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This attachment summarizes the current process for submitting waiver requests and appeals, including required information. The information below is publicly available (https://clinicaltrials.gov/policy/faq#faq_waiver_3 and https://clinicaltrials.gov/policy/faq#faq_waiver_4).

What is the process to submit a request to waive clinical trial results information submission requirements?

The responsible party must submit a waiver request via email to register@clinicaltrials.gov. The subject line of the electronic message should read "Waiver Request: NCTxxxxxxx." For example, for NCT98765432, the subject line would read "Waiver Request: NCT98765432."

Each waiver request must include the following information, as specified at [42 CFR §11.54\(a\)\(2\)](#):

- (1) NCT number, Brief Title, and Name of the Sponsor of the applicable clinical trial for which the waiver is requested;
- (2) the specific clinical trial results information requirement(s) of [42 CFR Part 11, Subpart C](#), for which the waiver is being requested;
- (3) a description of the extraordinary circumstances that the responsible party believes would justify the need for a waiver; and
- (4) an explanation of why granting the waiver request would be consistent with protecting public health or in the interest of national security.

Additionally, a copy of the ClinicalTrials.gov registration receipt for the relevant record (NCTxxxxxxx) must be attached to the email as a PDF file. Instructions for downloading a PDF receipt are available in the [PRS User's Guide](#).

An electronic notification will be provided to the responsible party communicating the determination of whether the waiver request is granted or denied.

For additional information, see also:

- FAQ: [How do I determine who is the responsible party for a study?](#)
- OMB No. 0925-0586, Expiration Date: XX/XX/XXXX, [Burden Statement](#)

What is the process to submit an appeal after a request to waive clinical trial results information submission requirements has been denied?

As specified in [42 CFR § 11.54\(b\)](#), responsible parties may appeal a denied waiver request. The appeal must be submitted no later than 30 calendar days after the date that the electronic notification was sent to the responsible party indicating that the waiver request had been denied.

To submit an appeal, responsible parties must respond via email to the electronic notification and include the original waiver request. In the appeal, responsible parties are expected to elaborate or clarify factors that justify why the initial waiver denial should be overturned with sufficient detail to allow for evaluation.

An electronic notification will be provided to the responsible party communicating the determination of whether the appeal is granted or denied.