

PROTECT Jan 11, 2024 Release Notes

'Internal Server Error' on Scientific Review form Documents page has been resolved
Users were experiencing an 'Internal Server Error' when clicking Finish on the Documents page of the Scientific Review form for External studies. This has been fixed.

Some fields have been marked as required in the SmartForms
Several fields in the SmartForms have been marked as required now:

7. * Total Accrual Ceiling (at all NIH sites):

23

Add Tech Transfer Agreement

1. * Type of agreement:

CRADA

CTA

[Clear](#)

2. * Name of partner:

3. * Are you receiving funding from this partner?

Yes No [Clear](#)

Add IDE and HDE Information

1. * IDE or HDE number:

2. * Who holds the IDE or HDE?

Sponsor

Investigator

Other

[Clear](#)

3. * If "Other," identify the IDE holder:

4. * FDA Division:

CBER

CDER

CDRH

[Clear](#)

Add IDE and HDE Information

1. * IDE or HDE number:

2. * Who holds the IDE or HDE?

Sponsor

Investigator

Other

[Clear](#)

3. * Who is the sponsor of the IDE?

4. * FDA Division:

CBER

CDER

CDRH

[Clear](#)

Add IND Information

1. * IND number:

2. * Who holds the IND?
 Sponsor
 Investigator
 Other
[Clear](#)

3. * If "Other," identify the IND holder:

4. * FDA Division:
 CBER
 CDER
[Clear](#)

Add IND Information

1. * IND number:

2. * Who holds the IND?
 Sponsor
 Investigator
 Other
[Clear](#)

3. * Who is the sponsor of the IND?

4. * FDA Division:
 CBER
 CDER
[Clear](#)

Scientific Merit score no longer marked as 'required'

On the Scientific Review workspace > Submit Committee Review activity, the Scientific Review score is no longer marked as required.

6. Scientific Merit Assessment Score:

1
 2
 3
 4
 5
 6
 7
 8
 9
 10
[Clear](#)

New question added to the Reportable New Information (RNI) form

To accommodate the new policy for enrollment of non-English speaking research participants, a new Short Form Use check box has been added to the following question on the RNI form:

outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects, or others (which may include research staff, family members or other individuals not directly participating in the research) at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or expected

Short Form Use: Use of the short form consent to enroll a non-English speaking subject.

Audit: Audit, inspection, or inquiry by a federal agency.

Confidentiality: Breach of confidentiality.

Unreviewed change: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

Incarceration: Incarceration of a subject in a study not approved by the IRB to involve prisoners.

Suspension: Premature suspension or termination of the research by the sponsor, investigator, or institution.