

NIMH CRADAs

Review and Approval Process

Initiation

- Principle Investigators (PIs) from both parties jointly develop a Research Plan (using NIH CRADA Subcommittee guidelines) and determine the resources needed to accomplish project goals. They then submit Appendix A (Research Plan) and Appendix B (Financial & Staffing Contributions of the Parties) to the NIMH Technology Development Coordinator (TDC).
- Collaborating party concurrently reviews CRADA boilerplate and contacts TDC with any questions or areas of negotiation. Proposed boilerplate amendments (after negotiated with the TDC) are attached as Appendix C.
- NIMH PI submits NIH/NIMH-specific papers (CRADA Clearance form, Conflict of Interest statement, resource impact memo, etc.) to TDC

Reviews

- NIMH IRP Technology Advisory Committee
- NIH CRADA Subcommittee (TDC submits negotiated package to the NIH CRADA Subcommittee for review)
- Subcommittee recommendations are discussed with the Collaborator, the CRADA is revised and resubmitted to OGC, OTT and the CRADA Subcommittee Chairman for signature.

Internal Approvals (Signature on NIH CRADA Clearance Form)

- Principle investigator, NIMH
- Lab/Branch Chief
- NIMH Technology Development Coordinator (TDC)
- Scientific Director, Intramural Research Program, NIMH
- Office of General Counsel (OGC)*
- NIH Office of Technology Transfer (OTT)*
- CRADA Subcommittee Chairperson*
- NIH Deputy Director for Intramural Research

*Reviews the CRADA in preparation for the CRADA Subcommittee meeting and approves any final changes made before final signature.

Signatures on the CRADA

- NIMH Director
- Collaborating Party (or Parties)