

CHECKLIST FOR PROTOCOL SUBMISSION TO GCRC ADVISORY COMMITTEE

Please e-mail to Amy Hartkemeyer at amy.hartkemeyer@cchmc.org
1 Electronic Copy and provide one hard copy of the following:

- ❑ Abstract* (or Summary of the Study) **No longer than 1 page, please*
- ❑ Protocol Submission Form
- ❑ Protocol
- ❑ Consent Form(s)
- ❑ Human Subjects Addendum, including Data and Safety Monitoring Plan (DSMP). If your study has a Data and Safety Monitoring Board (DSMB), please furnish a copy of the charter.
- ❑ If applicable, Research Plan from grant application (helps to answer questions) **or:** Investigator Brochure and/or company protocol for industry studies

Please send or bring to Amy Hartkemeyer, CRC/A3S, Room A3-300 (MLC 5006), Cincinnati Children's Hospital (U.C. ML 0054):
1 Hard Copy:

- ❑ IRB approval form (**Can be submitted pending IRB approval, but copy of approval notification must be sent to Andrea Smith when received**)
- ❑ Other pertinent committee approvals, i.e., Radiation Safety Committee
- ❑ Any other material that you feel is necessary to facilitate scientific review (i.e., correspondence with IRB, etc.)
- ❑ Grant or industry budget and budget justification pages for any projects that do have or will potentially have grant or industry support
- for Dr. Heubi (**will be held confidential**)

All of these elements are essential for adequate review. Please contact Amy Hartkemeyer (phone 636-4273; fax 636-4695; e-mail: amy.hartkemeyer@cchmc.org) if you have any questions.