

How does the IRB review exception requests?

Rush exception requests received via email are assigned for immediate processing.

For exception requests that are not time-sensitive, IRB review and screening of the submission will occur in alignment with standard IRB processing. Upon receipt of an exception request, the action will be assigned to the appropriate IRB administrator and for screening and an assessment of the level of IRB review required.

The level of review required for exception requests (expedited or convened) is dependent upon the following factors:

- The time sensitivity of the request;
- The level of risk involved in both the study itself and the planned alteration;
- Whether the exception request is thought to be in the best interest of the subject;
- Whether the exception request holds out the prospect of direct benefit to the subject;
- Whether the risk/benefit ratio specifically related to the exception request is favorable;
- Submission of revised consent or addendum to the consent; and
- Plans to modify the protocol permanently.

Expedited Review: Exceptions with potential safety implications require review by an IRB Chair or appropriate IRB physician scientist member. The following exceptions are eligible for expedited review:

- Exception requests where the planned exception poses no more than minimal risk to the subject;
- Exception requests where the planned exception may pose greater than minimal risk to the subject, but the request is time sensitive and:
 1. The exception is in the best interest of the subject and/or the prospect of direct benefit exists; and
 2. The risk/benefit ratio for the proposed exception request is favorable.

Convened Review: Exception requests will be reviewed by a full committee at the next planned meeting when they may pose greater than minimal risk to the subject and any of the following apply:

1. It is unclear whether the exception is in the subject's best interest or whether there is the prospect of direct benefit to the subject;
2. It is unclear whether the risk/benefit ratio is favorable; or
3. The request is not time sensitive and there is sufficient time to allow convened IRB review to occur.