

## Applying for an Exemption?

Please include the following information and send to the address at the bottom of this page:

- Principal Investigator:
  - Name
  - Department
  - Campus Mailing Address
  - Current DEA and/or MNBP registration, if any
  - Qualifications, including a curriculum vitae
  - Names and Departments of any co-investigators
  
- Research Project:
  - Title
  - Statement of the purpose
  - Name of the controlled substances involved and the amount of each needed
  - Description of research to be conducted, including the number and species of research subjects, the dose to be administered, the route and the method of administration, and the duration of the project
  - Location where the research will be conducted
  - Statement of security provisions for storing the controlled substances (in accordance with 21 CFR §1301.75) and procedures to prevent diversion
  - If the investigator desires to manufacture or import any controlled substances used in this project, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported
  
- Authority
  - Signature of Department Head (In the event that a Department Head is the PI, please obtain the signature of the Dean.)
  - Approval documentation from Research Subjects Protection Programs (IRB and IACUC) if human or animal subjects will be used in the project
  - Investigational New Drug number, if applicable
  - Funding information, including grant number, if applicable
  
- Changes in approved protocol (see 21 CFR §1301.18 (c) and (d))
  - MUST be approved by the DEA, IRB or IACUC (if applicable) BEFORE changes are implemented
  - Send copy of correspondence to and from the DEA, IRB and/or IACUC to the Department of Environmental Health and Safety

NOTE: If you plan to perform a human study involving a Schedule I controlled substance, please note the specific information required in the regulations (21 CFR §1301.18 (b)). Please call the Office of Regulatory Affairs (612-624-2431) with any questions.

*Environmental Health and Safety  
Boynton Health Service  
410 Church Street, W-137  
Minneapolis, MN 55455*

Requests for an exemption must be reviewed and approved by the Dept of Environmental Health and Safety and the Office of Regulatory Affairs. A letter from the Office of Regulatory Affairs will be sent, indicating the approval or denial of the exemption request.