

Note from the GCSP Chair - Charlie Williams
Subject: Shanghai Health Study

The GCSP reviewed the current recommendations of the Shanghai Health Study Oversight Committee. Because of the time pressures only myself as Chairman represented the GCSP. The position paper furnished by API is quite accurate and factual. Further, on behalf of the GCSP, I am recommending and supporting the advance payment of \$2million dollars to ensure survival of the lab and staff to complete the study.

However, I think it is the responsibility of the GCSP to inform you on some additional risks/considerations. There is a wide variation of opinion amongst various staff and Companies involved in this study. The Oversight Committee has worked diligently and is aware of these risks/considerations. They include:

- 1- As indicated in your information note, the sudden involvement of Cinpathogen - a for-profit company that has Dr. Irons, a co-principal investigator, also as a principal in the company. Dr. Irons has indicated the Fudan University prefers working with CinPathogen rather than the University of Colorado. Dr. Irons has informed the Oversight Committee that a contract is in place between CinPathogen and Fudan, although neither API nor the committee has seen the contract. The University of Colorado and Dr. Irons have jointly signed a letter to API and the committee indicating that they will be providing separate, but complementary proposals to finish the study. Colorado will retain 2 subcontracts in support of the study. Initially Cinpathogen wanted the University of Colorado dropped entirely.
- 2- Dr. Irons has been unclear relative to his fixed cost needs and what deliverables are tied what costs. Many numbers provided simply do not add up. He has been particularly unclear in what is required to maintain the lab until new contracts are in place. The current payment is based on the best estimate of the Oversight Committee with what data they have available.
- 3- No new contracts have been available for API review and thus payment of this advance will only be covered by a short letter agreement yet to be resolved.
- 4- The Oversight Committee has developed a new QC and phased payment plan. This is a great step forward. However, this plan does not include pay-for-performance and payments that are tied to QC results. This may be able to be corrected in the final contracts. But even in the best case, the Oversight Committee is concerned about the level of their QC review and the plan will not guarantee delivery.
- 5- Thus far only half the cases as prescribed by the protocols have been delivered. The new promise is that all the cases should be delivered in the final remaining year. I think most feel that full delivery of cases is unlikely.
- 6- Ownership of the data is with the University of Colorado and most likely will be transferred to Fudan or CinPathogen and likely we have no ownership interest
- 7- The Oversight Committee has taken the position that this is the final year of case accrual, with data analysis in 2008 and publications then being produced regardless of the results delivered.

Certainly Dr. Irons is working under difficult circumstances and many trust in his promise to deliver. However, I think it is important for the EC to realize that it is very difficult to achieve normal commercial leverage in this situation. The current funding with Colorado is through a grant; the new funding is recommended to be through a contract with CinPathogen. There is a risk that we will end up at the end of this new contract period

having spent the full funds and with the project still not delivering the original promise. It is assumed that publications will be generated on what data is available.