PRMS Amendment Submission Portal

1. To submit an amendment, please access the Amendment Submission Portal at:
https://prms.cctsi.ucdenver.edu/amend/

2. Login using your university login/password. If you are not located in a University of Colorado Denver building, you will need to use VPN. Enter the COMIRB number for the study.

3. Once you have logged in, complete the amendment details. Please note that once submitted, you cannot go back and fix errors in the submission. It is important that the information is accurate.

Amendment Details

Must match protocol verbiage, i.e. addendum, revision, etc

Amendment Number **

Amendment Date **

Protocol Status
Select protocol status

List Summary Changes **
(700 characters max)

This must match protocol (i.e. - Revision 10, Addendum 8, Update 1, Amendment 2, etc.

Type of Amendment **
select all that apply

- ☐ Addition or removal of study site or Off-site location (Lone Tree, VA, UCH North/South, Children's)
- ☐ Administrative or Editorial Changes, Protocol Clarifications
- ☐ Change in IND status
- ☐ Change in local accrual (this is the number you plan to enroll on study)
- ☐ Change in local consent number (this is the number you plan to consent for the study)
- ☐ Change in national accrual
- ☐ Change in primary or secondary objectives
- ☐ Eligibility Criteria
- ☐ Informed Consent Change with accompanying amendment change
- ☐ New cohort, arm, disease site or new drug
- ☐ New Sponsor
- ☐ PI Change
- ☐ Statistical Section
- ☐ Title Change
- ☐ Updated procedures
- ☐ Other

If other type of amendment, please describe.
(700 characters max)

This field is required if any accrual changes are included

If local or national accrual change, please describe.

Amendment Documents

Clean Protocol	Choose File No file chosen
Summary of Changes	Choose File No file chosen
Tracked Changes Protocol	Choose File No file chosen
Protocol Clarification Document	Choose File No file chosen
Supporting Document 1	Choose File No file chosen
Supporting Document 2	Choose File No file chosen
Supporting Document 3	Choose File No file chosen
Supporting Document 4	Choose File No file chosen
Supporting Document 5	Choose File No file chosen

Comments

Comments for Reviewers
(500 characters max)

Additional comments can be added here if needed

Email address of additional recipient(s)
enter ; between each email address
(test1@test.edu;test2@test.edu)

Additional recepients can be added to receive confirmation email

Submit Amendment for Revi
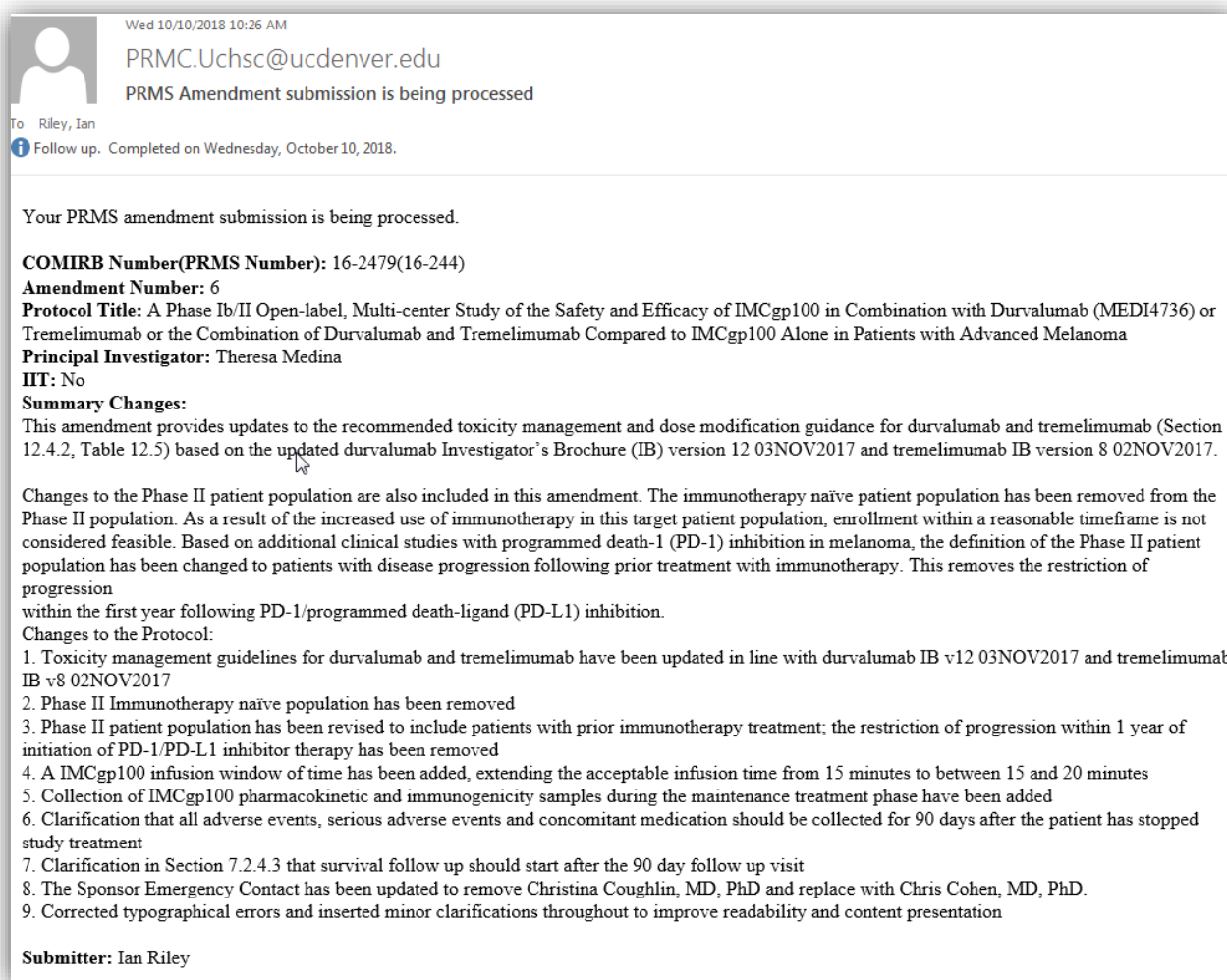
If you need help contact the Administrator at PRMC.Uchsc@ucdenver.edu.

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4. Please note, the summary of changes is limited to 700 characters. If changes are longer, please summarize to your best ability.

5. Upload documents (clean protocol if available, tracked changes, summary of changes). Comments can also be added at the bottom of the screen. Enter additional recipients if you would like others to receive the confirmation email that is sent when the amendment is submitted.

6. To save the submission form prior to submitting, Right-click and choose Print (or Ctrl+P). Save as Adobe PDF.

6. When your submission is ready, click submit protocol for review at the bottom right of screen:

7. You will receive an email confirming your submission.

8. Once amendment submission has been reviewed and approved, you will receive an email notification of approval.