

This internship will take place with the LCCC Clinical Development Team where the intern will get to learn about development of clinical protocols, consent forms and investigational new drug (IND) applications. The intern will write an initial consent form, write an administrative letter(s), review protocols/protocol amendments, and review IND applications of investigational products from UNC, new treatments given by external pharmaceutical companies, and CAR-T cell therapies. The intern will get to participate in review meetings of protocols and/or consent forms as opportunities present including the Patient Advocacy for Research Council, Protocol Review Committee, and Protocol Review Meetings with the operational study team. The intern will also get to work on completing an initial IRB application. There will be several opportunities for the intern to attend lectures on clinical trial development, sponsor responsibilities, INDs, and clinical operations. In addition, the Intern will learn about medical writing/ regulatory writing strategies to ensure compliance of sponsor trials submitted to the FDA.