Devices Pre-Application Checklist

Thank you for your interest in applying for Devices run by the Investigator Support Program (ISP). Before proceeding with your application, please ensure that you have the following:

- **Study protocol**
- **Principal Investigator's updated CV**
- **Ethics committee (EC) or Institutional Review Board (IRB)** submission plan or approval
- **EC/IRB approved consent form**
- **Study app** or a plan for app development
- **Data Collection Plan**
  - Understand HealthKit and which HealthKit data types you plan to collect; create a list.
  - Understand SensorKit and which SensorKit data types you plan to collect; create a list, if applicable. If you are planning to use SensorKit, you must apply separately for a SensorKit entitlement. The application can be found here.
  - Understand watchOS Health Features and determine which Health Features are available in your region. watchOS feature availability can be found here.
- **Data Privacy and Storage Plan**
  - Set of guidelines to ensure proper storage and protection of sensitive data.
  - If applicable, please ensure you have a plan to set up a backend server.
- **Legal Review and Signatory**
  - Identify who at your organization must be involved in reviewing and signing legal agreements on the organization's behalf. The ISP agreement must be signed before Apple can grant any Apple devices or other support through the program. If the agreement is not signed in a timely fashion, then you may need to reapply for the grant in a later cycle.
  - If SensorKit data is required for your study, you must identify your institution's Apple Developer Program Account Holder who will review and sign the Apple Developer Program License and a SensorKit addendum.
- **iPhones**
  - Note that an Apple Watch must be paired to an iPhone. Thus, if the support you are requesting under the ISP is a quantity of Apple Watch devices, then you will need a plan for how you will pair each Apple Watch. For example, your research participants may need to already own an iPhone they can use for the study or you may need to otherwise buy or lease iPhones.
- **Device Shipment and Storage**
  - If you are asking that we provide you with devices over a period of time (for example, as your study achieves different enrollment milestones) rather than all at once, then please identify the desired cadence for shipment.
  - If you are asking that we provide you with devices all at once but the devices will not be used with participants right away, then you will need a plan for storing the devices until they are needed and for ensuring that they are charged and have up-to-date software.

When you're ready to apply, complete the application and send it to research_proposals@apple.com.
Please submit a copy of the PI's updated CV with this application

For more information, refer to the FAQ.

Building a Study App Pre-Application Checklist

Thank you for your interest in applying for help Building a Study App powered by Apple's Study App Builder (SAB). Before proceeding with your application, please ensure that you have the following:

- **Study App Status and Plan**
- **Applicable Developer Information**
- **Data Collection Plan**
  - Understand HealthKit and which HealthKit data types you plan to collect; create a list.
  - Understand SensorKit and which SensorKit data types you plan to collect; create a list, if applicable. If you are planning to use SensorKit, you must apply separately for a SensorKit entitlement. The application can be found here.
  - Understand watchOS Health Features and determine which Health Features are available in your region. watchOS feature availability can be found here.
- **Data Privacy and Storage Plan**
  - Set of guidelines to ensure proper storage and protection of sensitive data.
  - If applicable, please ensure you have a plan to set up a backend server.
- **Legal Review and Signatory**
  - Identify who at your organization must be involved in reviewing and signing legal agreements on the organization's behalf. The ISP agreement must be signed before Apple can grant any Apple devices or other support through the program. If the agreement is not signed in a timely fashion, then you may need to reapply for the grant in a later cycle.
  - If SensorKit data is required for your study, you must identify your institution's Apple Developer Program Account Holder who will review and sign the Apple Developer Program License and a SensorKit addendum.

When you're ready to apply, complete the application and send it to research_proposals@apple.com.
Please submit a copy of the PI's updated CV with this application.

For more information, refer to the FAQ.

ISP Device and Study App Builder Application

Please do not disclose any intellectual property, confidential, and/or proprietary information here or elsewhere within this proposal.
Email the completed application to research_proposals@apple.com.

Study Overview

Project / Study Title	
Principal Investigator (PI) Name, Institution/Dept, Title, and Email.	
Sponsor Organization / person who initiates the study and has authority and control over the study.	
Primary Study Contact Name, Institution/Dept, Title, and Email. Please enter "N/A" if not applicable.	
Collaborators / Co-Investigators Name, Institution/Dept, Title, and Email. Please enter "N/A" if not applicable.	
Study Sites/Countries Please indicate the countries where participants will be enrolled and where devices will be shipped.	
Please submit a copy of the PI's updated CV with this application	
Ethics Committee or IRB Approval Status	☐ Submitted ☐ Approved ☐ In Progress ☐ Not Started If '**In Progress or Not Started**', please share more:
ClinicalTrials.gov NCT Number If no number, share public info or website	
Publication Plans Please state whether you intend to publish study results and any more detailed plans available at the time of this proposal.	
Funding Sources Briefly describe forms of financial support applied for, the status of these applications, and whether your study is gated by this funding. If other forms of support restrict institutional rights (e.g., IP, commercialization), please explicitly describe those limitations	

Study Details

Summarize Study Plan Provide a project description—including hypotheses, specific aims, planned enrollment (N), and experimental design details/schematics as applicable. Please also include inclusion and exclusion criteria if known at the time of application. Please do not disclose any IP, confidential, and/or proprietary information	
List Condition(s) Studies Specify the disease, disorder, syndrome, illness, injury, and/or health-related issues being studied..	
Future Directions Describe the planned future direction of this work—including future trials among an expanded or larger population, product development or commercialization plans	
Describe Enrollment Plan Please include total time dedicated to recruitment	
Subject Duration Total time subject on study	
Study Duration Total study length	
Study Start Date Anticipated date is sufficient	

Study Method

Describe Participant Workflow For in-person encounters, describe the purpose, anticipated time commitment, and experience. Do you expect to collect data through other channels (e.g. phone calls, in-person clinic visits, labs)?	
Describe usage of Apple devices, products, and features Sub text	
Describe non-Apple devices used If you are using any non-Apple devices as an investigational device or as a reference/ comparator device in your study, please identify these, and describe how they will be used.	

Data Privacy and Storage

Data Storage, Transfer, and Security Plan: Describe you data plan—including how study data will get from the participant's device to where it's stored, where it will ultimately live and for how long, who will have access, and what security measures will protect it.	

Study Devices Requested

Device	Quantity	Size or Model	Justification
Apple Watch			
AirPods			
Vision Pro Please note that Apple Vision Pro is available only in the US.			

iPhone Plan

iPhone Sourcing Plan Please note each Apple Watch must be paired to an iPhone in order to collect data. Please indicate your plan to source iPhones for your study.	☐ We plan to recruit participants who already own an iPhone. ☐ We own or will purchase iPhones that will be dedicated to the study. ☐ We would like to lease iPhones. Other; please clarify below:

Study App

App Development Status Please clarify plans and/or resources for app development for your study. For more information about Apple's Study App Builder, please visit: https://healthresearch.apple.com	☐ I **already have** a study app and/or an app developer. App Name: App Developer: ☐ I **would like to be considered** for Apple's **Study App Builder**. Other; please clarify below:
List data types collected from Apple Devices Please include **HealthKit data types** and **WatchOS features**	
SensorKit https://developer.apple.com/documentation/sensorkit *Link to SensorKit application: https://healthresearch.apple.com/accessing-sensorkit-data *Link to SensorKit data types: https://developer.apple.com/documentation/sensorkit	☐ Yes ☐ No ☐ I don't know ☐ N/A If '**yes**', please indicate status of your SensorKit entitlement request: ☐ Not started ☐ Submitted ☐ Granted ☐ I don't know If '**yes**', please list which data types:
Background Processing Runs while the app is in the background to prepare essential data for health study	☐ Yes ☐ No ☐ I don't know ☐ N/A If '**yes**', please follow this link to apply for the Background Processing Entitlement