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Running a SPARK Research Match Recruitment Study

Operations Guide for Investigators

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1. Introduction

This guide is intended for investigators whose studies have been **approved to recruit participants through SPARK Research Match**. It provides an overview of the processes, requirements, and responsibilities involved.

This document focuses on the **post-approval phase**, including preparing and building recruitment workflows, participant tracking, and data sharing.

2. Key Roles and Contacts

Successful execution of a SPARK recruitment study involves coordination between several teams:

- **SFARI Data and Biorepository (SDBR) Team**
  Manages SFARI Base and supports application review, SFARI released data access, and data sharing processes.
- **Research Match Project Director**
  Provides overall oversight of the Research Match service, including study feasibility, workflow design, and alignment with SPARK policies and priorities.
- **Research Match Project Manager**
  Serves as your primary point of contact throughout the study. The project manager works closely with you to plan recruitment materials, coordinate study build and launch, and support recruitment tracking and troubleshooting.
- **Tempus Dynamics (IT partner)**
  Supports the technical infrastructure for study workflows and the secure recruitment portal (Synapse).

3. Overview of the Research Match Lifecycle

Once your study has been approved, it will move through several key phases before, during, and after recruitment. While timelines and workflows may vary depending on the specifics of your study, most projects follow a similar lifecycle.

Investigators will be introduced to many of these steps during an introductory call with the Research Match team, which may occur before or after formal approval. The purpose of that discussion is to better understand your study design, assess feasibility, and begin planning for potential implementation.

The outline below is intended to reinforce those discussions and provide a clear roadmap of what to expect as your study moves forward.

3.1 Before Recruitment: Study Planning and Feasibility

During the introductory call, the Research Match team works with investigators to:

- Review study objectives and design
- Clarify eligibility criteria and recruitment targets
- Determine the most appropriate recruitment workflow (hand-off vs. online survey)
- Identify any potential challenges related to participant burden or study complexity

These conversations help ensure that studies are well-positioned for review and, if approved, for successful implementation.

3.2 Before Recruitment: Study Preparation

Following initial discussions and, if applicable, after approval, investigators will work with the Research Match team to prepare their study for launch.
This phase may include:

- Refining recruitment materials (e.g., invitation/reminder emails, screener, authorization forms)
- Providing survey spreadsheets and required copyright language for published measures (for online survey studies only)
- Updating consent forms, including inserting the **required** bidirectional data sharing language (language included in the FAQs section at the end of this document)
- Submitting materials to local IRB
- Finalizing study procedures and workflows

The goal of this phase is to ensure that all study materials and processes align with SPARK requirements and are ready for implementation.

3.3 Before Recruitment: Study Build and Testing

Once materials are finalized and approved by the investigator's local IRB, the Research Match team and Tempus Dynamics will:

- Configure the study workflow within the Synapse portal, Tempus Dynamics' custom research platform
- Build and integrate surveys or other study components (if applicable)
- Test all elements of the workflow to ensure functionality and accuracy

Investigators and their accompanying study team members will be asked to test the built workflow(s) prior to launch. Please note that the investigator is responsible for review and final sign-off of the workflow.

3.4 During Recruitment: Study Launch

When the study is ready, SPARK will initiate recruitment by sending invitation emails to eligible participants.

Depending on the study design (hand-off or online survey):

- Participants may complete screening, authorization, or consent steps within Synapse
- Participant contact information may be shared with the investigator's research team via the Synapse portal after authorization (for hand-off studies)
- Participants may proceed directly into study activities (for online survey studies)
- For both online survey and hand-off studies, a total of **3** reminders will be sent to participants who do not respond to the initial invitation email.

3.5 During Recruitment: Recruitment Management (for hand-off studies ONLY)

During the recruitment period, investigators are responsible for:

- contacting participants once contact information has been securely shared via the Synapse portal
- obtaining informed consent and following study procedures according to their local IRB-approved protocols
- tracking participant status in the Synapse portal (e.g., consented, declined, lost to follow-up). Updates should be made at least every other week
- communication with the Research Match team regarding batching of new participants (please note in some cases limits may be placed on batching or participant criteria)

The Research Match Project Manager will provide guidance on required tracking fields and processes. In general, investigators and/or their study personnel are expected to keep SPARK participant recruitment statuses up to date and regularly maintained.

3.6 After Recruitment: Study Completion and Data Sharing

At the conclusion of recruitment:

- Study teams work with the Research Match Project Manager to close out all participant statuses and shut down the workflow(s) (for hand-off studies only)
- Study data are extracted, reviewed, and prepared for delivery to the study team (for online survey studies only).

For both hand-off and online survey studies, investigators are responsible for sharing study data back with SPARK in accordance with data-sharing agreements as outlined in the Researcher Distribution Agreement.

4. Recruitment Period and Study Renewal

Research Match projects are typically authorized to recruit for one year from the time of study approval. Rare deviations from this timeline will be discussed with individual investigators. Recruitment activity may vary over time depending on factors such as eligibility criteria, participant burden, and study design. **Research Match cannot guarantee a specific response rate or number of participants.**

Investigators should work closely with their Research Match Project Manager to monitor progress and address any challenges that arise during recruitment.

4.1 Modifications During the Recruitment Period

If changes to the study protocol are required after launch (e.g., significant updates to study protocol, eligibility criteria, or participant incentives), investigators must:

- Notify the relevant Research Match Project Manager
- Obtain approval from their local IRB, as required
- Receive confirmation from SPARK Research Match before implementing changes

Significant changes may require updates to recruitment materials or workflows and, in some cases, may require further review from the SPARK Research Match Participant Access Committee (PAC).

4.2 Study Renewal

Investigators who wish to continue recruiting participants beyond the initial one-year period must submit a renewal application for review unless instructed otherwise by the Research Match team. Renewal applications follow the same quarterly submission deadlines and review cycles as initial applications and can be accessed through SFARI Base.

Renewal requests are evaluated by the PAC and are **not automatically granted.** Approval is based on several factors, including:

- Progress toward recruitment goals
- Justification for and feasibility of continued recruitment
- Ongoing scientific value of the study
- Participant burden and engagement
- Prior use of SPARK Research Match resources

As part of the renewal application, investigators will typically be asked to provide:

- A summary of recruitment activity to date (e.g., number of participants contacted, consented, completed)
- Justification for additional recruitment time
- Any proposed updates to the study design or procedures

Please note: If recruitment has not launched within one year of the original application approval, a renewal application is **still** required. These requests may be subject to additional review and require a plan to launch the project in a timely manner.

Any additional questions about the renewal application and/or process can be sent to sdbr@simonsfoundation.org.

5. Frequently Asked Questions

When will my study launch?
Time to launch varies depending on study complexity, IRB timelines, and workflow development. In most cases, studies launch approximately 3–6 months after approval, though timelines may be shorter or longer.

How quickly will participants be recruited?
Recruitment rates vary widely depending on eligibility criteria, study burden, and participant interest. While SPARK Research Match conducts feasibility assessments using cohort queries prior to study approval, it is not possible to predict how many eligible participants will ultimately respond to outreach. As a result, SPARK Research Match cannot guarantee a specific number of participants or recruitment timeline.

When do I receive participant contact information?
For hand-off studies, participant contact information becomes available in the **Synapse portal** after participants complete the authorization step (following receipt and engagement with the invitation email). Information is released in real time as participants authorize. No contact information is shared in the case of online survey studies.

What information will I receive about participants?
For hand-off studies, investigators receive limited data via the authorization step that may include:

- Participant first name
- Participant last name
- Parent/legal guardian first and last name (if applicable)
- Sex at birth
- Date of birth
- Email
- Phone number
- Mailing address
- Diagnosis
- Other variables needed pre-consent (e.g., race/ethnicity, language level, etc.)

Additional SPARK data are only available after participants consent to the study and data linkage requirements are met.

Please be aware: Data transferred as a result of an authorization CANNOT be used for research unless/until the individual(s) in question have consented for a project and may not be shared outside of the approved study team. The data transferred during authorization expire and must be destroyed by the researcher after one year if the research participant does not join the study.

For online survey studies, data are provided to investigators in a de-identified format unless explicit consent has been obtained for identifiable data sharing.

How do I know what information should be included in the invitation email and authorization form? What about my consent forms?

Template email and authorization form scripts are provided at the end of this document for your convenience (Appendices A and B). You will work with your Research Match Project Manager to optimize these materials.

For your consent form, you must be sure to include two aspects of data transfer (bidirectional data-sharing language):

- Consent for you (the Investigator) to receive linked, identified phenotype and genetic data from the SPARK database using the participant's SP_ID.
- Consent to transfer participants' data from your study into the SPARK database.

You must receive approval from the Research Match Project Manager before submitting these consent changes to your IRB. Failure to follow this step may result in you being unable to obtain the linked SPARK data. Note that in most cases, a PI must submit one additional IRB amendment as part of the pre-recruitment launch process. This submission should include your final, approved consent forms with bidirectional data sharing language, authorization form, and recruitment emails (invitation and reminder emails), as well as any other documents required to build your workflow as discussed with your Research Match Project Manager.

What is the bidirectional data sharing language that must be included in my consent form?

For projects approved to link SPARK data to their Research Match study data, this language allows you to receive linked, identified data from SPARK on the participants in your study. These data are shared using a linked ID number (SP_ID) that is not provided until participants consent to be in your study and sign their agreement to bidirectional sharing of their data. This language also provides consent for you to share your study's data back with SPARK, for inclusion in the SPARK database, in order to continue to enhance the SPARK resource.

Suggested language is provided below. Please allow your assigned Research Match Project Manager to review your consent forms during the study preparation phase before resubmission to your IRB. Failure to do so, or failure to include the language in your consent form at all, may result in delays to and/or withdrawal of your project, or make it impossible for SPARK to share identified data with you.

> "(If study contains non-SPARK participants, start with: 'For those individuals who participated in the SPARK study,') we are asking your consent for the SPARK study, hosted by the Simons Foundation, to share with {University} the clinical, demographic, and genetic data collected during your participation in SPARK. This information will be shared using your linked research ID number and using a secure transfer system. We are also asking for your consent to share the data we collect during the study here at {University} with SPARK in order to add to the information that was collected during your participation in SPARK. Please note that because you are a participant in both studies, SPARK and this study will be able to share and link your identifying information, as well as any future data you may contribute to either project.
>
> The Simons Foundation funds innovative research and provides coded data access (data with your identifying information removed) to qualified researchers. Researchers can file an application with the Simons Foundation to obtain access to your study data for research purposes. Experts at the Simons Foundation who protect health and science information will look at every request carefully to minimize risks to your privacy."

Please ensure that you have accounted for all roles (e.g., parents, siblings, individuals with ASD) for which you want to obtain data. Data sharing consent must be obtained for each individual, and all independent adults must consent for themselves.

Can I contact participants about other studies/future research?
No**. Participant contact is limited strictly to the approved study**. Investigators may not use SPARK recruitment to build independent registries or contact participants about unrelated research not approved by SFARI. Consent forms with future contact sections should be revised to make this clear.

When do I receive SPARK participant IDs (SP_IDs)?
SP_IDs become available only after a participant has consented to your study and has therefore agreed to the required bidirectional data sharing language. SP_IDS allow you to link your study data to SPARK phenotypic and genetic data through SFARI Base. Studies not approved for linking SPARK data may not receive the SP_ID and will instead utilize a temporary ID for data sharing.

How long do I have access to participant contact information?
For hand-off studies, access to participant contact information is available only while your study is actively recruiting. Once the recruitment period ends, access to this information is removed.

When will I receive my study data?
For online survey studies, datasets are typically provided once the target sample size has been met. Timing may vary depending on data processing and cleaning; however, investigators can expect to receive data within 2 weeks of study close-out.

What are my data sharing responsibilities?
SFARI and SPARK will work with you on data sharing terms, but in general, the expectation is that data will be made available for SFARI/SPARK to distribute via SFARI Base to researchers publicly upon publication or within one year of the end of data collection, whichever comes first. These terms are also outlined in the **Researcher Distribution Agreement (RDA)**, which your institution signed, and the Joinder to the RDA that you acknowledged when you first created an account on SFARI Base. SPARK has templates for the documents needed for data sharing, which are sent after the introductory call, at study close-out, and/or upon request. Data should be shared using either the SPARK ID or a temporary ID. Individual project details will be discussed with your Research Match Project Manager.