

## WHY WOULD ANYONE CHANGE IRBS IN THE MIDDLE OF A STUDY?

A decision to change IRBs is never taken lightly. Although Congress and FDA have expressed concern about IRB shopping, there are indeed valid reasons to transfer. The most common reason is the demise of the first IRB as when an institution disbands it's board.

## WHAT REVIEW ISSUES ARE PERTINENT TO TRANSFERRING A STUDY?

Subject protection considerations. Will there need to be any downtime during the transfer? If so, what is to be done to assist subjects who are already enrolled?

Communication. The new IRB will need to be brought up to speed quickly and efficiently. Little time can be spent in becoming acquainted with each other.

Consent forms. The board will make an effort to keep changes to the minimum to be both compliant and communicative especially if enrollment is under way. We do require consent documents to be simple, clear and complete.

Training. IRC requires that all investigators complete CITIPProgram.org training or provide certification for an equivalent course within the past three years. If this was not previously required, investigators should start immediately.

Forms. IRC forms must be used for study-related information. For investigator specific forms, although we prefer use of our own forms as we are familiar with them, we will also accept forms from an AAHRPP accredited IRB.

Combining initial and continuing review. Although the study is new to the new IRB and requires an initial review, it is no longer only prospective. The study is active and is generating experience and information beyond what was available for initial review. The person in charge of transferring the study should provide a summary of that information (SAEs, enrollment, problems, etc). in a manner generally expected in a continuing review.

## SUBMISSION

Talk to one of our IRB administrators to discuss timing possibilities and submission requirements. It is wise to e-mail the consent form to the administrator to get an idea of whether revision might be needed beyond replacing the old IRB's name. Our IRB Administrator will guide you through the process.

The study.

Complete the initial review cover form and any required supplements and a sponsor transfer request form. Provide a cover letter telling the board 1) why the transfer is requested, 2) the status of the on-going study, and 3) any important new information not contained in the protocol. Submit all the study documents currently in use.

Investigators:

Submit at least one investigator package (form 4.20, CV, license, etc). If the board finds the information to be sufficient, it may determine that other investigators may be added using the expedited review process.

## SPEED

Transfers often need to happen quickly. IRC will make every effort to move expeditiously on these studies.

## PRICE

Standard pricing applies. (The fee schedule is posted on the IRC website.) Should an emergency meeting be requested, all charges will be 150% of standard.

