I. STATEMENT OF PRACTICE

When watermarking consent documents and recruitment materials, the watermark “Approval Date” is assigned in accordance with the date that the application was either “Approved” or “Approved with Contingencies.” This determination may be made by the Board or by an Expedited Reviewer.

A. For new applications that are approved with contingencies, study activities may not begin until all outstanding contingencies have been met and verified with the IRBMED. At that time, consent documents and recruitment materials will be watermarked (when possible) with the “Approved with Contingencies” date.

B. For Scheduled Continuing Review or Amendment applications approved with contingencies, study team members should continue utilizing the most recently approved consent documents and recruitment materials until all contingencies are cleared and new/updated documents and materials are issued under “Approved Documents.” At that time, consent documents and recruitment materials will be watermarked (when possible) with the “Approved with Contingencies” date.