SOP-DA-001	**DESIGN & ANALYSIS WORKGROUP RECOMMENDATIONS**	Date Approved: 4/3/2002
Approved by: Steering Committee	Date Revised: 4/3/2002 Revised by:	Page 1 of 1

The following are recommendations from the Design & Analysis Workgroup to the Steering Committee for final approval:

1. The charter of the D&A Workgroup (last revised on 3/5/2002).

2. The membership of the D&A Workgroup should consist of clinical trial and scientific experts (to focus on science/design), biostatisticians (to focus on analysis/design), and CTP representatives (to focus on feasibility/addiction treatment practice).

3. Two representatives from the D&A Workgroup (a clinical/research expert and/or CTP member and/or biostatistician) will be on each protocol development team. The two D&A representatives on the protocol development team may overlap with the lead clinician and/or statistician of the same protocol.

4. A clinical/research expert, a CTP member, and a biostatistician from the D&A Workgroup will review each protocol and present their review to the rest of the D&A Workgroup for discussion. One D&A representative may serve two or even all three roles if competent to do so. However, the D&A representatives may not be on the development team of the same protocol they are reviewing.

5. The D&A Workgroup should not be viewed as an approval body. Instead, the written protocol reviews from the D&A Workgroup should be viewed as assisting LIs in the design and analysis of their protocols.

6. The D&A Workgroup should receive a copy of the PRB review comments for each of the protocols. This would be helpful towards subsequent protocol revisions and development.

7. Because of the overlap between the functions of the D&A Workgroup and DMAS-Stat, and the critical need for involvement of statisticians in the early protocol development phase, the D&A Workgroup recommends to combine the membership of the D&A Workgroup and DMAS-Stat. The new D&A Workgroup will maintain a subgroup of biostatisticians that will work closely with DMAS.