

Complainant Statement for HHS Inspector General

I am the unnamed complainant in OSC File No. DI-06-0767. This statement is in response to the Report of Investigation of the Office of Inspector General (OIG) of the Department of Health and Human Services OI File No. 4-06-00243-4.

I strongly disagree with the decision of the OIG that no criminal or civil violation has occurred in this matter. I believe that the parties interviewed who were accused of wrongdoing have misrepresented the facts in order to avoid liability. I contend that their motivation to be truthful and forthcoming is highly suspect. I had nothing to gain from coming forward and reporting this matter to the Office of Special Counsel. To the contrary, despite the fact that I acted honorably and ethically in this matter, I have been the one who has been harmed and penalized for my actions.

The Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG) is funded by the National Heart, Lung, and Blood Institute (NHLBI) as a contract mechanism. As such, the NHLBI contracts with medical scientists around the country to purchase their expertise in the accomplishment of a list of requirements outlined in the BABY HUG statement of work, the protocol, and the consent form.

NHLBI put in place a process for deciding what the design of this trial would be, and any modifications to the protocol and consent form as the trial progressed. This process involved a regularly held meeting of NHLBI staff including the Director of the Division of Blood Diseases and Resources (DBDR), the Deputy Director of DBDR, the Executive Secretary of the BABY HUG Data and Safety Monitoring Board (DSMB), the BABY HUG Contracting Officer, and the BABY HUG Project Officer. As the BABY HUG Project Officer, it was my responsibility to bring proposed suggested modifications to the protocol, such as ancillary studies, from the investigators to the NHLBI BABY HUG staff for review in order that the statement of work, protocol, and consent form could be modified so that NHLBI could purchase this science from the BABY HUG investigators. All individuals and entities involved clearly understood that, absent specific written authorization from NHLBI, no modifications, deviations or enlargements of the statement of work, the scientific studies and testing involved, or the use of the data and specimens acquired would be permitted.

Immortalization of the genetic material from the BABY HUG subjects was an important scientific concept, given the interest of the sickle cell disease research community in further exploring the genetic modifiers of the clinical severity of sickle cell disease, which is the current "Holy Grail" of sickle cell disease clinical research. However, although I recognized the scientific importance of this proposed ancillary study by Dr. Russell Ware, I never authorized him in writing to either perform or continue his proposed ancillary study. Furthermore, I could not - and did not - bring this matter forward to the NHLBI staff for review and approval to add to the BABY HUG statement of work, protocol, and consent form for the following reasons:

1. Dr. Charles Peterson, Director of DBDR, had announced at a BABY HUG staff meeting in early 2005 that he was **opposed to the scientific merit of Dr. Ware's ancillary study of VDJ mutations** that was at that time in the protocol. Therefore, I knew that Dr. Peterson would not look favorably on the addition of another ancillary study by Dr. Ware.
2. BABY HUG had developed an approximately \$7 million deficit. This led the BABY HUG contracting officer to state that adding additional ancillary studies were not in the trial's best interest since insufficient funds were in the DBDR contract line budget to complete even the main trial questions. **At a BABY HUG staff meeting, Dr. Peterson stated that BABY HUG was to be shut down at the June, 2005 DSMB meeting, and the protocol was to be offered to the investigators of the proposed Sickle Cell Disease Phase III Clinical Trial Network.**

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3. When I came to work for NHLBI in 1990, it was my responsibility to review the autopsy reports of the patients who were participating in the Cooperative Study of Sickle Cell Disease (CSSCD). There was an autopsy report of a 40 year old African American man that was identified only by the standard CSSCD code number that startled me when I reviewed it. The patient had undergone a gall bladder removal operation that became complicated when, 24 hours postoperatively, he began to complain of severe abdominal pain. His doctors had told him that he was seeking narcotics for sickle cell pain, but he protested that this pain was different from his sickle cell pain. He did not receive a proper evaluation of his medical condition, and adequate pain medication was withheld. Ultimately, he died. At autopsy, a large retroperitoneal hematoma (large collection of clotted blood) was found that arose from the site of his gallbladder surgery. He had literally bled to death while his pleas for appropriate medical evaluation and pain relief were ignored.

4. Robert Taylor Bonds was one of the first African Americans from the District of Columbia to receive his commission as an officer in the United States Army after President Harry Truman integrated the armed forces at the end of World War II. Mr. Bonds was trained at Fort Benning Georgia, and was commissioned as a second lieutenant in the infantry on September 25, 1945. He served in the Army Reserve until his unit was called up to active duty at the start of the Korean War. While deployed in Korea as a first lieutenant, a white Army dentist performed dental surgery on him without anesthesia. I did not learn of this breach of medical ethics until 1990 when I attempted to refer him to one of the premier hematologists in this country who specializes in coagulation disorders. Mr. Bonds had thrown blood clots to his lungs (pulmonary emboli), and because of a family history of a disorder that leads to a tendency to make blood clots easily, I felt that he should be seen by a specialist in blood clotting disorders. I had to explain to him that the white doctor to whom I wanted to refer him was different from the uncaring Army dentist who had so grievously harmed him while he served in Korea. With that assurance, he finally went to be properly evaluated for hypercoagulable state (making blood clots too easily).

All of these examples, including the obtaining of genetic material from the BABY HUG subjects without the consent of the parents, point up the problem with 45 CFR 46. Although all of these incidents are clearly examples of unethical conduct on the part of health care providers, there is no legal recourse for any of the individuals who were harmed. Malpractice law suits might have brought some redress for Mr. Bonds and the unnamed CSSCD patient, but the family of Henrietta Lacks, the Tuskegee Syphilis Study subjects, and the BABY HUG subjects have had no way to be justly compensated for either the unethical conduct of the clinical research in which they participated or the obtaining of tissue samples without informed consent or compensation.

The Federal Code that contains 45 CFR 46 needs to be amended so that these sorts of incidents will be punishable by criminal and/or civil penalties. Fines must be imposed to compensate victims whose tissue samples are obtained without consent or financial compensation. This law must be passed swiftly so that these types of incidents can be deterred particularly with regard to the health care of minority individuals.

African Americans, historians, and bioethicists will view the breach of bioethics in the conduct of BABY HUG to be on the same level as the Tuskegee Syphilis Study and the obtaining of the cells that lead to the *He La* cell line without the consent or compensation of Henrietta Lacks' family. It has always been difficult to recruit African Americans to clinical trials. President Clinton apologized on behalf of the nation for the Tuskegee Syphilis Study. The parents of the BABY HUG subjects deserve to have the immortalized genetic samples from their children destroyed since they were obtained without their consent, and they should be apologized to for having this happen in a major phase III clinical trial sponsored by the National Heart, Lung, and Blood Institute, which is the lead federal agency responsible for the funding of research to treat and cure patients with sickle cell disease.

I have reviewed the forgoing three pages of my statement and declare, under penalty of perjury, that the statements contained in those pages are true and accurate.

Duane R. Bonds, M.D.
Duane Robina Bonds, M.D.

November 9, 2006
Date

Response to Office of Special Counsel Report March 23, 2007


It is with great sadness that I reviewed the report submitted by the Office of Special Counsel from Health and Human Services (HHS) and the National Heart, Lung, and Blood Institute (NHLBI) in response to my Whistleblower Complaint concerning the obtaining of genetic material from the subjects in the Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG) without the informed consent of the patients' families. The attempts of the agencies to defend the indefensible is unconscionable and immoral.

My only substantive comment to the HHS and NHLBI responses is that those responses have omitted what I contend is a critical point; namely, that it is important for the OSC to realize that although the project of Dr. Russell Ware was scientifically worthwhile, it was not in the original BABY HUG contract statement of work, the protocol, and therefore the informed consent. The project would have had to have been presented to the BABY HUG Data and Safety Monitoring Board (DSMB) by me as the project officer so that the protocol and the consent form could be amended to include Dr. Ware's project. I did not bring the project forward because Dr. Peterson opposed Dr. Ware's other projects in the BABY HUG protocol. Since the BABY HUG contract had an approximately \$7 million deficit, it was not possible for me to introduce new ancillary studies since there were insufficient funds to pay for the answering of the main clinical trial hypothesis: could hydroxyurea prevent the onset of end-organ damage in young children with sickle cell anemia?

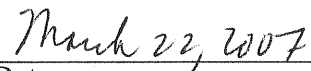
We have all taken the same training in human subjects protection. I feel vindicated that the Institutional Review Boards of most of the BABY HUG clinical sites agreed with my original decision to order the destruction of the genetic material that had been obtained from the BABY HUG subjects without their families informed consent. The failure of Dr. Peterson to support my order to destroy the genetic material that was obtained without informed consent is not defensible by any stretch of the imagination. In addition, BABY HUG would not have been faced with a \$7 million deficit if Dr. Peterson had performed his duty¹ to see to it that the contracts which all of the clinical sites and the coordinating center had signed in good faith had been exercised properly by allowing the BABY HUG clinical trial to proceed in a timely fashion instead of being held up for more than 2 years without allowing subjects to be recruited.

History will view Dr. Peterson's management of the BABY HUG Clinical Trial on par with the Tuskegee Study in the mistreatment of a vulnerable minority population. The fact that NHLBI did not prevent Dr. Peterson from sabotaging the science and the human subjects protection of this clinical trial during my tenure as the BABY HUG project officer means that NHLBI is culpable for the waste in taxpayer funds since the trial was not completed in a timely fashion with the best science that should have been allowed to be studied. For NHLBI, which is the lead agency at the National Institutes of Health for the funding of basic and clinical research in sickle cell disease to not be a better steward of the BABY HUG clinical trial makes me feel ashamed of my Institute.

In closing, I continue to contend that I acted appropriately in all aspects of my position as the BABY HUG project officer and that the actions taken against me, since September 2005, were illegal, retaliatory and discriminatory.



Duane Robina Bonds, M.D.



Date

¹ First as the Director of the Blood Diseases Program and later as the Director of the Division of Blood Diseases and Resources.