



Teen-LABS Ancillary Study Launch Checklist

1.) Final Steering Committee Approval: The Teen-LABS Steering Committee requires that Ancillary Studies send the following to the Teen-LABS Central Coordinator at the Data Coordinating Center (see below for contact information):

- Written confirmation that you have received funding. If the budget was cut and these cuts will affect the conduct of the study, the changes being made need to be outlined
- Letters from participating Teen-LABS site Principal Investigators confirming their willingness to participate in the Ancillary Study.
- IRB-approved consent forms, IRB-approved research protocol at the Principal Investigator's institution as well as each participating site, and IRB approval letter(s)
- Letter outlining when data from the DCC will be needed (quarterly, every six months) Below are specifications required

The Teen-LABS Steering Committee will consider several additional issues before granting *final* approval to conduct an Ancillary Study. Please visit teen-labs.org for Ancillary Study Guidelines for definitions and more details.

Specifically,

- Methods to assure participant confidentiality
- Assurance that the Ancillary Study provides funding for all costs that may be incurred by the Teen-LABS Clinical Centers or DCC
- Agreement to provide Adverse Event/Unanticipated Problems reports as required by Teen-LABS Data Safety Monitoring Plan

2.) Requests for Teen-LABS Data: Provide the DCC with the timeline of when you expect to need data transmitted from the DCC (e.g. only at the end of the study, after recruitment is over, quarterly, to be determined) with a brief justification. The specific Teen-LABS Data items requested from the DCC in the original proposal should be re-stated with this timeline as well as when you expect the database to be locked down for the transmission. Ad hoc data requests require justification and must allow **at least 6 weeks** for the DCC to prepare the requested dataset. If additional data or measures other than those detailed in the original proposal are requested, please see #3 below.

3.) Additional data / measures: To request additional data or measures other than those originally requested and approved by Teen-LABS, send a list of the additional items and justification to the Central Coordinator at the DCC. Each request for additional data or measures will need to be approved by the Teen-LABS Steering Committee.

4.) Study Publications: All publications using data from the Teen-LABS main study will be subject to the guidelines outlined in the Teen-LABS Publications & Presentations Guidelines (note that these guidelines are subject to change).

5.) Data Management: If the DCC is managing the data for the Ancillary Study, the following must be provided to the DCC prior to beginning recruitment:

- Study Forms
- Study Manual of Operations
- Copyright / Licensing Permissions for data collection instruments

In addition, the Investigator will be expected to comply with the timeliness of data submissions after collection as well as data clarifications requests.

6.) Data submission to Teen-LABS: Provide the DCC with the plan to provide Ancillary Study data to the DCC for inclusion with the master Teen-LABS database, including schedule, mechanism, data dictionary, and format. The DCC will provide a letter of approval.

7.) Recruitment & Retention: Provide the DCC with a one-page summary of your study which may be shown to prospective participants or posted on the Teen-LABS participant web site to explain your specific study.

DCC Checklist of items required in order to give the “green light” for Teen-LABS Ancillary Studies.

1. Documentation:

- a. The DCC must have physical copies of the Ancillary Study documentation including:
 - IRB approval letters
 - Final funded grant proposal, Study Protocol, Consent, Data Collection Forms, Data Safety Monitoring Plan, and Manual of Operations
 - Copyright / Licensing Permissions
- b. For those studies using forms not already used by Teen-LABS, forms and Manuals of Operation must be reviewed by DCC to assure that data are being collected consistently. The DCC will provide forms when the data specific to the Ancillary Study are being managed by the DCC.

2. Site burden:

- a. Before a site can begin recruitment and data collection for a substudy, the Teen-LABS site must be collecting data for Teen-LABS and the DCC must have data on at least 5 participants with 30 day follow-up data to assess completeness and accuracy. Data collection and data entry activities for Teen-LABS must be satisfactory prior to beginning Ancillary Study participation. This requires that:
 - i. data are being collected in a timely manner.
 - ii. data are being entered and verified in a timely manner.
 - iii. missing data and data discrepancies are being resolved in a timely manner.
 - iv. adequate numbers of participants are being enrolled and followed.

3. Site Responsibility: There must be a person at the Ancillary Study Principal Investigator’s site who is in charge of overseeing the day-to-day operations of the Ancillary Study (typically the Principal Investigator or a coordinator) and who will be the DCC’s primary contact.



Teen-LABS Ancillary Study Launch Checklist: approved ancillaries must send the following to Teen-LABS Data Coordinating Center for final Steering Committee approval prior to start of the study.

Ancillary Study Launch Checklist	Check Each Item Once Completed
1) Written confirmation of funding	
2) Outline changes if budget cuts affect the conduct of the study	
3) Letters of collaboration from PI for each participating Teen-LABS site	
4) Data Safety Monitoring Plan	
5) Copyright / Licensing Permissions	
6) Manual of Operations (For those studies using forms different than already used by Teen-LABS, the Manuals of Operation must be reviewed by the DCC to assure that data are being collected consistently. The DCC will provide forms when the data specific to the Ancillary Study are being managed by the DCC.)	
7) Final funded grant proposal	
8) IRB approval letters from each site	
9) IRB approved Study Protocol	
10) IRB Informed Consents from each site	

Data Collection Forms: **Investigator will be expected to comply with the timeliness of data submissions after collection as well as data clarifications requests.**

The Teen-LABS Steering Committee will consider several additional issues before granting final approval to conduct an Ancillary Study. Please visit www.Teen-LABS.org for Ancillary Study Guidelines for definitions and more details.

For further information, please contact:
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