PI CHECKLIST FOR SUBMITTING A RESEARCH APPLICATION

☐ **Initial Submission Includes:**
  - ✓ IRB Initial Application Consent form (if consenting subjects)
  - ✓ HIPPA and NOPP form (if consenting subjects)
  - ✓ HIPAA Waiver form (i.e. chart review studies)
  - ✓ Research Proposal Outline/Protocol
  - ✓ CITI Course Certificate(s) for all investigators on the study protocol
  - ✓ Copy of Grant (for grant funded study)

☐ **Determine the <u>Review Category</u> of your project** (*the final determination will be made by the IRB; see Attachment A, Section I for instructions and Attachment B, pages 1 and 3 for citations*).

☐ **Write your Proposal.**

☐ **Fill out the <u>Initial Application</u> form and obtain the following signatures:** Principal Investigator, Co-Investigators, study staff, Lab Director, Dr. Gans (KIR personnel on the project) and Dr. DeLuca (KF personnel on the project)

☐ **If your project falls under either the Full Board or Expedited category, prepare a <u>Consent Form</u>.** *See Attachment A, Section II.A.4 for instructions and Attachment B, pages 5-7, for federal regulations pertaining to informed consent.*

☐ **Research Review Committee (RRC) –** Unfunded study protocols will be reviewed by this committee. Provide comments from a researcher other than the mentor.

☐ **MRI Study Protocols –** Requires MRI Committee to review prior to the RRC and IRB

☐ **For Expedited and Full Review protocols** submit your application to the IRB (see forms for number of copies)

☐ **Submit hard and electronic copy of your entire application via email** Microsoft Word format; submit your application to the IRB (see forms for number of copies)

☐ **Read carefully the document describing <u>Responsibilities of Investigators</u> and retain a copy for your files** (see Attachment C).

☐ **The PI is <u>required</u> to attend the Research Review Committee and IRB meetings at which your protocol is to be reviewed.** You may appoint a co-investigator to represent you.

☐ **<u>Collaborative Institutional Training Initiative (CITI)</u>** All members of the study team are required to submit certification. **CITI Course:** www.citiprogram.org

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