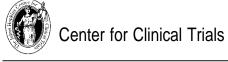
JOHNS HOPKINS

U N I V E R S I T Y



Department of Biostatistics Department of Epidemiology Department of International Health Department of Medicine Department of Ophthalmology Oncology Center

(Saturday) 13 January 2001

Memorandum

- To: Center faculty, staff, and friends
- Fr: Curt Meinert
- Re: Credits and acknowledgments in study manuscripts

Definitions

- **credit** *n* [MF, fr OIt *credito*, fr L *creditum* something entrusted to another, loan, fr neut of *creditus*; pp of *credere* to believe, entrust] 1. Recognition by name of some person, **group**, or **agency** for having performed specific functions or duties in relation to some activity, project, or production. 2. Such a recognition appearing in print in a published **manuscript** or at the start or end of a film. rt: **acknowledgment**
- **acknowledgment** *n* 1. An expression of appreciation or thanks for something done or contributed or for a kindness given. 2. A written expression of such appreciation or thanks, eg, as appearing in a **published manuscript**. rt: **credit**

Credit formats

Nonspecific: Undifferentiated listing of personnel arranged in alphabetic order (not recommended)

Ann J Brown, MD Frank M Curran, MD Kate S Duran, RN Raymond V Ellison, PhD Beth L Grant Milton J Handly, BS Etc

Discipline/activity specific Physicians

Ann J Brown, MD Frank M Curran, MD William J Dutton, MD

Nurses

Kate S Duran, RN Estelle N Lawson, LPN Carol J Morrison, RN 48 Credits and acknowledgments in study manuscripts (Saturday) 13 January 2001

Data processors

Raymond V Ellison, PhD Nancy L Harrison, MSc Etc

Position specific

Center directors

Ann J Brown, MD Frank M Curran, MD William J Dutton, MD Raymond V Ellison, PhD Etc

Clinic coordinators

Kate S Duran, RN Emily N Eaton, BS Marie K Fisher Etc Etc

Center/committee specific (recommended for multicenter trials) Clinics

University of California, Davis

Ann J Brown, MD (Director) Van H Ho, MD (Deputy director) Amy B Butler, BS (ECG technician) Kate S Duran (Clinic coordinator) Joe T Mews, BS (Lab technician)

Etc for other clinics

Coordinating Center: University of Minnesota, Mpls

Raymond V Ellision, PhD (Director) Mary W Baker, MD (Deputy director) S Kern Forster, PhD (Sr statistician) Elaine B Garrison, MSc (Coordinator) Edward N Hartman, MSc (Programmer) Grace R Zelier, BA (Secretary)

Etc for other resource centers

Steering Committee

Ann J Brown, MD (Chair) Raymond V Ellision, PhD (Vice chair) Frank M Curran, MD Credits and acknowledgments in study manuscripts (Saturday) 13 January 2001

Kate S Duran, RN William J Dutton, MD (nonvoting) Etc Etc other committees

Example: CAMP credit list (as submitted to the <u>NEJM</u>)

Clinical centers

- ASTHMA, Inc, Seattle, WA: Gail G. Shapiro; Leonard C. Altman; Jonathan W. Becker; C. Warren Bierman; Tamara Chinn; Dan Crawford; Thomas R. DuHamel; Heather Eliassen; Clifton T. Furukawa; Babi Hammond; Michael S. Kennedy; Mary V. Lasley; Dominick A. Minotti; Chris Reagan; Marian Sharpe; Frank S. Virant; Grace White; Timothy G. Wighton; Paul V. Williams.
- Brigham & Women's Hospital, Boston, MA: Scott Weiss; Sally Babigian; Peter Barrant; Linda Benson; Jose Caicedo; Tatum Calder; Anthony DeFilippo; Cindy Dorsainvil; Julie Erickson; Phoebe Fulton; Jennifer Gilbert; Mary Grace; Dirk Greineder; Stephanie Haynes; Margaret Higham; Deborah Jakubowski; Susan Kelleher; Jay Koslof; Nancy Madden; Dana Mandel; Agnes Martinez; Jean McAuliffe; Paola Pacella; Paula Parks; Anne Plunkett; Johanna Sagarin; Kay Seligsohn; Meghan Syring; Martha Tata; Walter Torda; June Traylor; Melissa Van Horn; Carolyn Wells; Ann Whitman.
- The Hospital for Sick Children, Toronto, Ontario, Canada: Joseph Reisman; Yola Benedet; Susan Carpenter; Jennifer Chay; Michelle Collinson; Jane Finlayson-Kulchin; Kenneth Gore; Anita Hall; Noreen Holmes; Sharon Klassen; Henry Levison; Ian MacLusky; Melody Miki; Joseé Quenneville; Renée Sananes; Christine Wasson.
- Johns Hopkins Asthma & Allergy Center, Baltimore, MD: N. Franklin Adkinson, Jr.; Nancy Bollers; Peyton Eggleston; Karen Huss; Kimberly Hyatt; Betsy Leritz; Mildred Pessaro; Stephanie Philips; Leslie Plotnick; Margaret Pulsifer; Cynthia Rand; Barbara Wheeler.
- National Jewish Medical and Research Center, Denver, CO: Stanley Szefler; Bruce Bender; Kristin Brelsford; Jessyca Bridges; Jody Ciacco; Ronina Covar; Michael Eltz; Michael Flynn; Melanie Gleason; Joseph Hassell; Marcia Hefner; Caroline Hendrickson; Daniel Hettleman; Charles G. Irvin; Jeffrey Jacobs; Tara Junk-Blanchard; Alan Kamada; Andrew Liu; Harold S. Nelson; Sai Nimmagadda; Kendra Sandoval; Jessica Sheridan; Joseph Spahn; D Sundström; Trella Washington; Michael P. White; Eric Willcutt.
- University of California, San Diego and Kaiser Permanente Southern California Region, San Diego, CA: Robert Zeiger; James G. Easton; Noah Friedman; Linda L. Galbreath; Ellen Hanson; Kathleen Harden; Anthony Horner; Al Jalowayski; Elaine M.

Jenson; Shirley King; Alan Lincoln; Brian Lopez; Michaela Magiari; Michael H. Mellon; Avraham Moscona; Kathleen Mostafa; Catherine A. Nelle; Senia Pizzo; Eva Rodriquez; Karen Sandoval; Michael Schatz; Nevin W. Wilson.

- University of New Mexico, Albuquerque, NM: H. William Kelly; Robert Annett; Teresa Archibeque; Naim Bashir; H. Selda Bereket; Marisa Braun; Shannon Bush; Michael Clayton; Angel Colon-Semidey; Sara Devault; Roni Grad; David Hunt; Jeanne Larsson; Sandra McClelland; Bennie McWilliams; Elisha Montoya; Margaret Moreshead; Shirley Murphy; Barbara Ortega; Hengameh H. Raissey; Mary Spicher; David Weers; Jose Zayas.
- Washington University, St. Louis, MO: Robert C. Strunk; Ellen Albers; Leonard Bacharier; Gregg Belle; Gordon R. Bloomberg; W. Patrick Buchanan; Mary Caesar; James M. Corry; Marisa Dolinsky; Edwin B. Fisher; Stephen J. Gaioni; Emily Glynn; Bernadette D. Heckman; Cathy Hermann; Debra Kemp; Claire Lawhon; Cynthia Moseid; Tina Oliver-Welker; Diana S. Richardson; Denise Rodgers; Elizabeth Ryan; Sharon Sagel; Thomas F. Smith; Susan C. Sylvia; Carl Turner; Deborah K. White.

Resource centers

- Bone Age Reading Center, Washington Unversity, St Louis, MO: William McAlister; Keith Kronemer; Patty Suntrup.
- Chair's Office, National Jewish Medical and Research Center, Denver, CO: Reuben Cherniack.
- **Coordinating Center, The Johns Hopkins University, Baltimore, MD**: James Tonascia; Debra Amend-Libercci; Marc Bacsafra; Patricia Belt; Karen Collins; Betty Collison; Christopher Dawson; Dawn Dawson; John Dodge; Michele Donithan; Vera Edmonds; Cathleen Ewing; Judith Harle; Robert Huffman; Rosetta Jackson; Kung-Yee Liang; Curtis Meinert; Jill Meinert; Jennifer Meyers; Deborah Nowakowski; Laura Oelberg; Bonnie Piantadosi; Michael Smith; Alice Sternberg; Mark Van Natta; Robert Wise.
- **Dermatology, Allergy and Clinical Immunology Reference Laboratory, Johns Hopkins University School of Medicine, Asthma and Allergy Center, Baltimore, MD**: Robert G. Hamilton; Carol Schatz; Jack Wisenauer.
- **Drug Distribution Center**, **McKesson BioServices Corporation**, **Rockville**, **MD**: Robert Rice; Ken Farris; Bob Hughes; Jun Lee; Tom Lynch.
- **Fundus Photography Reading Center, University of Wisconsin, Madison, WI**: Barbara Klein; Larry Hubbard; Michael Neider; Kurt Osterby; Nancy Robinson; Hugh Wabers.

- Immunology and Complement Laboratory, National Jewish Medical and Research Center, Denver, CO: Ronald J. Harbeck; Rhonda Emerick; Brian Watson.
- Patient Education Center, National Jewish Medical and Research Center, Denver, CO: Cindi Culkin; Jeryl Feeley; Colleen Lum Lung; Ann Mullen; Sarah Oliver; Christine Szefler; Anne Walker.
- PDS Instrumentation: Arlin Lehman.
- **Project Office, National Heart, Lung, and Blood Institute, Bethesda, MD:** Virginia Taggart; Paul Albert; Suzanne Hurd; James Kiley; Pamela Lew; Sydney Parker; Margaret Wu.
- University of Iowa, College of Pharmacy, Division of Pharmaceutical Services, Iowa City, IA: Rolland Poust; Dennis Elbert; David Herold.
- Pharmaceutical suppliers

AstraZeneca, Westborough, MA.

Glaxo Inc Research Institute, Research Triangle Park, NC.

Rhone-Poulenc Rorer, Collegeville, PA.

Schering-Plough, Kenilworth, NJ.

Data and Safety Monitoring Board

Howard Eigen; Michelle Cloutier; John Connett; Leona Cuttler; Clarence E. Davis; David Evans; Meyer Kattan; Sanford Leikin; Rogelio Menendez; F. Estelle R. Simons.

Likely uses of credits lists

- For inclusion in manuscripts submitted for publication
- As a document detailing composition of the study group and its committees
- Documentation of participation (eg, as requested by the FDA or a promotions committee)
- For compiling and updating study address directories
- For inclusion in requests for renewal of funding
- For inclusion as front or back material in study handbooks or other documents issuing from the study
- For use by others in contacting or locating people

Considerations and questions

- Who crafts philosophy reflected in listing? Recommendation: Study officers, executive or steering committees
- What are the limits of listing? Recommendation: Study investigators as represented by centers of record and associated personnel, study officers, committees and memberships, funding sponsors, contributors of drugs or other materials needed for conduct of trial
- Will the list be maintained (a recommended activity)? If yes, who will have that responsibility?
- Who will be the keeper (custodian) of the list? Recommendation: office of study chair or coordinating center
- How will listing be checked for accuracy; for completeness? Recommendations: Require custodian to circulate at periodic intervals to solicit updates from individual centers; require a "sign-off" process of center directors prior to use of list in regard to manuscripts being readied for submission for publication; for ensuring accuracy and completeness; supplement process with central review to ensure uniformity of listing and fairness of listings
- Degrees of persons listed? Recommendation: Limit to advanced degrees of relevance; expect task to be difficult and tedious and likely to be error prone unless concerted effort made for accuracy; expect list to need period updating
- Time coverage of listing: Snapshot or cumulative? Recommendation: Maintain to be cumulative (ie, to include dates and times of comings and goings in regard to centers, investigators, and committee members); reduce to snapshot only when appropriate, eg, for inclusion in funding renewal; use cumulative in regard to most publications
- Format of listing: abridged or unabridged? Recommendation: Maintain as unabridged; trim as needed
- List submitted with study publications? Recommendation: Use in relation to all publications; submit full unabridged listing in relation to primary and mainline publications; produce shortened abridged listed for secondary and ancillary publications

Sample policy ala SOCA

Full credit format: For primary publications (corporate authorship)

Funding sources: Footnote to title page

- Key committees: Steering committee, executive committee (Officers), and treatment effects monitoring committee; members as of publication, plus past members in special cases (eg, paper on methods and procedures)
- Other committees and working groups: As indicated depending on nature of paper Centers: Clinics, resource centers, and support centers pertinent to publication, exclusive of past centers except in special cases
- Research group: List by center, by position or function within center, exclusive of past personnel except in special cases

Acknowledgments: As indicated

Abbreviated format: For secondary publications (modified corporate or modified conventional form of authorship attribution)

Funding sources: Footnote to title page

Key committees: Steering committee, executive committee (Officers), and treatment effects monitoring committee; members as of publication; exclusive of other committees except as relevant to paper

Centers: Name and location of clinics and resource centers pertinent to publication Research group: Not listed, or listed alphabetically without regard to center affiliation Acknowledgments: As indicated

This is the tenth (and last?) in a series of memos concerning issues in the presentation and publication of results from trials. Previous memos have dealt with the obligation to publish, investigator right of primacy, limits to that right, type and place of publication, deposit of finished datasets, presentation of primary results at scientific meetings, internal presentation of results, authorship formats, and titling of manuscripts.

Trialists should take a leaf from movie producers when it comes to credits. Everyone who is anyone gets listed in movie credits. The actors of course, but also stunt people, the boom operator, the gaffer, the head carpenter and assistants, the head electrician and assistants, the key grip, focus pullers, riggers, people in charge of wardrobes, caterers, etc. The credits provide insights into where and how the movie was made.

Surely the film with the longest run of credits (6+ minutes of run time) has to be for *Who killed Roger Rabbit?* The movie, for me was boring (I got dragged to it by my family), but the credits were good! (Perhaps, had they run at the beginning, I would have dozed less during the movie.) The sheer length and dozens and dozens of animators made it clear that the film was a technological (even if boring) first.

The credits inform the audience. The same is true of credits in trials. But journal editors, unlike movie producers, are loathe to use space for credits. They will ask authors to shorten and condense credits to "save" space. If the credits are extensive, as in large multicenter trials, they may try to have them published in NAPS (National Auxiliary Publications Service) – the movie equivalent of a film without credits, save for a screen note indicating that credits may be found at <u>www.moviecredits.com</u>.

It is up to study leaders to hold fast on publication of credits as part of each publication. They be prepared to withdraw manuscripts from publication rather than submit to the "NAPS solution". The credits list should be considered part and parcel of the manuscript. Publication with the manuscript is important for two reasons. First, because people should be recognized for what they do. Second, because the information is useful in understanding the trial and in how it was done.

However, even if one wins the battle for inclusion, investigators will have little say over the format of those credits. The tendency is for editors to relegate credits to tiny fonts and "packed" formats. Consider, the credits list published in the <u>NEJM</u> in the recent CAMP publication (reproduced below) compared to as submitted as displayed above.

CAMP credit list (facsimile as published in the <u>NEJM</u>; vol 343, 2000; 1,054 - 1,063)

The members of the Childhood Asthma Management Program (CAMP) Research Group are as follows: Asthma, Inc., Seattle: G.G. Shapiro, L.C. Altman, J.W. Becker, C.W. Bierman, T. Chinn, D. Crawford, T.R. DuHamel, H. Eliassen, C.T. Furukawa, B. Hammond, M.S. Kennedy, M.Y. Lasley, D.A. Minotti, C. Reagan, M. Sharpe, E.S. Virant, G. White, T.G. Wighton, and P.V. Williams; Brigham and Women's Hospital, Boston: S. Weiss, S. Babigian, E. Barrant, L. Benson, J. Caicedo, T. Calder, A. DeFilippo, C. Dorsainvil, J. Erickson, E. Fulton, J. Gilbert, M. Grace, D. Greineder, S. Haynes, M. Higham, D. Jakubowski, S. Kelleher, J. Koslof, N. Madden, D. Mandel, A. Martinez, J. McAuliffe, P. Pacella, P. Parks, A. Plunkett, J. Sagarin, K. Seligsohn, M. Syring, M. Tata, W. Torda, J. Traylor, M. Van Horn, C. Wells, and A. Whitman; Hospital for Sick Children, Toronto: J. Reisman, Y. Benedet, S. Carpenter, J. Chay, M. Collinson, J. Finlavson-Kulchin, K. Gore, A. Hall, N. Holmes, S. Klassen, H. Levison, I. MacLusky, M. Miki, J. Quenneville, R. Sananes, and C. Wasson; Johns Hopkins Asthma and Allergy Center, Baltimore: N.E Adkinson, Jr., N. Bollers, P. Eggleston, K. Huss, K. Hyatt, B. Leritz, M. Pessaro, S. Philips, L. Plotnick, M. Pulsifer, C. Rand, and B. Wheeler; National Jewish Medical and Research Center, Denver: S. Szefler, B. Bender, K. Brelsford, J. Bridges, J. Ciacco, R. Cover, M. Eltz, M. Flynn, M. Gleason, J. Hassell, M. Hefner, C. Hendrickson, D. Hettleman C.G. Irvin, J. Jacobs T. Junk-Blanchard, A. Kamada, A. Liu, H.S. Nelson, S. Nimmagadda, K. Sandoval, J. Sheridan, J. Spahn, D. Sundstrom, T. Washington, M.P. White, and E. Willcutt; University of California, San Diego, and Kaiser Permanente Southern California Region, San Diego: R. Zeiger, J.G. Easton, N. Friedman, L.L. Galbreath, E. Hanson, K. Harden, A. Horner, A. Jalowayski, E.M. Jenson, S. King, A. Lincoln, B. Lopez, M. Magiari, M.H. Mellon, A. Moscona, K. Mostafa, C.A. Nelle, S. Pizzo, E. Rodriquez, K. Sandoval, M. Schatz, and NW Wilson; University of New Mexico, Albuquerque: H.W Kelly, R. Annett, T Archibeque, N. Bashir, H.S. Bereket, M. Braun, S. Bush, M. Clayton, A. Colon-Semidey, S. Devault, R. Grad, D. Hunt, J. Larsson, S.

McClelland, B. McWilliams, E. Montoya, M. Moreshead, S. Murphy, B. Ortega, H.H. Raissey, M. Spicher, D. Weers, and J. Zayas; Washington University, St. Louis: R.C. Strunk, E. Albers, L. Bacharier, G. Belle, G.R. Bloomberg, W .P. Buchanan, M. Caesar, J.M. Carry, M. Dolinsky, E.B. Fisher, S.J. Gaioni, E. Glynn, B.D. Heckman, C. Hermann, D. Kemp, C. Lawhon C. Moseid T. Oliver Welker, D.S. Richardson, D. Rodgers, E. Ryan, S. Sagel, T.E. Smith, S.C. Sylvia, C. Turner, and D.K. White; Bone Age Reading Center, Washington University, St. Louis: W. McAlister, K. Kronemer, and E. Suntrup; Chair's Office, National Jewish Medical and Research Center, Denver: R. Cherniack; Coordinating Center, Johns Hopkins University, Baltimore: J. Tonascia, D. Amend-Libercci, M. Bacsafra, P. Belt, K. Collins, B. Collison, C. Dawson, D. Dawson, J. Dodge, M. Donithan, V. Edmonds, C. Ewing, J. Harle, R. Huffman, R. Jackson, K.-Y. Liang, C. Meinert, J. Meinert, J. Meyers, D. Nowakowski, L. Oelberg, B. Piantadosi, M. Smith, A. Sternberg, M. Van Natta, and R. Wise; Dermatology, Allergy, and Clinical Immunology Reference Laboratory, Johns Hopkins Asthma and Allergy Center, Baltimore: R.G. Hamilton, C. Schatz, and J. Wisenauer; Drug Distribution Center, McKesson BiaServices Corporation, Rockville, Md.: R. Rice, K. Farris, B. Hughes, J. Lee, and T. Lynch; Fundus Photography Reading Center, University of Wisconsin, Madison: B. Klein, L. Hubbard, M. Neider, K. Osterby, N. Robinson, and H. Wabers; Immunology and Complement Laboratory, National Jewish Medical and Research Center, Denver: R.J. Harbeck, R. Emerick, and B. Watson; Patient Education Center, National Jewisb Medical and Research Center, Denver: S. Szefler, B. Bender, C. Culkin, J. Feeley, C. Lumlung, A. Mullen, H. Nelson, S. Oliver, C. Szefler, and A. Walker; IDS Instrumentation, Louisville, Colo.: A. Lehman; Project Office, National Heart, Lung, and Blood Institute, Bethesda, Md.: V. Taggart, P. Albert, S. Hurd, J. Kiley, P Lew, S. Parker, and M. Wu; University of Iowa, College of Pharmacy Division of Pharmaceutical Services, Iowa City: R. Poust, D. Elbert, and D. Herold; Data and Safety Monitoring Board: H. Eigen, M. Cloutier, J. Connett, L. Cuttler, C.E. Davis, D. Evans, M. Kattan, S. Leikin, R. Menendez, and F.E.R. Simons.

Someone has to assume responsibility (usually someone in the coordinating center or in the chairman's office) for creating and maintaining credit rosters. The rosters should be created when the trial is founded and updated at periodic intervals over the course of the trial, and in conjunction with each publication.

An issue, as in movies, is billing. What are the places qualifying as centers in the trial and what is the order of billing among centers? What is the billing for affiliated operations not rising to the level of center, such as drug distribution centers, banks for specimens, and central laboratories?

Another issue is whether the credits accompanying a manuscript should be abbreviated or full and whether the credit list should be cumulative (ie, inclusive of past and present centers and personnel) or merely current (ie, include only those centers and personnel presently associated with the trial; Recommendation: Publish the full cumulative list in at least one key publication).

There are advantages in maintaining cumulative lists, even if they are never used in publications. The information has historical value when describing and writing about the trial.

Investigators have to establish policy on credits. They have to decide who is eligible for listing and the way in which persons are listed (eg, CL Meinert or Curtis L Meinert). They have to decide whether the listing is to include degree (eg, Curtis Meinert or Curtis Meinert, PhD) and, if degrees are listed, whether the listing is limited to graduate degree?

It is a good idea, in trials with extensive credits, to maintain an abbreviated credits list for uses where the full list is "excessive" (eg, in some secondary and most tertiary publications from the trial; see above for policy in SOCA regarding use of the two lists). The abbreviated format should be reviewed by study officer before use and should be revised and updated whenever the full list is revised and updated.

\PubPol\Credits.WPD