient in the 'consultee' section, then complete the questionnaires. A FREEPOST envelope is provided for you to return the Consent Form and questionnaires. Thank you for your time and consideration.

Thank you for taking the time to read this sheet



ICNARC
Tavistock House
Tavistock Square
London WC1H 9HR
tel +44 (0)20 7554 9770
fax +44 (0)20 7388 3759
email rain@icnarc.org

CONSENT FORM

Chief Investigator: Dr David Harrison

Improving the treatment of adult patients with acute traumatic brain injury

Please **initial** boxes

- 1 I confirm that I have read and understood the Information Sheet (v1.8) for the above study and have had the opportunity to ask questions.
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without any future medical care or legal rights being affected.
- 3 I understand that sections of my care record have been looked at by responsible individuals involved with the study. I give my permission for these individuals to use this information for the Study.
- 4 I understand that information held by the NHS and records maintained by The NHS Information Centre may be used to keep in touch with me and follow up my health status.
- 5 I agree to take part in the above Study.

Name of participant:
(block capitals)

Today's date:

Signature:

(Where patients are unable to sign, a consultee should sign here and state their name and relationship to the participant below)

For the consultee	
Name of consultee: (block capitals)	_____
Relationship to the participant	_____

YOUR HEALTH - QUESTIONNAIRE

We would be grateful if you would complete this questionnaire. We would like to understand how you have been feeling since leaving the intensive care unit.

There are no right or wrong answers. We have found the best way to answer the questions is to go with your first instinct; whatever you think is the correct response for you.

A pen is provided and a FREEPOST envelope for return of the questionnaire.

Please complete today's date below:

____ / ____ / ____
Day Month Year

Please also let us know whether you completed this questionnaire:

- Alone
- With help
- Or it was completed by someone who cares for you

NOW PLEASE TURN THE PAGE TO START THE QUESTIONNAIRE ►

If you do not wish to complete this questionnaire, please return the unanswered questionnaire in the FREEPOST envelope provided.

Your current and future care will not be affected whether you decide to, or not to, fill out this questionnaire.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state
today**

Best
imaginable
health state

100

90

80

70

60

50

40

30

20

10

0

Worst
imaginable
health state

The following questions are about changes in your lifestyle since your injury. There are also some questions about how things were before the injury. The questions can be answered by you, or by a close relative or friend, or by you both together. We are interested in the recovery you have made up to now.

Please answer each question by ticking one box which is true for you.

1. Before the injury were you able to look after yourself at home?

Yes

No

2. As a result of your injury do you now need help in the home?

I do not need help or supervision in the home

I need some help in the home, but not every day

I need help in the home every day, but I could look after myself for at least 8 hours if necessary

I could not look after myself for 8 hours during the day

I need help in the home, but not because of the injury

3. Before the injury did you need help to shop?

Yes

No

4. As a result of your injury do you now need help to shop?

I do not need help to shop

I need some help, but I can go to local shops on my own

I need help to shop even locally, or I cannot shop at all

I need help to shop, but not because of the injury

5. Before the injury did you need help to travel?

- Yes
- No

6. As a result of your injury do you now need help to travel?

- I do not need help to travel
 - I need some help, but can travel locally on my own (e.g. by arranging a taxi)
 - I need help to travel even locally, or I cannot travel at all
 - I need help to travel but not because of the injury
-

7. Employment before the injury:

- | | |
|--|--|
| <input type="checkbox"/> Working | <input type="checkbox"/> Looking for work |
| <input type="checkbox"/> Caring for family | <input type="checkbox"/> Studying as a student |
| <input type="checkbox"/> Retired | <input type="checkbox"/> None of these (e.g. unfit for work) |

8. As a result of your injury has there been a change in your ability to work?

(or to study if you were a student; or to care for your family if you were the main caregiver)

- I can still do the same work
 - I can still work, but at a reduced level (e.g. change from full-time to part-time, or change in level of responsibility)
 - I am unable to work, or only able to work in sheltered workshop
 - My ability to work has changed, but not because of the injury
-

9. Before the injury did you take part in regular social and leisure activities outside home (at least once a week)?

Social and leisure activities include: going out to a pub or club, visiting friends, going to the cinema or bingo, going out for a walk, attending a football match, taking part in sport

- Yes
- No

10. As a result of your injury has there been a change in your ability to take part in social and leisure activities outside home?

- I take part about as often as before (the activities may be different from before)
- I take part a bit less, but at least half as often
- I take part much less, less than half as often
- I do not take part at all
- My ability to take part has changed for some other reason, not because of the injury

11. Before the injury did you have any problems in getting on with friends or relatives?

- Yes
- No

12. As a result of your injury are there now problems in how you get on with friends or relatives?

- Things are still much the same
- There are occasional problems (less than once a week)
- There are frequent problems (once a week or more)
- There are constant problems (problems every day)
- There are problems for some other reason, not because of the injury

13. Are there any other problems resulting from your injury which have interfered with your daily life over the past week?

*(Problems sometimes reported after head injury: **headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.**)*

- I have no current problems
- I have some problems, but these do not interfere with my daily life
- I have some problems, and these have affected my daily life
- I have some problems for other reasons, not because of the head injury

14. Before the injury were similar problems present?

- I had no problems before, I had minor problems
- I had similar problems before

Are there any other comments that you would like to make?

(Please continue on a separate sheet if you wish)



HEALTH SERVICES QUESTIONNAIRE

We would be grateful if you would complete this questionnaire. It will help us understand the care you needed after leaving the intensive care unit.

The RAIN Study aims to improve care for patients who have suffered a traumatic brain injury.

A pen is provided and a FREEPOST envelope for return of the questionnaire. Please answer multiple choice questions by putting a ✓ in ONE BOX for each question.

Please complete today's date below:

____ / ____ / ____
Day Month Year

Please also let us know whether you completed this questionnaire:

- Alone
- With help
- Or it was completed by someone who cares for you

NOW PLEASE TURN THE PAGE TO START THE QUESTIONNAIRE ►

If you do not wish to complete this questionnaire, please return the unanswered questionnaire in the FREEPOST envelope provided.

Your current and future care will not be affected whether you decide to, or not to, fill out this questionnaire.

The questions refer to ALL health services that you have used since leaving the hospital on [insert date], and before [insert date].

Part 1. Hospital Stay

A Since you left hospital on [insert date] have you stayed overnight in hospital for any reason (this includes hospital stays that were not due to your head injury)?

No - Go to Part 2

Yes - Please give details about the number of stays below

B For EACH TIME you stayed in hospital please answer the following

	Number of nights		1-3 nights	4-10 nights	11 or more nights	Did you spend any part of your stay in intensive care?
1 st stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 nd stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 rd stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 th stay*	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If you have stayed in hospital overnight more than 4 times, please could you provide information on these further hospital stays in Part 6 of the questionnaire.*

Part 2. Hospital outpatient visits

Outpatient visits are when a patient comes to the hospital to see a specialist (e.g. neurologist) but does not stay overnight.

A Since you left the hospital on [insert date] have you visited hospital outpatients about ANY ASPECT of your health?

No - Go to Part 3

Yes - Please give details about the number of outpatients visit(s) below

B

Number of visits		1-3 visits	4-10 visits	11 or more visits
<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 3. Visits to health care providers

A Since you left the hospital on [insert date] have you VISITED any of the health care providers listed below?

No - Go to Part 4

Yes - Please give details about your visits below

B For EACH PROVIDER please answer the following

Did you visit this provider?	Number of visits		1-3 visits	4-10 visits	11 or more visits
GP <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse at your GP clinic <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse at hospital or elsewhere <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health visitor <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 4. Visits to your home by health care providers

A Since you left the hospital on [insert date] have you had HOME VISITS from any the following health care providers about ANY ASPECTS of your health?

No - Go to Part 5

Yes - Please give details about your visits below

B For EACH HOME VIST please answer the following

Were you visited at home by this provider?	Number of visits		1-3 visits	4-10 visits	11 or more visits
GP <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse from your GP clinic <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational therapist <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health visitor or District nurse <input type="checkbox"/>	_____	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 5. Visits to other service providers

A Since you left the hospital on [insert date] please indicate whether you have had ANY contact (either visits to the provider or home visits) with any of the following service providers about ANY ASPECT of your health?

No - Go to Part 6

Yes - Please give details below

B For EACH PROVIDER please answer the following

Have you had contact with any of these providers?	Number of visits		1-3 visits	4-10 visits	11 or more visits
Clinical psychologist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speech and language therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mental health service <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hospital discharge coordinator <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Counsellor <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cognitive behavioural therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Continuing care nurse <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social worker <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Art therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 6. Other services not listed so far

A Since you left the hospital on [insert date] have you had further hospital stays or used ANY other health care services for ANY ASPECT of your health that you haven't included above?

No - Go to Part 7

Yes - Please give details below

B For EACH PROVIDER please answer the following

Type of service provider	Number of visits	Reason
e.g. Neurological rehabilitation centre	4	Check-up

Part 7. Comments

Your views are important to us. Please feel free to provide any other comments you have when completing the questionnaire in the box below.

Thank you for help

If you would like to ask us any questions about completing the questionnaire please email or call:

Gita Prabhu
rain@icnarc.org
020 7388 9770

Richard Grieve
Richard.Grieve@Ishtm.ac.uk
020 7927 2255

Telephone Interview Schedule

RAIN Study six month follow-up

1. Hello. I am (*interviewer's name*). I am calling about a medical research study we are carrying out to improve the care of people who have suffered a head injury. Can I speak to (*name*)?

If (*name*) did not answer the phone say the first two lines of 1., when *he/she* picks up the telephone and then continue through the numbered points.

If (*name*) is **unable to consent** go to the **red sheet**.

If you are speaking to (*name*):

2. The study is being carried out by ICNARC, the Intensive Care National Audit & Research Centre. It involves answering a few questions about your current health to help us improve the care of people who have had a head injury. Would you have time for me to tell you a little about what is involved now, this would only take a few minutes, or could I phone you back at a time that is more convenient to you? Would you be interested in hearing more about the Study?

If the patient does not want to take part in the study, thank them for their time. Interview ends.

If the patient would prefer to be **called back** at another time go to the **green sheet**.

If the patient is happy to continue:

3. We have been contacting people who have suffered a head injury to find out how well they have recovered since leaving the Intensive Care Unit. This will help us improve the care of future patients. By linking the medical treatments you received in hospital and the type of injury you had to how well you feel now, we can discover why some people make a better recovery than others. For instance this could then help doctors understand which treatments are best for which patients.
4. If you agree to take part in the study all you need to do is answer a few questions on how you have been feeling since your head injury. This will take about 10 minutes to complete. We would then link this information to which hospitals you stayed in and the medical treatments you received.
5. We are covered by the Data Protection Act. All information is kept on secure servers and no personal data is allowed off the premises. The results of the study will be published and if you would like a copy of the final results I can send this to you.

If yes note the participant's request.

6. Importantly, taking part in the study would not affect your medical care, but it will help future patients who suffer a head injury.

7. Would you be interested in taking part in the study?

If the patient says ‘no’, thank them for their time. Interview ends.

If the patient says ‘yes’:

8. Thank you for agreeing to take part. Would you be happy to answer the questions now? It will only take about 10 minutes to complete.

If the participant would prefer to arrange another time - go to the box at the end of this page:

9. Before we start the questions, remember there are no right or wrong answers. We have found that the best way to answer the questions is to go with your first instinct, whatever you think is the correct response for you.

10. The questions are about changes in your lifestyle since your injury. There are also some questions about how things were before the injury. We are interested in the recovery you have made up to now.

Fill out the questionnaire (**blue sheet**)

1. When would be a convenient time for me to call back?

Time

Date

When calling the participant back:

1. This is (*interviewer’s name*) I called on *date* about a research study we are carrying out looking at people that suffered a head injury. You mentioned that you would be interested in taking part in the study and asked me to call you back today.

2. The questions will take about 10 minutes to complete, would you be happy to answer the questions now?

If yes go to question 9 above

If no rearrange another time

Patient is unable to consent

1. Is there someone I could speak to someone who cares for (*name*)?

If the person who we need to speak to is not available, then arrange a time to **call back** later. Go to **green sheet**.

If the carer is happy to continue/the appropriate carer is given the phone:

2. This study is being carried out by ICNARC, the Intensive Care National Audit & Research Centre. It involves answering a few questions about the current health of (*name*) to help us improve the care of people who have had a head injury. Would you have time for me to tell you a little about what is involved now, it will only take a few minutes, or could I phone you back at a time that is more convenient to you?

If the carer does not want to take part in the study, thank them for their time. Interview ends.

3. If you agree to take part in the study all you need to do is answer a few questions on how (*name*) has been since *his/her* head injury. This will take about 10 minutes to complete. We would then link this information to which hospitals (*name*) stayed in and the medical treatments *he/she* received.
4. We are covered by the Data Protection Act. All information is kept on secure servers and no personal data is allowed off the premises. The results of the study will be published and if you would like a copy of the final results I can send this to you.

If yes note the carer's request.

5. Importantly, taking part in the study would not affect (*name's*) medical care, but it will help future patients who suffer a head injury.
6. If (*name*) is not well enough to decide for *himself/herself* whether or not to participate. We would like you to give your opinion as to whether or not you think (*name*) would object to taking part in this research. If you feel that (*name*) would be interested in taking part in the study, would you be willing to answer a few questions about *his/her* health?

If the carer says 'no', thank them for their time. Interview ends.

If the carer says 'yes':

7. Thank you for agreeing to take part. Would you be happy to answer the questions now? It will only take about 10 minutes to complete.

If the carer would prefer to arrange another time - go to the box at the end of this page

If the carer is happy to continue:

8. Before we start the questions remember there are no right or wrong answers. We have found that the best way to answer the questions is to go with your first instinct, whatever you think is the correct response.
9. The questions are about changes in (*name's*) lifestyle since the injury. There are also some questions about how things were before the injury. We are interested in the recovery (*name*) has made up to now.

Fill out the questionnaire (**blue sheet**)

1. When would be a convenient time for me to call back?

Name:

Relationship to participant:

Time

Date

When calling the participant back:

1. This is (*interviewer's name*) I called on *date* about a research study we are carrying out looking at people that suffered a head injury. You mentioned that you would be interested in taking part in the study on behalf of (*name*) and asked me to call you back today.

2. The questions will take about 10 minutes to complete, would you be happy to answer the questions now?

If 'yes' go to question 8 above

If 'no' rearrange another time

Patient/Carer wishes to be called back

If patient:

1. What time would be best for me to call you?

Time:

Date:

If carer:

1. Could you tell me the name of the person I should call concerning the care of (*name*)?

Name:

Relationship to patient:

2. What time would be best for me to call (*name*)?

Time:

Date:

When calling back:

1. This is (*interviewer's name*) could I speak to (*name*)?
2. I called on *date* about a research study aiming to help patients who have suffered a traumatic brain injury. You asked if I could call you back today. I would like to ask you a few questions about your current health to help us improve the care of people who have had a head injury. Would you have time for me to tell you a little about the study?

If the patient/carer does not want to take part in the study, thank them for their time. Interview ends.

If the patient would prefer to be **called back** at another time go to the start of this sheet.

If the patient is happy to continue go to **question 3 (front sheet)**.

If the carer is happy to continue go to **question 2 (red sheet)**.

If the patient says 'no', thank them for their time. Interview ends.

Patient/carer agrees to take part in the RAIN Study

This form was completed via telephone interview by:

Name (interviewer):

Name (interviewee):

If a carer, state the relationship of interviewee to participant:

Date:

1. Before the injury were you able to look after yourself at home? Yes No

2. As a result of your injury do you now need help in the home? (please tick one box)

I do not need help or supervision in the home

I need some help in the home, but not every day

I need help in the home every day, but I could look after myself for
at least 8 hours if necessary

I could not look after myself for 8 hours during the day

I need help in the home, but not because of the injury

3. Before the injury did you need help to shop? Yes No

4. As a result of your injury do you now need help to shop? (please tick one box)

I do not need help to shop

I need some help, but I can go to local shops on my own

I need help to shop even locally, or I cannot shop at all

I need help to shop, but not because of the injury

5. Before the injury did you need help to travel? Yes No

6. As a result of your injury do you now need help to travel? (please tick one box)

I do not need help to travel

I need some help, but can travel locally on my own
(e.g. by arranging a taxi)

I need help to travel even locally, or I cannot travel at all

I need help to travel but not because of the injury

7. Employment before the injury: (please tick one box)

Working

Looking for work

Caring for family

Studying as a student

Retired

None of these (e.g. unfit for work)

8. As a result of your injury has there been a change in your ability to work? (or to study if you were a student; or to care for your family if you were the main caregiver)

I can still do the same work

I can still work, but at a reduced level (e.g. change from full-time to part-time, or change in level of responsibility)

I am unable to work, or only able to work in sheltered workshop

My ability to work has changed, but not because of the injury

9. Before the injury did you take part in regular social and leisure activities outside home (at least once a week)? Yes No

Social and leisure activities include: going out to a pub or club, visiting friends, going to the cinema or bingo, going out for a walk, attending a football match, taking part in sport.

10. As a result of your injury has there been a change in your ability to take part in social and leisure activities outside home? (please tick one box)

I take part about as often as before
(the activities may be different from before)

I take part a bit less, but at least half as often

I take part much less, less than half as often

I do not take part at all

My ability to take part has changed for some other reason, not because of the injury

11. Before the injury did you have any problems in getting on with friends or relatives?

Yes No

12. As a result of your injury are there now problems in how you get on with friends or relatives? (please tick one box)

Things are still much the same

There are occasional problems (less than once a week)

There are frequent problems (once a week or more)

There are constant problems (problems every day)

There are problems for some other reason, not because of the injury

13. Are there any other problems resulting from your injury which have interfered with your daily life over the past week? (Problems sometimes reported after head injury: **headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration problems.**)

(please tick one box)

I have no current problems

I have some problems, but these do not interfere with my daily life

I have some problems, and these have affected my daily life

I have some problems for other reasons, not because of the head injury

14. Before the injury were similar problems present? (please tick one box)

I had no problems before, I had minor problems

I had similar problems before

Are there any other comments that you would like to make?

(Please continue overleaf if you wish)