

Sample prototype publication policy for the XYZ Trial

General publication principles

- Publication of finished results is a duty that is to be carried out in a timely fashion following completion of the trial or in relation to a major treatment protocol change
- Decisions regarding timing, content, and conclusions of publications to rest solely with XYZ investigators
- Publication to be via peer-reviewed, indexed, medical journals
- Primary outcome results to be published before being presented
- All study publications to contain credit rosters listing key personnel and participating centers
- Sponsors and oversight bodies to be provided opportunity to comment on primary manuscripts prior to submission but no sign off authority for sponsors or oversight bodies

Design, methods, and baseline results manuscripts

- Manuscripts to be submitted to peer-reviewed, indexed, medical journals
- Presentations prior to publication allowed

Authorship format: Modified corporate or modified conventional

Credit list: Full list (all key personnel of participating clinics, resource centers, and sponsors)

Commissioning authority: Steering committee

Sign off authority: Study chair and Coordinating Center director

Primary results manuscripts (manuscripts reporting primary outcome data by treatment group)

- Manuscripts to be submitted to peer-reviewed, indexed, medical journals
- No presentation prior to publication
- Analyses by treatment assignment (intention to treat) and to include all observed events regardless of when observed and regardless of treatment being administered at time of observation

Authorship format: Corporate

The XYZ Trial Research Group (no authors listed on title page or in credits section)

Credit list: Full list (all key personnel of participating clinics, resource centers, and sponsors)

Commissioning authority: Steering committee

Sign off authority: Study chair and Coordinating Center director

Publication policy for the XYZ Trial

Secondary results manuscripts (manuscripts reporting secondary outcome data by treatment group)

- Manuscripts to be submitted to peer-reviewed, indexed, medical journals
- No presentation prior to publication
- Analyses of results to be by treatment assignment (ie, analysis by intention to treat) and to include all observed events regardless of when observed and regardless of treatment being administered at time of observation

Authorship format: Modified conventional

Ann L Jones, Fred A Brown, Ian F Smith, Carol W Jackson for the XYZ Trial Research Group

Credit list: Partial to full depending on manuscript

Commissioning authority: Steering committee

Sign off authority: Study chair and Coordinating Center director

Tertiary results manuscripts (manuscripts of results by treatment group for a measure not related to a stated aim of the trial; manuscripts produced from ancillary studies; "natural history" publication (publication of trends over time in the placebo assigned group or in a no treatment control group)

- Ideally published in peer-reviewed, indexed, medical journals, but may be published in conference proceedings or other forms of publication
- No proscription on presentation prior to publication

Authorship format: Conventional

Ann L Jones, Fred A Brown, Ian F Smith, and Carol W Jackson

Credit list: As appropriate on a per paper basis

Commissioning authority: Steering committee or interested investigators

Sign off authority: Study chair

Policy and procedures for presentations

Invited presentations

- Study Officers recommend whether or not to accept the invitation
- Approval of Study Officers or Steering Committee required to accept invitation
- Study Officers, in conjunction with the Steering Committee, decide who will present and who will be listed on the abstract as authors

Publication policy for the XYZ Trial

- Data analyses, unless otherwise specified and agreed upon, is the responsibility of the proposing investigator
- Authorship format is modified conventional

Investigator-initiated presentations

- Any member of XYZ Research Group has the right to propose a presentation, such proposals being subject to review and approval
- Members of the XYZ Research Group submit presentation ideas on the Manuscript/Presentation Proposal Form to the Chairman's Office
- The Chairman's Office will present the proposal before the Study Officers at their scheduled monthly meetings
- The Study Officers are required to review the abstract and act within 30 days
- An investigator may submit an abstract before approval by the Study Officers with the understanding that the abstract must be withdrawn if not approved
- Data analyses, unless otherwise specified and agreed upon, is the responsibility of the proposing investigator
- If data are analyzed outside the Coordinating Center and it is necessary for the proposing investigator to obtain data from the XYZ Trial database, provisions and methods for access should be discussed and approved during review of the presentation proposal
- Authorship format is modified conventional

Ratification and modification

2/3rd majority vote (closed) of research group