



# REDCap Feasibility Form for Protocol Amendments User Manual

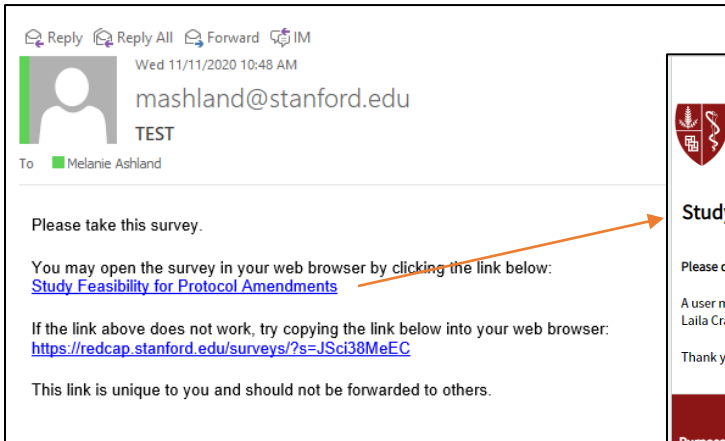
This document details how to complete the study Feasibility Form for Protocol Amendments in REDCap. Similar to CCTO’s Intake submission format, this questionnaire will allow users to return to the Feasibility Form at different times for multiple sessions in order to complete all required fields for submission. Once submitted, a pdf of submission can either be downloaded or emailed to the submitter, which can then be sent to the designated reviewer (e.g. CRG manager) who should then review the submitted feasibility form within REDCap and sign-off on the study.

Managers, please see the manager’s version of this document for further details on how to review and sign-off on submissions for Protocol Amendments (RedCap Feasibility\_Manager's User Manual v4.0).

## DO NOT ENTER PHI IN THIS DATABASE

### 1. Navigate to the Feasibility Form:

- I. You will receive an email from your Manager with a link to the Feasibility Form for Protocol Amendments.



**Study Feasibility for Protocol Amendments**

Please complete the Study Feasibility for Protocol Amendments form below.

A user manual is available directly below for assistance with filling out this form. For any issues or technical difficulty, please email Laila Craveiro ([craveiro@stanford.edu](mailto:craveiro@stanford.edu)) or Melanie Ashland ([mashland@stanford.edu](mailto:mashland@stanford.edu)).

Thank you!

**Purpose of Clinical Research Trial Feasibility Review:**

1. Conduct a full feasibility review of new and continuing clinical trial protocols for CRG prior to PSOS approval and maintain with study documents.
2. Prioritize competing protocols for all sources; those initiated at Stanford, by NCI and industry.

See User Manual below for information on completeing Feasibility Form.

**PLEASE NOTE: No PHI should be entered in this questionnaire.**

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Date of Amendment Review Initiated:  M-D-Y  
\* must provide value Today's date

Form completed by:

Who will review this Feasibility Form?

\* must provide value

**2. Complete the Feasibility Form:** See below for more information on each section.

I. Initial Information:

- Complete all fields as designated. You will be prompted to enter your SUNet ID to access the questionnaire. Entering the SUNet ID of the person reviewing the form (e.g. the CRM), will auto-fill the remaining fields. You can also enter the information directly.

II. Protocol Information:

- Complete all fields as designated. Entering the SUNet ID of the Principal Investigator will auto-populate the required fields. You can also enter the information directly.
- Provide the study OnCore number, IRB number, and SPO number. This will help with study identification for the reviewer, later data analysis, and any discrepancy resolution.
- If applicable, indicate if the Study Title, Principal Investigator, or CRG changed. You may select more than one answer.
- Upload a copy of the protocol amendment to help with tracking of initial documents. Provide the version number and/or version date.

III. Protocol Review:

- Complete all fields as designated, answering questions 1 through 17. Entering 'Yes' or 'No' to each question will prompt new sub-questions to appear. If 'Other' is selected, a text box will appear for entry of the desired response. Every question will have an accompanying 'Comments' field for further information to be added to the Feasibility Form.

IV. Funding:

- Complete all fields as provided.

V. Location of Research:

- Complete all fields as provided. Once a location of research and/or specialty departments is selected, the option to upload any documents or email correspondence related to the agreement of feasibility for that location. This is not required, it is optional.

VI. Resources:

- Indicate, if applicable, the changes in accrual goal and/or staffing.
- For staffing change, if answer is 'Yes', it will ask for designation of the Primary CRC, Back-up CRC and Data Manager with corresponding % efforts and availability of each member to ensure available personnel.

VII. Opal Score:



- Complete the Opal Score questions as directed.
- If reviewing a Phase I trial, an automatic initial base score of 8 will be applied. The form will then prompt for answers to Optional Elements questions, foregoing Central Process and Special Procedures questions.

Total OPAL score (These will auto-populate, do not edit)	
Initial Score	8
Base Score	0
Optional Elements Score	4.5
Total Score	12.5

Reviewing a Phase 1 trial automatically scores eight on Initial Score and skips Base Score

Total OPAL score (These will auto-populate, do not edit)	
Initial Score	0
Base Score	7
Optional Elements Score	4.5
Total Score	11.5

Not a Phase 1 trial

- If not a Phase I trial, then select which type of trial is being reviewed. If none of the options are applicable to the type of trial being reviewed, select 'Not Applicable'. **Each option must be selected with either 'Yes' or 'No'**.
- All scores will auto-populate based on entered responses.

VIII. Total Opal Score

- These fields will auto-populate with the Initial, Base, Optional Elements and Total Scores based on previous answers to the Opal questions.

3. Save & Return Later:

- If it becomes necessary to stop and return to the form at a later time, select the 'Save & Return Later' option at the bottom of the form. You can email yourself a link for returning to the form, or you can bookmark the link in your web browser for later review.

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**Your survey responses were saved!**

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need the survey link to this survey.

**Survey link for returning**  
You may bookmark this page to return to the survey, OR you can have the survey link emailed to you by providing your email address below. If you do not receive the email soon afterward, please check your Junk Email folder.

Enter email address  Send Survey Link  ← **Email yourself a link to return to the survey at a later date**

\* Your email address will not be stored

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Or if you wish, you may continue with this survey again now.

Continue Survey Now

- II. **WARNING:** Do not leave the web browser open or unattended for too long, entries and responses could be lost if the system times out. If this happens, the submission might need to be re-started.

**4. Submit the Feasibility Form:**

- I. When ready, submit the Amendment Feasibility Form. Note: you will not be allowed to submit until all required fields have been completed. **Once submitted, you will NOT be able to return and change your responses.**

Submit

Save & Return Later

←

- II. Download and save a pdf of the submission or enter an email address to receive an electronic pdf of the submission.

Close survey

**Thank you for completing the Feasibility Form.**

**Please download a pdf of the submitted Feasibility Form and email it to your manager to signal review and sign-off is needed.**

Thank you!

Please take 1 minute to complete this 4-question user survey to help us better understand how this was useful to you: <http://j.mp/2FHASsY>.

**Enter your email to receive confirmation message?**  
A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

Enter email address  Send confirmation email  ← **Enter your email here to receive a pdf of your submission**

\* Your email address will not be stored

Download your survey response (PDF):  Download  ← **OR Download and save a copy here**

- III. Send a copy of the pdf to the designated reviewer (CMR) for notification that the submission is ready for review and sign-off.