IRB Recommendations

Below is the list of common mistakes investigators make when coming to the IRB. The list is written as "positive" tips for researchers, rather than focusing on "mistakes"

1. Talk to the IRB Coordinator.

    a. Are you applying to the right IRB?
    b. Does your study qualify as research?
    c. Which forms (s) do you need to complete?
    d. What are the deadlines for submission?
    e. How long will it take to get a response from the IRB?
    f. What other requirements does the IRB have (e.g. training for investigators, # copies to be submitted, conflict of interest, ..)

2. Complete IRB application forms.

    a. Answer every question fully.
    b. Follow directions.
    c. No handwritten documents.
    d. Append to the application form (s):
        1. final protocol
        2. data collection instruments
        3. surveys/questionnaires
        4. recruitment materials
        5. other pertinent information

    e. Justify the sample size – statistical power analysis

3. Create an informed consent (and assent) document.

    a. Write in language understandable to the subject (6^{th} grade level).
    b. Follow your institution's template language.
    c. Include timeline for procedures – duration of each visit, total duration of study.
    d. Use proper grammar.
    e. Information should match the protocol.
    f. Include local phone number for subjects to call with questions.

g. Address HIPAA authorization requirements – either in this document or separately.

4. Complete your training in protection on human subjects (as per your institution).

5. Submit materials to IRB on time.

   a. Submission after a deadline delays review of your project.
   b. Respond to IRB request for information promptly.

6. Don't start the study until you have an IRB-approval letter in hand!

7. After IRB approval, remember to:

   a. Conduct study according to approval protocol and IRB conditions.
   b. Get prior IRB approval for changes / amendments.
   c. Apply for re-approval before your study's approval expires.
   d. Tell the IRB when the study is completed.
   e. Retain records according to federal & state regulations, including those for HIPAA and special regulations for children.

From the IRB Forum: http://www.irbforum.org/