

EXHIBIT 1

WPATH

WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH

www.wpath.org
wpath@wpath.org

phone: 1+(847) 752-5328
fax: 1+(224) 633-2166

1061 E Main Street Ste 300
East Dundee, IL 60118

STAFF

Executive Director
Sue O'Sullivan
sue@wpath.org

**Executive Director of Global
Education & Development**
Donna Kelly
donna@wpath.org

Deputy Executive Director
Blaine Vella
blaine@wpath.org

Educational Program Coordinator
Taylor O'Sullivan
taylor@wpath.org

Assistant Associate Director
Jamie Hicks
jamie@wpath.org

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Gail Knudson, MD, MEd, FRCPC

August 26, 2020

Dear Karen:

We hope this email finds you well.

On behalf of the Executive Committee, the SOCV8 Chair and Co-Chairs of WPATH, we wanted to be sure to respond to you in writing prior to the 30 days deadline of the current 2 submitted manuscripts to WPATH.

In addition, we want to set out in writing to you how we would like you and your team at JHU to proceed with writing and publishing future manuscripts from the WPATH SOCV8 data.

The last 2 manuscripts were submitted for review on 27 July 2020. While the manuscripts have been under review, there have been many concerns noted regarding these papers by our Board of Directors and SOCV8 Chair and Co-Chairs.

In essence, the 2 manuscripts were evaluated on as per our Policy & Procedures Regarding the Use of WPATH SOC8 Data and the outcome of this evaluation was that the 2 manuscripts do not adhere to our Policy & Procedures Regarding the Use of WPATH SOC8 Data. This was due to point c of the Aim section: *"involves the Work Group Leader of the Chapter or, alternatively, a designated representative of that specific SOC8 Chapter, or alternatively the Chair or Co-Chairs of the SOC8 in the design, drafting of the article, and the final approval of the article"*.

We have discussed as a group how we can help you and your team addressing these issues in order for the two papers to be ready for submission.

As per the Policy & Procedures Regarding the Use of WPATH SOC8 Data you will need to reach out to the Work Group Leader of the Chapters related to the 2 manuscripts and ask him/her/they to identify one person within the chapter group to work with your team in order for the manuscripts to be finalised. Should you have difficulties getting into contact with a Work Group Leader, the SOCV8 Chair or Co-Chairs will be available to assist. This will ensure that the quality of the manuscripts fulfils adequate standards of form and content in trans health care; and is conform our Policy. It would be reasonable for this expert to be listed as a co-author of the manuscript.

In order to guaranty a quicker process for the development of future publications that use the WPATH SOCV8 data, the Policy has been adapted in order to include an approval process at an earlier stage. If anyone involved in the SOCV8 process, including yourself, would like to write a publication using the

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SOCv8 data they should follow a designated approval process (please see Figure 1 below).

We have revised our Policy & Procedures Regarding the Use of WPATH SOCv8 Data to ensure that further publication of WPATH SOCv8 is carried out in an orderly fashion; and that the Policy & Procedures are adhered to in full. We do hope that this process would encourage collaboration between your team and members of the SOCv8, who are the experts in their field, as this will be of benefit to everyone.

We would like to organise a Zoom meeting between us and yourself so the content of this letter can be discussed. Therefore, we would like to request that the 2 manuscripts are put "on hold" for submission, until we are able to meet with you (via ZOOM video call).

Please let Blaine know of your availability for the next two weeks, August 31 – September 4, between 10am ET – 4pm ET, and September 7 – 11, between 10am ET – 4pm ET, so that we can send a doodle to the EC and co-chairs to participate in our discussion.

We appreciate your understanding that these papers have a significant impact on JHU, WPATH, the work completed so far, and the eventual completion and release of the SOCv8. Great time, expertise, and care has been spent and we want to ensure that all our combined work is duly recognized, applied, and captured effectively.

Please confirm that you have received this email in good order and will defer the submission until our call and the subsequent outcome of such call.

Thank you and best regards,

WPATH EXECUTIVE COMMITTEE

Vin Tangpricha, MD, PhD – President

Walter Pierre Bouman, MD, PhD – President Elect

Randi Ettner, PhD – Secretary

Baudewijntje Kreukels, PhD – Treasurer

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Enc. *Policy & Procedures Regarding the Use of WPATH SOC8 Data
(version 2)*

Designated approval process for publication of Data (Figure 1)

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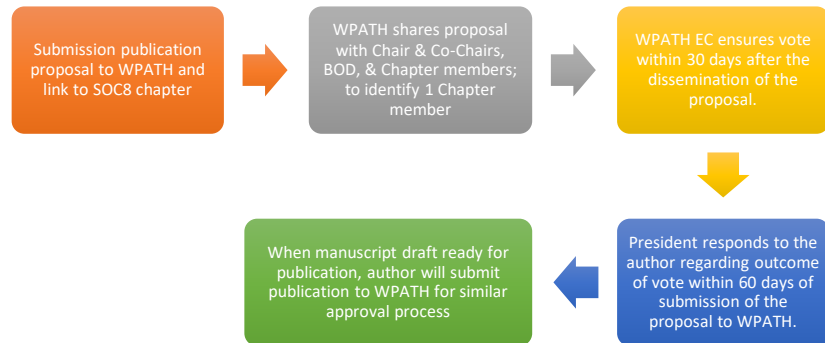
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Figure 1 - Designated approval process for publication of Data





Policy & Procedures Regarding the Use of WPATH SOC8 Data
Revised August 2020

This policy will be shared with every SOC8 member in order to inform them of the process of SOC8 Data Use and to allow each SOC8 member to apply to access the existing SOC8 data as described below

Background to the Policy

In April 2018 WPATH commissioned John Hopkins University (JHU) to support the development of the 8th edition of the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (SOC8). WPATH entered into a Sponsored Research Agreement with John Hopkins University on behalf of its School of Medicine with Dr Karen A. Robinson, Director at JHU Evidence-based Practice Center as principal investigator in conducting the research for WPATH. WPATH contracted Dr Robinson and her team to perform systematic literature reviews and other activities to support the development of the 8th edition of SOC.

The contract between WPATH and JHU states the following regarding Data use and Publications: “the term "Data" principally includes raw data, research data, records, reports, notes, tables, writing, sound recordings, pictorial reproduction, drawings or other graphical representations, and works of any similar nature (whether or not copyrighted) which are generated or specified to be delivered by Dr Robinson and her team in connection with the update and development of the SOC8”.

“Notwithstanding anything to the contrary contained in the contract between WPATH and JHU, WPATH shall retain the unrestricted right to use the Data, or any part thereof at any time, in any manner and for any purpose, including the publication of the Data and the communication of Data to third parties. No other parties other than Dr Robinson and her team will have any

WPATH Policy Use of Data for SOC8 – Version 2
Approved by WPATH Board of Directors – August 2020

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access to the Data without written permission by WPATH. Prior to the publication of the Data or any part thereof by Dr Robinson and her team, WPATH shall have thirty (30) days in which to review and comment on the proposed publication. Dr Robinson and her team will give due regard to WPATH's comments. WPATH has the right to request the deletion of any content within materials intended for publication by Dr Robinson and her team”.

Since the start of the contract between WPATH and JHU Dr Robinson and her team have provided systematic literature reviews for the development of statements of the following chapters: Assessment, Primary Care, Endocrinology, Surgery, Reproductive Medicine, and Voice Therapy. Dr Robinson and team have also provided guidance regarding the methodology of the SOC8 and feedback for some of the statements.

Aim of the Policy

WPATH commissioned and financed an update and the development of the SOC8 for the benefit of transgender healthcare in order to promote health, research, education, respect, dignity, and equality for trans people globally.

Therefore, the aim of this policy is to develop and to describe a process to ensure that any manuscripts developed from the systematic literature reviews commissioned by WPATH benefit transgender healthcare and promote health, research, education, respect, dignity, and equality for transgender people globally.

A decision-making process to give access to the Data should be underpinned by a number of good practice directives. Hence, WPATH grants access to the data to any interested party, which:

- a. has the intention to use the Data for the benefit of advancing transgender health in a positive manner and;
- b. has the intention to publish the Data in reputable, academic, peer-reviewed journals and;
- c. involves the Work Group Leader of the Chapter or, alternatively, a designated representative of that specific SOC8 Chapter, or alternatively the Chair or Co-Chairs of the SOC8 in the design, drafting of the article, and the final approval of the article and;

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- d. involves at least one member of the transgender community in the design, drafting of the article, and the final approval of the article and**;
- e. adheres to the WPATH Language Policy and/or similar publications***.

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Pathway to approval for use of WPATH Data

WPATH grants approval to use the Data for publication to any interested party, when:

- a. the directives outlined under the aim of this policy have been fulfilled and;
- b. the author(s) have acknowledged that WPATH has sponsored the acquisition of the data in the publication and;
- c. the author(s) have acknowledged that the authors are solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH in the publication and;
- d. The publication (“manuscript”) has been approved by WPATH via a designated approval process.

Designated approval process for publication of Data (see Figure 1)

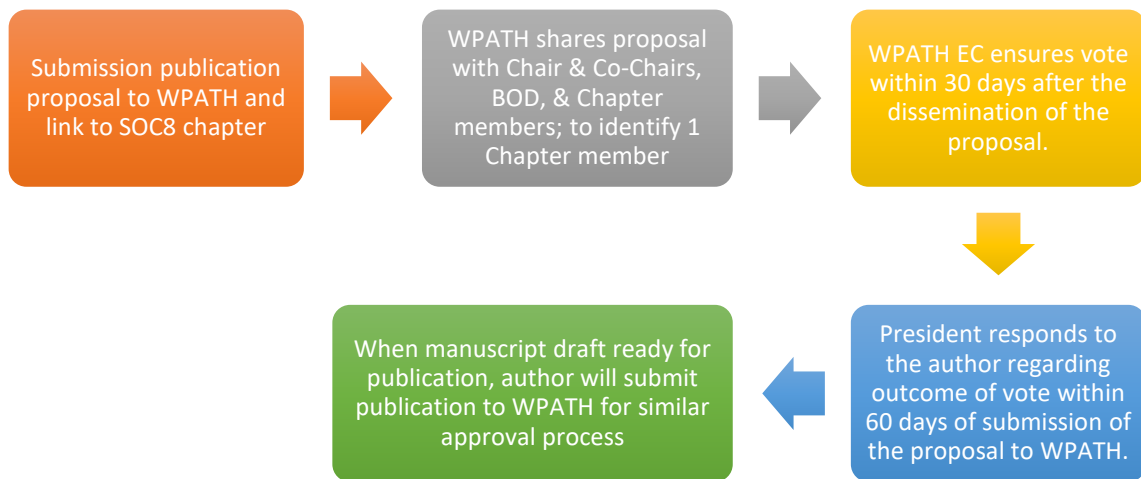


Figure 1 - Designated approval process for publication of Data

1. The lead author submits a proposal of the publication to WPATH with the following headings: Background; Aim(s); Method; Results;

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- Conclusion (Maximum 1 page and states which SOC8 chapter the publication is linked to);
2. It is WPATH's responsibility that the proposal is shared with the Chair and Co-Chairs of the SOC8, the members of the WPATH Board of Directors and all members of the SOC8 chapter linked to the proposed publication within 14 days after receipt of the proposal. The aim will be to identify an individual (s) from the chapter (maximum 2 individuals if a publication concerns more than one chapter) who will work with the lead author(s) of the proposed publication (unless the lead author is already working with one or more Working Group members); it is the responsibility of the Working Group as a whole to identify and to nominate one of their members, either by vote or general consensus within the Working Group.
 3. WPATH will keep a record of the possible proposals with deadlines for draft submissions - in order to avoid the development of multiple papers with the same aims using the same data;
 4. It is WPATH Executive Committee's responsibility to ensure that a vote is held within 30 days after the dissemination of the proposal.
 5. It will be a blind vote and approval to write the paper is granted to the author(s) by majority vote. In case of a tie, the WPATH President will have the deciding vote.
 6. It is the President's responsibility to respond to the author(s) with approval or disapproval within fifty-six (56) days of submission of the proposal to WPATH.
 7. Once the manuscript draft is ready for publication, the lead author will submit the publication to WPATH
 8. It is WPATH Executive Committee's responsibility to ensure that the manuscript is disseminated to the Chair of the SOC8, the Co-Chairs of the SOC8, and the members of the WPATH Board of Directors within 7 days after receipt of the manuscript.
 9. It is WPATH Executive Committee's responsibility to ensure that a vote is held within 14 days after the dissemination of the manuscript to the Chair and Co-Chairs of the SOC8 and Board members.
 10. It will be a blind vote and approval is granted to author(s) for publication by majority vote. The Chair and Co-Chairs of the SOC8 and Board members all have one equal vote. In case of a tie, the WPATH President will have the deciding vote.

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11. It is the President's responsibility to respond to the author(s) with approval or disapproval within thirty (30) days of submission of the manuscript to WPATH.
12. In case of disapproval, the President may decide to hold a special meeting with the Chair and Co-Chairs of the SOC8 and Board members to discuss the manuscript and the reasons for not approving publication.
13. There may be cases where it will be in the benefit of the SOC8 development process to publish the manuscript before the SOC8 has been completed, but there may be cases when the manuscript will only be approved for submission after the SOC8 has been published, acknowledging that the data for the manuscript may need to be refreshed.

- * This will be referred to as “Confidential Information”, which means all non-public, confidential, and/or proprietary information that is marked as “Confidential Information” as described below and which is disclosed by one party to the other, including but not limited to software, inventions (whether patentable or not), algorithms, diagrams, drawings, processes, research, product or strategic plans or collaborations or partnerships, financial information, or business models. Confidential Information, if in tangible or readable form, shall be marked as such at the time of disclosure and if disclosed orally, shall be reduced to writing, marked confidential, and addressed to the other party within ten (10) days after disclosure.
- ** See T’Sjoen, G., Motmans, J., Arcelus, J., & Bouman, W. P. (2017). The need of patient involvement in transgender healthcare research. *Journal of Sexual Medicine*, 14(12), 1494-1495.
Bouman, W. P., Arcelus, J., T’Sjoen, G., De Cuypere, G., Galupo, M. P., Kreukels, B. P. C., Leibowitz, S., Riggs, D. W., Schechter, L. S., & Veale, J. (2018). Transgender and gender diverse people’s involvement in transgender health research. *International Journal of Transgenderism*, 19(4), 357-358 or <https://www.tandfonline.com/doi/full/10.1080/15532739.2018.1543066>
- *** See Bouman, W. P., Suess, A., Motmans, J., Green, J., Deutch, M., Adams, N., Safer, J., Smiley, A., and Winter, S. (2017). Language and transgender health. *International Journal of Transgenderism*, 18(1), 1-6 or <https://www.tandfonline.com/doi/full/10.1080/15532739.2016.1262127>
See T’Sjoen, G., Radix, A., Motmans, J. (2020). Language & Ethics in Transgender Health. *Journal of Sexual Medicine*. Advanced online publication. doi.org/10.1016/j.jsxm.2020.05.017

From: [Karen Robinson](#)
To: [Lisa Wilson](#); [Kellan Baker](#); [Kristen McArthur](#); [Vaadeem Dukhanin](#)
Subject: FYI FW: Letter from Your WPATH EC and SOC8 Co-Chairs - re: SOC8 Data
Date: Wednesday, October 21, 2020 8:44:39 AM
Attachments: image003.png
Policy & Procedures Regarding the Use of WPATH SOC8 Data Final Approved Aug 2020.pdf

All –

I think some of you know but, with this last message from WPATH and a canceled call, I wanted to be sure you were all aware of the situation.

Please work diligently to get manuscripts (re)submitted and let me know if you receive messages from members of WPATH or journal editorial boards.

I am happy to have a Zoom call to talk through any concerns or questions you may have – just let me know and we will get something in the calendar.

Thanks for all of your hard work on this project!

Thanks,
Karen

From: Karen Robinson
Sent: October 20, 2020 8:23 PM
To: WPATH EC <wpathec@wpath.org>; Jon Arcelus <Jon.Arcelus@nottingham.ac.uk>; Eli Coleman <dreli@umn.edu>; Asa Radix <asa.radix@gmail.com>; Blaine Vella <blaine@wpath.org>
Cc: Stephen Fisher REDACTED ; Stefanie Gregory REDACTED
Subject: FW: Letter from Your WPATH EC and SOC8 Co-Chairs - re: SOC8 Data
Importance: High

All –

I am concerned about this message sent to the members of SOC8 Working Group Members as it suggests that there continues to be incorrect interpretation regarding data ownership and publications. WPATH approval for our publications is not required under the terms of the agreement, the WPATH policy was not incorporated into the executed agreement so it is not binding on us, and the JHU institution policies on academic freedom and intellectual property prohibit such restrictions/approvals regarding publication.

It seems as though the misunderstanding may be based on the sentence in section 7 of contract that states that WPATH “retains the unrestricted right to use to Project Data ... including the publication of the Project Data and the communication of Project Data to third parties.” Retains the right is not the same as ownership, and it also does not preclude JHU from also having those same rights in the Project Data.

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We have the right to publish and any JHU publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. We will continue to send draft manuscripts to WPATH for review and will give any comments received due regard.

I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018. I suggest that a call might be useful and I have copied in individuals from our Office of Research Administration and Office of General Counsel.

Thanks,
Karen

Karen A. Robinson, PhD

Professor of Medicine, Epidemiology, and Health Policy & Management

Director, Johns Hopkins University Evidence-based Practice Center

Johns Hopkins University

REDACTED

REDACTED

REDACTED

REDACTED



From: Jamie Hicks <jamie@wpath.org>

Sent: October 20, 2020 11:39 AM

To: Blaine Vella <blaine@wpath.org>

Cc: WPATH EC <wpathec@wpath.org>; Jon Arcelus <jon.arcelus@nottingham.ac.uk>; Eli Coleman <dreli@umn.edu>; asa.radix@gmail.com

Subject: Letter from Your WPATH EC and SOC8 Co-Chairs - re: SOC8 Data

Importance: High

External Email - Use Caution



Dear SOC8 Working Group Members,

Thank you very much for your hard work on the SOC8. Many of the chapters are going through Delphi at present whilst many chapters also are finalizing the text of their chapters and/or recommendation statements. This is an exciting accomplishment! We are hoping to see completed chapters in early 2021.

We are writing you today to inform you of an update of our Policies & Procedures regarding the WPATH SOC8 Data. As you know, WPATH commissioned a number of systematic reviews to be conducted by John Hopkins University. These systematic reviews are the property of WPATH. We would like to see as many systematic review manuscripts as possible to be published (ideally in our official journal, International Journal of Transgender Health). We want to let you know that if you or any other of your chapter members are interested in contributing a manuscript based on one of the systematic reviews, there is a policy on how to request a copy of the reviews and permission to publish these reviews. Please see the attached policy approved by the WPATH board that provides the details on how to initiate this process.

As a final note, we offer our apologies regarding the tardiness of this message and the recently developed Policy & Procedures Regarding the Use of WPATH SOC8 Data. We were caught on the wrong foot when the John Hopkins University Team informed us of wanting to publish 3 papers based on the SOC8 data.

Subsequently, we developed the attached Policy, which was ratified by the Board of Directors and the SOC8 Chair and Co-Chairs.

One paper from the John Hopkins University Team has recently been published online in the International Journal of Transgender Health, whilst two papers have not received the green light to be published. It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense.

We hope that you find the Policy & Procedures Regarding the Use of WPATH SOC8 Data helpful. We thank you very much again for your support of the SOC8 revision.

Sincerely,

Vin Tangpricha
Gail Knudson
Randi Ettner

Baudewijntje Kreukels
Walter Bouman
On behalf of WPATH

Enc. *Policy & Procedures Regarding the Use of WPATH SOC8 Data*

Jamie

Jamie Hicks
She/her/hers
Assistant Associate Director
[1061 East Main Street](#)
[Suite 300](#)
[East Dundee, IL 60118](#)

