PERSPECTIVES ON AUTHORSHIP

Deborah Yelon
Herbert Stern Professor of Biological Sciences
University of California, San Diego

Editor, Developmental Biology
PERSPECTIVES ON AUTHORSHIP

• How to get your manuscript started
• Common misconceptions about writing
• Tips for selecting a journal
• How to handle reviews and revisions
• Thoughts on authorship policies
HOW TO GET STARTED

• Start with your abstract
  • General question of interest
  • Focused statement of interest
  • What we know so far
  • How this work fits in
  • What is accomplished here

• Our conclusions and how they move us forward
HOW TO GET STARTED

• Start with your figures
  • See your figures as a storyboard
  • How many points dictates how many figures
• Select your punchline
  • Use schematics to ease figure digestion
COMMON MISCONCEPTIONS ABOUT WRITING MANUSCRIPTS

• Only a few drafts will be necessary
• There’s one best way to tell the story
• The significance will come across easily
• Formatting, grammar, spelling, etc. are not crucial
A FEW EXTRA TIPS

• Set the stage in your introduction
• Put things in perspective in your discussion
• Improve your writing through reading
• Use presentations as drafts of manuscripts
TIPS FOR SELECTING A JOURNAL

• Identify your audience

• Where do you see papers on similar topics?

• Where do you see papers of similar scope?

• Use your network (of potential reviewers)

• Talk to editors
A FEW TRENDS IN PUBLISHING TO CONSIDER

• New styles of peer review

• Focus on major points, less fussiness over minor points

• Attention to opportunities for junior faculty
HANDLING REVIEWS AND REVISIONS

• Expect to revise and resubmit
• Distinguish major from minor critiques
• Talk to the editor
• Be diplomatic at all times
THOUGHTS ON AUTHORSHIP POLICIES

• The PI should establish an authorship policy for the lab.

• This policy should be explicitly documented and shared.

• This policy should be actively discussed when designing projects.

• This policy should be applied consistently, including in the context of collaborations.
Manuscript Authorship: or Maximizing the Effort
### D. V-D - Criteria Matrix Ranks and Tracks

**R** = Required  **S** = Suggested

#### COM FACULTY RANKS CRITERIA

*Under exceptional circumstances, promotions may be recommended when the candidate does not meet all of the basic criteria. These will be unusual cases.*

<table>
<thead>
<tr>
<th>Professor</th>
<th>Academic Investigator</th>
<th>Academic Inv/Ed</th>
<th>Academic Clinician</th>
<th>Clinician Educator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues to meet all the criteria for Associate Professor with major accomplishments in research, teaching, and/or clinical service</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Distinguished career exemplifying scholarship. Excellence &amp; productivity in research, outstanding success as a teacher, and/or outstanding service contributions are required. Involved in teaching activities, including formal lectures, grand rounds, and/or continuing medical education. (Leadership in interprofessional teaching and interdisciplinary research encouraged)*</td>
<td>R*</td>
<td>R*</td>
<td>R*</td>
<td>R*</td>
</tr>
<tr>
<td>Principal investigator on significant research grants</td>
<td>R</td>
<td>S</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Co-investigator on research grants.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct involvement in research.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Key individual in training of students, post-graduates and mentorship of junior faculty</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Serves as Course Director for one or more major courses</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continues to carry a heavy clinical or teaching load</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continued publication of reviews, chapters, textbooks, peer reviewed papers, and/or innovative teaching materials (new curricula, educational programs, syllabi, video materials, computer programs, etc.) that influence the science and practice of medicine at the regional &amp; national levels</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Continued publication of important and original clinical and/or laboratory investigations with significant authorship.</td>
<td></td>
<td></td>
<td></td>
<td>R</td>
</tr>
<tr>
<td>Publications with significant authorship since promotion to Associate Professor (line 1), and in total (line 2)</td>
<td>≥10</td>
<td>≥10</td>
<td>≥10</td>
<td>≥30</td>
</tr>
<tr>
<td>Publications with authorship since promotion to Associate Professor (line 1), and in total (line 2)</td>
<td>≥5</td>
<td>≥5</td>
<td></td>
<td>≥5</td>
</tr>
<tr>
<td>National recognition, as evidenced by election to generalist or specialty societies, service on national committees, study sections, editorial boards, visiting professorships, and/or invitations to speak in CME courses</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Leadership roles in appropriate department, hospital and college</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>
What is “significant authorship”? 
The “sequence-determines-credit” approach

• The sequence of authors reflects the declining importance of their contribution

• Authorship order only reflects relative contribution, whereas evaluation committees often need quantitative measures.

• First author should get credit for the whole impact (impact factor), the second author half, the third a third, and so forth, up to rank ten.

• When papers have more than ten authors, the contribution of each author from the tenth position onwards is then valuated just 5%.
The “equal contribution” norm

• Authors use alphabetical sequence to acknowledge similar contributions or to avoid disharmony in collaborating groups.

• Contribution of each author is valuated as an equal proportion (impact divided by the number of all authors, but a minimum of 5%).
The “first-last-author-emphasis” norm

- In many labs, the great importance of last authorship is well established.
- First author should get credit of the whole impact, the last author half, and the credit of the other authors is the impact divided by the number of all authors.
The “percent-contribution-indicated” approach

• There is a trend to detail each author’s contribution

• This should also be used to establish the quantified credit.
B. I have given final approval of the submitted manuscript.
   _____ Yes          _____ No

C. I have, or a coauthor has, had sufficient access to the data to verify the manuscript’s scientific integrity.
   _____ Yes          _____ No

D. I have participated sufficiently in the manuscript to take public responsibility for (check only one)
   _____ part of the content       _____ the whole content.
E. To qualify for authorship, you must have made substantial contributions to the intellectual content of the paper. Please indicate your contribution(s) to this manuscript. Check all that apply.

_____ conceived and designed the research
_____ acquired the data
_____ analyzed and interpreted the data
_____ performed statistical analysis
_____ handled funding and supervision
_____ drafted the manuscript
_____ made critical revision of the manuscript for important intellectual content
_____ other (specify) ________________________________
Significant Contribution to Science as a ‘Team’ Member

Team Science
A. Personal Statement

• Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C).
A. Personal Statement

• I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project and coordinate the team. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several multi-author peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic team-based research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

C. Contribution to Science

• Briefly describe **up to five** of your most significant contributions to science.
• For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work.
• For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution.
• The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
C. Contribution to Science

• 1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator or team member in all of these studies.


C. Contribution to Science

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.


Summary

• ‘Team Science’ contributions can be identified as “significant” with appropriate justification and detail.

• The ‘Team Science’ contribution will be continue to be important and recognized.
MUSC Women Scholars Initiative Workshop

Authorship II
July 23, 2015

“Authorship Disputes”

Ed Krug, PhD
Professor, Regenerative Medicine and Cell Biology
Associate Dean for Postdoctoral Affairs
MUSC Research Integrity Officer
How prevalent are authorship disputes?

<table>
<thead>
<tr>
<th>Top ten behaviours</th>
<th>All</th>
<th>Mid-career</th>
<th>Early-career</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Falsifying or ‘cooking’ research data</td>
<td>0.3</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>2. Ignoring major aspects of human-subject requirements</td>
<td>0.3</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>3. Not properly disclosing involvement in firms whose products are based on one’s own research</td>
<td>0.3</td>
<td>0.4</td>
<td>0.3</td>
</tr>
<tr>
<td>4. Relationships with students, research subjects or clients that may be interpreted as questionable</td>
<td>1.4</td>
<td>1.3</td>
<td>1.4</td>
</tr>
<tr>
<td>5. Using another’s ideas without obtaining permission or giving due credit</td>
<td>1.4</td>
<td>1.7</td>
<td>1.0</td>
</tr>
<tr>
<td>6. Unauthorized use of confidential information in connection with one’s own research</td>
<td>1.7</td>
<td>2.4</td>
<td>0.8 ***</td>
</tr>
<tr>
<td>7. Failing to present data that contradict one’s own previous research</td>
<td>6.0</td>
<td>6.5</td>
<td>5.3</td>
</tr>
<tr>
<td>8. Circumventing certain minor aspects of human-subject requirements</td>
<td>7.6</td>
<td>9.0</td>
<td>6.0 **</td>
</tr>
<tr>
<td>9. Overlooking others’ use of flawed data or questionable interpretation of data</td>
<td>12.5</td>
<td>12.2</td>
<td>12.8</td>
</tr>
<tr>
<td>10. Changing the design, methodology or results of a study in response to pressure from a funding source</td>
<td>15.5</td>
<td>20.6</td>
<td>9.5 ***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other behaviours</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Publishing the same data or results in two or more publications</td>
<td>4.7</td>
<td>5.9</td>
<td>3.4 **</td>
</tr>
<tr>
<td>12. Inappropriately assigning authorship credit</td>
<td>10.0</td>
<td>12.3</td>
<td>7.4 ***</td>
</tr>
<tr>
<td>13. Withholding details of methodology or results in papers or proposals</td>
<td>10.8</td>
<td>12.4</td>
<td>8.9 **</td>
</tr>
<tr>
<td>14. Using inadequate or inappropriate research designs</td>
<td>13.5</td>
<td>14.6</td>
<td>12.2</td>
</tr>
<tr>
<td>15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate</td>
<td>15.3</td>
<td>14.3</td>
<td>16.5</td>
</tr>
<tr>
<td>16. Inadequate record keeping related to research projects</td>
<td>27.5</td>
<td>27.7</td>
<td>27.3</td>
</tr>
</tbody>
</table>

Note: significance of $\chi^2$ tests of differences between mid- and early-career scientists are noted by ** ($P < 0.01$) and *** ($P < 0.001$).
Prevalence of doubting the integrity of research by others (academic psychologists; n = 2,155)

Is unethical behavior in conducting research getting worse or ... is there a greater awareness of its impact?


US HHS ORI Policy on Plagiarism

“Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.”

“Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.”
Core Issues of Collaborations

• What are the scientific issues, goals, and anticipated outcomes?
• When is the project over?
• Do all members of the research team have a agree on these issues?
• What are the expected contributions of each participant?
• Who will write any progress reports and final reports?
• How will you decide about redirecting the research agenda?
• How will you ensure that all appropriate members are kept fully informed?
• How will you negotiate the development of new collaborations or projects?
• How, and by whom, will personnel decisions be made? How and by whom will personnel be supervised?
• What will be the criteria and the process for assigning authorship and credit?
• How will credit be attributed to each collaborator's institution for public presentations, abstracts, and written articles?
• How and by whom will public presentations be made?
• How and by whom will media inquiries be handled?
• When and how will you handle intellectual property and patent applications?
• How and by whom will data be managed? How will access to data be managed? How will you handle long-term storage and access to data after the project is complete?
• Should one of the principals of the research team move to another institution or leave the project, how will you handle, data, specimens, lab books, and authorship and credit?
Bottom lines for effective collaborations

- Communication from beginning to end
- Establish different roles and expectations at the onset
- Identify a data retention plan
- Agree on reagent distribution
- **Discuss authorship at the onset and throughout**
- Discuss intellectual property issues at the onset
- Establish who is in charge – and who will be the responsible agent
According to the International Committee of Medical Journal Editors …

“Authorship credit should be based on:

• **Substantial contributions** to conception and design, or acquisition of data, or analysis and interpretation of data;

• Drafting the article or revising it critically for important intellectual content; and

• Final approval of the version to be published.”

Authors must meet all three conditions!

[http://www.icmje.org/#author](http://www.icmje.org/#author)
Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.”

“All persons designated as authors should qualify for authorship, and all those who qualify should be listed.”

“Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.”

http://academicdepartments.musc.edu/research/policies/
Authorship Case Study

Dr. Colleen May is a participating neurologist in a clinical trial to assess the efficacy and toxicity of a new anticonvulsant medication. For the duration of the two-year study, each neurologist is to meet with each of his or her patients for an average of 30 minutes each month. In Dr. May's case, this amounts to an average of 20 hrs/month. During each visit, the physicians administer a variety of specialized tests, requiring judgments dependent on their experience and training in neurology. At the completion of the study, the results are to be un-blinded and analyzed by the project leaders. It is anticipated that at least 2 publications will be prepared for the New England Journal of Medicine. Dr. May has just learned that she will be listed in the acknowledgements, but not as an author of the manuscript. Dr. May argues that she has provided nearly 500 hours of her expert time, far more than needed to complete a publishable study in her experimental laboratory.

Does Dr. May have a case for authorship? Why or why not?

http://research-ethics.net/topics/authorship/#discussion
Art and Science of Successful Authorship in Clinical Research

Bruce Ovbiagele, MD, MSc

MUSC Women Scholars Initiative (WSI) Authorship Workshop II
July 23, 2015
Disclosures

- NONE
Outline

- Overview of General Concepts
- Preparing Sections of a Manuscript
- Manuscript Submission
- Publishing Trial Results
General Concepts
A Recognized Challenge

“There is no form of prose more difficult to understand and more tedious to read than the average scientific paper!”

-Dr. Francis Crick, 1994

*The Astonishing Hypothesis*
Manuscript Segments

- Title/title page
- Abstract
- Introduction
- Methods
- Results
- Discussion
- (Conclusion)
Editors’ Responses to Key Questions

1. What section contains the most flaws?

2. What section responsible for outright rejection?

3. How frequently do Editors encounter manuscript problems?

- Poorly written, excessive jargon
- Inadequate/inappropriate presentation
- Poor description of design
- Excessive zeal and self promotion
- Rationale confused, contradictory
- Essential data omitted, ignored
- Boring
- Important work of others ignored

Byrne DW, Publishing Medical Research Papers, Williams and Wilkins, 1998
Sections Unbalanced

Article of 3650 words

- Abstract
- Introduction
- Methods
- Results
- Discussion

Byrne DW, Publishing Medical Research Papers, Williams and Wilkins, 1998
General Suggestions

- Use the **present** tense when referring to work that has already **been published**
- Use **past tense** when referring to your own study
- Use the **active voice** for introduction and discussion, and **passive voice** for methods and results
- Avoid complex sentence structure; use simple and clear English
- Keep in mind that the **paragraph** is the essential unit of thought
- Avoid lengthy or unfocused reviews of previous research
- Aim to generally cite **one key reference** per point
Title

- First reviewed by Journal Editors before abstract

- What is the single most important point of this study?
  - Start with a short descriptive working title

- Write last—your findings and conclusions may alter your title

- One approach - make a list of the most important keywords

- Short, Specific, Relevant, Descriptive
  - Should describe main findings or purpose of study
Preparing Manuscript
Abstract

- Write it **after** completion of the main paper; Do NOT give any information or conclusion that is not stated in the main paper.

- **Background** (*1-2 sentences*)
  - *What is the major problem/question that prompted the study?*

- **Objective** (*1 sentence*)
  - *What is the purpose of the study?*

- **Methods** (*At least 2 sentences*)
  - *How was the study done?*

- **Results** (*At least 2 sentences*)
  - *What are the most important findings?*

- **Conclusion** (*1-2 sentences*)
  - *What is the most important conclusion drawn? (and what is the clinical relevance of the results?)*
  - *State clearly with essential qualifications*

Dickersin K et al. BMC Medical Research Methodology. 2007;7:44
Introduction

- Convinces (or not) the reader whether your study...
  - Has merit and asks important research questions
  - Is focused and supported by relevant recent citations
  - Is ultimately important to human health and human disease

- You will better focus your introduction AFTER you construct your findings (results) and consider them (discussion)

- The research question is the most important part of your introduction
Methods

- Study design or analysis type and period of study
- Condition or disease studied
- Human subjects approval
- Details of sample
  - Number, recruiting methods of study subjects, patients, how organized
- Interventions, outcome measures, statistical analyses
- Include the locations and times that data were collected
- Present in logical order and your subsequent results should follow that same order
- Give enough information to replicate the study
Results

- Write after figures and tables are constructed
  - Consider your data critically, allow to speak for self
  - Construct tables, figures and include them in outline
  - Write the results corresponding to order listed in methods
  - Use logical subheadings

- State **ALL** the findings
  - Whether significant or not
  - Without bias or interpretation
  - Avoid using descriptive terms (e.g. markedly, prominent)
  - Do not include weaknesses, strengths of study, i.e. don’t discuss results

- Present absolute numbers & percentages so reviewers can judge the significance of the findings
  - Statistical significance ≠ clinical significance

*Results confirm or reject your hypothesis: they do not prove anything*
Discussion

- Make it brief but informative!
  - ~20% of total text; Don’t restate all the results

- First state the answer to the question posed in the Introduction

- Provide evidence in support of answer

- Describe conflicting results and reasons for such differences

- Establish newness of findings, but avoid speculations, recommendations, and suggestions for future studies until the end

- Relate observations to other relevant findings

- Discuss limitations as well as strengths
Manuscript Submission
Factors to Consider in Choosing Journal

- What does the journal publish? What is your Topic?
- Human vs. animal work; Clinical vs. non-clinical
- Full articles vs. short communications; Reviews
- Audience Yours and Journal’s):
  - National vs. International; General vs. specialty vs. subspecialty
- Impact factor
  - Attracts (some) authors
Draft of the Paper

- Look at the information for Authors (on line)

- Look at a recent issue
  - Format
  - Style
  - Content

- Try to cite recent work in the journal to which you submit (if applicable)
Suggesting Reviewers (at least 5)

- Choose experts (senior and junior)
- Avoid non-experts
- Choose rigorous scientists
- May improve acceptance chances 😊

Strategies for Annoying Editors & Reviewers

- Leave traces of a previous rejection
- Show you are not familiar with the journal’s Info for Authors and the “look” of a paper in its published form
- Editorialize: “This work is very important”
- Say your paper, case, data are “the first”, “unique”, “novel”
- Ignore a recent paper (or editorial) in the journal
- Repeat material:
  - from the Introduction in the Discussion
  - from Results in the Discussion
  - from Tables or Figures in the Results
  - from Abstract in a “Summary” or “Conclusion” at the end of the paper
What Do Reviewers Look For?

- Creativity and originality
- Scientific importance
- Relevancy to readership
- Study design
- Interpretation
- Clarity and brevity
- Likely significance after revision
- Ranking
Response to Review

- If your paper is rejected:
  - Focus on the critiques
  - Address them in a revision for a different journal

- In the revision for the Same Journal:
  - State each entire and exact comment followed by your reply
  - Point-by-point response to the comments made
  - Indicate where changes have been made in the manuscript
  - Explain why you disagree with a comment or why you feel suggested changes are not necessary
Publishing Trial Results
Clinical Trial Registration

- Increases transparency and strength/validity of scientific database
- Alleviates selective data presentation on clinical trials in medical literature
- Increases public awareness and access to trials
- Assigns trial identifier

- Required by law in the United States
  - Efficacy trials for IND studies for serious diseases or conditions (FDA)
- Required by the International Committee of Medical Journal Editors (ICMJE) for publishing clinical trial research
Which Trial should be Registered if You Plan to Publish the Results in a Journal?

- All clinically directive trials which test any clinical hypothesis about health intervention and its outcomes
- No need for registration
  - Phase 1 trials
  - Trials investigating disease biology
  - Trials providing preliminary data
- The best answer to doubts about reporting – register it!
A Study to Assess the Safety and Efficacy of Alefacept in Kidney Transplant Recipients

This study is not yet open for participant recruitment.
Verified by Astellas Pharma Inc, December 2007

<table>
<thead>
<tr>
<th>Sponsored by</th>
<th>Astellas Pharma Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information provided by</td>
<td>Astellas Pharma Inc</td>
</tr>
<tr>
<td>ClinicalTrials.gov Identifier</td>
<td>NCT00543569</td>
</tr>
</tbody>
</table>

Purpose

A study to assess the safety and efficacy of Alefacept in de novo kidney transplant patients.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phase II</td>
</tr>
</tbody>
</table>

ChemiDplus related topics: Tacrolimus  Mycophenolate Mofetil  Tacrolimus anhydrous  Alefacept

U.S. FDA Resources

Study Type: Interventional
Welcome to the CONSORT Statement Website

CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).

The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.

The CONSORT Statement comprises a 22-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial. The Statement has been translated into several languages.

Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.

The CONSORT “Explanation and Elaboration” document explains and illustrates the principles underlying the CONSORT Statement. We strongly recommend that it is used in conjunction with the CONSORT Statement.
Conclusions

- Analyze and present data in manuscript appropriately
- Review relevant literature
- Choose correct journal
- Tell a convincing, concise story stressing the novelty and importance of the findings
- Format the paper as per journal specifications
- Register your Clinical trial and Follow CONSORT Guidelines for Reporting results!
"What is written without effort, is in general read without pleasure"

- Samuel Johnson

(English author, critic, & lexicographer (1709 – 1784))