The University of Louisville IRB requests that copies of federal grant applications be submitted with IRB protocols. The following questions and answers are provided to explain this requirement.

Why is the IRB requiring that a copy of the grant be submitted?
Department of Health and Human Services (DHHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board.

What portion of the grant must be submitted?
Investigators must submit a copy of the entire proposal (exclusive of appendices). If a grant is linked to multiple IRB protocols then the IRB needs to know which protocols so that they can all be reviewed. Only one copy of the grant proposal is required in the IRB office. The IRB cannot review a protocol unless the entire grant application has been submitted.

What exactly is the IRB looking for?
The grant proposal must be found to be consistent with information related to the protection of human subjects. Examples include information about (i) the number and qualifications of collaborating investigators and other members of the research team; (ii) cooperating institutions or performance sites that may require separate or additional IRB review or an Assurance of Compliance; (iii) characteristics of proposed research facilities that may affect subject safety or the confidentiality of data; (iv) the feasibility of financial commitments made to subjects; and (v) the cost of proposed subject protection measures, such as consent monitors or translators.

What will happen if the research protocol is found to be inconsistent with the proposal?
The IRB protocol must be consistent with the grant proposal. Any discrepancies will require the PI to either amend the current protocol or to submit a new protocol that is consistent with the grant application. If the IRB and PI are unable to reconcile these differences, then the Office of Grants Management will be contacted regarding this discrepancy.

What if my grant is not from a federal agency?
The IRB protocol for any grant funded study must be consistent with the grant proposal. The IRB may request a copy of your non-federal grant to ensure consistency between the grant proposal and IRB protocol. The principal investigator is responsible for ensuring that the IRB protocol matches the non-federal grant proposal.