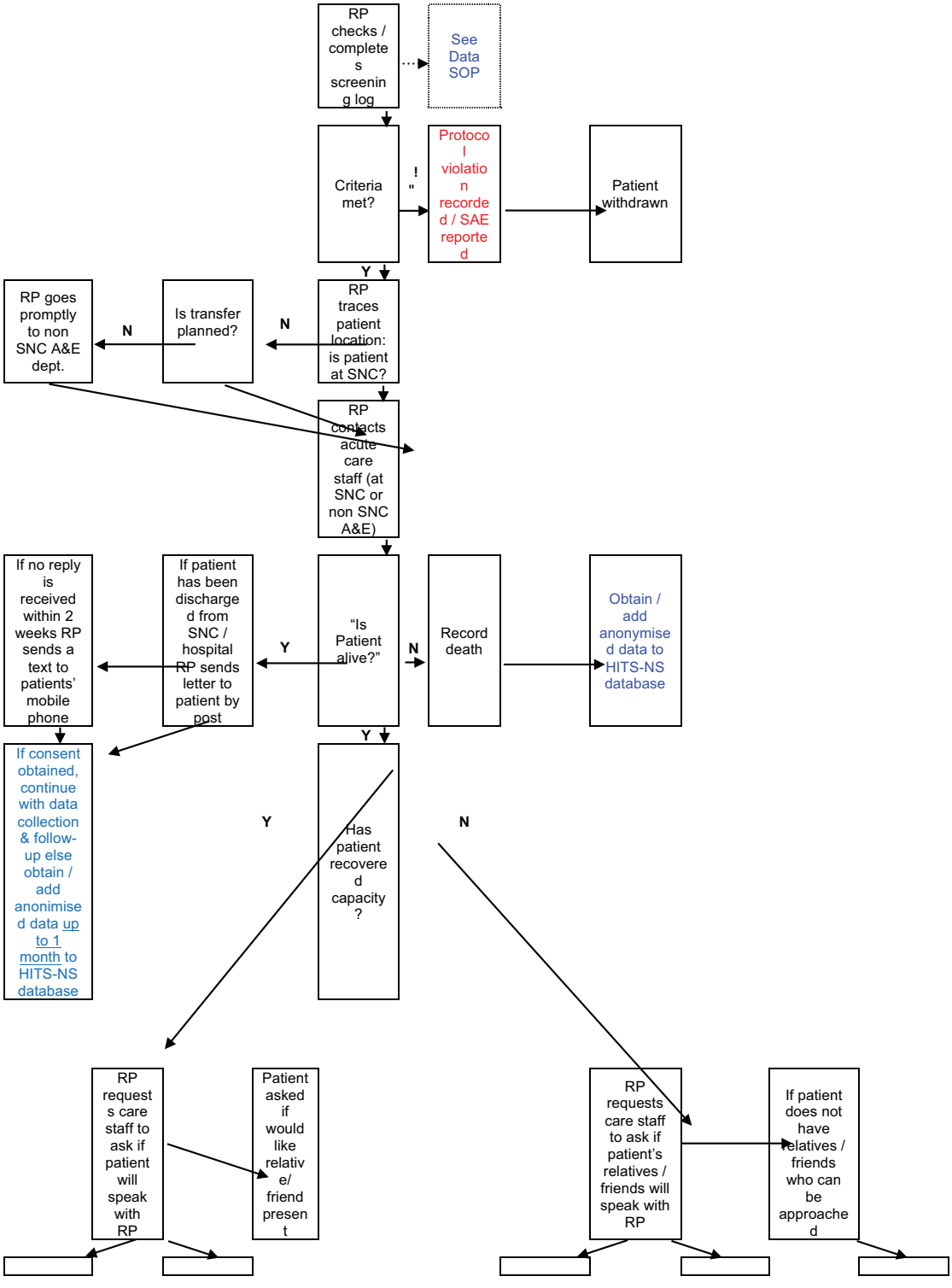
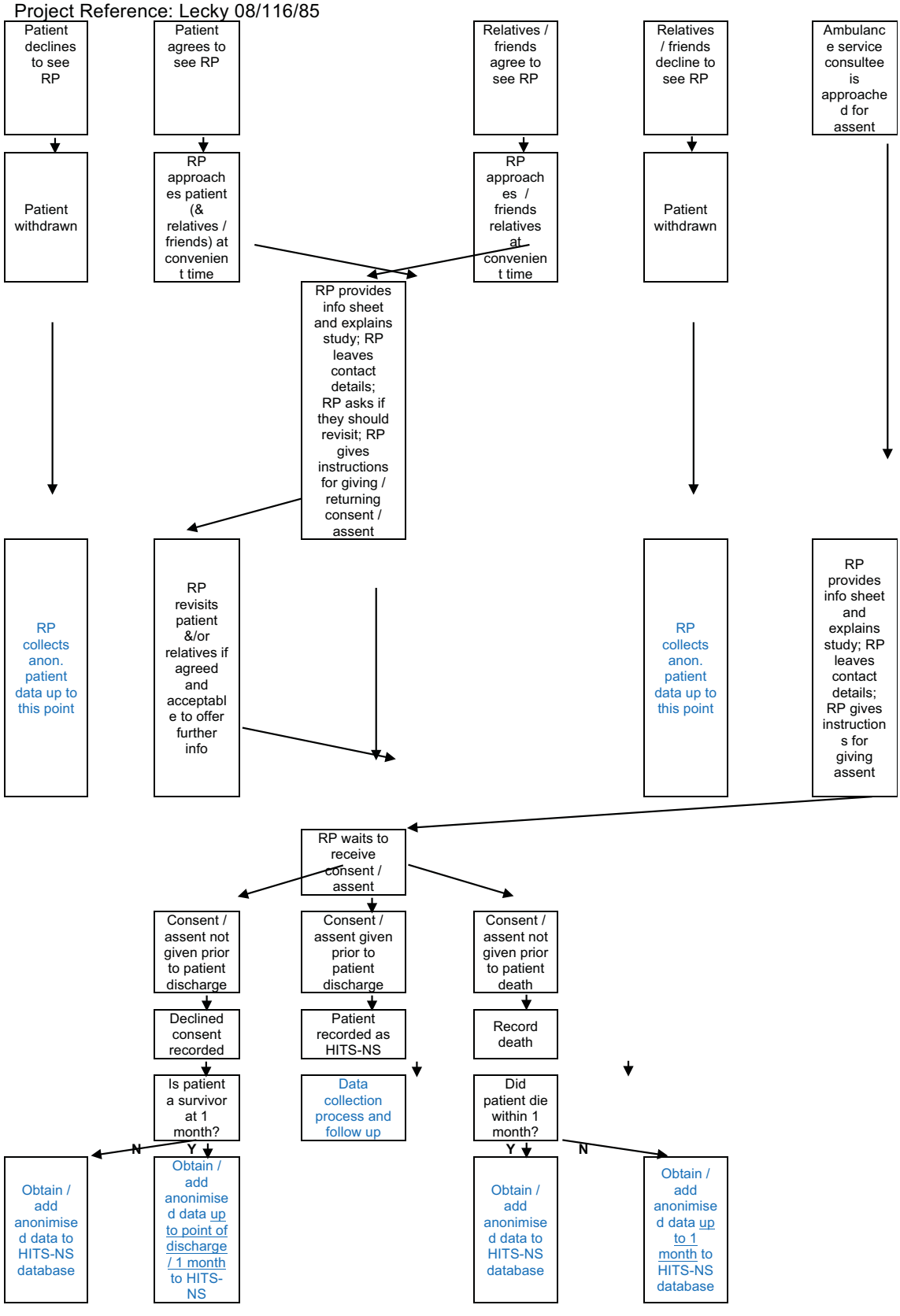
Appendix 3.

HITS-NS Consent process *(draft version 6.0)*



Project Reference: Lecky 08/116/85



Project Reference: Lecky 08/116/85

database

KEY:

SAE SOP

Data SOP

RP= Research Paramedic

HITS-NS Consent SOP v.4

Continuing from Step 9 or Step 10 of the HITS-NS Recruitment SOP:

I Scenario A:
A patient in the intervention group has been taken straight to the neuro centre from the scene of injury or a patient in the control arm has already been transferred from a PIC to the neuro centre.

11. The research paramedic (RP) liaises with acute care staff at the neuro centre within a couple of days after the patient's injury to begin the consent taking process.

12. If the patient is alive:
    - If the patient has been discharged from hospital the RP sends a letter inviting the patient to return a slip if they wish to be contacted and informed about the study; if no reply is received to this letter the RP sends a mobile text (if known) to the patient to remind the patient of the letter and to invite them to reply if they wish to be receive more information.
        - If the patient does not respond:
            - RP collects anonymised data up to this point
            - ***Proceed to HITS-NS data collection & management SOP***
        - If the patient requests further information the RP contacts the patient and provides information about the study.
            - If the patient gives consent, the RP records the patient as HITS-NS
            - ***Proceed to HITS-NS data collection & management SOP; refer to Follow-up SOP***
        - If the patient declines consent:
            - The patient is withdrawn from the study the RP
            - RP collects anonymised data up to this point
            - ***Proceed to HITS-NS data collection & management SOP***

    - The RP (or research nurse) determines if the patient has recovered capacity
    - If the patient has recovered capacity*:
        - The RP (or research nurse) requests care staff to ask if the patient will speak with him/her
        - Care staff are also instructed to ask if the patient would like to have a relative or friend present during the meeting with the RP (or research nurse)
        - If the patient declines to speak with the RP (or research nurse):
            - The patient is withdrawn from the study
            - RP collects anonymised data up to this point
            - ***Proceed to HITS-NS data collection & management SOP***

        - If the patient agrees to speak with the RP (or research nurse):
            - RP (or research nurse) liaises with care staff to determine a convenient time to approach the patient (with relative / friend present if requested)
            - RP (or research nurse) visits the patient and: introduces him/herself, explains the study, provides the trial information sheet and consent form, and leaves his/her contact details
            - RP (or research nurse) also asks the patient if the patient would like for the RP (or research nurse) to re-visit at a later time in order to answer any questions should they arise
            - If the patient requests that the RP (or research nurse) re-visits at a later point in time, the RP (or research nurse) informs the care staff that he/she will re-visit and liaises with care staff to arrange this

- The RP (or research nurse) gives instructions for giving / returning consent
- If a re-visit has been agreed the RP (or research nurse) visits the patient on a further convenient occasion and responds to any questions the patient may have
- The RP (or research nurse) waits to receive consent from the patient
- *go to step 5.*

- If the patient has not recovered capacity*:
  - The RP (or research nurse) requests care staff to ask if the patient's relatives / friends will speak with him/her

  - If the patient's relatives / friends decline to speak with the RP (or research nurse):
    - The patient is withdrawn from the study
    - RP collects anonymised data up to this point
    - ***Proceed to HITS-NS data collection & management SOP***

  - If the patient's relatives / friends agree to speak with the RP (or research nurse):
    - RP (or research nurse) liaises with care staff to determine a convenient time to approach the patient's relatives / friends
    - RP (or research nurse) visits the patient's relatives / friends and: introduces him/herself, explains the study, provides the trial information sheet and consent form, and leaves his/her contact details
    - RP (or research nurse) also asks the patient's relatives / friends if they would like for the RP (or research nurse) to re-visit at a later time in order to answer any questions should they arise
    - If the patient's relatives /friends request that the RP (or research nurse) re-visits at a later point in time, the RP (or research nurse) informs the care staff that he/she will re-visit and liaises with care staff to arrange this
    - The RP (or research nurse) gives instructions for giving / returning consent
    - If a re-visit has been agreed the RP (or research nurse) meets with the patient's relatives / friends on a further convenient occasion and responds to any questions that they may have
    - The RP (or research nurse) waits to receive consent from the patient's relatives / friends
    - *go to step 5.*

If the patient has died:

- RP records the patient's death
- RP collects anonymised data
- ***Proceed to HITS-NS data collection & management SOP***

II Scenario B:

A patient in the control group has not been transferred from a PIC to the neuro centre either because they are too unwell for transfer or they do not need to be transferred.

13. The RP contacts acute care staff at the PIC as soon as possible to determine the reason why the patient has not been transferred.

14. If the patient is too ill for transfer:
    - The RP reviews the situation on a regular basis
    - If the patient dies before transfer:

- RP records the patient's death
- RP collects anonymised data
- ***Proceed to HITS-NS data collection & management SOP***

- If the patient is transferred later:
  - *go to step 1.*

- If the patient does not require transfer:
  - RP acts quickly and contacts care staff at the PIC to begin the consent taking process
  - The RP (or research nurse) requests care staff to ask if the patient will speak with him/her
  - Care staff are also instructed to ask if the patient would like to have a relative or friend present during the meeting with the RP (or research nurse)
  - If the patient declines to speak with the RP (or research nurse):
    - The patient is withdrawn from the study
    - RP collects anonymised data up to this point
    - ***Proceed to HITS-NS data collection & management SOP***

  - If the patient agrees to speak with the RP (or research nurse):
    - RP (or research nurse) liaises with care staff to determine a convenient time to approach the patient (with relative / friend present if requested)
    - RP (or research nurse) visits the patient and: introduces him/herself, explains the study, provides the trial information sheet and consent form, and leaves his/her contact details
    - RP (or research nurse) also asks the patient if the patient would like for the RP (or research nurse) to re-visit at a later time in order to answer any questions should they arise
    - If the patient requests that the RP (or research nurse) re-visits at a later point in time, the RP (or research nurse) informs the care staff that he/she will re-visit and liaises with care staff to arrange this
    - The RP (or research nurse) gives instructions for giving / returning consent
    - If a re-visit has been agreed the RP (or research nurse) visits the patient on a further convenient occasion and responds to any questions the patient may have
    - The RP (or research nurse) waits to receive consent from the patient
    - *go to step 5.*

15. If consent is given:
    - The RP records the patient as HITS-NS
    - ***Proceed to HITS-NS data collection & management SOP; refer to Follow-up SOP***

If consent is not given prior to patient discharge:

- The RP records consent declined
- If the patient is a survivor at 1 month:
  - RP collects anonymised data up to point of discharge / 1 month
  - ***Proceed to HITS-NS data collection & management SOP***

- If the patient dies within 1 month:
  - RP collects anonymised data
  - ***Proceed to HITS-NS data collection & management SOP***

If consent is not given prior to patient death:

- RP records patient's death

- The RP records consent declined
- If the patient had died after 1 month:
    - RP collects anonymised data up to 1 month
    - ***Proceed to HITS-NS data collection & management SOP***

- If the patient had died within 1 month:
    - RP collects anonymised data
    - ***Proceed to HITS-NS data collection & management SOP***

If consent is specifically declined at any time:

- The RP records consent declined
- The patient is withdrawn from the study
- If the patient declines within 1 month
    - RP collects anonymised data up to point of declined consent
    - ***Proceed to HITS-NS data collection & management SOP***

- If patient declines after 1 month
    - No further data is collected
    - ***Proceed to HITS-NS data collection & management SOP***

Patient capacity guidelines:

When the RP attends to provide study information with a view to obtaining consent they should further check that the patient has full capacity to give consent by checking the following:

The patient understands the information about the study provided verbally and in the PIS.
The patient is able to retain that information (can tell the RP their understanding of what participating in the study entails).
The patient is able to make a decision/ give consent about participation based on said information.

If any of these three aspects are not met then the patient should be assumed not to have capacity and appropriate advice from a personal or ambulance service consultee, about the appropriateness of the patient participating in the study - should be sought.