

IHAST2 Update

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The Update will be published at least quarterly throughout the course of IHAST2. Its purpose is to enhance communications among participating centers. The *Update* will contain news about the conduct of the trial, answers to questions that have been received in the CCC or DMC, as well as some the "business" of the trial, e.g. protocol changes, important regulatory matters, updates to the Operations Manual, etc.

Individuals at participating centers should feel free to submit materials to us for inclusion in the *Update*. Please contact Janan Winn in the CCC office (319-356-0461 or ihast2@uiowa.edu) if there is anything you would like circulated.

This first *Update* is coming to you as a printed document. It is also available via the web at

<http://ctsdmc.public-health.uiowa.edu/ihast2/update>

In the future, our intention is to distribute this entirely electronically. An e-mail notice will be sent to all participating centers and individuals, telling everyone that the newest issue of the *Update* has been posted on the IHAST2 web page. You will be able to read the *Update* on-line, download it as text or as a PDF document (and you will need to get Adobe Acrobat Reader to permit viewing this - the link will be provided on the page).

Please File Your IHAST2 Updates

Just a reminder. Each center needs to file at least one copy of each IHAST2 Update in the Site Regulatory Binder (See Chapter VII.A.5 of the Operations Manual). The Site Regulatory Binders are being shipped with the first patient notebooks as center become certified.

NEWS

1. Since Chicago

We want to thank everyone for coming to the Organizational Meeting in Chicago in September. It took us a bit longer to accomplish some of the tasks we promised, but we are now on track. Our major efforts have been directed at getting certification materials prepared and distributed (and you've now all seen our Hollywood-level movie-making abilities, edited personally by your PI), and everyone should now be well into the certification process (see Item 5 below). We've also now established our Supplementary Studies Committee, recruited our Physician Protocol Monitor, and started the distribution of the Site Regulatory Binders and Patient Notebooks. Most importantly,

WE'VE ACTUALLY ENROLLED PATIENTS!!!

at least "practice" patients (Congratulations to the Cleveland Clinic for being Numero Uno!).

We've also encountered a small snag with the US Office for Protection from Research Risks (OPRR) - but this will be solved shortly.

For more information on these and other matters, read on.

2. Supplementary Studies

In Chicago, there was a great deal of interest in Supplementary Studies to be performed on IHAST2 patients at individual centers or on a multicenter basis. We are definitely interested in encouraging such studies, but everyone must recognize that carelessly adding a study, altering the protocol, or doing something that could introduce bias or risk unblinding could seriously damage the integrity of the primary trial. This means that proposed studies need to be carefully reviewed.

We now have our Supplementary Studies Committee in place. The individuals below have graciously agreed to serve on this group:

Basil Matta (Anesthesia) & Peter Kirkpatrick (Neurosurgery), Addenbrooks Hospital, Cambridge, Great Britain

Samra Satwant (Anesthesia) and Greg Thompson (Neurosurgery), University of Michigan, Ann Arbor, MI, USA

Arthur Lam (Anesthesia) and Richard Winn (Neurosurgery), University of Washington, Seattle, WA, USA

William Lanier (Anesthesia) and David Piepgras (Neurosurgery), Mayo Clinic, Rochester, MN, USA.

Centers interested in either conducting a supplementary project at their hospital, or in organizing a multicenter "add-on" project should contact the CCC, and send a written proposal. We can provide you with information on the application process-just call or e-mail. We will distribute the proposal to the Committee, and get back to you as soon as possible.

3. Physician Protocol Monitor

IHAST2 is organized in such a way as to maximize the blinding of as many people as possible. Since this is a procedural trial, this has involved some interesting tricks. This is quite different from a drug trial in which blinding is easy - the pharmacy just makes up drug syringes with "numbers" instead of labels. One by-product of this blinding is that the intraoperative records must be kept concealed from members of the CCC - including our on-site auditors. In effect, this would mean we would be unable to audit the actual performance of the protocol (cooling).

To provide oversight for this critical aspect of the study, the NIH has now approved a **Physician Protocol Monitor (PPM)**.

We are happy to announce that David Warner MD, Dept. of Anesthesia at Duke University (and one of the founders of IHAST2 before leaving Iowa) has agreed to serve as the PPM.

The DMC will provide the PPM with unblinded copies of the ANESTHESIOLOGIST and the TEMPERATURE forms and a copy of your local hospital anesthesia and early postoperative records. He will then examine the records to verify compliance with the trial protocol. He will, however, have no information concerning patient outcome.

As the trial progresses, don't be surprised if you receive phone calls from David. Part of his job is to contact participating centers with questions regarding various actions in the O.R. and immediate postoperative period.

4. IHAST 2 Web Site is now up.

The IHAST2 web site is now available at the following web address:

<http://ctsdmc.public-health.uiowa.edu/ihast2>

This is a central source for participating centers to enter comments from case report forms, to obtain information, and learn more about the operations of the DMC and CCC. The IHAST2 web site contains the following:

- a. info about the origins of IHAST2
- b. info about the DMC and CCC
- c. HTML and PDF versions of *Updates*
- d. the Operations Manual in HTML & PDF
- e. the Comments web entry system

Anyone can gain access to items a through c; to access the Operations Manual you will be asked to enter your certification number. If you are not yet certified, but need to access the Operations Manual, e-mail Michelle at the DMC to obtain a "temporary" number. This will expire within a specified period, so you will eventually need to become a "certified" IHAST2 individual. The address is:

ihast2@mail.public-health.uiowa.edu

When you e-mail the DMC, include your first and last name, the name of your local center, your role in IHAST2 (Coordinator, Co-PI, etc.), and your complete phone number.

Item e (the Comments system) can only be accessed with your official IHAST2 certification number. Multiple comments for a patient can be entered (i.e., you can enter comments in the morning and then again that afternoon if you remembered something you may have left out earlier). However, once a comment is submitted to the DMC, it can't be changed.

BUSINESS

5. Certification and Start Up

Certification

As you know, each center must have a certified Local Study Coordinator, Anesthesiologist, Neurosurgeon and Neurologic Examiner before patients can be enrolled. In addition, all anesthesiologists and neurosurgeons caring for enrolled IHAST2 patients need to be certified. We have "relaxed" the rules a little bit - your Neurologic Examiner does not need to be "on board" prior to doing your two "practice" patients (since no neurologic outcomes will be tracked). However, you will need a certified Neurologic Examiner before enrolling the first "real" patient. In addition, don't forget to send us the name, CV/resume and identifying information about your Neuropsychology Examiner. certification of these people will be done on a more "personal" basis by Steve Anderson and the Neuropsych staff here at Iowa.

Every center has now received its certification materials (for the Local Study Coordinator, Anesthesiologist, Neurosurgeon and Neurologic Examiner); we have been getting completed "exams" back on a daily basis. We would like to thank those of you who have been so diligent. The biggest "lag" involves neurosurgeons. One suggestion is for the Local PI or CoPI and/or Study Coordinator to meet with a group of surgeons and complete the material. The same approach might be taken with anesthesiologists.

Remember, the goal of our Anesthesiologist and Neurosurgeon certification procedures is to ensure that everyone understands the protocol, data collection efforts, etc. The "tests" are not meant to be onerous - they are intended to help participants to understand

procedures and protocols. If the Local PI or Coordinator would like to present this material to a group of anesthesiologists or surgeons, and go over the test questions directly, we would have no objections. Just don't fill out a batch of them for people - it really is important that participants understand the material that has been provided.

Are You Ready to Begin?

Each center needs to carry out the hypothermic protocol on two "practice" patients. This is intended to a) give each center the chance to work through the notification and enrollment procedures; b) to use the telephone enrollment procedures (although both practice patients will be assigned the "hypothermic" group); c) to actually carry out the cooling protocol; and d) to become experienced with data collection and case report form submission, etc. It also provides us with a chance to work out the "bugs" in our systems at both the CCC and the DMC.

Following is a checklist of items which each center, in conjunction with University of Iowa IHAST2 DMC/CCC, must accomplish prior to enrolling the first "practice" patient:

- a. Each center must have three members certified including an Anesthesiologist, a Local Study Coordinator, and a Neurosurgeon. Since no neurologic follow-up is required in these patients, a Neurologic Examiner is not mandatory - although such a person will be required before a center will be approved to enroll "real" patients.
- b. SPA (Single Project Assurance) numbers must be obtained for PCC's outside of the United States. We are working with PCCs on an individual basis to obtain these numbers. This

basically means that OPRR approves your local consent documents.

- c. Each PCC must have a PolarAir™ unit from Augustine Medical and a box of 20 esophageal stethoscope/temperature probes from Mallinckrodt. Delivery of PolarAir™ units are being prioritized according to the order in which items a. and b. above are completed. Hopefully, everyone will have their temperature probes and connecting cables just after the first of the year.
- d. Each PCC should have received two Practice Patient Notebooks. If you do not have these notebooks please contact the DMC at

ihast2@mail.public-health.uiowa.edu

or

319-353-5978.

6. Human Studies Problems

On December 10th, we were contacted by the Office for Protection from Research Risk (OPRR). This is the US Federal Agency charged with protecting research subjects. Many of you have heard about their shutting down all human studies work at Duke, Colorado, Illinois, etc - these guys play "hardball." Anyway, they expressed concerns regarding our basic consent document - specifically the one that was accepted here at the University of Iowa and used by almost all of you as a template for your own IRB applications and consents. Not only did they have some concerns - but they asked us to halt patient enrollment!

How did OPRR get involved in this? They don't normally look at individual consent forms. The reason is related to the "Single Project Assurance (SPA)" process for nonUS centers. In the US, almost all Human Studies Committees are covered by "Multiple Project Assurance (MPA)" agreements. In essence, this means that OPRR approves each local Human Studies Committee to handle all consent issues, as long as that committee operates according to the rules. The reason behind most of the recent shutdowns has been related to local problems with administrative issues.

Human Studies Committees outside the US typically don't have "MPA's". However, if a nonUS center wishes to participate in a US Federally funded trial (i.e. get US taxpayer's money!) they must meet OPRR's standards. This means OPRR reviews each IRB approval and issues a "Single Project Assurance (SPA)" number for each nonUS center. The University of Iowa, as the actual recipient of the grant, is under contractual obligation not to send money to any center without an SPA.

Anyway, we forwarded all of the local consent documents to OPRR - including our own (as the model) - and before they even got to the other documents, they said, in essence, "we have concerns regarding the consent document from the U of Iowa."

Fortunately, all of the changes they suggested are related to the language of the document - not the protocol per se. Once we got the details of their concerns, we were able to alter the consent document easily (about an hour's work). In addition, our local Human Studies Committee was able to approve these changes administratively (i.e. without sending the document back to the entire committee).

I wish this were only a UI problem but it's not:

OPRR requires that ALL participating centers (US and non-US) modify their local consent documents to "match" the new and revised UI consent.

They have also suggested that patient enrollment not proceed until this is done.

A copy of the newly approved Iowa consent document is attached to this *Update*. We are also working very hard to review each local consent form that we have on file. In some cases, we suspect that no changes will be needed. In others, greater changes may be required. We will be contacting each center individually to detail the changes that need to be made. [NOTE: OPRR mandates the changes - but we are charged with doing the actual work and making sure that the forms are all in compliance.]

Please - this does not mean you should stop with the process of "getting ready". With some luck this can be sorted out in a few weeks. When we sort out what needs to be done, we would strongly recommend that you

contact the local Chair of your IRB directly and explain this situation. Hopefully, the modifications can be handled very quickly.

SEE ATTACHMENT #1

(Copy of revised Iowa consent)

7. NIHSS Certification

A number of people have had problems with the NIH Stroke Scale certification process. In retrospect, we think this may stem from a description in the Operations Manual that was too brief. In an effort to help, we have attached a more extensive description of the various test items, their assessment and their completion. The document was modified from one created for the t-PA study (the same source as the videotapes). This material is not a substitute for what you've already received - simply a supplement to it.

Please distribute a copy of these instructions to members of your team who will be certified to administer the NIH Stroke Scale.

SEE ATTACHMENT #2

(supplementary NIHSS instructions)

8. Money

We would like to get centers paid! On December 1st, 1999, an e-mail was sent to centers that had not yet returned a "Generic Invoice" to the CCC so that we could initiate payments to your center. The memo requesting a "Generic Invoice" was sent with the subcontract in late September. If you haven't seen it, check with your institution's Sponsored Programs Office, or equivalent; the form may be there and they have not yet attended to its completion.

If you would like the address to which this memo and your subcontract were sent, please e-mail the CCC. In addition, a copy of a prototype "MEMO" is attached at the end of this Update.

SEE ATTACHMENT #3

(copy of draft memo and generic invoice)

9. "Who Can Do What"

A Protocol Change Regarding Interim NIHSS Exams

IMPORTANT

Interim NIH Stroke Scale (NIHSS) exams are required prior to surgery and 2-, 24- and 72-hours after surgery, and on the day of discharge. An NIHSS exam is also required three months after surgery.

Some questions and concerns have been raised in the last several weeks about who can do which exams. We want to address these questions - and to make a change in the trial protocol.

3-month Follow-up Exam

The assessments done at the 3-month postoperative visit are really the key to this study - they represent our primary outcome variables and must be defended "at all costs." The final outcome assessments (Glasgow Outcome Scale, NIHSS, Barthel's, neuropsychology battery, *etc.*) must must must be made by an IHAST2-certified Neurologic Examiner who is not aware of the patient's temperature group assignment and/or any intraoperative or early (first two hours) postoperative temperature data.

PLEASE UNDERSTAND - IF THIS FINAL EXAM IS NOT "DONE RIGHT" EVERYTHING THAT HAS GONE BEFORE IS A WASTE OF TIME!!!

The Neurologic Examiner performing the final assessments cannot be the Local Study Coordinator, the Local P.I., the Local Co-P.I., or any participating Neurosurgeon or Anesthesiologist. The Neurologic Examiner performing the final assessments should not be routinely involved in the day-to-day surgical,

anesthetic, or postoperative care of surgical SAH patients. In general, the Neurologic Examiner performing the final assessments should be at considerable "distance" from the care of patients enrolled in IHASt2, and have virtually no chance of accidentally discovering critical aspects of specific patient management. Examples of appropriate Neurologic Examiners for the final assessment(s) include:

- a. A neurology faculty, fellow, or resident not routinely involved in the postoperative care of SAH patients;
- b. An Emergency Room physician not routinely involved in the postoperative care of SAH patients;
- c. A neurology nurse not routinely involved in the postoperative care of SAH patients;
- d. A surgical or anesthesia faculty or fellow with no routine involvement in the care of SAH patients;
- e. A neurosurgery or neuroanesthesia fellow with no clinical commitments at the time of the final outcome assessments and no prior knowledge of specific study patients.

In addition, it would be best if the Neurologic Examiner were someone with extensive medical (and ideally) neurologic experience. Anyone can be "trained" to do these exams - but the better they understand medicine and neurology, the more reliable their scores.

Interim NIH Stroke Scale Exams

An interim NIHSS must be performed at 2-, 24- and 72-hours after surgery, and at discharge. This exam must be done by an IHASt2-certified person who has passed the NIHSS examination (*i.e.*, NIHSS qualified).

Originally, the protocol specified that the Local Study Coordinator could not perform these interim NIHSS exams, except for the one at 2hr postop (Chapter VIII, page 18; and Chapter XI (Appendix), Section G). Recently, a number of centers have indicated that it was extremely difficult, impossible or prohibitively expensive for them to arrange for fully-certified Neurologic Examiners to perform these interim NIHSS exams. After a lot of thought and consultation, we have decided to revise the protocol to resolve this difficulty.

Specifically, the protocol now permits the Local Study Coordinator to perform the interim NIHSS exams.

There are two reasons behind this change. The first is entirely practical - we recognize the difficulties related to having a Neurologic Examiner (particularly a highly qualified one) "on call" for these interim exams. We also realize that the patient will be seen daily by the Study Coordinator who is already a certified to perform NIHSS exams. However, more importantly, we wish to defend the quality of the data, both for the interim exams AND for the 3-month exam. In an effort to meet the "outside blinded examiner" requirements, some centers were finding it necessary to enlist and train individuals with little or no medical/neurology/neurosurgical experience. We felt that, overall, NIHSS's performed at 2-, 24-, and 72-hrs by a Local Study Coordinator would be more reliable than one performed by a less experienced - even though perfectly blinded - examiner. In addition, we did not want to see the "pool" of Neurologic Examiners in a given center unduly expanded in an effort to meet this requirement. The danger, of course, would be that the 3-month exams would now be more likely to be performed by less qualified individuals.

This does not mean that the Study Coordinator **MUST** perform these interim exams. Certified

(and blinded) Neurologic Examiners are still preferred if available. In addition, we recognize that there may be times when the Local Study Coordinator is unavailable or has become unblinded with respect to a given patient (and, hence, shouldn't be doing the exam).

If the Local Study Coordinator or a Neurologic Examiner is not available, interim (BUT NOT THE FINAL!!) NIHSS exams may be conducted by other IHAST2 certified personnel when all of the following conditions are met:

- a. The person performing the interim NIHSS exam has passed the NIHSS certification exam (*i.e.*, they are NIHSS qualified);
- b. The person performing the interim NIHSS exam is not aware of the patient's temperature group assignment and/or any intraoperative or early (first two hours) postoperative temperature data;
- c. The person performing the interim NIHSS exam was not in the operating room during the patient's primary aneurysm surgery nor was in the presence of the patient for the first two hours after surgery.

Unless all three of these requirements are met, then the person who was to perform an interim NIHSS exam must exclude himself or herself from performing any of these exams. Obviously, people are "on their honor" with respect to these issues. However, if a Study Coordinator does become inadvertently "unblinded" he/she **MUST** find another qualified person who can do at least the 24-, 72-hr and discharge NIHSS exams.

For a tabular summary of these changes:

SEE ATTACHMENT #4

10. How to Handle The Study Packet

The process of selecting and opening the correct Study Packet - and more importantly, the process of getting the right things back into the various envelopes at the end of the case - is critical. The more we looked at this step, the more we recognized the potential for confusion - there are a lot of things that must be done correctly. In an effort to avoid such confusion, we've put together a step-by-step set of instructions that we hope will clear things up.

Note: The Study Packets are provide with the first shipment of Patient Notebooks.

The Study Packet

The Study Packet is a large (10 x 13 in.) envelope which is pre-labeled with an IHAST2 patient identification (PID) number. The PID number on the outside of the Study Packet envelope must correspond to the PID number assigned to the patient by the phone enrollment system. The Study Packet envelope contains the following items:

- a. One (1) (9 x 12 in.) sealed white RANDOMIZATION ENVELOPE pre-labeled with the same PID number.
- b. One (1) (9 x 12 in.) sealed brown RANDOMIZATION ENVELOPE pre-labeled with the same PID number.
- c. Two (2) white (6.5 x 9.5 in.) unsealed envelopes pre-labeled with the same PID number.
- d. Eight (8) white (0.5 x 1.75 in.) adhesive labels pre-labeled with the same PID number.

Except for one of the RANDOMIZATION ENVELOPES (the one which is NOT to be

opened), the Anesthesiologist will need the entire Study Packet—including the Study Packet envelope itself (see below). Because the Anesthesiologist should only be provided with the sealed RANDOMIZATION ENVELOPE that matches the color and PID assigned to the patient by the phone enrollment system, the other (unassigned) RANDOMIZATION ENVELOPE should be removed from the Study Packet before it is given to the Anesthesiologist. See Step #2 in the Suggested Practice and Time-Table section below. [The unopened Randomization Envelope may be kept in the Patient Notebook until returned to the DMC.]

Paperwork the Anesthesiologist Needs While in the O.R.

While in the O.R., the Anesthesiologist must have:

- a. One (1) ANESTHESIOLOGIST form (6 pages).
- b. The one (1) sealed RANDOMIZATION ENVELOPE which matches the PID and color assigned to the patient.

The RANDOMIZATION ENVELOPE contains a TEMPERATURE form which indicates the temperature group to which the patient has been randomized, and which is the only place where intraoperative temperature data for IHAST2 is to be recorded.

- c. Two (2) white (6.5 x 9.5 in.) unsealed envelopes pre-labeled with the PID number.

On the outside of these envelopes are instructions telling the Anesthesiologist into which of these envelopes the two copies of the completed TEMPERATURE form

(upper white original and lower canary-colored copy) are to be placed and sealed at the end of surgery. (The blue paper inside each envelope is to reduce transparency—just leave it in). After these two envelopes are sealed, they are to be returned to the Local Study Coordinator (the sooner the better).

Paperwork the Anesthesiologist Needs after Leaving the O.R.

After leaving the O.R., the Anesthesiologist must have:

- a. The same ANESTHESIOLOGIST form that was used in the O.R.

This is needed in order to record early postoperative patient status (section G) as well as Intercurrent Events that take place over the first two hours after surgery (section H (page 6) of the ANESTHESIOLOGIST form). Once sections G and H are completed (~two hours after surgery), the ANESTHESIOLOGIST form may be returned to the Local Study Coordinator (the sooner the better). Section H is faxed to the CCC; Sections A- G (the entire form) is mailed to the DMC as part of the 48hr postoperative shipment.

- b. The white (0.5 x 1.75 in.) adhesive labels which are pre-labeled with the PID number.

These labels are to be affixed to photocopies of the local hospital anesthesia record and early (first two hours) postoperative ICU (or recovery) records. Any data on these records which are specific to the patient (e.g., name, local hospital identification number, social security number, birth date, *etc.*) are to be removed or

covered up. Any unused labels may be discarded.

- c. The Study Packet envelope. The Study Packet envelope is used to place photocopies of the local hospital anesthesia record and 0-2 hour postoperative recovery or critical care records.

After these items are in place, the Study Packet envelope is sealed. Once sealed, it is to be returned to the Local Study Coordinator (the sooner the better). To preserve "blinding" the Local Study Coordinator is not to view the local hospital anesthesia record or early postoperative data, ever.

After leaving the O.R., the Anesthesiologist may also need **Intercurrent Event (IE) forms** to complete.

It is preferred that the Anesthesiologist complete all IE forms triggered by responses to section H (page 6) of the ANESTHESIOLOGIST form. However, the Local Study Coordinator may assist in completion of these forms provided that s/he remains unaware of patient group assignment and temperature data.

Suggested Practice and Time-Table Steps

Step 1. Once you have recorded the PID and envelope color from the telephone randomization system on page 3 of the ELIGIBILITY form, obtain the Study Packet with the corresponding PID.

Step 2. Remove the UNassigned RANDOMIZATION ENVELOPE from the Study Packet and set it aside. Thus, if randomized to the "White," remove the "Brown" RANDOMIZATION ENVELOPE; if randomized to "Brown," remove the

"White" RANDOMIZATION ENVELOPE. **Only the RANDOMIZATION ENVELOPE which matches the PID and color assigned to the patient remains in the Study Packet envelope.**

(Remember, do not open and do not lose the UNassigned RANDOMIZATION ENVELOPE because it must be mailed to the DMC at 48hrs along with other completed forms).

Step 3. Remove one (1) adhesive label from the Study Packet and attach it to the spine of the patient notebook. Leave the rest of the adhesive labels in the Study Packet for the Anesthesiologist to use (see Step #8).

Step 4. Give the Anesthesiologist the entire **Study Packet** (only the UNassigned RANDOMIZATION ENVELOPE and one adhesive label have been removed) and the **ANESTHESIOLOGIST form** from the patient notebook.

Step 5. The RANDOMIZATION ENVELOPE which matches the PID and color assigned to the patient is opened only by the Anesthesiologist in the O.R.

Step 6. At the end of surgery, the TEMPERATURE form (which was contained in the assigned RANDOMIZATION ENVELOPE) is to be completed by the Anesthesiologist. While still in the O.R., the Anesthesiologist separately seals the original (white) and underlying (canary-colored) copy of the TEMPERATURE form in the two (6.5 x 9.5 in.) white envelopes present in the Study Packet which are pre-labeled with the matching PID. If

desired, the Anesthesiologist may return these two sealed envelopes to the Local Study Coordinator as soon as the patient leaves the O.R. However, we suggest the Anesthesiologist keep these two envelopes until two hours after surgery, at which time the ANESTHESIOLOGIST form will also be completed and returned to the Local Study Coordinator—see step #7.

Step 7. Approximately two hours after leaving the O.R. the Anesthesiologist is to have completed the ANESTHESIOLOGIST form. By this time, it is anticipated that all patients randomized to hypothermia will be completely rewarmed. Accordingly, approximately two hours after leaving the O.R., the Local Study Coordinator is to perform an NIHSS examination. It is at this time (two hours after surgery) that we suggest that the Anesthesiologist transfer the two sealed envelopes (which contain the TEMPERATURE form—original and copy) and the completed ANESTHESIOLOGIST form to the Local Study Coordinator. If the 2-hour NIHSS exam is performed by a Neurologic Examiner, we suggest the Anesthesiologist contact the Local Study Coordinator two hours after surgery and arrange a time and place for the transfer of these materials.

(Remember, at two hours after surgery, the Local Study Coordinator (or Neurologic Examiner) is not to record any other data other than the NIH Stroke Scale. The person performing the NIH Stroke Scale at two hours after surgery must not to discuss the patient's status with anyone, and must not review any postoperative data).

Step 8. In the interval between two and 24 hours after leaving the O.R., the Anesthesiologist is to make photocopies of the local hospital anesthesia record and early (first two hours) postoperative recovery or critical care records. Any information on these records that identifies the patient (*e.g.*, name, local hospital identification number, social security number, birth date) must be removed or covered up. This is required because patient-identifying information can only be kept by local centers, but not by the IHAST2 coordinating center. The Anesthesiologist is to label these records with the (0.5 x 1.75 in.) adhesive labels (which have the PID on them) that were provided in the Study Packet envelope. The records are then sealed inside the large (10 x 13 in.) Study Packet envelope, and returned to the Local Study Coordinator. Any unused adhesive labels can be discarded.

Remember, the copies of the local hospital anesthesia record and early postoperative recovery/critical care records are to be sent to Data Management Center with the first data submission—48 hours after surgery. Hence, Anesthesiologists must be quite prompt in providing these copies. The Local Study Coordinator may not make the photocopies for the Anesthesiologist because information regarding patient temperature will be present on these records. The Local Study Coordinators are never to learn of group assignment, nor intraoperative or early postoperative patient temperatures. Thus, the Local Study Coordinators may not view these documents at any time.)

11. PCC Correction Report Forms

The PCC Correction Report forms are to be used when personnel at the PCC find an error on a CRF which has already been sent to the DMC. Please refer to Chapter XI, H.c (Appendix) of the Operations Manual for a copy of this report. Its also attached to this Update as

ATTACHMENT #5

Below are the steps you should follow to complete this form:

Step 1

Item 1. Name of form being corrected.

Write in the name of the CRF that is being corrected. The name of the form is found in the upper right side on the first page of the CRF (e.g., SCREENING, ELIGIBILITY, PRE-SAH, etc....)

Step 2

Item 2. Complete all applicable header information below. Applicable means list only the header variables from that particular CRF and leave all other header fields in Item 2 blank. For example, on the Contact Follow-up CRF, Patient ID number and Date of exam, follow-up or onset would be answered since they are applicable to the Contact Follow-up CRF, but Center ID number, Log number, and Time of exam or onset would be left blank since they are not applicable to this particular CRF.

Step 3

Item 3. Indicate which field(s) you wish to correct below, the old value, and the new correct value. Field to be corrected should be a few words describing the field; Old value is the erred value; New correct value is the correct value; and Comments provides

one line to briefly describe why an error occurred. For example, on the Contact Follow-up CRF, suppose while completing the 3-month follow-up you find additional medical records showing that on the 6-week follow-up an incorrect response was marked. On page 2, item #9, a 'no' for "in the time since last contact, has the patient been readmitted to an acute care hospital?" was marked and it should have been a 'yes.' Below is how you might fill out Item 3:

Item #9 (page 2) Field to be corrected

0 Old value

1 New correct value

Additional medical records found
Comments

Comments should be brief, simply describing how the error occurred (e.g., transcription error, updated or additional records found later, calculation error, etc.). Lengthy explanations are not necessary. If you find you need more room to write than the Comments line allows, attach a sheet of paper behind the original white copy with identical information from Items 1-3 plus your comments concerning that particular field.

There are two sections available, allowing for two incorrect fields, per PCC Correction Report form. If you have more than two errors that need to be corrected, you must fill out another PCC Correction Report form with identical information in Items 1 and 2.

Step 4

Sign your name at the bottom of the PCC Correction Report form, write in your certification number and the date you completed the form.

Step 5

Return the white original of the PCC Correction Report form, and a photocopy of

the corrected CRF and send both to the DMC. If you have more than one page of PCC Correction Report form for a given CRF, attach the multiple sheets together before sending it. The canary-colored copy of the PCC Correction Report form is for you to keep in your files.