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Part 1: GUIDELINES ON DATA/ SPECIMENS' OWNERSHIP AND SUBMISSION OF ABSTRACTS AND MANUSCRIPTS

A. Ownership of data / specimens

As used in these guidelines, "data / specimens" means information or products that are generated and recorded during the execution of research activities. These include **samples / products thereof, ethnographic reports, demographic data, field notes, memoranda, information material, clinical protocols, computer databases, and all other records**. Access is given by the project management and samples may only be analysed and results only presented as per written agreement.

The collected data is sensitive and BRIGHT is committed to ensure safe use and storage at all times in accordance with the EU Data Protection Directive. Misuse could result in stigmatisation and discrimination and illegitimate use must be prevented. Data / specimens use is jointly supervised by UKZN and OUS. The data / specimens are owned by the members from the Institutional Representatives / Board of Tutors that have participated in adding particular data / specimens. Only project management may give access to data/ specimens. Limited variables, relevant for each particular researcher will be issued. Only scientists, trusted recruitment officers and data entry staff may access these limited data after permission from the project management on a 'need to know bases'. Data and sample circulation can only be authorised by the project coordinators, Dr. Eyrun Kjetland, OUH and Professor Myra Taylor, UKZN or their representatives.

Employees or visiting researchers (ie. co-investigators, research assistants, consultants, students, trainees) of the research project are not allowed to remove specimens or products thereof, duplicate copies of the data or take original copies of data when they leave the project without the express, written permission of the principal investigators, and as per the data / specimens use agreement. Any data leaving the research station, UKZN or the European partners has been pseudonymised, truncated and, encrypted. The data will be accessed using a 128 bits encrypted https line to the server. Consent forms must be left for storage for minimum 5 years.

The PSCo *usually* meet the last Wednesday of every month: schisto4u@gmail.com. Admin: planner2012.vibeyclinic@gmail.com

B. Submission of conference abstracts and manuscripts

The following guidelines are intended to cover all work conducted as part of the study which is hereafter referred to as the BRIGHT project. The goals of these guidelines are to ensure that manuscripts and abstracts resulting from the BRIGHT project:

- Are developed in a collaborative manner, encouraging the active participation of interested investigators and/or students participating in the study as outlined below;
- Are of rigorous scientific quality and reflect accurate reporting of the design, conduct, and analysis of studies;
- Are published/presented in a timely manner and disseminated widely to a scientific audience
- Include publications designed to disseminate information to non-scientific communities with an interest in the study findings, particularly the population under study (published in any language).

T*he name 'VIBE' is for community liaison purposes and the term may not be used in academic work*.

1. Authorship

Authorship requires an intellectual contribution to the publication resulting from the BRIGHT project. We are working in a setting with many important contributors. **As a first step when thinking about a publication kindly ensure there are several contributing co-authors from South Africa.** The preparation for this might take weeks. Discuss how to approach this with the project management.

Determination of authorship for abstracts/manuscripts from the BRIGHT project will follow the guidelines set forth by the International Committee of Medical Journal Editors (ICMJE). The entire document appears at www.icmje.org. The primary criteria for authorship are intellectual contributions to protocol design, conduct of the protocol, interpretations and analysis of specimens / protocol data, including relating the results to other information in the literature, and drafting substantial portions of the manuscript. As per the ICMJE:

"Authorship credit should be based on 1) substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) be able to defend the scientific content. **Authors should meet conditions 1, 2, 3 and 4.** Acquisition of funding, collection of data/ specimens, 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 ". At an early stage investigators, especially from collaborating institutions, should be invited to participate in the development of manuscripts as co-authors, ensuring that there will be no exploitation of the South by the North.

1a. Contributors listed in Acknowledgments

Contributors to the publication who do not meet the criteria for authorship should, if they wish, be listed in the acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under a heading such as "clinical investigators" or "participating investigators," and their function or contribution should be described—for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients."

1b. Availability of data/specimens, authorship

If an outside investigator (ie. colleague, student, research assistant) is interested in analyzing study data / specimens and reporting/publishing results, it must first be established that the area of interest does not conflict with those of any of the original investigators. In this case, the person may, with permission, work under the leadership of the investigator studying that issue, ensuring active participation in the article /

thesis by project members as agreed at an early stage with project management. Submission of a data / specimens use request to the BRIGHT project steering committee (PSCo), followed by written authorization from the project management in the form of a data use agreement must be obtained as a first step, prior to any data / specimen release or analysis.

2. Abstract submissions

Prior to submitting an abstract for consideration at a conference, its lead author is required to propose the topic of the abstract and the conference to the project management using the attached form, Part 2, the "publication proposal form", and having obtained agreement, should send the abstract to the co-authors for review before submitting to project management. Upon distributing the abstract to co-authors, the lead author should stipulate the deadline by which all feedback must be provided, which shall be no less than two weeks from the day of distribution. It will be assumed that co-authors who do not respond by the feedback deadline approve of the abstract for submission. It is the responsibility of the lead author to ensure that sufficient time is allotted for feedback from the co-authors and any revisions to occur prior to submission of the abstract. The project management will have final approval of any abstract before submission to a conference for presentation.

Once the abstract is accepted for presentation, the lead author should notify the co-authors, the BRIGHT PSCo and send them the citation. Following the presentation, a copy of the materials used – poster, powerpoint and/or handouts should be sent to the project management and to the admin office to be archived.

3. Manuscript Proposals

Manuscript development will begin with completing the "Publication Proposal Sheet" (see Part II) and distributing it to all co-investigators. The purpose of the proposal sheet is to identify and remedy and conflicting or overlapping manuscript writing projects as well as any data analysis issues. It also serves to invite other relevant investigators to participate in the development of the manuscript as co-authors.

The lead author should distribute the form to other co-investigator authors at least two weeks prior to submitting it to the BRIGHT PSCo by email for review. If necessary, publication proposal sheet can be discussed during a PSCo meeting. Approval for the author to proceed will be decided, at which point the manuscript will be considered "in progress." If no substantial work has been done on a manuscript for a period of 6 months, the concept will be considered available again, which would allow another investigator to proceed with the manuscript.

It is recommended that the lead author periodically distribute the manuscript to the co-authors in order to receive feedback before sending final version of the manuscript to the co-authors for review. Upon distributing the manuscript to the co-authors, the lead author should stipulate the deadline by which all feedback must be provided, which shall be routinely no less than two weeks from the day of distribution. It will be assumed that co-authors who do not respond by the feedback deadline approve the manuscript for submission. The project management will have final approval before submission of any manuscript.

Once the manuscript is accepted for publication, it is the responsibility of the lead author to notify the co-authors, BRIGHT project and coordinators and to supply them with the accepted manuscript and complete citation for the work.

This document replaces previous versions pertaining to the same matter. Please sign below to acknowledge receipt of these guidelines and to signal agreement to comply with them. The investigator must scan and send to project management, lead co-author(s), known co-authors, and to the BRIGHT administration.

_____	_____	_____
Signature	Printed Name	Date

Part 2: PUBLICATION/ABSTRACT PROPOSAL SHEET/ DATA / SPECIMENS ANALYSIS PLAN

Date of submission: _____Submitting Investigator: _____

Email_____Phone_____

Proposed Title of Manuscript:

Proposed Conference & Date/Journal

Proposed Co-Authors: Email Phone

Objectives and hypothesis

Brief Summary of Analysis Plan

Data / specimens required for the analysis (this will be supplemented by an explicit detailed data request)

As a general rule the funders shall not be thanked or mentioned by the Master students or PhD students in the project unless the Project management decides otherwise. Researchers may only thank those (individuals) who wish to be thanked, ask them. If the above conditions are met funders below must be thanked with the following sentence: The research leading to these results has received funding from the....

Mention of funders **depends on several factors**, please liaise with BRIGHT tutor	applicable
... European Research Council under the European Union's Seventh Framework Programme (FP7/2007-2013) /ERC Grant agreement no. PIRSES-GA-2010-269245	
... University of Copenhagen with the support from the Bill & Melinda Gates Foundation (Grant no. OPPGH5344)	
... South-Eastern Norway Regional Health Authority Network project no. 2011073 or 2012032	
... Centre for Imported and Tropical Diseases, Oslo University Hospital	
... Oslo University Hospital Ullevaal (VIRUUS)	

There may be other funders that should be thanked. Please note them in this list.

Acknowledgements: _____

_____

Suggested main contact(s) in BRIGHT_____

Suggested secondary contact in BRIGHT_____

BRIGHT project management approved, by_____ Date: _____

The applicant must scan and send this to the project management, lead co-author(s), known co-authors, and schisto4u@gmail.com; planner2012.vibeyclinic@gmail.com. The original must be given / sent to the BRIGHT administration (contact planner2012.vibeyclinic@gmail.com for address).

Part 3: BRIGHT PROJECT DATA / SPECIMEN USE AGREEMENT

It is hereby agreed with:_____(the investigator) That s/he will have access to the following data/ specimens / data sets (list below or attached):

The following conditions will apply:

1. The investigator will not release the datasets / specimens to any person (including media and subcontractors) except with the written approval of the BRIGHT project management;

2. The investigator will not use the data / specimens in any way other than listed in the analysis and publication plan, without prior approved by the project management. The investigator will ensure that the data / specimens are kept in a secured environment and that only authorized users have access to the data/ specimens;

3. The investigator will not give others access to any data / specimens

4. Data that identifies persons, schools or places, directly or indirectly must not be released;

5. BRIGHT PSCo reserves the right to request the return of the dataset/ specimens should any of the above conditions be violated;

6. For investigators who are not directly involved in BRIGHT project or who are not part of the named co-investigators, or are students, the data / specimens use agreement is valid for one year from the date of the data sets / specimens being made available, after which time the data use / specimens agreement will be reviewed by the BRIGHT PSCo and, if requested, the copy of the data / specimens returned or destroyed.

7. The investigator is responsible for reporting any data quality inconsistencies to the relevant BRIGHT PSCo representative.

8. The name BRIGHT is reserved for local community liaison purposes; it must not be mentioned in publications or scientific writing.

Data / specimens User:

_____ Date: _____

Project management:

_____ Date: _____

Date of Data / Specimens Release:_____

The applicant must scan and send this to the project management, lead co-author(s), known co-authors, and schisto4u@gmail.com; planner2012.vibeyclinic@gmail.com. The original must be given / sent to the BRIGHT administration (contact planner2012.vibeyclinic@gmail.com for address).