Literature Search Guidelines

Ideally, a PI should always be well informed of the literature relating to his/her particular field of study and should be conducting reviews of the available literature on a regular basis. The need for a literature search is to assess the risk level and alternatives to participation of each study was given additional emphasis following the federally-imposed halt on research at Johns Hopkins University. A volunteer on a Hopkins research study died after being exposed to a drug for which the government determined that risk information had not been adequately researched.

Consequently, the federal agencies governing research have heightened their emphasis on the need for a thorough review of available applicable literature both before research is started and as an ongoing process throughout the research. The University of Chicago BSD IRB therefore requires that a literature search be conducted and the results presented to the IRB at the time of original submission as well as at each continuing review (renewal).

PIs should search on one or more web-based search engines for articles relating to 1) the condition being studied and 2) the specific drug/device/process being studied. For example, for studies of a new drug for IBD, PIs should not only search for articles on the risk of that drug, but should also search for articles on new treatments for IBD that would present available alternatives to study procedures. The Committee is also concerned with the applicability of the proposed research; that is, if a literature search reveals that the study being proposed replicates studies that have already been completed with definite results, the PI should consider whether his or her study is likely to yield new information and if not, if the study should be performed.

While the IRB has faith that investigators are responsibly conducting research, the IRB does not accept merely a statement that a literature search has been performed. The Committee requests that PIs provide the IRB with the name of the search engine that is used, the search strategy (keywords), and the results of the search, along with a description of the results’ impact on the risk level and/or alternatives to participation of the research.

Example of an acceptable literature search for a renewal:

SEARCH ENGINE: PubMed
SEARCH TERMS: Drug Name (generic), Drug Name (brand), Disorder Name
RESULTS: 1200 articles.
SUMMARY: Most of the articles were not applicable to the study at hand as they dealt with the risks of or descriptions of standard of care drugs for this disorder. Searching on the drug itself yielded only a few results having to do with animal studies; these are already covered in the investigator’s brochure. One article, “DRUG XYZ in Disease Y”
by A. Jones, indicated a possible new alternative therapy, but this is still in Phase I
development. Overall, there is nothing in the literature to indicate any new information
on the risks or benefits of this study. Risks found in the literature are already covered in
the protocol and consent form for this project.

If your study is still enrolling subjects OR if enrollment is closed, but subjects are still
actively participating in study procedures or receiving study drug, then a literature review
should be submitted.

If your study is permanently closed to enrollment and all subjects have completed all
research-related interventions, then a literature review is not required. However, the IRB
does require that you provide a justification for not providing a literature search. (“Not
applicable” is not considered a sufficient justification. Please explain why a search is not
applicable.)