W1310R

March 17, 2009

Constance Lewin, MD, MPH
Branch Chief, Good Clinical Practice Branch I
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Ref 09-HFD-45-02-04 Warning letter

Dear Dr. Lewin:

This letter is in response to your warning letter dated March 2, 2009, which I received on March 3, 2009. A point-by-point response is provided. I have restated the comments from the warning letter for ease of reading in bold font and provided a response in regular font.

The emphasis of the warning letter centers on several key issues surrounding supervision, documentation of informed consent, and recording of study data. As the PI of the two studies inspected, I understand that I am ultimately responsible for the conduct of the clinical investigations, and specifically for supervising the investigation, ensuring appropriate procedures for obtaining and documenting informed consent, ensuring that all study staff are adequately trained, and maintaining adequate records of data collection. I would like to assure you that no subjects were harmed during their participation in the studies and that study procedures specific to drug dosing were followed at all times. I also wish to point out that many of the concerns raised in this report became known to me prior to the FDA visit and I had already taken proactive steps in reporting these concerns to the IRB, utilizing our institution's internal quality improvement program, and contacting subjects where appropriate. Since the FDA visit, as noted in my response to FDA form 483 dated May 22, 2008, I have put many additional safeguards in place so as to minimize the risk of similar issues occurring in the future. These safeguards include a

formal initial team meeting prior to activation of new protocols, routine periodic meetings throughout the life-cycle of the study, and orientation and ongoing education for my research staff. I have and will continue to emphasize the informed consent process and have created a written tool to ensure proper documentation. Please see the responses to individual points below for details regarding these safeguards.

Of utmost concern, as explained in my discussions with the FDA inspectors and noted in my May 22, 2008 letter, a number of my signatures and parent signatures as well as initials on consent forms were forged presumably by my research nurse. I feel it is necessary to note this problem again in some detail in this response, as it informs many of my subsequent responses in this letter.

My former research nurse worked under my supervision from March 13, 2006 until June 2, 2007. In mid January 2007 she informed me that she was suffering from a very serious terminal illness. The issue of signature falsification on consent forms was discovered approximately six months later on July 26, 2007 through an internal audit that was undertaken at my request and for unrelated reasons by the (b) (4) (b) (4) Program). At the time of our internal audit it was noted that my research nurse apparently falsified signatures on several consent forms that had been misplaced, as she was the only person other than myself with access to the documents. Upon discovery of the apparently falsified signatures, I filed appropriate protocol violation forms with the IRB. On November 12, 2007, the (b) (4) Program conducted an additional audit of the only other study this nurse was involved with; another consent form was discovered with both the parent and my signature falsified. Again appropriate protocol violation forms were sent to the IRB. Shortly after this discovery, I was informed that my former research nurse was observed to be apparently quite well and I began to suspect that her reported illness/diagnosis was not clinically possible given the time that had transpired, the diagnosis she had given to us, and her current state of health. These observations prompted us to escalate our investigations, which led to the discovery of falsified parental initials on a number of consent forms and one subject signature on an assent form. We reported these additional events to the IRB and the IRB made a decision to report this situation to the state Board of Registration in Nursing and to the FDA [See enclosures 1 (3 pages) and 2 (9 pages)]. It should be further noted that at the time of the FDA audit in April 2008, auditors Noe and Murphy provided a copy of a 1572 form upon which my name was forged [See enclosure 3 (2 pages)]; this clearly indicates an intentional behavior pattern on the part of my former research nurse.

1. **You failed to conduct the studies according to the signed investigator statement [21 CFR 312.60].**

   When you signed the investigator statements (Form FDA 1572) for the above-referenced clinical investigations, you agreed to take on the responsibilities of a clinical investigator. You specifically agreed to personally conduct, or supervise those aspects of the study you did not personally conduct, and to ensure that all associates, colleagues, and employees assisting in the conduct of the study were informed about their obligations.

   a. You failed to adequately supervise individuals to whom you delegated study tasks. The FDA inspection revealed that your supervision of personnel to whom you delegated study tasks was not adequate to ensure that the clinical trials were conducted according to the signed investigator statement and applicable regulations. Your failure to provide adequate oversight resulted in inadequate informed consent documentation and inadequate and inaccurate records as outlined in items 2 and 3 below. In your May 22, 2008 response to the Form FDA 483, you stated that although you were personally involved in the study, you did not ensure that the delegated staff were fully trained, and you did not verify their performance as documented in the case report forms (CRFs). We acknowledge your assurance that corrective actions have been taken to assure more rigorous documentation.

I understand my responsibility to ensure that my staff are adequately trained and supervised. To ensure this, for all future studies, a team meeting will be held prior to activation of new protocols. This team meeting will review: my delegation of responsibility, study procedures and drug dosing, the informed consent process and document, and expectations for study data documentation (source documentation, CRFs). Questions and any needed clarifications on such study documentation will be made with the Sponsor prior to subject enrollment. Routine meetings during the active phase of the study will ensure that staff receive proper oversight and are properly calculating, transcribing, and/or documenting study data. If questions arise as to the appropriate documentation of the data, I will contact the Sponsor representative and/or CRO. Meetings will be documented in a log book along with the topics covered.
We have conducted these team meetings for two protocols recently initiated for which I am the PI.

We are fortunate that the MGH institution offers a number of educational sessions to which I actively encourage my research staff to attend. Educational offerings cover various topics including institutional policies and good clinical practice. As an example of the various experience my staff can acquire, I have attached a list of educational offerings my new research coordinator has attended in the past year [See enclosure 4 (27 pages)]. Training is documented and for IRB sponsored training sessions, certificates of attendance are maintained in personnel files.

b. Regarding protocol (b) (4) you did not list the names of all subinvestigators who would be assisting in the conduct of the investigation, as required by the Statement of Investigator, Form FDA 1572. The FDA regulations specified that in the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team [21 CFR 312.3(b)]. During the inspection, you told the FDA investigator that the protocol-required blinded assessments were done by residents present in the operating room on the day of surgery. By performing these significant study activities, the residents should have been listed on the Form FDA 1572 as subinvestigators. We acknowledge your assurance that in the future, the individuals who are involved in research-related assessments will be included on a Form FDA 1572.

The Sponsor protocol did not specifically indicate who was to do the blinded assessments, i.e., it did not specify that the intubations had to be performed by an investigator. As a teaching hospital nearly every anesthetic is conducted with residents in training (on pediatric anesthesia rotations, residents have generally completed at least one year of residency training). It was my error to assume that my residents' assessments were part of their routine training; it did not occur to me that they should be included on FDA form 1572. After I was made aware of this misunderstanding (after the 5th subject was enrolled), I asked each resident to sign a note that they were in fact blinded as to drug dose and these forms are contained in our study binder. I now understand that all individuals on my study team, including residents, who perform significant study activities, should be listed on FDA form 1572.

2. **You failed to obtain legally effective informed consent [21 CFR part 50 and 21 CFR 312.60].**

Except as provided in 21 CFR 50.23 and 21 CFR 50.24, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative [21 CFR 50.20]. Informed consent must be documented by the use of a written consent form approved by the institutional review board (IRB) and signed and dated by the subject or the

subject's legally authorized representative at the time of consent [21 CFR 50.27(a)]. You also failed to obtain proper assent as determined to be appropriate by the IRB [21 CFR § 50.55].

a. Fabricated signatures of the subject's legally authorized representative were found on the consent forms for subjects 114403 and 114601, who were enrolled in protocol (b) (4), and subject 124402, who was enrolled in protocol (b) (4). We note that you discovered the fabricated signatures through your own internal audit, and that you sent letters dated September 10, 2007 to the parents of subjects 114403 and 114601, and a letter dated December 11, 2007 to the representatives of subject 124402, requesting that the informed consent documents be signed again. In addition, you promptly reported the findings to the IRB. In your May 22, 2008 response to the Form FDA 483, you stated that you asked the study coordinator to ensure that copies of the original, signed consent forms were placed in the subjects' medical records, according to institutional policy, but you did not confirm this action. You stated that had this occurred, you would have been able to retrieve a copy of the original consent forms. You stated that it is presumed that your former research nurse (study coordinator) apparently falsified the signatures after she lost the original, signed consent forms. You also stated that you reported these findings to the Board of Registration in Nursing. As the clinical investigator, you are responsible for oversight of study activities delegated to study staff.

   In your written response you also stated that you took immediate action to contact the families that had consent forms with apparently false signatures. You stated that you was able to reach two out of three and they sent confirmatory signed statement that they had allowed their child to participate in a research project prior to study procedure. You stated that the third family had vacated their apartment and you were not able to contact them. You stated that documentation by the CRO exists to confirm that you did in fact obtain consent from all subject parents prior to participation in the study on a valid consent form. We do not find your response to this observation adequate as it does not include documentation to support your statements.

As the PI, I understood the importance of obtaining informed consent prior to initiation of study procedures and I did personally obtain and document consent from subjects 114403, 114601, and 124402 prior to their participation. See the CRO's monitoring notes dated July 6, 2006 and finalized on July 19, 2006 as well as the monitoring notes from February 13, 26 and 27, 2007 and signed off on March 3, 2007 [See enclosure 5 (5 pages)].

It is of major concern that, after informed consent was obtained and documented by me, the documentation was lost and apparently subsequently forged by my research nurse. There was no reason to reexamine these documents once obtained and filed, and my research nurse did not ever bring to my attention that any original forms had been lost. Once the apparent forgery was discovered by the (b) (4) Program, I took immediate action. I attempted to contact the families of the involved subjects to obtain a confirmatory-signed statement that they agreed to participation in the research. Each family was first contacted by phone when possible and then sent a (b) (4) envelope with return (b) (4) asking them to confirm their agreement to participate (these records were reviewed at the time of FDA audit and are enclosed)[See enclosures 6 (4 pages), 7 (4 pages), and 8 (2

pages)]. I was not able to reach the third family by phone and the (b) (4) was never returned despite multiple calls and two (b) (4) mailings so we assumed that they had vacated their apartment

I take full responsibility for not ensuring adequate oversight of the activities delegated to my staff. I have met with my current staff to explain the importance of proper documentation of informed consent and the steps we must take as a study team to report missing consent forms if we are faced with this situation again. In addition to requiring all research staff to be knowledgeable about institutional policies surrounding informed consent, I have instituted a policy for my staff in which the person obtaining consent completes a form that documents the informed consent process including the following information: that XX study was explained, questions were answered (if any), subject agreed to participate and signed the consent form, the date and time of consent/assent (filled in by the consenting individuals), all option sections were completed (if any), and a copy of the signed and dated consent form was given to subject and placed in the medical record [See enclosure 9 (1 page)].

b. **Regarding protocol (b) (4), page 5 of the informed consent document asks "Do you agree to allow your child to have blood samples taken?" followed by a space for the subject or subject's legally authorized representative to respond by checking "YES" or "NO" and initial. However, pharmacokinetic samples were collected from subjects without obtaining informed consent for blood sampling. Examples include, but are not limited to, subjects 114403 and 114503. We note that you sent a letter dated December 11, 2007 to the IRB informing the IRB that these subjects did not consent to blood draw. In your May 22, 2008 response to the Form FDA 483, you stated that you will ensure that you are aware of any options sections included in the body of the consent form. However, you did not state how you will ensure that proper consent is obtained.**

I take full responsibility for not being aware that an 'Option Section' was included in the body of the consent form. It was my practice to review all of the proposed study procedures including the pharmacokinetic sampling during the consenting process and therefore I am certain that I informed the parents of this optional procedure and that they agreed to the insertion of a second IV and the taking of the blood samples. However, I do not have any documentation for this agreement. Upon notification of this issue from the CRO, all subsequent patients had the form filled in correctly.

As noted above in 1a, initial team meetings will review the unique characteristics of the informed consent document, including option sections. As noted in 2a, the documentation of the informed consent process (which would include completion of option sections, if applicable) will prompt the person obtaining consent to ensure option sections are complete. Additionally, research coordinators will be instructed to double check that all appropriate places of the consent form have been filled in correctly (See enclosure 9).

c. Regarding protocol (b) (4), the IRB requires that subjects who are 7-13 years old sign a Research Assent form. Subject 124501 was seven years old at the time of

consent, but did not sign a Research Assent form prior to being enrolled in the study. We note that you sent the subject's representative a letter dated December 11, 2007 requesting that the subject sign and date a Research Assent form. Therefore, you failed to obtain proper assent as determined to be appropriate by the IRB [21 CFR § 50.55].

A sub investigator obtained the consent and assent for this subject and he specifically asked my research nurse if the child's signature on the assent form was required and was told it was not. This direction from the research nurse is documented on the consent form. After discovery of this mis-instruction, this violation of institutional policy was reported to the IRB. I take responsibility for not ensuring that my sub investigators clearly understood the institutional policy for documenting assent. I have included a copy of the letter I sent to this family but they did not return the document to me [See enclosure 10 (6 pages)].

In the future, my study staff and I will be adequately informed of institutional policies surrounding documentation of informed consent and assent. I will ensure this education by directing new study staff to the institutional policies for such documentation and discussing how these policies apply to each study during the meetings held prior to study activation.

d. According to the study records, representatives for subjects 114302 and 114504 were non-English speaking. The subjects' representatives signed informed consent documents written in English rather than a language understandable to the representatives. The subjects' representatives were not provided with either a translated consent document or a "short form" translated consent document. We note that the names of the translators were written on the signed consent documents. In your response to the Form FDA 483, you acknowledged that you failed to provide translated consent documents to these subjects, but stated that you would train your staff on this requirement so it would not happen in the future. We acknowledge your assurance that corrective actions will be taken to ensure that this finding is not repeated in any future studies.

I take responsibility for not adhering to the institutional policy and for not providing the family with a translated consent form or short form translated into Spanish. In retrospect I thought of this as similar to our consents obtained for surgery and anesthesia. We often make use of medical interpreters to ensure that all the procedures, risks and benefits are explained to the subject if there is not a language specific consent available for families. A note is then made in the chart stating that this consent was obtained through a medical interpreter; this mechanism is considered appropriate for their child's surgery and anesthesia. For the specific cases noted above, I did go through the entire multi page consent with a hospital approved medical interpreter physically present and documented their name on the consent forms. At the end of the interpretation, I felt satisfied that the

parent(s) understood the procedures, risks and benefits of the study because all questions related to either the conduct of anesthesia or the study procedures were answered through the interpreter.

I have reviewed the institutional policy for obtaining and documenting informed consent from non-English speaking subjects. All research personnel have been informed of this policy and in these situations in the future a translated short form will be provided to the parents in order to obtain and document informed consent. A copy of the short form consent form, signed and dated by the subject (or their legally authorized representative) and the witness who is fluent in both English and the language understandable to the subject, and a copy of the English language version of the IRB-approved consent form, signed and dated by me and the witness, will be inserted in the subject's medical record (as appropriate) and subject's research files.

e. Informed consent documents were dated by study personnel rather than the legally authorized representative for subjects 114302, 114401, and 114504 enrolled in protocol (b) (4) , and subject 124601 enrolled in protocol (b) (4) . In your May 22, 2008 response to the Form FDA 483, you acknowledged that it was your routine practice to insert the date yourself, prior to the parents' signatures, in order to simplify the process. You stated that you now know that subjects and parents must date the consent forms themselves. We acknowledge your assurance that corrective actions have been taken to ensure that this finding is not repeated in any future studies.

I accept responsibility for not adhering to institutional policy and filling in the date myself. I have informed my study staff of the necessary institutional policies for documenting informed consent.

3. **You failed to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation [21 CFR 312.62(b)].**

   Examples include, but are not limited to, the following:

   a. Regarding protocol (b) (4) the primary efficacy parameter was the total dose from administration of intubating dose to reappearance of T_3 after the last maintenance bolus dose of Zemuron®, or discontinuation of Zemuron® infusion. The duration of drug administrations used to calculate the total dose (mg) does not correspond to the time interval of drug administration recorded on the Train-of Four Watch (TOF-Watch) source document for the following subjects:

Subject No.	TOF-Watch (mcg/kg/min)	TOF-Watch Source Document Time (h:mm:ss) / Duration (mm:ss)	Duration Used in Calculation
114403	adjust to 14	10:15:49-10:23:28 / 7:39 (459 sec)	499 sec
	adjust to 12	10:23:28-10:28:18 / 4:50 (290 sec)	429 sec
	adjust to 8	10:31:57-10:44:58 / 13:01 (781 sec)	790 sec
114404	start at 10	13:36:52-13:39:09 / 2:17 (137 sec)	177 sec
	adjust to 12	13:39:09-13:42:01 / 2:52 (172 sec)	212 sec
	adjust to 10	13:42:01-13:44:25 / 2:24 (144 sec)	165 sec
	adjust to 8	13:44:25-13:47:52 / 3:27 (207 sec)	186 sec
	adjust to 6	13:47:52-13:51:02 / 3:10 (190 sec)	230 sec
	adjust to 4	13:51:02-13:54:38 / 3:36 (216 sec)	226 sec
	adjust to 2	13:54:38-14:03:33 / 8:55 (535 sec)	565 sec
	adjust to 5	14:03:33-14:15:01 / 11:28 (688 sec)	128 sec
	adjust to 4	14:23:24-14:46:14 / 22:50 (1370 sec)	1402 sec
	adjust to 6	14:46:14-15:15:39 / 29:25 (1765 sec)	1773 sec
114501	start at 10	14:42:40-14:48:07 / 5:27 (327 sec)	361 sec
114505	adjust to 8	9:01:32-9:6:10 / 4:38 (278 sec)	318 sec
	adjust to 5	9:26:45-9:37:25 / 10:40 (640 sec)	680 sec
	adjust to 5	9:55:54-10:07:15 / 11:21 (681 sec)	721 sec
114602	start at 10	12:56:21-13:04:20 / 7:59 (479 sec)	519 sec
	adjust to 8	13:09:52-15:25:32 / 2:15:40 (8140 sec)	8732 sec
114603	adjust to 8	12:34:59-12:38:29 / 3:30 (210 sec)	220 sec
	adjust to 2	12:41:52-13:00:45 / 18:53 (1133 sec)	1128 sec
114607	adjust to 5	11:43:04-12:00:49 / 17:45 (1065 sec)	1125 sec

I understand that I am responsible for the inaccurate records and in the future I will ensure that staff delegated to transcribe and calculate doses are adequately trained. This training will take place as noted above in #1a.

However, I would like to note that the above subtraction of minutes and seconds calculations were performed incorrectly by my research nurse and the CRO working together. It should be further noted that Mr. (b) (6) , an auditor from Organon, made two separate inspections of our records and he missed these same errors. Further the company quality assurance team entering the data into their master database also missed these errors. It would seem that although we made the initial miscalculations, that 3 higher levels of audit that are supposed to prevent data entry problems and whose responsibility is to assure the veracity of the data after it leaves the investigators office did not find them. Had these three subsequent sponsor reviews functioned as expected, we would have realized the math errors and made the appropriate corrections earlier. In fact at the time of the FDA audit, Mr. (b) (6) agreed to "unlock" the "locked" database and review all such calculations from all sites acknowledging that they had failed in their responsibility as well. It is important to emphasize that these duration calculations are important for determining drug efficacy in the protocol overall, but do not affect the

doses administered to individual subjects. No subjects were inappropriately dosed as a result of these calculation errors.

b. Regarding protocol (b) (4) , the "Infusion Rate (mL/min)" was not recorded for the 10 subjects who were randomized and received the infusion maintenance dose for protocol 021048. In your May 22, 2008 response to the Form FDA 483, you acknowledged you recorded the dose in mcg/kg/min that was obtained from the computer generated TOF-Watch and did not appropriately calculate the infusion rate in ml/min.

As noted in my letter dated May 22, 2008, the infusion rates were captured in "real time" on our computer generated Train-of Four Watch (TOF Watch) such that the infusion dose in µg/kg/min and the exact seconds of infusion are clearly recorded and verifiable. This however was not transcribed into "weight times rate times duration in seconds divided by 60" and then further converted to the full strength concentration of 10 mg/mL to give "Infusion rate (mL/min)" on the CRFs. In addition, the numbers documented in the TOF Watch were in some instances transcribed incorrectly by my research nurse which resulted in another level of miscalculation.

As PI of this study, I take full responsibility for the inaccurate records found in the CRFs. For my planned corrective action, please see response to item # 1a.

c. The study records indicate that informed consent for subject 114403 enrolled in protocol (b) (4) was obtained on June 2, 2006, and informed consent for subject 124402 enrolled in protocol (b) (4) was obtained on November 30, 2006. Each of these informed consent documents contains a signature similar to yours entered on the line above the statement "Study Doctor or Person Obtaining Consent." During the inspection, you stated that the signatures on these documents were not yours. In your May 22, 2008 response to the Form FDA 483, you stated that the signatures on these documents were fabricated.

Please see response to item #2a.

I take responsibility for not ensuring adequate supervision and oversight of the activities delegated to my staff. As noted above in item #2a, I have met with my staff to explain the importance of appropriate documentation of the informed consent process and have instituted a policy for my staff in which the person obtaining consent complete an additional study form that documents the occurrence of and certain details about the informed consent process.

d. Regarding protocol (b) (4) the "Concentration of Zemuron® Infusion (mg/mL)" on the source document for the administration of (infusion) maintenance dose was recorded as "1:1" or "0.5:1" for subjects 114201, 114406, 114505, 114602, 114603 and 114607. Based on this documentation, the actual drug concentration is uncertain. In addition, the concentration on the source document does not match the concentration reported on the CRF for subject 114501. In your response to the FDA Form 483, you stated that your research nurse recorded these doses. You also stated that, in the future, you will ensure that staff delegated to document specific information, such as dilutions, are adequately trained on how to do so.

In order to accurately administer rocuronium to children of all sizes on a µg /kg/min basis and to assure that the drug would be delivered without delay it was necessary to dilute the drug for small children and infants. The use of a device called the (b) (4) is a requirement for administration of medications in the operating rooms of the Massachusetts General Hospital as a safety measure, and was used for all children during this study. A description of the (b) (4) was provided in my May 22, 2008 response. I also demonstrated how this system works several times for the FDA inspectors and with varying size syringes. I also pointed out that this in fact improved accuracy and prevented errors because the rate of infusion is automatically tied to the (b) (4) once the concentration and the child's weight are added to the programing menu (the built in computer eliminates manual calculation errors). This (b) (4) will not function unless specific information is entered and at each step in the process you must confirm that the choice is correct: turn on, confirm syringe manufacturer, confirm syringe size, confirm drug concentration, confirm rate (in this case mcg/kg/min), insert and confirm child's weight. When the infusion needs to be changed it is simply a matter of pressing the "change dose" button, entering the change (e.g. 10 mcg/kg/min to 8 mcg/kg/min), pressing "restart", and the (b) (4) automatically makes the change.

As I explained in my May 22, 2008 letter, each time I diluted the drug I told my research nurse, who was present in the operating room, the concentration I was using (mg/mL) and this was entered into the (b) (4) menu. I was not aware that she was recording this on the paper documentation in such a way that later would be confusing. It is my responsibility for not adequately training my research nurse on proper documentation of the diluted drug and additionally for not reviewing the data after it had been recorded. The drug doses administered (mcg/kg/min), the times of change in infusion, and the duration of these infusions were tracked on the computer in real time so the actual drug exposure is accurate and verifiable.

In the future I will ensure that staff delegated to document specific information, such as dilutions, are adequately trained. This training will take place as noted in item #1a and 3a. In addition, for future studies involving calculations, I will create a worksheet to document each step. Note, this type of documentation was not contained in the protocols (b) (4) and (b) (4) and was never requested by the sponsor or the CRO. I will carefully review these worksheets and the case report forms as noted in #1a.

In summary, I regret the occurrence of the concerns reported by me and identified by the FDA and the circumstances that gave rise to them. I do not believe the work environment I fostered was responsible for inciting or precipitating this behavior as I have successfully worked with diverse colleagues and support staff at various institutions for many years, and never previously experienced these problems. I have taken the above-described steps to minimize the risk of this happening in the future. Please to not hesitate to contact me with any further questions or concerns.

Sincerely,

Charles J Cote', MD
Professor of Anaesthesia, Harvard Medical School
Department of Anesthesia and Critical Care
Director of Clinical Research in Pediatric Anesthesia
Division of Pediatric Anesthesia
The MassGeneral Hospital for Children
Massachusetts General Hospital
55 Fruit Street
Boston, MA 012114

Direct phone with phone mail (b) (6)
Secretary (b) (6)
FAX (b) (6)

e-mail cjcote@ (b) (6)