

The IRB Approval Letter

Letter Issuance Date
Date letter written & sent - Notification date

January 1, 2001

RECRUITMENT DEMOGRAPHICS
The IRB will ask about distribution of risk during Continuing Review

Approval Date
The date IRB approval officially starts.

EXPIRATION DATE
The date IRB approval expires. IRB approval can be a maximum of 1 year.

John Doe, M.D.
123 Elm Street
Anytown, USA 123456

Randomized, Controlled Study of the Elements of an IRB Approval Letter

Doe,

The IRB meeting December 31, 2001, the members voted to approve this study, and your position as a principal investigator, for a period of one year.

PROTOCOL and CONSENT VERSIONS
The documents approved by the IRB are identified by their version and/or date.

Action type & approval number	Full Board 12/31/01	01255-01
The sponsor of the study is	IRB Documents, Inc.	
Expiration date for this study is	Data on gender and ethnic recruitment will be requested	12/31/05
Your principal investigator number		1234-001
The protocol version and/or date	Version 1.4	12/1/05
Consent form ID and/or date	Version 1.2	12/31/05
Advertising & recruitment materials	Recruitment letter	12/20/05
	Waiting room flyer	12/20/05
Other study documents ID and/or date	Subject questionnaire	9/1/05
	Subject diaries	9/1/05
	Number of subjects approved for your site is	400

CONDITIONS OF APPROVAL
These must be done, or the IRB's approval may be suspended.

There are five conditions attached to all approval letters:

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (PIs and sponsors are responsible for initiating Continuing Review proceedings. See IRC's web site at www.irb-irc.net or call us for more details.)
2. All unanticipated or serious adverse events must be reported to the IRB within 5 days.
3. All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk. This includes any change of investigator, or site address.
4. All protocol deviations must be reported to the IRB within 5 working days.
5. All recruitment materials and methods must be approved by the IRB prior to being used.

See Explanations of the Elements of the IRB Approval Letter Below

Elements of the IRB Approval Letter

1. Expiration Date - This date shows when the IRB's approval will expire. If any study activity will continue after this date, the sponsor and investigator(s) are responsible for initiation of Continuing Review proceedings.
2. Protocol and Consent Versions - The approval letter lists the major documents that have been approved by the IRB. These documents may have been changed by the IRB, so please make sure you have read, and are using, the approved versions.

IRC does not "stamp" approval letters, consent forms, or study documents unless requested. The approval letter clearly shows all the study documents approved by the IRB, as well as other elements and conditions of approval. The format can be changed to suit the needs of clients; however, this should be requested before the letter is issued.

3. Recruitment Demographics - The IRB will ask for information showing the distribution of enrollment. This is in accord with the Belmont Report's principle of Justice. Numbers will be asked for at Continuing Review.
4. Number of Subjects - The maximum allowable number of subjects to be enrolled at each site. Any increase in this number must be approved by the IRB first.
5. Conditions of Approval - There are five conditions attached to all approval letters:
 - a. **No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (PIs and sponsors are responsible for initiating Continuing Review proceedings. See IRC's web site at www.irb-irc.net or call us for more details.)**

This means that nothing can be done with subjects until after the date on the IRB approval letter, and before the expiration date.
 - b. **All unanticipated or serious adverse events must be reported to the IRB within 5 days.**

This means within 5 working days. See IRC's Guide regarding adverse events for more information. ([Guide 3.3.03](#)).
 - c. **All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk. This includes any change of investigator, or site address.**

Call us first (whenever possible) before making prospective changes to the study procedures. If you know anything will change, the IRB should also know. Use IRC Form 4-32. [Go to forms page](#).
 - d. **All protocol deviations must be reported to the IRB within 5 working days.**

For those inadvertent times when something was done differently, the IRB should be notified. Use IRC Form 4-33. [Go to forms page](#).
 - e. **All recruitment materials and methods must be approved by the IRB prior to being used.**

These would be considered modifications. Submit to the IRB by using IRC Form 4-32. [Go to forms page](#).

IRC reserves the right to change the layout and contents of its approval letter template.

