When Will My New IRB Application Be Approved?

Common Reasons for Delay in the Review and Approval of New Research Proposals

1. **Consent Form Issues.**
   a. Use the most recent IRB consent form template.
   b. Language must be clear and understandable. Define technical terms. Organize procedure descriptions in a chronological manner and combine redundant information when possible
   c. Include short title and local consent version dates in the footer of the consent so that you can easily determine when the consent form was written and revised
   d. Upload consent forms in Word, not as PDFs so that the reviewers can provide specific edits

2. **Missing Documents.**
   a. Use the Application Checklist found in IRBNet to ensure that all of the required forms are completed and uploaded. Commonly missed documents are the research plan/protocol, CV, and appendices for consent waivers and vulnerable subjects. Call the IRB Office if you are not sure which documents apply to your study.
   b. Do not save blank IRB forms/templates on your computer. Always download forms from IRBNet to ensure that you are using the most recent version.
   c. Answer all questions on the application forms
   d. When providing the lay summary in Application Part 2 use non-technical language that could be understood by a non-scientist
   e. Studies presenting greater than minimal risk must have an adequate Data and Subject Safety Monitoring Plan. See Section VI of the application for guidance.
   f. PI must submit a HIPAA Security Assurance annually

3. **Missing Signatures.** The PI and the Department Chair must sign the application package before the application will be processed for review

4. **Missing Training Dates.** All personnel listed in Research Application part 1 must have completed Human Subject Protection training through CITIProgram within the past 3 years. And all must complete HIPAA for research training annually.

5. **Failure to address ALL modifications requested by the IRB.**
   a. If your application is undergoing review by the full board you may receive a list of questions and recommendations prior to the meeting. Responding to these comments in a timely manner before the meeting can significantly increase the efficiency of the review process
   b. After your application has been reviewed you will receive a list of modifications required. Be sure to address each of the noted items completely. Failure to address each item will result in a further delay of approval

For further assistance please contact IRB Support Staff within the Research Protection Office (RPO)
Janice Muratori, Director 444-6897 Candy Frater, Manager 444-5808 Alexandra Boutros, Manager 444-6646
Alli Jean (RIH-1) 444-0354 Leann Snead (RIH-2) 444-2032 Adrienne McParlin (TMH) 444-3527,

Or contact the Research Compliance Program Manager, Jacqui Poore 444-5843

Tips for Preparing Retrospective Chart Review applications

1. Complete Research Application Part II for CHART REVIEWS. Often the wrong version of the application form is often attached.
2. Record review period (date range) must be prior to the date of submission to the IRB
3. Enter dates in mm/dd/yyyy format and make sure they are consistent across all documents (research app 2, the protocol, and the HIPAA docs).
4. If there is a possibility that the research could include deceased records, submit a decedent data form
5. Include a version date in the footer of the Protocol (electronic version date is not sufficient)
6. Include a data collection form (in word or excel with a list of the data fields to be collected
7. Personnel (including the PI) who are not employed by Lifespan who review PHI for research must include a memo stating that they will maintain an accounting of disclosures. (Note: affiliate-practice personnel are not considered to be part of the Lifespan workforce)
8. If you submit a prep to research for a chart review, you don't need to submit Appendix 2 (Alteration of consent) with section b completed.