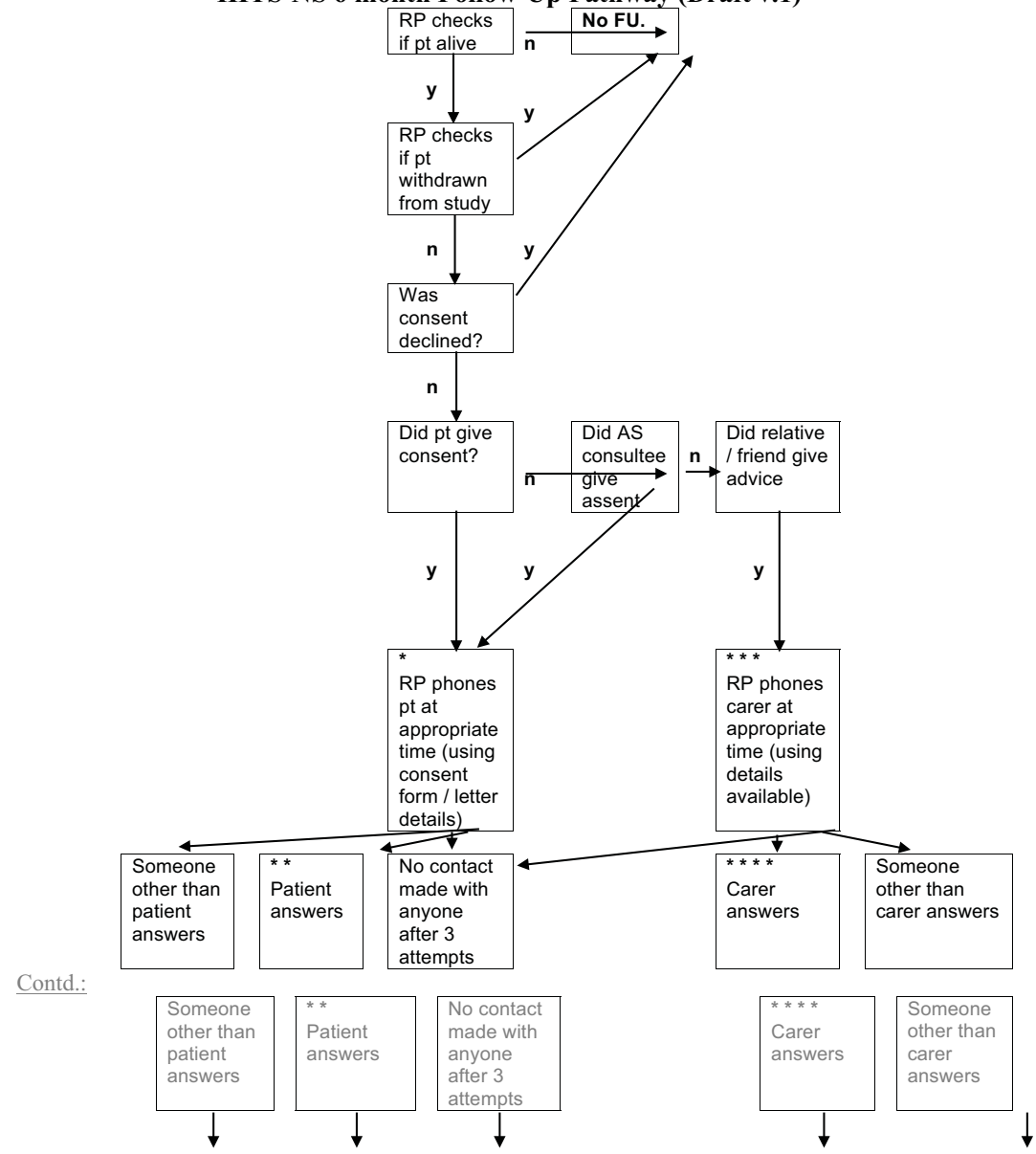
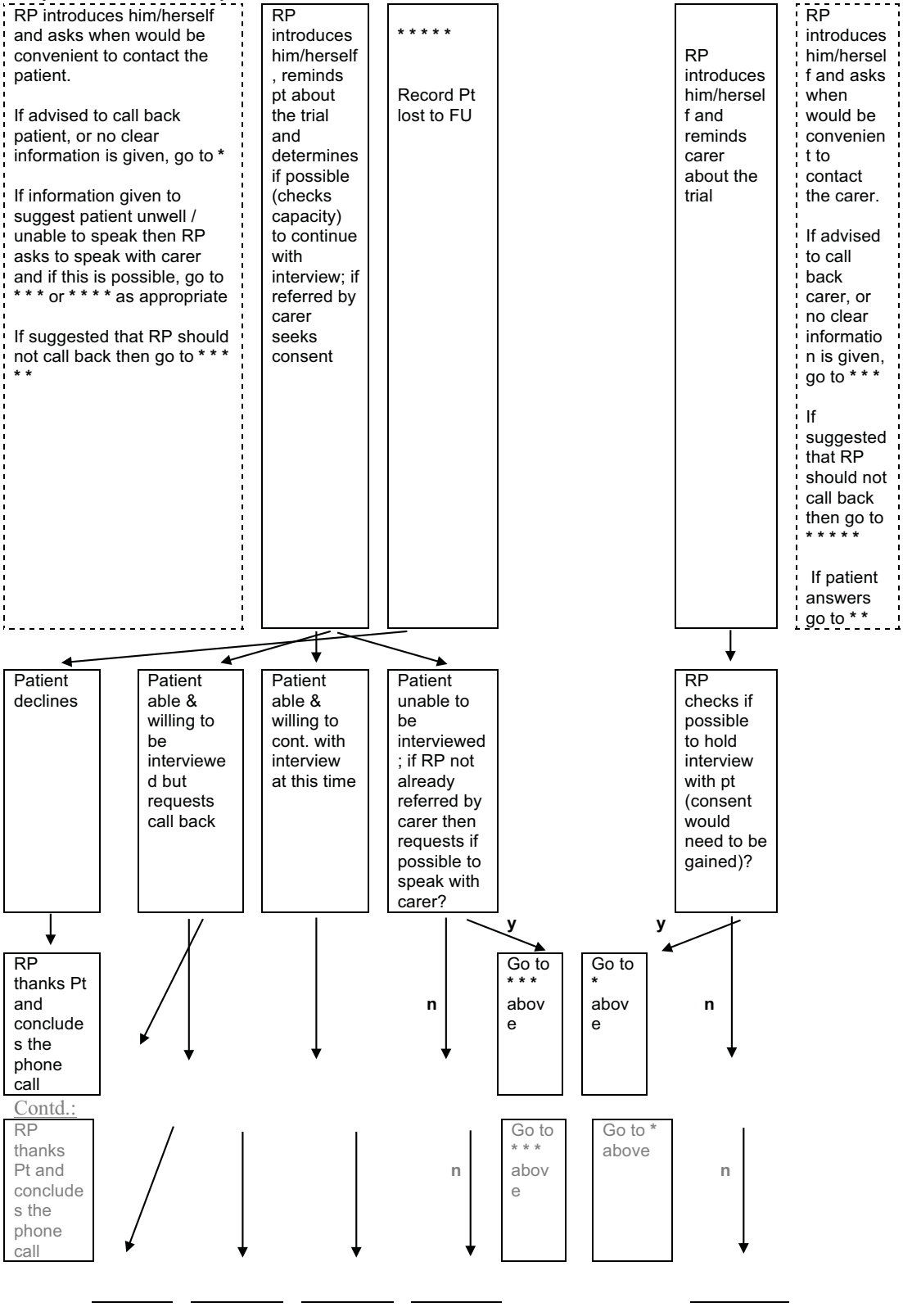
**Appendix 5 Further Trial SOPS:**

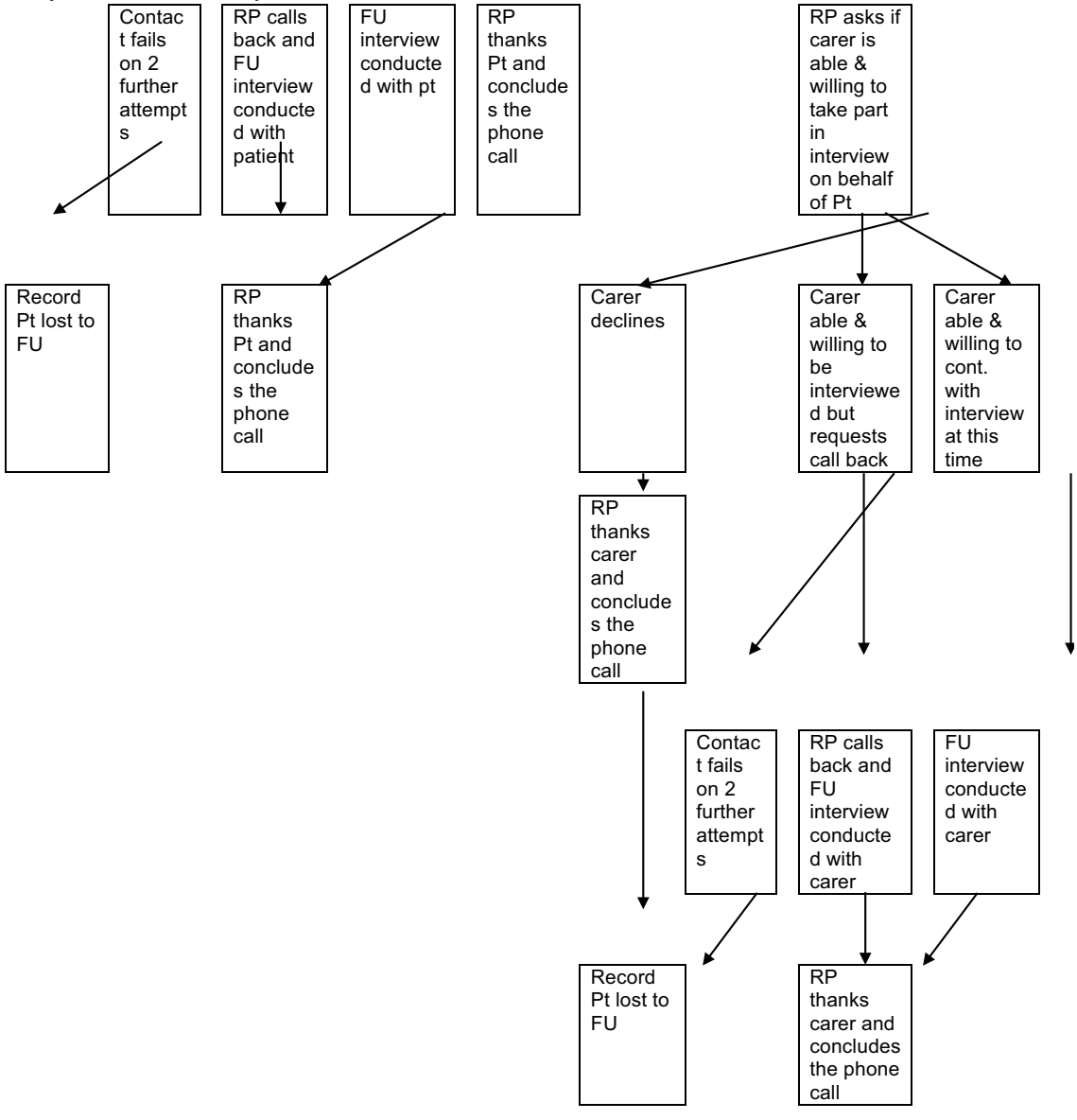
## HITS-NS 6 month Follow-Up Pathway (Draft v.1)



Project Reference: Lecky 08/116/85



Project Reference: Lecky 08/116/85



# HITS-NS Data Management SOP *(Draft v1.)*

## I PRF (patient report form) screening

16. Electronic PRF's:

- the research paramedic (RP) checks the daily ***HITS-NS pre-alerts spreadsheet*** sent by the ambulance service informatics department – the spreadsheet is a list of all pre-alerts into any hospital in the study area including all head injury cases. The spreadsheet information includes:
    - incident id
    - date
    - patient demographics (e.g. age, gender) (this information varies)
    - notes including reason for call (e.g. cardiac arrest, head injury etc.)
    - outcome (level of response / referral)
- once relevant (e.g. those with appropriate clinical notes, response level and referral etc.) head injury cases have been screened out the RP then uses the incident id number in a PRF search screen which provides more complete incident and clinical information recorded by paramedics at the scene
- paramedics from intervention stations are expected to indicate "HITS-NS bypass" on the electronic PRF for patients meeting the HITS-NS eligibility criteria therefore intervention patients recruited into the trial should be identifiable at this stage
- the RP determines which eligible patients should be included in the HITS-NS trial – these should include (a) patients already identified as "HITS-NS bypass" by intervention paramedics, and (b) patients who appear to be eligible who have been attended by intervention paramedics but who do not have "HITS-NS bypass" recorded on the PRF, and (c) any patients who meet eligibility criteria attended to by paramedics from control stations
- the RP updates the ***HITS-NS screening spreadsheet*** adding a new row of information per each date that PRF screening is done as follows:
    i. date of screening
    ii. number of pre-alerts screened
    iii. number of possible patients (i.e. electronic PRF's reviewed)
    iv. number of eligible HITS-NS patients (these should be the sum of (a) + (b) + (c) from above paragraph
    v. number of patients flagged as HITS-NS bypass intervention patients on the electronic PRF
    vi. no. of records not found
- the RP begins a new record entry in the ***HITS-NS eligibility spreadsheet*** for each eligible patient identified
- for each patient recorded in the ***HITS-NS eligibility spreadsheet*** the RP verifies that HITS-NS trial criteria have been successfully met as quickly as possible (e.g. by contacting the critical care staff at, or by going to the receiving neuro centre or PIC) and if the patient is confirmed as eligible, the RP begins a new record entry in the ***HITS-NS recruitment and follow-up spreadsheet*** for each eligible patient identified who should be approached for consent. Each such eligible patient will be given a unique HITS-NS trial number (see section **n** below). The ***HITS-NS recruitment and follow-up spreadsheet*** will be a regularly updated master spreadsheet maintained, completed and monitored for key patient event information as follows:
    i. date patient confirmed as eligible for trial inclusion
    ii. HITS-NS trial number
    iii. Confirmation that eligibility criteria have been reviewed by RP (Y/N)
    iv. Confirmation that eligibility criteria have been correctly applied (Y/N):
        - if the answer to this question is 'N' a protocol violation must be recorded:
            - The patient is withdrawn from the HITS-NS trial
            - ***Proceed to HITS-NS SAE SOP***

- if the answer to this question is 'Y':
  - ***Proceed to HITS-NS consent SOP***

v. Whether the patient is withdrawn (Y/N)
vi. Confirmation that patient / family or friend has been approached for consent is recorded
vii. Consent is obtained? (Y/N)
viii. If 'Y' to vii, Patient / relative or friend / consultee is recorded as the person giving consent
ix. If 'Y' to vii, Date of consent is recorded
x. If 'Y' to vii, Identification of the researcher who has taken consent is recorded
xi. Completion of non-TARN data fields in the ***HITS-NS non-TARN data spreadsheet*** is noted in this spreadsheet when done
xii. Completion of TARN data fields in the ***TARN database*** is noted in this spreadsheet when done
xiii. Date by which patient is due for 6-month follow-up is recorded for reference
- When patient is due for follow-up:
  - ***Proceed to HITS-NS follow-up SOP***

xiv. Confirm follow-up completed (Y/N)
xv. If follow-up not done, record reason according to follow-up SOP (e.g. patient has died, RP could not make contact, patient declined to participate in follow-up)

**II Patient CRF**

This will be formed by merging HITS-NS TARN data fields (as listed in the HITS-NS: Critical Data points document) in a spreadsheet which will be downloaded on a weekly (?) basis by TARN data analysts, with non-TARN data fields in the ***HITS-NS non-TARN data spreadsheet.***

- RP will email (using NHS.net if possible) all Trusts involved every week with a list of HITS NS patients (estimated to be no more than 1 or 2 per day across the region).
- TARN Coordinators will check for TARN eligibility and if included:
  - Prioritise the creation of these cases onto the TARN database and when discharged – dispatch to TARN as normal.
  - Make a note in the Diary section of each submission saying **"HITS NS Patient" .**
  - Feedback the Submission IDs of these patients to the RP.
  - If not TARN eligible: TARN Coordinators will notify the RP, who will then enter these cases onto the TARN database.

**III Monitoring**

- The latest version of the ***HITS-NS screening spreadsheet*** is emailed to the Trial Manager at the close of each weekday.
- The ***HITS-NS recruitment and follow-up spreadsheet*** is forwarded to the Trial manager at the close of each working week.
- A 'trial project' log book should be maintained by the RP which notes any issues arising during the screening / recruitment / consent processes. The date, nature of issue, and how resolved should be documented.

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## HITS-NS: SOP for temporary suspension of the trial

This SOP clarifies the mechanisms by which the above can occur.

Temporary suspension of HITS-NS is approved by the REC and the funder where clinicians in the neuroscience centre (Newcastle / James Cook / Royal Preston) feel

a) That HITS-NS is resulting in more than double the usual intake of severe head injuries to neurosciences.
b) That this increase in numbers is placing an unsustainable demand on their trust's resources.

If (a) and (b) are true then the Consultant Neurosurgeon or Intensivist can suspend the trial with immediate effect by the following pathway:

1. Call the HITS-NS research paramedic for their region on the mobile number……
2. If no reply call the HITS-NS trial manager on ……
3. If no reply call the HITS-NS Chief Investigator on ……..

HITS-NS will undertake to provide a point of contact on a 24/7 basis

HITS-NS will then be suspended into that hospital for 48hours maximum, if at that time the workload has not subsided the neuroscience centre should make a further request for an additional 48hours with the same criteria.

N.B. Any major incident to the ambulance service will cause suspension of the trial.

FL 30th November 2011

Project Reference: Lecky 08/116/85

# HITS-NS: SOP for the reporting of SAE's!

This SOP clarifies potential SAE's and the process for reporting such SAE's.

Serious Adverse Events (SAE's) might include the following:

a) There is a protocol breach whereby the paramedic(s) attending to a patient at the scene of injury identify the patient wrongly as a potential HITS-NS patient, i.e. the paramedics fail to apply the inclusion / exclusion criteria correctly.

b) A patient allocated to the intervention arm of the trial dies in the ambulance during the journey to the neuro centre.

c) Relatives / friends of an intervention arm patient, or clinical staff attending to an intervention arm patient, who dies in hospital believe that the patient's death was in some way linked to the patients' participation in the trial.

d) The journey time for an intervention arm patient being taken to the neuro centre exceeds the anticipated one hour maximum duration by an extra 50% of the maximum time i.e. the journey time is 90 minutes or longer.

- In each of the events outlined above, the HITS-NS research paramedic will notify the HITS-NS trial manager, who will in turn notify the HITS-NS Chief Investigator (CI).

- In the event of (b) above the HITS-NS CI or the HITS-NS Trial Manager will notify the Sponsor (Manchester University Research Office) immediately (at longest within 24 hours) of receiving notification of the SAE (i.e. patient death) and the Sponsor will in turn notify the REC, within 7 days of the SAE occurring.

- The HITS-NS CI will assess each SAE and complete the HITS-NS SAE reporting form. In the event of (b) the reporting form will be submitted to the Sponsor and in turn to the REC. Completed SAE reporting forms for all other types of SAE's will be filed in the Trial File. Each SAE will require an assessment of (i) seriousness, (ii) causality, (iii) expectedness (in accordance with Directive 2001/20/EC).

- A quarterly report will be prepared to summarise reported SAE's and forwarded to the Sponsor.

- In general, any complaints from any source regarding any aspect of the trial brought to the attention of any of the Trial Research Team should be submitted to the Trial Manager who will log and document the details of the complaint and arrange that the complaint is investigated appropriately, e.g. with the involvement of the CI.

December 2011

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# HITS-NS: Serious Adverse Event Reporting Form

| | |
|---|---|
| Current protocol version number: | |
| | |
| **Patient information:** | |
| Patient ID: | Patient initials: |
| Patient DOB: | Patient gender: |
| Report type: Initial report | Follow up report (#) |
| | |
| **Evaluation of the event:** | |
| Describe the type of event (e.g. patient death, protocol violation, etc.) | |
| Date and time of event: | |
| Date event first reported:<br><br>Event reported by:<br><br>Event reported to: | |
| Assessment of event: | |
| Have any patient safety measures been implemented due to the occurrence of the event? If yes, please give details: | |
| **Contact & Signatures:** | |
| Further information may be obtained from:<br><br>Name: | |

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| |
|---|
| Phone number:<br><br>Email address: |
| Signature (of person completing this report):<br><br>Print name: Date: |
| Chief Investigator Signature (if not completing this report):<br><br>Print name: Date |