

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Informed Consent process	Date Effective 9-16-04	Supercedes P&P dated

Review and Approval of Consent Forms

Consent forms must be approved and stamped by CHR before being used in the consent process. The only exception concerns sample consent forms developed by study coordinating centers or data management centers when CHR agrees that final approval of the forms used at the study sites should be given by the local IRB(s).

When CHR is the only IRB for a study, its approval is indicated by a stamp on the form(s). The stamp confirms that the forms can be used in the consent process.

When other IRBs are involved, CHR and the other IRB(s) must approve the form(s) that will be used in the consent process. This usually involves initial review and approval by CHR. The consent form is then stamped by CHR and sent to the local IRB(s) for review. If the local IRB requests substantive revisions, these must also be agreed by CHR. After CHR and the local IRB(s) agree, the revised form(s) are stamped by CHR and can be used in the consent process.

When other IRBs are involved and consent will not be obtained in English, the process is similar to that above. In addition, however, the investigators must arrange for translation of the form(s) into the relevant language by someone not on the study team. This may be done before or after review by the local IRB. If revisions are requested by the local IRB and agreed by CHR, a final translation of the revised form is required. A [Certificate of Translation](#) must be provided to CHR by the translator to attest to the accuracy of the final translation. CHR may, if it wishes, obtain a back translation of the local language forms to confirm their accuracy. When CHR is satisfied, it stamps the local language form(s) to indicate they may be used in the consent process.