Investigator Support Program Pre-Application Checklist

Thank you for your interest in applying to 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.

For more information, refer to the FAQ.

Investigator Support Program 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

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.	
Prior Work Briefly summarize prior work demonstrating investigator/institutional expertise and ability to carry out the described work. **Please submit a copy of the PI's updated CV with the application.**	

Study Details

Brief Summary Please provide details of the study plan, including how the study is designed and what the study is measuring. Clarify the objectives, hypothesis, endpoints, outcomes, and eligibility criteria.	
Planned Enrollment (N)	
Condition(s) Studied Specify the disease, disorder, syndrome, illness, or injury and/or any health-related issues, such as lifespan, quality of life, and health risks that are being studied.	
Study Method / Schematics Please describe the participant workflow and include how Apple devices, products, and features will be used in the study. **Non-Apple devices:** If you are using any non Apple-device as an investigational device or as a reference/comparator device in your study, please identify these, and describe how they will be used.	
Future Direction Describe the future direction of this work if the proposed study demonstrates the expected outcomes - e.g. future trials among an expanded/larger population, product development or commercialization plans.	

Study Timelines

Enrollment Duration Please indicate the length of time that will be dedicated to study recruitment (e.g., in months or years).	
Study Duration Please indicate the total study length (e.g., in months or years).	
Subject Duration Please indicate the length of time each subject is expected to participate in the study (e.g., in months or years).	
Study Start Date	
Ethics Committee or IRB Approval Status Please explain whether you have submitted, plan to submit, or have received ethics committee/ IRB approval for your study.	
ClinicalTrials.gov NCT Number If no NCT number, please provide a website or any details about public-facing information regarding the study.	
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.	

Study Experience

Study Experience Briefly describe the envisioned user experience. If applicable: • For app-based user experiences, append flow charts/wireframes if available. • 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)? • Briefly describe your data monitoring plan, if any.	

Diversity and Inclusivity

How will the study ensure diversity and inclusion?	

Study Devices

Devices Requested Clarify the type and quantity of device(s) requested for your study, and provide a brief justification for each.	
# of Apple Watch Requested Specify quantity requested.	
Justification for Quantity Requested Please provide justification for the quantity requested.	
Size Preferences Specify small vs. large	
Justification for Size Preferences Provide justification for the requested device sizes.	
# of AirPods Pro Requested Specify quantity requested.	
Justification for Quantity Requested Please provide justification for the quantity requested.	
# of Vision Pro Requested Specify quantity requested.	
Justification for Quantity Requested Please provide justification for the quantity requested. Please note that Apple Vision Pro is available only in the US.	
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.	Select the one that applies: ☐ We plan to recruit participants who already own an iPhone. ☐ We have iPhones in our possession that will be dedicated to the study. ☐ We plan to purchase iPhones for 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 Template, please visit: https://www.researchandcare.org/faq/	Select the one that applies: ☐ I **already have** a study app. App Name: App Developer: ☐ I **need** a study app and **have** an app developer. App Developer: ☐ I **need** a study app, I **don't have** an app developer, and I would like to be considered for **Apple's Study App Template** ☐ I don't need a study app.
I plan to include the following in my study app. (Check all that apply)	
ResearchKit https://www.researchandcare.org/researchkit/	☐ Yes ☐ No ☐ I don't know ☐ N/A
CareKit https://www.researchandcare.org/carekit/	☐ Yes ☐ No ☐ I don't know ☐ N/A
HealthKit https://developer.apple.com/documentation/healthkit *List of Healthkit data types available: https://developer.apple.com/documentation/healthkit/data_types	☐ Yes ☐ No ☐ I don't know ☐ N/A If 'yes', please list which data types:
SensorKit https://developer.apple.com/documentation/sensorkit *List of sensor streams available: https://developer.apple.com/documentation/sensorkit/srsensor *Link to SensorKit application: https://www.researchandcare.org/resources/accessing-sensorkit-data/	☐ Yes ☐ No ☐ I don't know ☐ N/A If '**yes**', please list which sensor streams*: If '**yes**', please indicate status of your SensorKit entitlement request: ☐ Not started ☐ Submitted ☐ Granted ☐ I don't know
watchOS Features listed on the Feature Availability page https://www.apple.com/watchos/feature-availability/	☐ Yes ☐ No ☐ I don't know ☐ N/A If 'yes', please list which features:
Consent If consent is not completed in person, will consent be collected via the study app?	☐ Yes ☐ No ☐ I don't know ☐ N/A
Surveys Will there be surveys in the study app?	☐ Yes ☐ No ☐ I don't know ☐ N/A
Background Health Research Task Learn more about Background Health Research Task: https://www.researchandcare.org/faq/	☐ Yes ☐ No ☐ I don't know ☐ N/A

Data Privacy and Storage

Where will study data be stored? (e.g. private cloud, dedicated server, local computer, REDCap, EMR, etc.)	
How will study data move from a participant's device to where study data will be stored? (e.g. typed in locally, copied in clinic from a participant's device, uploaded to private cloud, etc.)	
How will user privacy and data security be ensured?	