

Responsibility Reminder

2010

INFORMED CONSENT PROCESS

Compass IRB expects Informed Consent to be presented to all subjects by the Principal Investigator or a qualified member of his/her staff. The subject will have adequate time in a private environment to read, review and consider the Informed Consent. The Principal Investigator and/or member of his/her staff will be available to answer any questions or concerns subjects have regarding their participation in the study. Compass IRB also expects that all subjects will be given as much time as they feel is needed to make a decision to participate in this study.

When Compass IRB reviews your Initial Review Application, the Board will be looking for a detailed explanation of the Principal investigator's consent process (whether it is entered into the application or a copy of your site's formal process or SOP is attached). In this statement or process, the Board will expect you to include the person who will conduct the consent discussion, the person who will be expected to grant permission or consent, any waiting period between informing the potential subject and obtaining consent, steps taken to minimize the possibility of coercion or undue influence, the language to be used by those obtaining consent, the language understood by the prospective subject or legally authorized representative and the information to be communicated to the prospective subject or the legally authorized representative.

In the event that your site intends to enroll non-English speaking patients, the submitted consent process should also include whether or not you have a member of your staff that speak the other language and if not, how it will be ensured that the non-English speaking subject will be able to communicate with the study staff throughout the course of the study.

Compass IRB, LLC

5416 East Baseline Road
Suite 120
Mesa, AZ 85206

Phone: 877-660-11RB
Direct: 480-832-7373
Fax: 480-832-7376

E-mail: info@compassirb.com
www.compassirb.com

For your reference

Additional information on informed consent process can be located in the FDA Information Sheet: A Guide to Informed Consent <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

If you have additional questions, please visit our FAQ section at www.compassirb.com or feel free to contact us directly.