Urinary Incontinence Treatment Network

Ancillary Studies Policies and Procedures

I. Definitions

The UITN recognizes two types of studies:

- ***Index Study:*** A Network study for data collection using Network resources. Typically, this is a key study for the Network. Index studies must be proposed from Network members.

- ***Ancillary Study:*** A Network study, linked to one or more index studies, which proposes collection of *additional* data or a study in which UITN data are combined with data from other research groups. Participation may range from a single site to the full Network. Ancillary studies may be proposed from sponsored non-UITN investigators.

The UITN recognizes three types of analyses:

- ***Primary Analysis:*** Analysis of data collected to address primary outcomes/hypotheses that are prospectively stated within the final protocol of either index or ancillary studies.

- ***Secondary Analysis:*** Analysis of data collected to address secondary outcomes/hypotheses that are prospectively stated within the final protocol of either index or ancillary studies.

- ***Tertiary Analysis:*** Analysis of previously collected data that are not analyzed for prospectively stated primary or secondary analyses.

II. Types of Ancillary Studies

There are two types of ancillary studies:

1. New data acquisition studies. These studies require collection of data not collected as part of an index study. This may involve all centers, a subset, or even just one center.

2. Inter-group studies. In these studies, UITN data are combined with data from non-UITN research group data (e.g., a joint analysis of UITN data and Pelvic Floor Disorders Network data).

Analyses of previously collected data addressing new hypotheses are termed "tertiary analyses" and do not fall under the purview of the ancillary studies policy.

III. Ancillary Studies Subcommittee

The Ancillary Studies Committee is a subcommittee of the Publication and Presentation (P&P) Committee chaired by the P&P vice chair. The subcommittee comprises one representative from the NIH, one from the UITN Coordinating Center, and three other UITN investigators, including at least one urologist and at least one urogynecologist. The Subcommittee may choose to call on outside expertise during the review of a proposed Ancillary Study, if appropriate. (The outside expert would provide

input but would not vote.) If an Ancillary Study is proposed by a Subcommittee member, the Subcommittee will select a replacement for purposes of reviewing that proposal.

IV. Process for Development and Review of Ancillary Study Proposals

Principal investigators, co-investigators, and other members of UITN have the opportunity and the responsibility to propose ancillary studies to the Steering Committee for review and consideration as a Network study. Development of research concepts is an integral part of the Network as it introduces innovative ancillary studies for collaborative research. An ancillary study may be proposed by a UITN investigator or a non-UITN investigator. A non-UITN investigator must have a "sponsor" from the Network who will serve as the primary liaison between the UITN and the investigator and who will represent the interests of the UITN.

Development and review of proposed ancillary studies proceeds in the following three stages:

1. Concept Proposal. Concept proposals for ancillary studies should consist of a brief overview of a proposed topic of research, about 2 pages in length, including the following sections:

a. Abstract: a brief summary of the proposed research that includes the primary research question and hypothesis.
b. Background and significance: a brief summary of supporting research and preliminary studies.
c. Study design: a preliminary description of how the study will be executed, including the study population, inclusion and exclusion criteria, randomized groups (if applicable), and research methods. The sample size estimation must be included.
d. Funding: indication of how the proposed research might be funded.
e. References.

All concept proposals should be submitted electronically to the chair of the Ancillary Studies Committee, a subcommittee of the Publications and Presentations Committee. The chair of the Ancillary Studies Committee will circulate the concept proposal, collate comments and suggestions, and communicate them to the person who makes the proposal within three weeks of proposal receipt. By a simple majority vote, the Ancillary Studies Committee can recommend approval for further development or non-approval. The results of these votes will be informational items for the next regularly scheduled Steering Committee meeting.

2. Mini-Protocol. Once approved by the Ancillary Studies Committee, the investigator is responsible for developing a mini-protocol within 3 months (unless an extension is authorized by chair of the Ancillary Studies Committee). To assist with the development of the proposal, the investigator may set up a work group of interested individuals from the Network members. A statistician from the Biostatistical Coordinating Center (BCC) must be included in the work group. The mini-protocol is an expanded version of the concept proposal, about 10 to 20 pages in length, which should incorporate comments and recommendations made by the Ancillary Studies Committee at initial presentation. The mini-protocol should be expanded as follows:

a. Abstract
b. Background and significance: expanded as indicated.
c. Study Design: should include specific details of study implementation. The sample size calculation should be provided with detailed justification. Investigators should work with the BCC for assistance with sample size calculation.
d. Feasibility: practicalities of enrollment and conduct of research

e. Budget: a detailed estimate of research costs should be included, with the targeted funding source identified.

Mini-protocols should be submitted to the chair of the Ancillary Studies Committee, who will circulate the ancillary study proposal, collate comments and suggestions, and communicate them to the proposer within three weeks of proposal receipt. By a simple majority vote, the Ancillary Studies Committee can recommend presentation to the Steering Committee for approval for further development or non-approval.

The Steering Committee will review the mini-proposal at the next regularly scheduled SC meeting. A super-majority vote (8/11) is required to recommend the mini-protocol for further development into a full protocol.

3. Full Protocol. Once approved, the proposer(s) must develop the full proposal with a protocol committee, consisting of at least one representative from each site and a BCC statistician. At the next in-person Steering Committee (SC) Meeting, an expanded proposal should be presented for discussion. If the SC agrees that more time for development is needed, an extension may be granted by simple majority vote. This protocol should be a very detailed initial proposal, about 20 to 30 pages in length. The protocol should be submitted to the BCC at least 3 weeks before the Steering Committee meeting.

The Steering Committee will make one of three decisions:

1. A recommendation that the protocol be revised for reconsideration by the SC; or

2. Approval (requires super-majority vote (8/11); or

3. Non-approval.

Voting is by written ballots that are counted immediately after they are cast. If the protocol is approved, it is designated as a Final Protocol, although during the process of implementation, changes to the study procedures and even to the study design may still occur.

V. Review Considerations

1. Ordinarily, the proposer should have or anticipate funding to support the study, including support for statistical analyses. Coordinating center support may be available on a case-by-case basis, but first priority for these resources will be for support of index studies. It is recognized that, in some cases, the availability of funding for an ancillary study will require approval and support from the UITN.

2. An important consideration when reviewing new data acquisition study proposals is the potential for added patient and staff burden. In particular, acquisition of the new data should not interfere with the conduct of an index study (for example, by introducing a disincentive to accrual or retention because of added patient or staff burden). Another review consideration is the availability of funding to perform the proposed study.

VI. Papers and Presentations from Ancillary Studies

1. All papers and presentations emanating from an ancillary study will follow the P&P policies and procedures.

2. The principal proposer of the ancillary study usually will serve as the lead person or chair of the writing group for papers based on such studies. The proposer will notify the P&P Committee of the intent to prepare a paper or presentations on the ancillary study.

3. The selection of a writing group, the preparation and submission of papers, and the submission of abstracts will follow the guidelines for other UITN papers as outlined in the preceding sections.

4. If the ancillary study uses data from only one or a subset of centers, that center (or those centers) may request that authorship on associated papers be closed to investigators from other centers. However, this request must be approved by the Publications & Presentations Committee. It is recognized that inter-group studies may be subject to policies of the outside collaborator(s) (e.g., if UITN is just one of several contributors to a large collaborative study) or may require ad hoc procedures specific to the collaboration. These and other exceptions to the Publications & Presentations policies must be approved by the P&P Committee.

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Publications and Presentations of the Urinary Incontinence Treatment Network (UITN)

Policies and Procedures

I. Purpose

This document presents the policies and procedures governing publications and presentations of the Urinary Incontinence Treatment Network (UITN). The goal of the Network is to complete important studies regarding treatment of urinary incontinence.

It is the policy of the UITN that all data and text considered for all papers, and all abstracts for presentation at scientific meetings, be submitted to the Publications and Presentations (P&P) Committee for review and approval prior to presentation or publication. Also, the Biostatistical Coordinating Center shall review these materials to verify that they are accurate in nature and are consistent with data used in other UITN documents and papers.

The objectives of the UITN P&P policies and procedures are as follows:

1. Assure and expedite orderly and timely presentations to the scientific community of all pertinent data resulting from the UITN study.

2. Assure scientifically accurate presentations and papers from UITN investigators.

3. Assure that all investigators, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide presentations and publications of UITN data.

4. Assure that press releases, interviews, presentations, and publications of UITN materials are accurate and objective, and do not compromise the scientific integrity of UITN studies.

5. Establish procedures to allow the UITN P&P Committee and the NIDDK/NICHD to exercise review responsibility in a timely fashion for UITN publications and presentations.

6. Maintain a complete up-to-date list of UITN presentations and publications, and to distribute such lists to all UITN investigators and the UITN DSMB on a regular basis.

7. Provide an orderly process of approval for Ancillary Studies stemming from the overall UITN.

II. Publication and Presentation (P&P) Committee

II. A. Composition

The P&P Committee will be selected by the UITN Steering Committee and be composed of one investigator from each clinical treatment center, an investigator from the biostatistical coordinating center, and an NIH representative. The Committee will elect a chair and vice chair on an annual basis. Multiple year terms are allowed. A subcommittee, chaired by the vice chair, will be established for review of all proposals for ancillary studies.

The P&P Committee will meet in person at no less than two UITN meetings per year. Additional teleconferences will be scheduled by the coordinating center representative as needed. The P&P Committee will report regularly to the Steering Committee on the status of all publications and presentations.

II. B. Responsibilities

The P&P Committee will maintain the following:

- Procedures for initiating and completing written and oral communications regarding UITN data;

- Procedures that facilitate orderly and timely presentations of UITN research to the scientific community;

- Procedures that ensure scientific accuracy and objective reporting of UITN data;

- Procedures for review and approval of proposals for ancillary studies;

- Procedures that facilitate high-quality interactions with the media, as needed; a complete and current list of UITN presentations and publications; and

- A complete and current list of scientific venues (and abstract deadlines) suitable for network presentations.

The P&P Committee is also charged with facilitating cooperative efforts and minimizing investigator conflict regarding presentation and publication issues.

III. Paper/Abstract Proposals

III. A. Approval Process

The approval process for papers and abstracts is as follows:

1. For each approved UITN study, a list of primary outcome papers and likely secondary outcome papers will be developed by the Steering Committee. Each Center and the Biostatistical Coordinating Center (BCC) will be offered the opportunity to take the lead on a paper in order to ensure that manuscript development and authorship are distributed equitably across the participating institutions.

2. To initiate the process that might lead to a presentation at a scientific meeting or to writing a paper for publication not included on the approved list described above, all UITN investigators and professional staff are invited to submit written proposals for abstracts or for papers to the UITN P&P Committee.

3. The proposal form in Appendix A should be completed and submitted to the P&P Committee for review and approval. It should clearly state the research question or hypothesis and include a brief background statement to clarify the purpose and importance of the research question. If approved, a writing group will be formed, as specified below.

4. Approval by the P&P Committee should be made within one month of receipt of the proposal.

III. B. Selection of Writing Group Members and Writing Group Chair

The procedure for selecting Writing Group members and Writing Group chair is as follows:

1. As soon as the proposal for an abstract or paper has been approved by the P&P Committee, the chair of the P&P Committee will communicate with all centers requesting nominees of qualified and interested investigators to participate as members of a writing group for that paper, as well as seeking the rationale for each nominee for the writing group. The request for nominees will include a specific date (deadline) for submission of nominations. UITN members will be given priority in this process.

2. The P&P Committee will select from the submitted list of nominees the membership of the writing group for each paper and will also identify a lead person for that writing group so that the group may expeditiously proceed with the task. In general, the person who proposes the idea for the paper or abstract will be the lead person.

3. It is the responsibility of the lead person to communicate with other writing group members, to develop a detailed manuscript outline, to collaborate with the coordinating center statistician to identify needed data and analysis, and to assume leadership in writing the manuscript. In general, the lead person will be the first author of the paper.

4. To expedite publication, one or more meetings/conference calls of the writing group may be necessary. It is recommended that such meetings be kept to a minimum or, to the degree possible, be incorporated as part of other scheduled meetings, such as UITN Steering Committee meetings or national scientific meetings.

5. The P&P chair and Committee are charged with the task of periodic systematic review of the work of all writing groups, aiding and encouraging members as appropriate, revising their membership or reconstituting the group membership, with written notification, when indicated. It is the intent that selection of writing group members be equitable and fair to all groups and individuals participating in this collaborative program, including encouragement of participation by younger professional colleagues, with due regard paid to exceptional efforts of groups or individuals.

III. C. Preparation and Submission of Papers

The lead person or chair of each writing group should take the following steps in the preparation of UITN manuscripts:

1. Contact each writing group member and review the specific charge to the group;

2. Draft dummy tables that each member of the writing group considers appropriate and needed for writing the manuscript;

3. Be aware that the coordinating center will process all requests for data analysis according to the overall priorities of the UITN;

4. Collate comments and dummy tables; solicit opinions of the writing group members; and when a consensus is reached, submit the dummy tables (or data analysis requests) to the coordinating center with copies to the chair of the P&P Committee;

5. Obtain input from every member of his/her group. If any member of the writing group does not respond to the lead person's request, or does not contribute to the writing of the paper, the lead person may request a replacement from the P&P Committee. Members of each UITN writing group should participate actively in the writing and review of the paper assigned to that group. Input from every member of the writing group should be encouraged and adhered to by all groups;

6. Approve the final version of the paper before its submission to the P&P Committee. All members of the writing group should have reviewed the final draft before its submission to the P&P Committee;

7. Perform his/her duties under the review of the P&P Committee. The general rule is that the time from approval of paper proposal to submission to P&P Committee should not exceed 6 months. If in the judgment of the P&P Committee, a writing group is not working well, and if there is an unjustifiable delay in writing the paper assigned to it, the P&P Committee may change either the lead person or the entire membership if in the Committee's judgment this action will expedite the writing of that particular paper;

8. Ensure that, in general, membership of writing groups is restricted to UITN investigators and professional staff, including coordinating center staff and the project officers at the NIDDK/NICHD. Others not formally associated with UITN may become involved in some aspects of data analysis and publication if sponsored by a UITN principal investigator and approved by the UITN P&P Committee.

9. Ensure that every effort be made to accommodate the expression of differing interpretations and alternate analyses within the body of each manuscript, so that all points of view are represented to the satisfaction of every participant.

III. D. Authorship and Clearance

Procedures for authorship and clearance are as follows:

1. For primary outcome papers, it is preferred that authorship be stated as "The Urinary Incontinence Treatment Network" if allowed by the selected journal. A credit roster or all major committees, units and UITN centers with their members (generally no more than ten persons from each center) is to appear at the end of each main paper (See Appendix B). It is the responsibility of the coordinating center to solicit, obtain and prepare the final list for inclusion in each UITN paper.

2. As an alternative for main papers and presentations, names of members of the writing group shall be listed as authors in the masthead, followed by the phrase "for the Urinary Incontinence Treatment Network" (See Appendix B). Each member of a writing group will be required to complete a Manuscript Author Sign-Off Statement (See Appendix C). The lead person or chair of the writing group, with the concurrence of other members of the group, should determine the order of authorship based on this information. A major criterion for order of authorship shall be the effort and contribution made by each member of the writing group in preparation of the manuscript. Membership in a writing group without substantive contribution to the manuscript does not justify authorship. In general, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (*N Eng J Med* 1001; 324: 424-428) shall be adhered to with regard to authorship. Disagreement about the order of authors which cannot be resolved by the chair of the writing group will be resolved by the UITN P&P Committee or the UITN Executive Committee.

3. The phrase "for the Urinary Incontinence Treatment Network" added after the names of the authors in the masthead is expected in papers reporting local data, or ancillary studies using local data.

4. A credit roster of all major committees, units, and UITN centers with their members (generally no more than ten persons from each center) is to appear at the end of each main paper as allowed by the journal. It is the responsibility of the coordinating center to solicit, obtain, and prepare the final list for inclusion in each UITN paper.

5. All papers should credit the funding sources NIDDK and NICHD, acknowledge that the data were collected through the UITN, and credit the UITN participating institutions.

6. Since not all circumstances that might cause disagreement among UITN investigators on the merit of a given paper can be foreseen, these disagreements should be resolved by the UITN P&P Committee or the UITN Executive Committee.

II. E. Review and Approval of Papers

After review of a paper by all members of a writing group, the chair/lead of the Writing Group will submit the paper to the chair of the P&P Committee.

1. The chair of the P&P Committee will disseminate the paper to members of the Committee for review and comment. The P&P Committee may establish subgroups of members with specific expertise who would be assigned review of related papers.

2. The chair of the P&P Committee will be required to submit a final draft of each UITN paper to the coordinating center for a final check of data accuracy. This will be done simultaneously with submission of the paper to the P&P Committee for review.

3. The coordinating center staff will be requested to submit their review within a reasonable time limit (generally not to exceed one month), and provide feedback to the chair of the P&P Committee as soon as possible.

4. The chair of the P&P Committee will present the final recommendation of the Committee to the UITN Steering Committee in a timely manner for their approval. The UITN Steering Committee shall have the final authority to review and approve all UITN primary outcome papers prior to submission. For all other papers, including papers from ancillary studies, the chair of P&P Committee will submit the recommendation of the Committee to the Steering Committee for approval. The Steering Committee may choose to accept the P&P Committee recommendation with or without review of the paper.

5. Upon approval by the Steering Committee, the lead author will submit the paper to the selected journal.

6. Reprints of published manuscripts will be ordered by the coordinating center. All requests for reprints of main papers should be directed to the UITN Coordinating Center. Requests for reprints of other papers reporting data from a limited number of centers should be directed to the lead author (or the author's designee).

III. F. Preparation and Submission of Abstracts for National and International Meetings

1. The coordinating center will maintain a current list of all relevant meetings and their deadlines for submission of abstracts.

2. Any member of the UITN may prepare an abstract on a subject appropriate to UITN investigations. Such an abstract may be based on the topic already assigned to a writing group, in which case the person preparing the abstract should be a member of that writing group or, the abstract may be on an entirely new topic, in which case it could originate from any investigator member of the UITN. If an abstract is submitted for a topic for which there is no writing group, and if the topic and the abstract is approved, a writing group will be activated. Regardless of the nature of the abstract, it must be approved by:
    a. A UITN writing group if that abstract deals with the topic assigned to that group; and
    b. The UITN P&P Committee.

3. If an abstract is prepared on a topic for which a writing group has not yet been selected, it is the responsibility of the P&P Committee to select a writing group, if appropriate, as soon as the content of the abstract is approved. The coordinating center should have a representative on this writing group, as in most UITN writing groups, to expedite communication with the coordinating center and facilitate timely analysis of data.

4. All data analysis requests for the preparation of an abstract for a national or international meeting must be submitted to the P&P Committee at least 8 weeks prior to the abstract deadline.

5. All abstracts of main, other, and ancillary study papers must be approved by the Committee before they are submitted to any national or international organizations. Abstracts submitted to the Committee for review should be accompanied, if appropriate, by copies of tables and graphs to support the conclusions of the abstract. It is understood that some descriptive abstracts may not require data submission or the data may be contained in the abstract. Only tables that relate to the major topics of the abstract should be requested from the coordinating center. These tables will be provided to the senior author of the abstract at least 4 weeks prior to the abstract deadline.

6. Completed abstracts that have been reviewed by all co-authors must be submitted to the P&P Committee for final approval at least 2 weeks prior to the abstract deadline. The time limit for review and approval of an abstract by the P&P Committee will be a minimum of 1 week but should not exceed 2 weeks after the P&P chairman has received the abstract.

7. See Figure 2 for Timeline.

8. In general, no abstract shall be submitted to any national or international organization for consideration prior to approval of the P&P Committee and all co-authors. If the UITN P&P Committee disapproves of an abstract already submitted, the author(s) will be required to withdraw that abstract immediately.

9. The selection of the person who will present the material in the abstract at the respective national or international meeting will be at the discretion of the respective writing group (if any). If a writing group has not been constituted, the P&P Committee will make the selection of the presenter. In general, this will be the person proposing the abstract. Regardless of who selects the presenter, the selection must be approved by the P&P Committee.

10. All presentations should credit the funding sources NIDDK and NICHD, acknowledge that the data were collected through the UITN, and credit the UITN participating institutions.

IV. Preparation of Presentations

IV. A. Procedure

1. Prior to abstract presentation, the responsible writing group is required to submit a copy of visual aids, including tables and graphs to the P&P Committee for review prior to the date of the particular meeting. Unless these tables and graphs are approved by the P&P Committee, the paper shall not be presented, even though its abstract may have been approved for presentation. Also, it is desirable to submit to the P&P Committee a copy of the text for presentation, if available. Each presentation shall have a sentence at the beginning identifying it as the work of the UITN, and that it is presented by that particular member “for the Urinary Incontinence Treatment Network.” As with all publications, all presentations should credit the funding sources NIDDK and NICHD and the participating institutions. Likewise, the presenters of UITN ancillary studies or local center data, are encouraged to share their visual

aids and text of the presentations with the P&P Committee. These presentations need not include the phrase "for the Urinary Incontinence Treatment Network."

2. Once a main paper has been presented at a scientific meeting, the tables used should be available to UITN investigators and may be used by them at other scientific meetings. However, such subsequent presentations should not appear in published form unless the data in the original paper are already published.

3. In the case of papers scheduled for presentation before an organization issuing press releases, the presenter may submit, for release to the press, the text of the presentation after it has been approved by the P&P Committee. If the presentation is based on a manuscript not yet accepted for publication in a peer review journal, a sentence must be included on the front page indicating the preliminary nature of the results.

4. Slides for use at national or international meetings or for publications of the main trial results will be sent to UITN principal investigators by the coordinating center. Slides with approved text for presentations or publications of ancillary studies will be prepared by the presenting investigator.

5. A standard set of slides, representing the major results of UITN will be produced by the coordinating center for each clinical treatment center.

IV. B. Invitations to UITN Investigators for Presentations of UITN Materials

The UITN welcomes opportunities to participate and present reports at national and international scientific meetings. When an invitation is received by a member of the UITN, UITN policies with regard to publications and presentations must be followed.

1. When a personal invitation is received by a UITN investigator to make a presentation, this invitation shall be sent to the P&P Committee for review and approval.

2. When an invitation is extended to more than one investigator, or if it comes to the chairperson of the Steering Committee or the chairperson of the P&P Committee requesting a representative of the UITN, the P&P Committee shall decide who is to represent the UITN.

3. All presentations in response to such invitations are to be based on published UITN reports unless approved beforehand by the P&P Committee. All presentations in response to invitations from industry (and for which a UITN investigator would be paid) are limited to data or reports already published.

4. Any presentation of unpublished UITN data must be reviewed and approved by the P&P Committee prior to the date of presentation.

5. Requests received by the principal investigators or their staff to present or discuss at local meetings (city, state or regional) any previously published UITN data, need no prior clearance by the P&P Committee. All local presentations must be reviewed and approved by the principal investigator for the center making the presentation. UITN investigators should be encouraged to accept such invitations. It is requested that principal investigators receiving such requests notify the coordinating center so the center can keep record of these presentations.

VI. Policy Regarding Departing Investigators

Departing investigators or staff from the UITN can submit a proposal for authorship role on abstracts and/or papers to the P&P Committee for approval, based on the following guidelines:

1. A maximum time limit of two years from separation from the institution to submission of abstract/paper;

2. The departing individual can only petition for authorship on abstracts and/or papers in process at the time of separation;

3. The departing individual must meet all reasonable criteria for authorship as outlined in the requirements of journals and as judged by the WEC; and,

4. A current individual and a departing individual from the same institution may, appropriately, co-author a single abstract or paper.

The P&P Committee is responsible for monitoring adherence of departing individuals to this policy.

Figure 1

Timeline for Manuscript Preparation

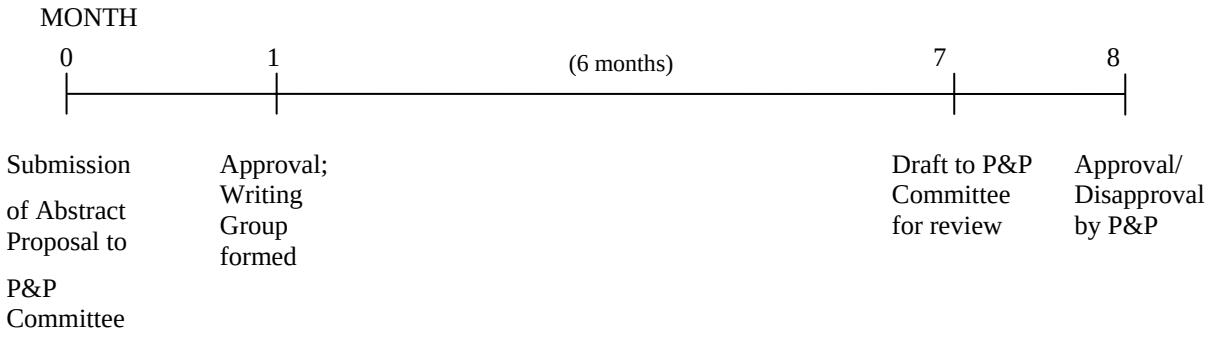
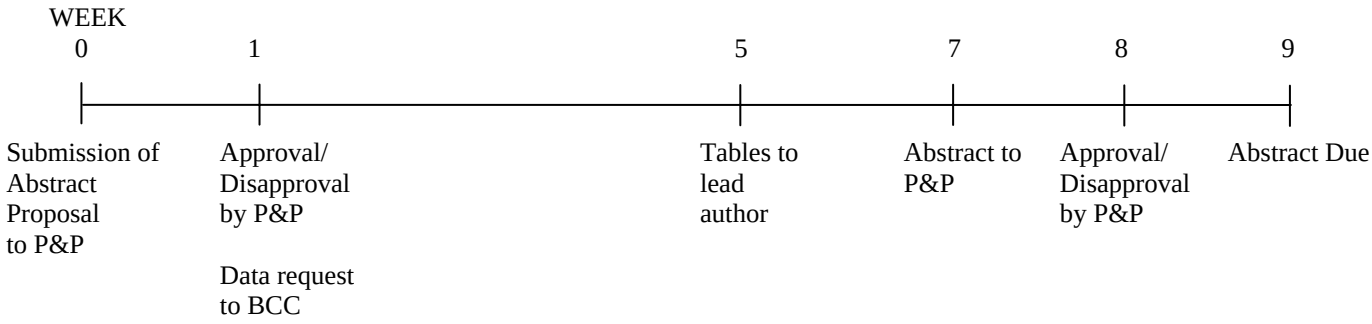


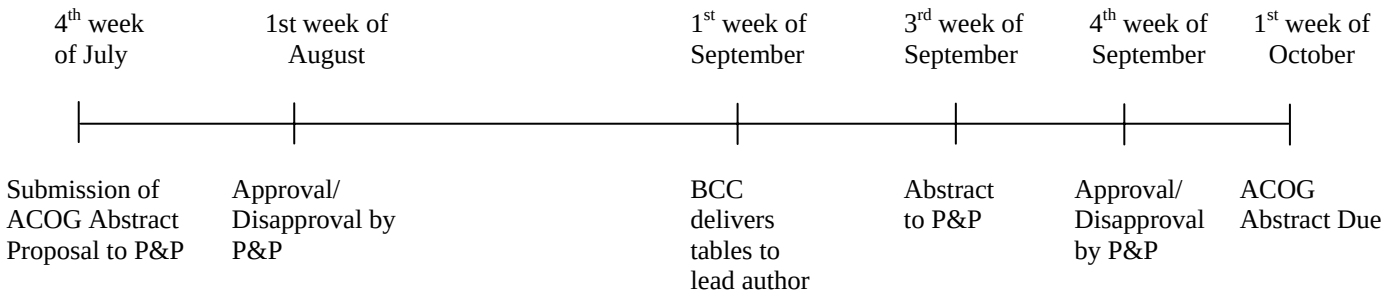
Figure 2

Minimum Timeline for Abstract Preparation

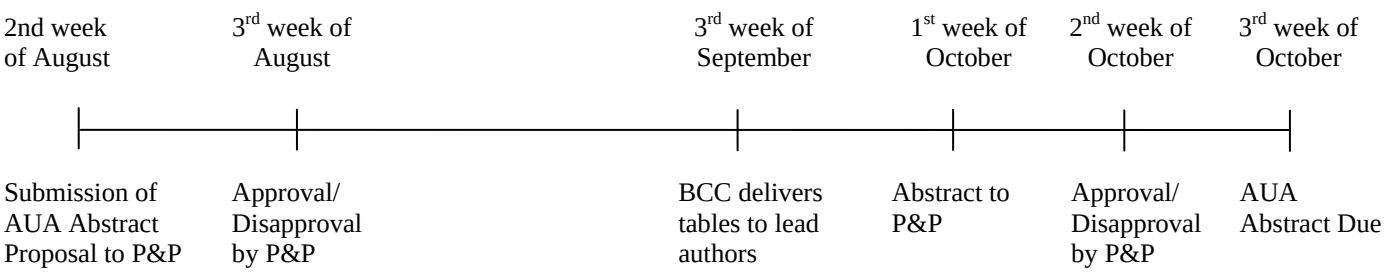
a. General Timeline



b. ACOG Timeline



c. AUA Timeline



APPENDIX A

PAPER/ABSTRACT ANALYSIS CONCEPT OUTLINE

1. Briefly describe prior research that highlights importance of proposed research topic.

2. Describe major goals of paper. List specific research hypotheses and how these relate to core research questions.

3. Patients (describe inclusion/exclusion criteria, comparison groups, etc.).

4. List analysis variables: outcome dependent variables, independent variables of primary interest, and other variables to control in the analysis.

5. Statistical methods/ approaches anticipated for paper (investigators are encouraged to consult with the BCC statisticians).

Submit this outline to the P&P Committee for review and approval.

APPENDIX B

FORMAT FOR CREDITING SITES AND FUNDING IN PUBLICATIONS

Jane Doe, MD, John Doe, PhD, for the Urinary Incontinence Treatment Network*

Ananias C. Diokno, MD, Veronica Mallett, MD, (William Beaumont Hospital, Royal Oak, MI; grant number); Linda Brubaker, MD, MaryPat FitzGerald, MD (Loyola University Medical Center, Maywood, IL; grant number); Holly E. Richter, MD, Keith Lloyd MD (University of Alabama, Birmingham, AL; grant number); Michael Albo, MD, Charles Nager, MD (University of California, San Diego, CA; grant number); Toby Chai, MD, Harry W. Johnson, MD (University of Maryland, Baltimore, MD; grant number); Halina M. Zyczynski, MD, Wendy Leng, MD, (University of Pittsburgh, Pittsburgh, PA; grant number); Philippe Zimmern, MD, Gary Lemack, MD, Joseph Schaefer, MD, (University of Texas, Dallas, TX; grant number); R. Duane Cespedes, MD, Stephen Kraus, MD (University of Texas, San Antonio, TX; grant number); Peggy Norton, MD, David Lesser, MD (University of Utah, Salt Lake City, UT; grant number); Sharon Tennstedt, PhD, Leslie Kalish, ScD (New England Research Institutes, Watertown, MA; grant number); Leroy M. Nyberg, MD, John W. Kusek, PhD (National Institute of Diabetes & Digestive & Kidney Diseases,); Anne M. Weber, MD (National Institute of Child Health and Human Development).

APPENDIX C

UITN Manuscript Author Sign-Off Statement

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6. Title of Manuscript:

7. Masthead Authors:

8. Printed Name of Individual Signing this Statement:

_____

9. My role in Manuscript Preparation (check only those that apply):

___ participated in design of the UITN Study
___ wrote part of the manuscript
___ contributed to the concept and/or development of the manuscript
___ participated in writing group conference calls
___ participated in revision of manuscript
___ contributed data to the manuscript
___ prepared analysis of data

Other Roles:

_____ _____

_____ _____

_____ _____

_____ _____

10. Signature/Date:

_____ _____

Please FAX a signed copy of this agreement to Kimberly Dandreo at New England Research Insitutes, Inc.
FAX #: 617-673-9515; Phone #: 617-923-7747 ext. 219.
Please keep a copy for your files

APPENDIX D: JOURNAL REQUIREMENTS FOR AUTHORSHIP

JOURNAL	GROUP AUTHORSHIP	#AUTHORS	AUTHORSHIP REQUIREMENT	ACKNOWLEDGEMENT STATEMENT	OTHER
JAMA	If authorship is attributed to a group (either solely or in addition to 1 or more individual authors), all members of the group must meet the full criteria and requirements for authorship described in the following paragraphs. A group may designate 1 or more authors to take responsibility for the group, in which case the other group members are not authors, but may be listed in an Acknowledgment.		With the cover letter include (1) the statement on and checklist for authorship responsibility, criteria, and contributions, (2) the statement on financial disclosure, and (3) either the statement on copyright or the statement on federal employment. Each of these 3 statements must be read and signed by all authors. (4) The corresponding author must sun the Acknowledgment statement.	Authors should obtain written permission from all individuals named in an Acknowledgment, since readers may infer their endorsement of data and conclusions. The corresponding author must sign the following statement: •I certify that all persons who have made substantial contributions to the work reported in this manuscript (eg, data collection, analysis, or writing or editing assistance) but who do not fulfill the authorship criteria are named along with their specific contributions in an Acknowledgment in the manuscript. •I certify that all persons named in the Acknowledgment section have provided me with written permission to be named. •I certify that if an Acknowledgment section is not included, no other persons have made substantial contributions to this manuscript.	2,000-4,000 words (not including tables/figures or references For RCT, use the CONSORT flow diagram – the CONSORT checklist should be completed and submitted with the manuscript.
NEJM	(1) Authorship attributed only to a group (the Boston Porphyria Study Group) will not be acceptable. At least one person's name must accompany the group name. The group name should appear after the authors' names, as follows: "Thelma J. Smith, Louise J. Jones, and Duane J. Brown, for the Boston Porphyria Study Group." If more than 12 authors are listed for a multicenter trial, or more than 8 for a study from a single institution, we shall require that each author sign a statement attesting that he or she		Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Condition (a), (b), and (c) must all be met.	We shall leave to the authors the choice of those acknowledged, but limit the space devoted to acknowledgments. To conserve space, those acknowledged will be listed only once, along with their institutions (one each). Committee names, numbers of patients contributed, and other details about the process of the trial will not be included. If acknowledgments fill more than a column of *Journal* space (about 600 words of small type), we shall deposit them with the National Auxiliary Publications Service. At the author's request we shall consider publishing fuller acknowledgments, including committee assignments, in reprints of	

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	fulfills the criteria for authorship of the Uniform Requirements.			the paper.	
OB-GYN	NO COMMENT				2000 Words
AM. J. OF OB/GYN	Multicentered studies are permitted to list a maximum of twelve authors, regardless of the number of institutions involved. Additional authors may be listed at the end of the article.	The number of authors permitted on regular articles is seven.	For manuscripts with two or more authors, each author must qualify by having participated actively and sufficiently in the study that is being performed and reported. The inclusion of each author in the authorship list of a report is based only (1) on substantial contributions to (a) concept and design, or analysis and interpretation of data and (b) drafting the manuscript or revising it critically for important intellectual content; and (2) on final approval by each author of the version of the manuscript. Conditions 1 (a and b) and 2 must both be met. Others contributing to the work (including participants in collaborative trials) should be recognized separately in an Acknowledgment. *In the covering letter that accompanies the submitted manuscript, it must be confirmed that all authors fulfilled both conditions.*		2,000-4,000 words (2,000 words = 8 pages) (3 tables/2 figures with legends)
INTN'L UROGYN					The manuscript must be accompanied by a letter signed by all authors indicating the following: a. The article is original; b. The article has not been published elsewhere; c. If human experimentation is included, the authors must state that the study was approved by the Institution and the Human Experimental

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J. OF UROL.		The number of authors should be limited to 6. If more than that number are listed, the senior author must justify the inclusion of each individual.	Manuscripts must be accompanied by a cover letter and AUA Disclosure Form signed by all authors. The letter should contain statements indicating the following: 1) that all authors have made a substantial contribution to the information or material submitted for publication; 2) that all have read and approved the final manuscript; 3) that they have no direct or indirect commercial financial incentive associated with publishing the article; 4) that the source of extra-institutional funding, particularly that provided by commercial sources, is indicated: 5) that the manuscript or portions thereof are not under consideration by another journal or electronic publication and have not been previously published.		
UROLOGY					3,000/max. 30 references