



University of California  
San Francisco

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## Protocol Enrollment Exception Request

### Enrollment Exception

To allow enrollment of a single individual who does not meet the entry criteria of your study, you may submit a request for a one-time enrollment exception to the IRB. This protocol enrollment exception request applies only to a single individual. Approval from the IRB is required **prior** to enrollment.

The request should be rare and justified in terms of serving the best interests of the potential study participant. Changes of entry criteria for more than one individual should be submitted as a regular modification.

#### Example

A potential study participant meets all study entry criteria with the exception that inclusion criteria specify that participants must have an MRI within 14 days prior to enrollment ? the potential participant?s most recent MRI is 18 days prior to enrollment. A one-time exception may be granted because the change does not significantly affect the welfare of the participant or the protocol design.

#### What to submit for enrollment exceptions

- Submit a Protocol Enrollment Exception Request Form via iRIS
  - Include approval from the study sponsor or PI if there is no sponsor (see below)
  - Make sure each question is completed with thoughtful responses
  - If enrollment in this study poses new risks not currently listed in the approved

- consent form, or increases the likelihood or severity of experiencing the known risks, you must include an addendum consent form <sup>[1]</sup> with the submission
- Send an email to [irb@ucsf.edu](mailto:irb@ucsf.edu) <sup>[2]</sup> with the study number and ?Protocol Enrollment Exception Request? in the title

## Sponsor review required

Changes in entry criteria also require approval from the study sponsor or cooperative group. Approval from the study sponsor is required and must be uploaded within the Protocol Enrollment Exception Request Form. If there is no study sponsor, confirmation from the PI must be provided.

## Review process

An IRB Chair or Vice Chair can approve the request if it constitutes a minor change to the study. The Chair or Vice Chair may decide that the change requires a higher level of review, and additional documentation may be requested.

## Data collection

Data collection should be reported using the standard study case report forms and become part of the scientific evaluation of the test article.

## Need Help?

For step by step guidance on how to fill out the form, refer to the ?Protocol Enrollment Exception Request Form? Quick Guide at <https://iris-help.ucsf.edu/irb-iris> <sup>[3]</sup>.

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**Source URL:** <http://irb.ucsf.edu/protocol-enrollment-exception-request>

## Links

[1]

<http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/peer%20consent%20form%20addendum%20jan%202018.docx>

[2] <mailto:irb@ucsf.edu>

[3] <https://iris-help.ucsf.edu/irb-iris>