

ORGANIZATION:	[insert lab/study identifier]		
SOP TITLE:	[insert title of procedure manual]		
SOP Creation:	[insert creation date]	SOP VERSION:	[insert version tracking info]

Sample: Activity Monitor Configuration

General Information

I. Purpose: *Briefly explain what will the reader know how to do after reading the document*

- a. This document is designed to assist study team members in proper configuration of the [insert activity monitor name] and regular downloading of [insert type of data] data.

II. Scope: *Indicate which studies and/or staff members to which this document applies; be specific:*

EXAMPLE: "This document applies to all studies that use the Jawbone UPmove™ pedometer and all staff responsible for: 1) distribution of the device, 2) interaction with subjects about their device, and 3) step count data transfers."

- a. This document applies to [insert study or studies or situation] that use the [insert type of device or system] and [insert which staff; who needs to know this information] responsible for: [insert specific responsibilities related to use of device].

III. Device Information: [Insert name of device/activity monitor]: *Describe the device and any components and/or associated software or apps*

EXAMPLE: "The Jawbone UPmove™ is part of the Jawbone lifestyle tracker product line. It consists of the UPmove™ wireless activity tracker (pedometer) and an accompanying iOS or Android app. The UPmove™ allows the wearer to track a variety of habits, including daily activity, sleep, eating habits and calories burned. The Jawbone app can interface with other fitness apps like MapMyFitness and MyFitnessPal."

[insert description of particular device and any peripherals or components and associated software or apps]

- a. Manufacturer: [insert name of manufacturer]
- b. Website: [insert URL, if applicable]
- c. Purchasing: [insert purchasing information: price, any research discounts, contact information, etc.]

IV. Indications for use: *Describe the purpose of the device within the context of your particular lab or project*

EXAMPLE: "To obtain daily step totals taken by individual; to evaluate activity (i.e. walking) patterns within and between individuals"

- a. To obtain [insert outcome variables from device/activity monitor]
- b. To evaluate [insert overarching goal of device/activity monitor within context of study or lab]

V. Contraindications to wear or use

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- a. *[list conditions or states in which the device/activity monitor should not be used]*

VI. Qualifications of research personnel responsible for distribution: *Describe what skills and/or experiences are necessary for staff responsible for this device*

EXAMPLE: Familiarity with the device and app; Ability to explain to how to wear and use pedometer to subject; Troubleshoot device and app over the phone; At least 1 week of wearing the pedometer

- a. *[list specific skills and/or experiences necessary for use of device/activity monitor within the context of the study or lab]*

VII. Equipment & Requirements

- a. *[list all required equipment and software; e.g. device, batteries, software version, particular cell phone operating system, etc.]*

VIII. Definitions: *Use this section to clarify any terms and phrases that are commonly used with respect your particular device/activity monitor*

- a. *[define terms and phrases specific to device/activity monitor and all associated components and software or apps]*

IX. Staff responsibilities

EXAMPLES:

- a. *Follow the test protocol and/or record any deviations*
- b. *Assign study email account to subject*
- c. *Configure device*
- d. *Complete all fields on the case report form & device inventory log*

Overview of Procedures: *This section is a chronological overview of what steps are necessary for distribution, data acquisition, compliance checks, data storage, etc.*

Include screen shots and images when appropriate.

I. Configuring the [insert device/activity monitor]:

List step-by-step instructions for each element: e.g. configuration, downloading data, confirming compliance, etc.

Be specific: outline any study or lab specific naming conventions for files and/or account names.

Be sure include any instructions regarding privacy and confidentiality.

EXAMPLE:

- a. *Create a Gmail account for subject*
 - i. *[study identifier][subjectID]@gmail.com*

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- ii. Do **not enter** personally identifying information into any field; use the information provided in the study-specific file
- b. Create a Jawbone account
 - i. Use newly created Gmail account information
 - ii. <https://jawbone.com/start/signup>
- c. Install app on device
 - i. Search Google Play (Android) or App Store (iOS) for Jawbone
 - ii. Enter subject profile information
- d. Block notifications from app

- II. **[Insert next element: e.g. “Downloading data”]:** Be sure to include all necessary information: browser requirements, website URLs, passwords and login information, data output format, etc.

Appendices: For elements that have a lot of steps, consider providing additional detail in an Appendix

Study-specific Information: Provide study-specific information if elements differ between projects.

Elements that might differ include: Subject and/or study naming conventions, Compliance requirements, Account parameters, Data storage location

I. **Study: [insert study name]:**

Describe study design, how the device/activity monitor fits within the scope of the study, and what outcomes are specific to the study

EXAMPLE:

“This study is a hypothesis-generating longitudinal cohort study designed to evaluate quality of life, physical activity patterns, and ambulatory blood pressure in patients with thoracic aortic disease. Each subject is expected to wear a Jawbone UPmove pedometer every day for the duration of his/her study enrollment. Weekly and monthly step counts will be used as an outcome measure and are surrogate indices of physical activity participation.”

II. **Compliance Requirements**

- a. [insert minimum compliance criteria]

III. **Subject Contact**

- a. [insert contact procedures in cases of missing data]

IV. **Data storage**

- a. [list procedures and conventions for downloading and storing data]

V. **Contacts**

- a. [list contact information for “super users” who are available to help troubleshoot problems]