

CRADA CHECKLIST

For Your Convenience, check off:

CRADA Clearance form

- fill in everything (except CRADA #); put "N/A" or "0" when box is not applicable
- make sure that the person-year box totals match what is said in Appendix B
- \$ box refers *only* to money actually transferred to NIH

Appendix A* (Research Plan)

- Research Plan must spell out clearly the intellectual, as well as material contributions of the other party(ies).
- Research Plan scope must be specific and narrowly defined. Specific drugs being tested, disease states, etc. must be listed if they are to be considered part of the CRADA research (you cannot just say "a variety of drugs" or "various diseases"). Basic research and clinical trials using the

CRADAs

involving patient care call for additional boilerplate language).

- Assure that Appendix A has followed exactly the format found in the "Supplement to Appendix A" guidelines (include a listing of all CRADAs, related MTAs, patent applications, etc.)
- Number the pages of Appendix A

Appendix B

- Using the template (sample Appendix B) supplied by this office, list all financial and staffing contributions to which the parties have agreed; list NIMH and each collaborator separately.
- List types of positions (rather than names of staff) and provide the % of time each will work on the CRADA project. Give a \$ estimate of the total salaries based on the % of time spent on the CRADA research.

- Please note any provision of travel being paid by the collaborator. The possibility of travel should be addressed even if the collaborator does not think at this time that such travel will take place because it is very difficult to obtain permission for sponsored CRADA travel if it is not expressly stated in Appendix B. (Appendix B can list it as an option requiring company permission.)

Appendix C*

- Collaborator should type any modifications to the legal boilerplate onto this page in a format which shows all deletions and insertions)

Cover sheets

- Fill in front cover page and the cover to Appendix A

Signature page

- Fill in addresses for notices

Miscellaneous

- Assure that the company sends appropriate documentation relating to **animal assurance or human subjects** information
- NIMH Principal Investigator must fill out **conflict of interest form**
- Impact of Resources memo** to Scientific Director (signed by Lab/Branch Chief)
- Put date of appropriate **CRADA Subcommittee meeting** on your calendar for presenting your CRADA to the Subcommittee

* If possible, please provide a **WORD disk** when the **final** draft is submitted to this office.