APPD LEARN Guidelines for Study Communications
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Key Principles

The mission of APPD LEARN is to conduct meaningful educational research that advances the training of future Pediatricians by developing and promoting participation and collaboration in research by program directors for the purpose of improving the health and well-being of children.

In furtherance of this mission, APPD LEARN espouses the following key principles of study communications:

- Integrity to the research data
- Transparency in messaging
- Inclusion of sites and investigators to the fullest degree possible
- Proactive communication to prevent conflicts or identify and address conflicts early

Study Group Organization

Every APPD LEARN study involves a study oversight group (SOG), a study investigator group (SIG), and one or more study writing groups (SWG).

- The SOG is the APPD LEARN "ad hoc project oversight committee." It is composed of the project principal investigator(s), APPD LEARN Director, Program Manager, and other staff, and other members selected by the principal investigator(s) and APPD LEARN Director. The SOG is formed upon approval of the study by APPD LEARN and should a standing SOG conference call, at least monthly, until the study is completed.
- The SIG includes site investigators from each APPD LEARN member site participating in the study, as well as all members of the SOG.
- Study writing groups (SWGs) are tasked with the drafting of individual study manuscripts. SWG members should be members of the SIG. In smaller studies, the SIG may serve as an SWG. An SWG should be formally identified before each manuscript is begun.

The project principal investigator should maintain the Table of Members below, and transmit it to the SOG at the outset of the study and whenever participation changes:

Table 1: Table of Members

SOG members (name and email)	SIG members (name, email, and site)	SWG members (indicate manuscript and repeat as needed if multiple SWGs)
Principal investigator(s):		
APPD LEARN: learn@appd.org		
Other members:		

Study communications

Each group formed for a study should have a group listserv managed through APPD for communications within the group. When groups communicate by conference call, call minutes or notes should be circulated via this listserv.

For Recruitment

Study processes prior to data collection focus primarily on site recruitment and site preparation (e.g. IRB approvals). Principles of study authorship consistent with APPD LEARN's Authorship Guidelines should be provided to potential sites at the time of recruitment. For example, the SOG may inform sites that all site investigators who qualify for authorship on a manuscript will either be listed individually in by-lines as authors (if they are SWG members) or listed as members of a group author included in manuscript by-lines. APPD LEARN will provide for online archival/sharing of study documents (protocols, IRB documents, instruments, scholarly products) as needed from the outset of the study, and can assist in helping groups share documents-in-progress.

The SOG oversees site recruitment. Site investigators should be added to the SIG as their sites obtain IRB approval and complete other prerequisites for data collection.

For Data Collection and Analysis

The study principal investigators should hold at least monthly communications with the SIG, either through the SIG listserv or by means of standing conference calls through the completion of data collection and analysis. APPD LEARN is available to assist in arranging conference calls. During these communications, the Principal Investigators should update the SIG about the progress of the study, including, as appropriate, quantity and quality of data collected to date, results of data analyses, and estimated times for the completion of data collection and data analyses. A standing SIG call may substitute for the standing SOG call.

For Scientific Presentations and Manuscripts

Although "manuscript" is used below, this also refers to posters, presentations, and other scientific communications. SOGs should think ahead during their studies to plan for submission deadlines and leave enough time for full SIG involvement. In exceptional cases, when there is limited time for submission, shortcuts should be chosen by the widest possible group based on upholding the key principles, and should always be communicated by email to the full SIG.

The SOG is responsible for developing a written process for reviewing proposed papers, presentations, and other communications about the study. The process should include provisions for avoiding overlapping publications, prioritizing publications, and designation of a lead author for each communication. A copy of the oversight group's process should be submitted for record to the APPD LEARN Director. A template for this process is available in APPD LEARN's Authorship Guidelines.

Manuscript planning is often easiest when several manuscripts are to be written and can be distinguished by different research questions to be addressed in each manuscript. Planning several manuscripts concurrently supports inclusion by providing opportunities for site investigators to choose from possible manuscripts in which to participate.

Unless the SIG will serve as the SWG, the SIG should be informed about the planned manuscripts and the formation of SWGs, and each SIG member should have the option of joining an SWG (or electing not to join any SWG). APPD LEARN has online survey tools that can be used to collect responses from SIG members about interest in joining an SWG.

In each SWG, the SOG should designate one author as the lead author for the communication. The lead author is responsible for managing the writing process, arranging for review of drafts by co-authors, making final decisions on language, obtaining approval by the SOG and SIG, submitting the communication to publication outlets, and regularly updating the SIG about the paper's publication process.

The table below details the suggested communications for a paper in which all SIG members will be authors. These papers will have one of the following bylines:

- The APPD LEARN Whatnot Study Group (in this form, a list of all authors – SIG members – must appear in the manuscript)
- Author 1, Author 2, Author 3; **and** the APPD LEARN Whatnot Study Group (in this form, SWG members may be listed individually in the by-line, and a section in the manuscript body must also list all SIG members as being the APPD LEARN Whatnot Study Group and indicate they are all authors of the paper).

Table 2: Communication process when all site investigators are authors

What	Who communicates	To whom	Notes
1. Solicit interest in participation in an SWG	SOG	SIG	Provide at least 2 weeks before announcing membership
2. Announce membership of SWG and designated lead author	SOG	SIG	
3. Develop the first draft of the manuscript, provide progress updates	SWG	SOG	
4. Announce the first draft and invite critical review/comments	SWG	SIG	Provide at least 2 weeks for comment; indicate the planned journal/venue; critical review is an author qualification
5. Develop further drafts, provide progress updates	SWG	SOG	
6. Announce proposed final draft and ask for approval to submit to particular journal	SWG	SIG, SOG	SIG approval is an author qualification; SOG approval is to manage publication timing/overlaps
7. Submit manuscript	SWG	SIG	
8. Decision received from journal: Rejection (revise and discuss next potential journal)	SWG	SIG	Go to step 5
9. Decision received from journal: Revise/Resubmit or Provisional Accept	SWG	SIG	Let SIG know if the revision is substantive or not. If substantive revision, go to step 6 If nonsubstantive, go directly to step 7
10. Decision received from journal: Accept	SWG	SIG	Include a copy of the final accepted manuscript for the record. Celebrate.
Note: When there is limited time for submission, shortcuts should be chosen by the widest possible group based on upholding the key principles, and should always be communicated by email to the full SIG.			

The table below details the suggested communications for a paper in which only SWG and SOG members will be authors, but all other SIG members will be named and indexed as Collaborators. These papers will have one of the following forms of byline:

- The APPD LEARN Whatnot Study Group[*] (note the asterisk; in this form, a list of authors must be provided in a section in the manuscript body, and a list of collaborators in the acknowledgments)
- Author 1, Author 2, Author 3; **for** the APPD LEARN Whatnot Study Group (in this form, all authors – SWG and SOG members – must be listed individually in the by-line, and the acknowledgments must also list all SIG members as being the APPD LEARN Whatnot Study Group and indicate they are all collaborators on the paper).

Table 3: Communication process when all site investigators are NOT authors

What	Who communicates	To whom	Notes
11. Solicit interest in participation in an SWG	SOG	SIG	Provide at least 2 weeks before announcing membership
12. Announce membership of SWG and designated lead author	SOG	SIG	
13. Develop the first draft of the manuscript, provide progress updates	SWG	SOG	
14. Announce the first draft and invite critical review/comments	SWG	SIG	Provide at least 2 weeks for comment; indicate the planned journal/venue; critical review is an author qualification
15. Develop further drafts, provide progress updates	SWG	SOG	
16. Announce proposed final draft and ask for approval to submit to particular journal	SWG	SOG	SIG approval is an author qualification; SOG approval is to manage publication timing/overlaps
17. Submit manuscript	SWG	SOG	
18. Decision received from journal: Rejection (revise and discuss next potential journal)	SWG	SOG	Go to step 5
19. Decision received from journal: Revise/Resubmit or Provisional Accept	SWG	SOG	Let SIG know if the revision is substantive or not. If substantive revision, go to step 6. If nonsubstantive, go directly to step 7
20. Decision received from journal: Accept	SWG	SIG	Include the full citation as it will appear in the journal. Celebrate.
Note: When there is limited time for submission, shortcuts should be chosen by the widest possible group based on upholding the key principles, and should always be communicated by email to the full SIG.			

Conflict Resolution

If a question or concern arises about study processes, investigators are encouraged to address it directly with the study principal investigators as soon as possible. If the study PIs cannot resolve the conflict satisfactorily (or wish assistance), it should be brought to the attention of the SOG, which includes the APPD LEARN Director and staff. If the SOG cannot resolve the conflict, the APPD LEARN Director will do so. Concerns about the APPD LEARN Director that cannot be directly resolved with the Director may be brought to the APPD LEARN Advisory Committee by contacting the Chair of that committee. The names of these individuals can be found on the APPD LEARN website (http://learn.appd.org) in the "Leadership" section.

Communications checklist for PIs of APPD LEARN Studies

☐ Complete (and regularly update) the table of members of the study oversight group (SOG), study investigator group (SIG), and study writing groups (SWG)

☐	Send copy of the table of members to all SOG members at each update
☐	Ask APPD LEARN to create listservs for the SOG, SIG, and any SWGs
☐	Schedule and hold monthly (or more frequent) calls with the SOG. Circulate call minutes to the SOG listserv
☐	Adopt principles of authorship to provide to sites at the time of recruitment Add new sites to the SIG as they are recruited or obtain IRB approval Update the SIG listserv as new sites are enrolled
☐	Adopt process for reviewing proposed papers, presentations, communications
☐	Schedule and hold monthly (or more frequent) study progress update calls with the SIG. Circulate call minutes to the SIG listserv
☐	Update the SIG whenever an SWG is being formed, and provide SIG members the option of joining the SWG
☐	Check in with SWG lead authors regularly to track progress (see Tables 2 and 3)

References

See also: APPD LEARN Authorship Guidelines,
http://www.appd.org/learnsite/sysimages/Authorship%20principles%202012-05-21.pdf