

Conference Call Participants

E: ERP; S: SRP

¹Consortium Technical Committee Co-Chair; ²SRP Vice-Chair; ³SRP Chair, ⁴API Staff

S Richard Albertini

Stuart Cagen¹

S John Cherrie

E Ellen Clayton

E Paul Lombardo

S Helmut Greim²

S Richard Larson

S Jerry Rice³

S Howard Rockette

S Robert Herrick

E Zong-Liang Xu & translator

Bruce Jarrot⁴

Absent:

S Harvey Checkoway

E Juhana E. Idänpään-Heikkilä

S Guilan Li

S Mark Minden

Administrative Items

- Ellen Clayton & Paul Lombardo were welcomed to the ERP
- The Consortium's "charge" to external review panels is available for review on Shanghai Health Study (SHS) website

Feedback on Progress since first annual research meeting (Asilomar 2003)

Dick Albertini:

- Has JCML's analytic capability been validated?
- Concern with analyses of Bz & Bz-metabolites in blood, bone marrow
- Did protocol changes include adoption of cytogenetic markers?

Helmut Greim:

- Progress of Bz & Bz-metabolite analysis in blood, bone marrow?
 - Detectable levels? Useful information? Practical?
 - Urinary metabolites (eg, SPMA) more useful
- Why was ELISA technique selected?
- Adducts may be better parameter in blood & bone marrow

Bob Herrick:

- 2003 DP/ME report suggested problems with QA/QC
- Is Dr. Liang best suited to provide data quality oversight?

Jerry Rice - expanding on QA/QC topic:

- Data quality expectations should be explicit; assumptions may be poorly founded
- Pls need to exercise continued diligence in quality control
- Data quality expectations might not otherwise be met

Helmut & Howard – HEI QA approach:

- Site visits, data quality audits?
- **ACTION:** Helmut/Howard to elaborate at Asilomar

Jerry– DP/ME study Consent Form language:

- Compliance with good ethical research practices needs to be appropriate
- Discrepancies have been noted in consent form language
- Xong-Liang Xu (through interpreter): Consent forms are appropriate and are consistent with contemporary Chinese practice
- **ACTION:** Panels to review issue & Forms at Asilomar

Jerry – Compensation:

- Assurance of proper payment to individual, or applied to defray
- Paul noted issue of control selection raised in mid-year CC report
- Compensation sufficient to attract inappropriate control selection / participation
- Ellen: difficult to parse amount of compensation (neither too low nor too high) from “ease of selection” by coordinator
- Compliance with good ethical research practices needs to be appropriate
- **ACTION:** Panels to discuss compensation, Consent Forms and control selection with Otto at Asilomar

Jerry – Neoplasia classification:

- WHO (ICDO, 3rd ed) provides the most current diagnostic criteria
- Leukemic vs. solid mass presentation recognized as variants of same disease, not different diseases, for many B-cell lymphoid neoplasms
- Need to assure no inappropriate exclusion (e.g., of “leukemias” from cases of “NHL” of same cell type), no artificial ‘skewing’ of disease population
- Potential for unconscious bias by using convenient terms (eg, NHL)

Helmut – Distribution of classification criteria reference:

- Summary on classification & diagnosis suitable for distribution
- ICD-(O)-3 too voluminous
- Need a shorter, illustrated publication (IARC/WHO “blue book” on lymphoid & hematopoietic neoplasms?)
- **ACTION:** Jerry to locate a suitable summary-type document
- **ACTION:** Bruce to distribute electronically, or post to website