UAB Office of Research and Center for Clinical and Translational Science Data Coordinating Center Assessment Group (DCCAG)

Background

As a research intensive university, one of our missions is scholarship and advancement of knowledge. Participating in study management and data coordinating center activities which contribute to research and scholarship is consistent with our mission and goals. We are committed to excellence in all that we do, and as we undertake projects and programs, we are committed to having the appropriate resources necessary for those programs and the understanding of the corresponding responsibilities, including federal regulatory responsibilities when applicable. Recognizing that full assessment of such roles and responsibilities may benefit from experienced input from colleagues within the university, the Clinical Trials Administration Committee (CTAC) proposes that in the spirit of CCTS Panels and School-based grant review committees, a working subcommittee, reporting to CTAC and through CTAC to the Vice President for Research and Senior Vice President for Medicine, provide feedback on study management and data coordinating center proposals and teams prior to submission to OSP or IRB.

Charge

The DCCAG is charged with supporting and providing advice and recommendations to the Vice President for Research and the Senior Vice President for Medicine and School/College leadership. Matters this group may consider include:

- Advising Chairs and School leaders on the research and scholarship involved in Data Coordinating and Management activities, including the capacities of the proposed teams.
- Ensuring that research being conducted to support a regulatory application is intended to be conducted according to international guidance (e.g., International Conference on Harmonization Good Clinical Practices; ICH GCP), Federal guidance or law (e.g., Food and Drug Administration, Federal Policy for the Protection of Human Subjects ('Common Rule', 45 CFR 46), state law, and UAB policy, procedure and best-practice.
- Providing advice, guidance or recommendations for faculty who intend to hold or hold Investigational New Drug (IND, FDA 21 CFR 312) or Investigational Device Exemptions (IDE, FDA 21 CFR 812).
- Assisting in the determination of proposed roles in regulatory studies for UAB Principal Investigators (e.g., investigator, sponsor, sponsor-investigator) funded by federal, state, philanthropic, or industry-based sources.
- Assisting in the determination of the ability of an investigator/team to fulfill role-specific responsibilities as guided by regulations (FDA 21 CFR 312 or 812).
- Assuring that the sole project purpose or primary responsibilities do not compete with private industry.

Membership

The membership of the DCCAG will include the Senior Associate Vice President for Research (co-

chair), the Chair of the Clinical Trials Administration Committee (co-chair), representative(s) from UAB Office of Sponsored Programs, Research Regulatory Oversight, Office of Counsel, University Information Security and the Clinical Trials Administrative Office (CTAO).

Other attendees may include representatives from central administrative offices, school/department leadership (e.g., chairs, division directors), school/department investigator team leadership and any other individuals that the co-chairs deem necessary to conduct its business.

Meetings

The DCCAG will typically meet on an as-needed basis. Requests for DCCAG review can be directed to the Administrative Director of the CTAO or either co-chair. The agenda will be developed by the co-chairs in consultation with other members, faculty and administrators requesting DCC support. The DCCAG will provide its assessment within 10 business days of receipt of the pertinent materials. It will provide its recommendations through CTAC to the VPR and SVP for Medicine as well as to the project team and its leadership. Minutes will be documented from each meeting.

External Resources

Ethics Documents

Belmont Report
Declaration of Helsinki
Nuremburg Code

Regulations

45 CFR 46 (Federal Policy for the Protection of Human Subjects ('Common Rule'))
Title 21 CFR 11 (Electronic Records and Signature)
Title 21 CFR 50 (Protection of Human Subjects)
Title 21 CFR 50 (Financial Disclosures by Clinical Investigators)
Title 21 CFR 56 (Institutional Review Boards)
Title 21 CFR 312 (Investigational New Drug Application)
Title 21 CFR 314 (FDA Approval to Market a New Drug)
Title 21 CFR 600 (Biological Products)
Title 21 CFR 601 (Licensing)
Title 21 CFR 812 (Investigational Device Exemptions)
Title 21 CFR 814 (Premarket Approval of Medical Devices)