

# IHAST2 Update

December 2000, Volume 1, No. 4



## IHAST2

INTRAOPERATIVE HYPOTHERMIA  
for  
ANEURYSM SURGERY TRIAL

### Inside

	page
200th Patient!	1
IHAST2 Investigators' Meeting San Francisco	1
2001 American Association of Neurological Surgeons Annual Meeting	2
Money	2
Who Does the 3-Month Exam?	3
The New IHAST2 Training/Testing Website	3
No Prisoners	4
Augustine Medical PolarAir Units: We Need Two More	5
Augustine Will Provide Bair Hugger Blankets	5
Revised MEDICATIONS Form	5
DAILY POST-OP SCREEN Recording Procedure Codes	6
IHAST2 Safety Monitoring	7
SCREENING and ELIGIBILITY forms	8
Patient Enrollment in Other Trials	10
Missed Answers Are Corrections	10
Data Edit Reports - A New Phase	11

## 200th Patient!

*Congratulations to the group at New York Presbyterian Hospital/ Cornell University! On November 30th, they randomized the 200th patient into IHAST2. Our thanks to Dr. Patricia Fogarty-Mack, Dr. Richard Fraser, Dr. Philip Stieg, Mr. Juntae Yu and their entire IHAST2 team!*

### IHAST2 Investigators' Meeting San Francisco

The annual IHAST2 Investigators' Meeting was held Saturday, October 14, 2000 at the San Francisco Hilton Hotel. We are happy so many people could attend and hope that those who could not attend will be able to do so next year.

The morning sessions were devoted to the Study Coordinators. Twenty-eight Study Coordinators from around the world attended. It's very nice to see the faces of the people with whom we work so closely. The sessions largely focused on questions related to eligibility, enrollment, postoperative assessments, and case report form completion. There were many thoughtful questions raised, and a healthy "give and take" among the participants regarding problems and

#### **Please File Your IHAST2 Updates**

Just a reminder. Please file one copy of each edition of the *IHAST2 Update* in your Site Regulatory Binder  
(See Chapter VII.A.5 of the Operations Manual).

solutions. The Study Coordinators are truly the foundation of the IHAST2 trial, and it's nice to know the foundation is strong!

Following lunch, the physician investigators joined the Study Coordinators. Fifty-seven participating Anesthesiologists and Neurosurgeons were in attendance. Dr. Todd reviewed the overall progress of the trial including total enrollment, basic demographics, and overall mortality. Dr. Todd expressed his thanks for the *great* job that is being done! Dr. Clarke reviewed processes related to safety monitoring, and Dr. Hindman highlighted the items most frequently missed on physician forms. Dr. David Warner, the IHAST2 Physician Protocol Monitor, helped place the great importance of the IHAST2 trial into perspective. The meeting concluded with a panel of Study Coordinators and Anesthesiologists who shared their methods for making IHAST2 work at their centers.

### 2001 American Association of Neurological Surgeons Annual Meeting

IHAST2 is planning a meeting in conjunction with the American Association of Neurological Surgeons (AANS) Annual Meeting, which will be held in Toronto in the spring of 2001. We would like to extend an invitation to all IHAST2 certified neurosurgeons attending the AANS to join us. The meeting will be held Monday, April 23, 2001 from 6:30-8:30 PM. We will meet in Conference Rooms D/E of the Sheraton Centre Toronto. If you plan to attend the AANS, and would like to also attend the IHAST2 meeting, please let us know at [ihast2@uiowa.edu](mailto:ihast2@uiowa.edu) or 319-356-0461.

### Money

**General Problems:** We realize that there have been some inordinate delays in getting some of you paid for randomized patients. The reasons are complex, but relate almost entirely to manpower issues in the CCC and to bureaucratic inertia in The University of Iowa financial management office. We think that we now have the problems solved. The last series of checks were issued in early December which should bring everyone up-to-date. We ask everyone to be patient; handling the disbursement of perhaps \$3,000,000 is quite an operation. Don't worry - we may be slow, but we aren't going to "go bankrupt" or leave for Tahiti with your money. However, if money isn't arriving, please let us know.

**Screening and Eligibility:** We also realize that the process of screening "ineligible" patients is a bigger job than originally anticipated. Our hope is that the requested increase in payments will go a long way toward covering this added expense. However, regardless of whether or not this added money is received, we have decided to reimburse each center \$50 for each screened but unenrolled patient (backdated to June 1, 2000). These payments will be delayed; we don't want to rewrite everyone's subcontracts now and then have to do it again if the supplementary funding is approved. We will, however, be keeping track of these patients and will make sure that payment is made.

**Status of Supplementary Funding Application:** As I think everyone knows, a formal request for over \$1,500,000 was submitted to NIH a few months ago. Our hope is to

increase the reimbursement for enrolled patients to somewhere between \$4000 and \$4500. This request has been reviewed by council, and was viewed positively by our PSMB oversight committee. The next step will be an audit of the UI center by people from NINDS. We expect this to take place before the end of January. Council will then meet again in early February to make the final decision. Keep your fingers crossed! We are optimistic; participating centers are doing a great job with accrual and in maintaining the quality of data submission. NIH is much more likely to provide supplementary funds to a well functioning trial than to one that is floundering - and we are definitely doing very well!

### Who Does the 3-Month Exam?

One troubling item that we've noted on reviewing incoming forms has been the fact that roughly 30% of 3-month follow-up exams have not been done by the designated Neurologic Examiners but by Local Study Coordinators. We realize that in many cases, this coordinator has been someone other than the individual who was involved in day-to-day postoperative follow-up of the patients. Nevertheless, we believe that this has the potential for unblinding, which would seriously damage the credibility of the trial. Unless there is absolutely no alternative, 3-month follow-up exams, **at least the GOS**, SHOULD BE PERFORMED BY A DESIGNATED NEUROLOGIC EXAMINER WHO HAS NO OTHER INVOLVEMENT WITH THE TRIAL. Each center has such a designated individual. Ensuring their availability to do the 3-month exam is an organizational issue that each center must address in their own way.

### The NEW IHAST2 Training/Testing Website

To streamline the certification (and recertification) process for IHAST2 personnel, we have created the IHAST2 Training/Testing Website. To access this site, go to the IHAST2 homepage (<http://ctsdmc.public-health.uiowa.edu/ihast2>) and click on the **certification** link. **Effective immediately, this site is to be used for certification of all new IHAST2 personnel, and for recertification** (more below). **Except for the NIH Stroke Scale (which is videotape-based), all IHAST2 certification materials and testing are now available on-line from this site.** Except for the NIH Stroke Scale, there is no need for the old paper-based training and testing materials.

**New IHAST2 participants** will be asked to register and provide basic contact information (name, address, phone, e-mail, etc.) and will be provided a temporary access code to access the training/testing site. Once in the site, individuals will be provided with a pull-down menu to select the IHAST2 "role" for which they wish to be certified. After passing the certification exams, individuals and their Local Study Coordinator will receive their IHAST2 certification number by e-mail within two working days. **IHAST2 participants who already have a certification number** will be asked to enter that number to gain access to the site.

**GOS Recertification:** Because the Glasgow Outcome Scale (GOS) is the primary outcome measure in IHAST2, it is important that everyone performing GOS determinations remain proficient. For this reason, the NIH committee that oversees the conduct of IHAST2 has recommended all

IHAST2 personnel who perform GOS determinations should be annually recertified. **Therefore, all Local Study Coordinators and all Neurologic Examiners will be asked to recertify on the GOS.**

To make this easier, GOS recertification is available via the IHAST2 Training and Testing Website. Go to the IHAST2 homepage (<http://ctsdmc.public-health.uiowa.edu/ihast2>) and click on the **certification** link. When you arrive at the IHAST2 Testing Center you will be asked to enter your IHAST2 certification number for access. The site will recognize your certification number and ask which materials you would like to review and test on. Using the pull down menu, select "GOS Recertification Test." The GOS Recertification Test consists of 10 questions and has links to help you. Once you pass the GOS recertification test, you're done!

**General Recertification:** IHAST2 protocols are complex. Accordingly, one needs to stay "in practice" in order to be proficient. Although all IHAST2 participants must pass certification examinations to obtain a certification number, in some instances, individuals may not have an opportunity to personally participate in IHAST2. Quite simply, if you haven't had the opportunity to actually do it, you'll almost certainly forget the "rules." **Therefore, all certified IHAST2 personnel who have not personally participated in the management of an enrolled patient within one year of certification will be asked to recertify for their designated IHAST2 role** (Anesthesiologist, Neurosurgeon, Study Coordinator, Neurologic Examiner). We will contact the Study Coordinator at each participating center and indicate those individuals who,

according to our records, have not participated in IHAST2 within one year of their initial certification. **Personnel that have participated within a year of initial certification will not need to recertify.**

To recertify, go to the IHAST2 homepage (<http://ctsdmc.public-health.uiowa.edu/ihast2>) and click on the **certification** link. The IHAST2 Testing Center will ask individuals to enter their IHAST2 certification number for access. The site will recognize the certification number. Using the pull down menu, individuals should select the appropriate role (Anesthesiologist, Neurosurgeon, Study Coordinator, Neurologic Examiner). The site will indicate which tests need to be passed in order to recertify. All IHAST2 Training and Testing materials are available at this site (except the NIHSS, which is videotape-based) and all exams have links to help the examinee answer the questions correctly. After passing the tests, the certification will remain active for another year.

### **No Prisoners**

Before the San Francisco meeting, we sent out an "emergency" e-mail concerning the enrollment of prisoners in the trial. The NIH, OHRP and all local IRBs have very strict rules about enrolling prisoners in clinical trials. Basically the concern is that prisoners may be coerced into consenting, either due to some belief that their sentences may be reduced if they do consent, or that they may be punished if they do not consent. Very different and special rules must be used for such situations - and if you have not specifically requested permission from your IRB to enroll prisoners, **DON'T DO IT.** I should note that if a prisoner

were inappropriately enrolled, most of the problems would fall on local investigators via your local IRB. Be careful!

**Augustine Medical PolarAir Units:  
We Need Two More**

Augustine Medical has very generously provided 27 PolarAir cooling units to centers participating in the IHAST2 trial. We currently have 25 centers actively enrolling patients and four other centers are in the process of joining us. Therefore we will need to procure two additional PolarAir units to ensure that all centers are able to participate. If any of you have access to a PolarAir, in addition to the one provided for the IHAST2 study, we ask that you consider allowing us to send the IHAST2 provided unit to one of the new centers. Dr. Bill Lanier, PI at Mayo Clinic, already volunteered to use their existing PolarAir for this study. Thank you very much Dr. Lanier!

Finally, we are interested in purchasing or borrowing PolarAir units from institutions not involved in IHAST2. If you know of a unit that is currently not in use, we ask that you please contact the CCC or have the owner of the unit contact us. Thanks!

**Augustine Will Provide  
Bair Hugger Blankets**

Augustine Medical, the supplier of our PolarAir Units, has offered to provide Bair Hugger Blankets for our IHAST2 study patients. To order blankets you may contact Augustine Clinical Research Manager, Lesa Hobright-

Turner, at [lhobright@augmed.com](mailto:lhobright@augmed.com). Please provide her with your: 1) Name; 2) E-mail address; 3) Telephone number and; 4) Appropriate shipping address to which the blankets should be shipped.

We would also like to say thank you to Ms. Hobright-Turner for all the time she has invested in coordinating the shipment of PolarAir Units and blankets to each of our centers.

**Revised MEDICATIONS form**

**Colloids:** You will soon be receiving a new, revised MEDICATIONS form that will include a new category, COLLOIDS. Agents in this category are macromolecules that act as colloids in the bloodstream, maintaining or increasing oncotic pressure. Most commonly, these agents are used to increase intravascular blood volume, although some are used to change blood rheology and/or coagulation. Colloids are often given as part of the therapy to prevent or treat Delayed Ischemic Neurologic Deficit (DIND) or “vasospasm.” Agents in this category include albumin, plasma protein fraction, hetastarch, pentastarch, dextrans (both high- and low-molecular weight), and gelatins such as polygeline, Haemaccel, Gelofusin, *etc.*

**Medication CATEGORY:** Remember, medications are grouped by functional category, by what they are intended to do, rather than by drug name or even pharmacological class. For example, the category Antimicrobial includes all agents given to treat any microbial infection, be it

bacterial, viral, or fungal. Please see the Operations Manual (Chapter IX, Section R) for complete definitions for each category. As an aid, the MEDICATIONS form gives examples for each medication category, but these are only a few examples - they are not all inclusive. For instance, under Neuromuscular Blockers, pancuronium is listed as the example, but any neuromuscular blocker qualifies; it doesn't need to be pancuronium. Likewise, for Antidysrhythmics, lidocaine and procainamide are listed on the form as examples, but any antidysrhythmic qualifies.

**“Other” Medications:** A review of 114 MEDICATIONS forms revealed 216 agents listed as “Other” medications. Twenty percent of the “other” medications (n=43) were agents for which there was an existing category. If you are not sure what a medication is, or why it is being given to the patient, look it up or talk with the physician(s) who prescribed it. However, the great majority of “Other” medications listed (n=104, 48%) were agents that are not necessary to list at all such as vitamins, dietary supplements, stool softeners, laxatives, skin lotions, electrolyte supplements, and nasal decongestants. In most cases, if an agent cannot be included in an existing medication category, do not list it under “Other” medications unless it has had a clear and major impact on patient outcome. Usually it is not necessary to list lipid- or cholesterol-lowering agents, antidepressants, anti-smoking agents, etc.

### DAILY POST-OP SCREEN Recording Procedure Codes

Item 13 of the DAILY POST-OP SCREEN form indicates that for any diagnostic or therapeutic procedures performed since the last evaluation, please enter procedure codes for the appropriate day. Diagnostic or therapeutic procedures are those which are performed either to make a diagnosis or to treat a disease state. Examples include electrocardiography, transcranial Doppler, x-ray studies, cardioversion, intubation, gastrointestinal endoscopy, *etc.* **We would like to emphasize that we are asking only for procedures to be coded here, not intercurrent events per se.** **BIG HINT:** Only procedure codes have 9 as the second digit. (Examples: 290 - Cardiopulmonary resuscitation; 294 - Cardioversion/defibrillation; 392 - Endotracheal intubation; 696 - Transcranial Doppler). On the DAILY POST-OP SCREEN form, there is space for up to five procedure codes for each day. If you need more, please list the extra procedures on the new DPS SUPPLEMENT form coming soon to your center.

In many instances, a diagnostic or therapeutic procedure is performed because of the occurrence or suspicion of, an intercurrent event (IE). Hence, whenever a procedure is performed, please consider whether it is associated with an IE. If a procedure **IS** associated with an IE, record the procedure code on the DAILY POST-OP SCREEN form and complete an IE form (include the relevant procedure code on the IE form too). If a procedure is **NOT** associated with an IE,

record the procedure code on the DAILY POST-OP SCREEN, and you're done.

### **IHAST2 Safety Monitoring**

IHAST2 has two related safety monitoring mechanisms. The first is an "in-house" review that is done at The University of Iowa by Dr. Hindman and Dr. Todd at the Clinical Coordinating Center (CCC) and by the IHAST2 Local Safety Monitor, Dr. Harold Adams from the Department of Neurology, at The University of Iowa. The second mechanism is the NIH Performance, Safety, and Monitoring Board (PSMB).

As the local coordinators know well, Drs. Hindman and Todd review all indicator or severe intercurrent events. The IE forms are faxed to them within 24 hours and they are reviewed for completeness and accuracy of coding. These events are immediately entered into a table in the IHAST2 database so that all safety reviews will be current.

The IHAST2 Data Management Center (DMC) periodically prepares a statistical summary of all intercurrent events for review by the Local Safety Monitor and the PSMB. They have prepared five of these reports since the study began. In the future they will prepare this report after each multiple of 60 patients has been randomized into the study. This summary is partially blinded. Treatment groups are labeled "Treatment A" and "Treatment B" in the report. The actual treatments assigned to "A" and "B" are randomly selected at the time the report is

generated. The actual treatment assignment is enclosed in a sealed envelope that can be opened if necessary to determine the true assignment. Dr. Harold Adams and Drs. James Torner and William Clarke from the DMC review these reports. It is their job to identify any safety concerns and report them to the NIH PSMB. They prepare minutes from each review.

The NIH PSMB has overall responsibility for the performance and safety review for IHAST2. The safety of study patients is their most important responsibility. Each member of the PSMB receives a copy of each in-house safety report, an executive summary of the report, and the minutes from the in-house review. If any member identifies a safety concern that has not been raised in the in-house review, then he or she can request that the full board review those concerns.

While a meeting can be called whenever a safety or performance concern arises, the PSMB is scheduled to meet approximately every six months. The first meeting of the board was June 2, 2000 and the second was November 13, 2000. The third meeting will be in June 2001. At the PSMB meeting on November 13, 2000, Drs. Clarke and Torner thoroughly reviewed the safety report with the board. The board had no concerns for the safety of study patients at that time. When the materials become available, the CCC will provide each PCC an official copy of a letter from the PSMB for distribution to its local IRB. A similar letter will be provided after each official meeting of the board. This letter should confirm to the IRB that the study is being carefully

monitored and that as of November 13, 2000, there were no safety concerns for IHAST2.

Mortality is a primary concern in every clinical trial. As of October 20, 2000, 158 patients had been randomized into IHAST2 and 14 patients (8.9%) had died. This is well within the rate that one would expect in patients undergoing surgery for ruptured aneurysms.

**SCREENING and  
ELIGIBILITY forms**

Several of you have asked “Why are we spending all this time collecting information on ‘unenrolled’ patients.” In fact, there is a very good reason (which was noted in our original grant and reinforced by comments from both our original NIH review committee and the PSMB).

The patients enrolled in any trial are a “sample” drawn from a larger population. The true population is something theoretical (e.g., everyone in the world having aneurysm surgery? or everyone with a SAH? or ..). However, from a practical perspective, the population of interest includes all patients undergoing open craniotomy for aneurysm clipping at all active centers during the active period of IHAST2. What we are trying to do is to define this population in some detail.

There are two reasons: The first is to define the level of surgical activity at each center. We know that experience has an effect on results. We’re sure you are all familiar with earlier work relating to the number of CABGs or coronary angioplasties done by a hospital and overall mortality and morbidity. The same is true of

aneurysm surgery. In 1996, Solomon showed that centers that performed more than 30 craniotomies for aneurysm clipping each year had better results than those that did fewer (Solomon, Relationship between the volume of craniotomies for cerebral aneurysm performed at New York state hospitals and in-hospital mortality, *Stroke* 27: 13-17, 1996). We believe that the total surgical experience in our participating centers may be an important covariate that may be useful in evaluating overall results. In other words, there may be differences between a center that enrolls 20 patients over 3 years but operates on 100 versus a center that enrolls 20 but operates on only 25. This is the primary reason we ask that a SCREENING form be completed on every patient undergoing surgery, regardless of whether or not they are eligible, regardless of whether or not they even have a ruptured aneurysm.

So what about the ELIGIBILITY form which we’ve asked be completed on every surgical patient with a SAH? Why do we want so much more information on patients with SAH? The basic answer is that we are trying to define the population of patients at active centers who have SAH and who undergo surgery. In one sense, we are trying to better understand WHY patients are NOT enrolled in IHAST2. When we finish this project, it is important to know who was enrolled - and to know whether this sample was drawn from a reasonable population of patients and whether patients were enrolled “objectively” or whether they were more highly “selected”.

The information gained from the SCREENING and ELIGIBILITY forms tells us a

great deal about our centers and the patients they care for. For example, at the mid-August review of SCREENING and ELIGIBILITY forms, a total of 99 patients had been randomized at 20 active centers. A total of 328 SCREENING forms (i.e., the total number of patients having craniotomies), and 247 ELIGIBILITY forms had been received. This means that 81 patients had undergone surgery for unruptured aneurysms. Of the 247 patients with SAH, a total of 112 patients were deemed “medically and procedurally eligible”, 104 of these consented to be enrolled, and 99 were actually randomized (i.e. the envelope was opened). The biggest reasons for a patient being deemed ineligible are a) WFNS score of 4 or 5, b) endotracheal intubation, c) pre-SAH Rankin Disability Score of  $\geq 2$  and d) surgery beyond 14 days after SAH. Six patients were excluded because the surgical team decided not to use nimodipine, 15 had a BMI $>35$ , one was pregnant, four were already in another trial, eight had severe medical or psychiatric illness, etc.

The experience at centers varies a great deal. For example, we have centers at which very few craniotomy patients are “eligible” (low is about 20%) and others with a very high eligibility rate (about 75%). In most cases, this reflects local referral patterns. Some centers have a large number of WFNS grade 4 and 5 patients, while others receive many intubated patients. Other centers have a problem getting their anesthesia and surgical teams together and exclude patients for “procedural” reasons.

In essence, we are trying to avoid one problem that plagued earlier clinical trials. Some of you may remember the ECIC trial done in the

1980s. (Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke. Results of an international randomized trial. The EC/IC Bypass Study Group. *New Engl J Med* 313:1191-200, 1985). In this trial, roughly 1300 patients were randomized to undergo superficial temporary artery-middle cerebral artery bypass grafts to treat occlusive cerebrovascular disease. The trial clearly showed no benefits to surgery and the operation quickly died (in fact, most insurance companies subsequently refused to pay for the surgery). However, subsequent investigations showed that only about 1/3 of the eligible patients were enrolled at the participating centers, with a large portion of the remainder undergoing surgery “outside” of the trial. (Goldring S, Zervas N, Langfitt T: The Extracranial-Intracranial Bypass Study. A report of the committee appointed by the American Association of Neurological Surgeons to examine the study. *New Engl J Med* 316:817-820, 1987, and Sundt TM Jr. Was the international randomized trial of extracranial-intracranial arterial bypass representative of the population at risk. *New Engl J Med* 316:814-816, 1987). Basically, participating surgeons were “selecting” the patients they wanted to enroll and may have been randomizing only those patients in whom they felt that surgery didn’t matter. They may have been correct, but they may also have inappropriately killed a possibly useful operation.

We don’t want to repeat this mistake. To adequately examine the effects of hypothermia, the therapy should be applied to ALL patients who meet eligibility criteria (at least within practical limits). In fact, efforts to define the characteristics of patients that are NOT enrolled

have become a standard component of all trials such as ours. Our data collection effort is intended to meet this goal.

### Patient Enrollment in Other Trials

As everyone knows, enrollment in another clinical trial may make a patient ineligible for enrollment in IHAST2. However, it may not be clear that this same exclusionary rule applies AFTER a patient is enrolled in IHAST2. In other words, once a patient is enrolled in IHAST2 and has been randomized, they should not be enrolled in any other clinical trials/research protocols prior to the 3-month outcome evaluation. There may be exceptions to this for trials that have nothing to do with neurologic function, temperature regulation, etc., and which are not trying to influence outcome. However, please don't make this decision on your own. If you encounter such a situation, please contact the CCC as soon as possible; we will get back to you quickly. Please DO NOT enroll the patient in another trial until you hear from us. The potential for unintentionally confounding IHAST2 is real and large.

### Missed Answers Are Corrections

When a line or box is left blank while completing an original form, and the form is then sent to the DMC, completing the answer later is considered a correction. *Therefore, it needs the proper documentation, i.e. initials and date the answer was completed.*

**Example:** The form date of completion was left blank: On your copy, fill in *the date the form was originally completed*, add your *initials and the current date*. FAX the corrected copy to the DMC. (Send a PCC Correction Report with the corrected form page only if you initiated the correction).

---

08/23/2000 Form Completion Date (mm/dd/yyyy) DA 9/7/00.

---

**Note:** Never use a new original once a form has been completed. Always make corrections on your copy and make sure there is not another copy-sensitive canary yellow form beneath the one you are writing on.

### Data Edit Reports – A New Phase

Though understandably not a favorite report for any coordinator, the Data Edit Reports are essential to the IHAST2 Data Management Center to ensure that all data received from enrolled patients is as accurate and complete as possible. The Data Edit Reports you have seen so far have concerned missing mandatory answers or answers that were out of the range of

possibilities as set by our computer programs. Sometimes you may wonder why we ask if a BMI is correct when you have already answered that the BMI was a disqualifying factor for enrollment of a patient in a study. This is a double-check to make sure.

We are now beginning a new phase, Phase III, of data edits that will check the logic of the data with new questions. For instance, if “8” for “other” has been checked for item 2, “Race,” on the SCREENING form, then the text box after should have an answer. If it does not, a question for a Data Edit Report will be generated. Another example of a Phase III question that might appear on a DER follows: The Date of Consent is 11/19/2000 at 09:00. The enrollment date and time is 11/18/2000 at 07:00. Because the Date of Consent must be within 24 hours of the Date of Enrollment, this will generate two questions: Is the Date of Consent correct? Is the Date of Enrollment correct?

In a short time, we will also begin the last phase of data editing, Phase IV. This phase will look for inconsistencies between forms for each patient. For instance, the date and time of the NIHSS pre-op form must be before the date and time of induction (item C.1 on the ANESTHESIOLOGIST form) but after the date and time of the SAH given in item A.3 on the ELIGIBILITY form. If these dates and times are not consistent, questions will be generated in a Data Edit Report.

We realize this can be a lot of work for coordinators, and it may not seem justified to ask that forms completed weeks or months ago and

already corrected with Phase II Data Edit Reports must be pulled and checked and possibly corrected again. However, because we do not want any of your previous work to be wasted because of incorrect or uncorroborated data, it is necessary that we ask these questions. This is another effort to “scrub” the data and make it as clean as possible.

So coordinators will not feel totally inundated (or at least any more so than you already are!), we will send out reports in incremental stages on the patients who have already been randomized into the study and for whom all or most forms have already been completed. We are also increasing the time before Data Edit Reports will be considered overdue. As things get caught up, you will get all Data Edit Reports for Phase II, III, and IV for each patient at one time, and will be able to make all corrections at one time for each form. Only you who actually evaluate the patients can possibly answer the questions. Of course, by the time we get to Phase IV, you will all be so accurate with completing the forms in the first place, that there won't be any questions or Data Edit Reports (or maybe only a few). We greatly appreciate your efforts and cooperation in this, another step toward a successful outcome for IHAST2!

Please feel free to contact Michelle Wichman or Diane Anderson at the DMC, if you have questions about Data Edit Reports. We will be happy to help!