Studies

Chapter 5
Studies

Section Objectives

At the end of this section, you should be able to:

- Create a study
- Maintain a study
- Grant access to a study
Create a Study

Study Setup and Access

In order to setup a study, a WePay™ Study Set-Up Form for Administrator or Business Office Manager must be submitted to the WePay™ Administrator (ADM) or WePay™ Business Office Manager (BOM). Only an ADM or BOM can create and maintain a study.

It is the intent of UPMC and the University that ADMs and BOMs shall only create or modify projects and studies for their respective organizations.

Once a project has been created in the WePay™ system, one or more studies must be created within that project in order for payments to be made to Subjects. Studies can be linked to only one parent Project.

- An ADM or BOM may grant study access to Study Coordinators (SC) and Study Aides (SA).
- A SC can grant access to a SA.

Study Status

Studies have one of three statuses associated with them.

1. **Active** – default status for a study after it is created. Studies must be Active to make subject payments.

2. **Completed** – a study is marked as Completed by an ADM or BOM, once it is past the identified IRB End date, and the IRB approval will not be extended. Once marked as Completed, a study cannot be returned to Active status, and no payments can be made.

3. **Disabled** – a study can be manually marked as Disabled by an ADM or BOM. No users may be granted access to it, and no payments can be made against it. A reason must be provided when disabling a study. An ADM or BOM may return a Disabled study to Active status.
Create a Study

Study and IRB Date Timeline

- No enforced relationship between IRB Approval Date and Project Start Date.
- No enforced relationship between IRB Expiration Date and Project End Date.
- Study Start Date must be later than or equal to both IRB Approval Date and Project Start Date.
- Payments are permitted after Study Start Date and before earlier of IRB Expiration Date / Project End Date, whichever comes first.
Create a Study

Once a WePay™ Study Set-Up Form for Administrator or Business Office Manager has been received, the study can be setup in the WePay™ system.

Create a study

1. Open the Create a Study window.
2. Enter Study Name.
   - The name has a maximum length of 64 characters and must be unique within its Parent Project.
3. Enter Study Number.
   - The number has a maximum length of 16 characters and must be unique within its Parent Project.
4. Select Project.
   - The Project drop down list contains only projects to which you have been granted access.
5. Enter Study START date.
   - The Study Start date must be no earlier than the Project Start date.
   - Payments can only be made against a study after the Study Start Date and before the earlier of either the IRB End Date or Project End Date.
6. Enter IRB Number.
7. Enter Confirm IRB Number.
   - The IRB number cannot be modified; therefore, any changes would require the creation of a new study.
8. Select IRB of Record.
9. Enter IRB Start date.
Create a Study

10. Enter IRB End date.

- The WePay™ system will send email notification to associated project users when the IRB approval is nearing its end date (90, 30, 5, 1 day(s) prior to expiration).

11. SSN Waiver: If the study does not have an SSN waiver (most studies do not use this non-standard processes), then skip the to the Maximum Payment Limits instruction. Approval must have been granted by the IRB to select the box and upload the appropriate documentation. Note: Newest input will overwrite existing documentation.

- Organizations like Pitt and UPMC are required by the IRS to request and collect SSNs for any individual receiving compensation payments. If an SSN is available or can be obtained for any participant, IRS regulations require that we attempt to obtain it.

- A waiver of the requirement to collect SSNs must be requested from the IRB and the documentation of the approval must be uploaded as an attachment in the appropriate field. Note that total annual incentive compensation payments made to any subject cannot exceed $100 in a calendar year.

- Tax withholding will be dictated by whether or not a study is designated as having an SSN Waiver. When a study is properly entered or modified by the WePay Administrator confirming the SSN Waiver, then no tax will be withheld from the compensation portion of a participant’s payment.

- When a study does not have an SSN Waiver, IRS-required 28% backup withholding will be deducted from any compensation payments made to participants who do not have an SSN entered into WePay. Further, an IRS Form 1099-MISC will be sent to that subject at year end, irrespective of how much is earned during the calendar year.

12. Man-on-the-street (MOS) payment methodology: If the study does not use the MOS designation (most studies do not use this non-standard processes), then skip the to the Maximum Payment Limits instruction. If approval has been granted by the IRB, then select the box and upload the appropriate documentation. Note: Newest input will overwrite existing documentation.

- In MOS-designated studies, compensation payments will not be permitted.

- In MOS-designated studies the participant, i.e., the PI or designate who is issued the WePay™ card and will cash that card, must include their SSN in their subject record.

- Inherent in an MOS-designated study is the fact that little information is gathered from the ultimate participant (the one paid in cash by the PI or designate), thus necessitating the
requirement that a separate record be maintained in sufficient detail to account for all payments (e.g., a subject receipt log initialed by recipient can be maintained.)

Please refer to the Man-on-the-Street detailed guidance in the Appendix.
Create a Study

Enter payment limits

The ADM and/or BOM should reference the Subject Payment details included in the IRB Protocol when establishing Payment limits for each study.

13. Enter Study Compensation Payment Limit.

14. Enter Expense Reimbursement Payment Limit.

15. Enter Max. $ per DAY paid from this Study by one USER.

16. Enter Max. $ amount to one SUBJECT for entire Study.

Note: For the first three payment limits, a payment will not be permitted if the limit is exceeded. For the last payment limit, if the limit is exceeded payment is permitted but an email alert is sent to the ADM for follow-up.

17. Verify all information.

18. Click the Save button.

19. The Initial Study Access window will open.

- This is where SC and SAs are assigned access to distribute payments from the study.
Create a Study

Grant initial study access

20. Select the desired Study Coordinators and/or Study Aides.

- Users must be granted a WePay™ user role before they will appear in the Eligible SCs or Eligible SAs list and can be assigned to studies.

21. Click the ADD button.

- The WePay™ system will send an email notification when users are granted study access.

22. Click the SAVE button.

23. The My WePay™ Studies window will automatically open for study review.

24. Click the menu button to return to the main menu.
**Maintain a Study**

Only an ADM or BOM can change attributes of a study once it has been created. If a study status has been marked as Completed, no attributes may be changed.

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**WePay™ system**

N → Studies → Maintain a Study

Maintain a Study

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**Maintain a study**

1. Open the My WePay™ Studies window.

![My WePay Studies](image)

2. Select the desired Study by clicking on the *Study Name*.

3. The Maintain a Study window will open with the selected study information.

4. All fields can be updated except for Project. If the associated Project is incorrect, the Study should be disabled and a new Study created.

5. Studies can be disabled, but cannot be marked as complete. That must be done at the Project level.

   Note: Marking a Project as complete will cause all studies associated with that Project to be considered complete. Please be cautious if there is more than one study associated with a Project, all must be finished before marking the Project complete.
Maintain a Study

6. A Study can be marked as Disabled only.
   - A reason must be entered when selecting the Disable Study checkbox.
   - A study is not automatically completed after it reaches the IRB End date. As noted above, marking as Completed must take place at the Project level.
   - Once the Project associated with a study is marked as Completed, neither the Project nor the Study may be reopened, and no further changes or payments may be made.

7. Study Access can be granted or removed.
Maintain a Study

Grant study access

8. Click the Study Access button.

   • Notice that you already have access as the ADM who created the Study. ADM and BOM users can not be removed from a study since their access is derived from their access to the parent project.

9. Select the appropriate user from the Grant new access to list.

   • A WePay™ user must be setup before they will appear in this list.

   • An ADM or BOM may grant or remove access to any SC or SA user.

   • An SC may only grant or remove access to any SA user.

<table>
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<th>Study Name:</th>
<th>Lindas Study</th>
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</tr>
</tbody>
</table>

Grant new access to:

10. When finished, click the Done button.

11. The WePay™ system will send an email notification when study access is granted or removed.
Studies: Summary

Studies

- Create a study
- Maintain a study
- Grant access to a study