RESPOND International Cohort Consortium of Infectious Diseases

Version: 7.1

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The International Cohort Consortium of Infectious Disease (RESPOND)

Governance and Procedures

Addendum of changes made between "The International Cohort Consortium of Infectious Disease (RESPOND); governance and Procedures" version 7.0 and 7.1 can be found below.

5. RESPOND Organisation; Committees, Scientific Interest Groups, Working Groups and Writing Groups:

- It has been specified that no single member of the SSC, including no representative from a funding body, can veto any project or scientific publication.

- Moreover, that the annual scientific retreat can be held in conjunction with IWHOD or EACS/Glasgow conference.

6. Scientific Projects:

- It has been specified that the RESPOND Secretariate facilitates all scientific communication and circulation of documents. There should be no direct communication between funding bodies and lead authors; all communication regarding scientific projects is managed by the RESPOND Secretariate.

7. Authorship in RESPOND

- It has been specified that members of funding bodies have to provide active scientific contribution to be considered for a writing group

- The text now specifies that abstracts are to be submitted with the core group on behalf of RESPOND

Addendum of changes made between "The International Cohort Consortium of Infectious Disease (RESPOND); governance and Procedures" version 6.0 and 7.0 can be found below.

This version 7.1 of the RESPOND Governance contains links to study documents, both public and internal. A username and password will be required to access internal documents and can be requested by study stakeholders.

1. Eligibility Criteria:

- Background: After analyses of the RESPOND dataset, it became evident that a RESPOND baseline definition including the date of integrase strand transfer inhibitor (INSTI) initiation, could artificially increase the incidence rates of clinical events for those on INSTIs compared to those on non-INSTIs. In short, including INSTI start in the baseline definition, causes the baseline for those initiating INSTIs to be later compared to those initiating a non-INSTI because individuals starting an INSTI had to start after the latest of cohort enrolment and 2012. On the other hand, the baseline for those starting a non-INSTI is not related to initiation of a specific antiretroviral treatment (ART)-class, but rather was defined only as the latest of cohort enrolment and 2012. This caused an unequal basis for comparison. This issue was previously described in *Analysis plan for RESPOND projects assessing clinical events and INSTI exposure, May 2021*

  Further, all previous analyses in RESPOND have accommodated for the potentially biased baseline definition, which has therefore never been applied.

Therefore, as decided by the RESPOND Scientific Steering Committee and the RESPOND Executive Committee, the default baseline will be defined as: **The latest of local cohort enrolment or 1 January 2012 for all participants regardless of ART exposure.**

However, the specific baseline for any individual analysis may vary depending on the type of analysis planned and which exact comparisons are intended, as assessed by the main statistician involved in the project with a rationale provided in the statistical analysis plan.

- In accordance with the RESPOND Governance V 6.0, 2020, individuals who initiated INSTI-based ART before local cohort enrolment were excluded. The criterion was formulated for safety reasons to ensure RESPOND prospectively captured all key data for individuals initiating INSTIs. However, since RESPOND was initiated in 2017, collecting data back to 2012, INSTIs have internationally become an integrated part of recommended 1st line and switch treatment for HIV. Thus, continuing only to include INSTI-naïve individuals onwards in RESPOND may pose a risk of introducing selection bias. In addition, RESPOND now has considerable follow-up time with INSTI-exposed individuals.

  Moreover, no INSTI-naïve individuals have ever been excluded based on prior exposure to other drugs. Therefore, removing the exclusion criterion related to INSTI exposure will ensure an equal comparison between antiretroviral classes within RESPOND. Following the same rationale, INSTI exposure before 2012 is no longer considered an exclusion criterion.

  Collectively, the inclusion criteria for future enrolments are:

1. **HIV-1 positive**
2. **Individuals ≥18 years of age at RESPOND_Baseline**
3. **Must have a CD4 count and HIV viral load measurement available within the 12 months before RESPOND_Baseline or within three months after baseline**
4. **Have at least one clinical visit >1 January 2012**

2. Data Collection:

It has been specified, that all available requested data should be submitted since Local_Cohort_Enrolment, with no time limited applied. Further it has been specified that a full history of ART, AIDS – and non-AIDS clinical events must be supplied for all participants, also prior to 1 January 2012.

3. Data Quality Assessment and On-site Monitoring:

This new version has added a section describing quality assessments and on-site monitoring.

4. Reimbursement:

This new version has added a section specifically dedicated to reimbursement and timelines.

5. RESPOND Organisation; Committees, Scientific Interest Groups, Working Groups and Writing Groups

It has been specified that the executive committee should aim to meet twice annually. Likewise, it has now been added that the Scientific Steering Committee will aim to meet every second month but may be changed by the committee chair(s) to accommodate current needs. Moreover, as much of the scientific work is generated in designated working and writing groups under a Scientific Interest Group, a specified number of Scientific Interest Group meetings is no longer specified in the document.

It has also been clarified that the chair(s) of the RESPOND Executive Committee will now have a seat in the RESPOND Scientific Steering Committee.

6. Scientific projects:

To reflect current agreed practice within RESPOND, the governance document no longer states the need for a short 4-5 lined concept sheet to be sent to the Scientific Steering Committee, before a proposal template and analysis plan is drafted, when a new project proposal is under development in the Scientific Interest Groups.

Instead, a scientific project proposal must be:

1) Scientifically sound
2) Inside the scope of the Scientific Interest Group's scientific agenda
3) Feasible within RESPOND
4) Not addressing the same question as analyses ongoing in one of the participating cohorts

as ensured by the Scientific Interest Group moderators. Specifically for point 4) this is ensured in collaboration with cohort representatives within the Scientific Interest Group, who may flag a proposal as overlapping with its own scientific agenda. If so, the Scientific Steering Committee will decide if the project has merit to continue within RESPOND and if there are timing considerations to be taken. All final approvals of proposed scientific projects lie with the Scientific Steering Committee

The approval process, timelines, and circulation routes, as agreed by the RESPOND Scientific Steering Committee and the RESPOND Executive Committee, have been specified within this section, to reflect current practice within RESPOND.

Requirements for proposed scientific projects from companies funding RESPOND and institutions outside the RESPOND collaboration have been specified.

Sections 7-11

New sections have been added to describe working groups and the selection of writing groups within RESPOND, criteria for joining RESPOND, the annual report, onsite monitoring, and statements for funding, data sharing and ethics.

Table of content

1. Eligibility Criteria

1.1. Enrolment Definitions

a) Local_Cohort_Enrolment is defined as the date of first recorded visit in the local cohort
b) RESPOND_Enrolment is defined as the latest clinical visit in the local cohort in the RESPOND dataset in which the participant first appears
c) RESPOND_Baseline is defined as the latest of local_cohort_enrolment, or 1 January 2012 (for internal use only)

A project specific baseline can be applied for individual analyses depending on the statistical analysis plan (SAP) and the intended comparisons assessed by the main statistician involved in the project, given that a rationale for not using the default baseline is provided in the SAP.

- *e.g., The previous RESPOND baseline, including INSTI start, may be preferred to avoid immortal time bias when analysing mortality outcomes.*

1.2. Inclusion Criteria

1. HIV-1 positive
2. Individuals ≥18 years of age at RESPOND_Baseline
3. Must have a CD4 count and HIV viral load measurement available within the 12 months before RESPOND_Baseline or within three months after RESPOND_Baseline
4. Have at least one clinical visit >1 January 2012

The below procedure should be used during enrolment when cohorts joining RESPOND are not enrolling all individuals under follow-up. This is to limit the risks of selection bias:

Individuals who satisfy the inclusion criteria, including those who have died or been LTFU in local cohort, should be assigned a unique random number, whereafter participants should be sorted in ascending order using these random numbers. the first X number of all participants should be enrolled into RESPOND.

- *E.g, if a cohort contributes 400 out of 10,000 eligible individuals in the local cohort into RESPOND, the cohort should assign each of the 10,000 eligible individuals a unique random number. This list of individuals can then be sorted by the random number, and the first 400 individuals should be selected for enrolment. To limit the potential for survival and selection bias, individuals who have been lost to follow-up or who have died, should still be included, provided they satisfy the inclusion criteria.*

2. Data Collection

For more details on the data collection within RESPOND, see Standard Operating Procedure (SOP) for Data Transfer in RESPOND.

The SOP for Data Transfer in RESPOND is revised annually to ensure contemporary data collection. The most recent version of the SOP is always available via the RESPOND website, following the link above.

2.1. Variables

RESPOND collects both a set of core must-have variables which all cohorts must be able to submit, and a set of additional variables related to specific projects within the consortium, which should be submitted to the extent possible. Both core data and project specific variables are merged in the RESPOND data lake (see **Figure 1**). *Must-have variables* are marked with yellow in the SOP for Data Transfer in RESPOND. Cohorts are required to provide ≥ 80% completeness for each must-have variable for each annual data submission (see **point 4.2**.).

Relevant variables for analyses may or may not already be collected as part of the standard RESPOND data collection. If collection of new variables is needed, funds for the collection of these and following analysis must first be obtained.

For both enrolment and follow-up data submission, all available data should be submitted from Local_Cohort_Enrolment, whenever possible. Specifically for ART, AIDS events (including AIDS-defining malignancies) and occurrence of the following non-AIDS events, a full clinical history *must* be supplied for participants' (i.e., not applying any time limits to supplied data):

- Myocardial infarctions
- Strokes
- Invasive cardiovascular procedures (coronary angioplasties/stenting, coronary by-pass surgery, carotid endarterectomy, and carotid stenting)
- Non-AIDS defining malignancies
- End-stage liver disease
- End-stage renal disease
- Fractures

The collection of clinical events follows rigorous definitions described in the annually updated Manual of Operations (MOOP) for clinical events, available via the CHIP website.

2.2. RESPOND Event Form

All incident clinical events mentioned above, including AIDS-defining malignancies, occurring after 1 January 2017 (RESPOND start date) should be accompanied by the submission of an electronic case report form (e-CRF) completed in the RESPOND event form project via the Research Electronic Data Capture (REDCap) system. Access to the project can be acquired for relevant personnel by contacting the RESPOND secretariat (respond.rigshospitalet@regionh.dk).

2.3. Cause of Death (CoDe) Forms

All deaths must be accompanied by submission of a CoDe CRF completed in the CoDe Project via the REDCap system. Access to the project can be acquired for relevant personnel by contacting the RESPOND secretariat (respond.rigshospitalet@regionh.dk)

2.4. Timelines

Data submission via the RESPOND Electronic Submission Tool (REST) is open annually in the period between 1 September to 1 December.

E-CRFs for incident clinical events and deaths (see **section 2.2** and **2.3**) should, to the extent possible, be submitted in real-time (i.e., as they occur). Only CRFs submitted before 1 April each year will be included in the dataset and reimbursement for the given year**.** Queries for missing RESPOND event e-CRFs and CoDe e-CRFs will be sent with the initial quality assessment (QA) report after data submission and in January and March each year.

3. Data Quality Assessment (QA) and On-site Monitoring:

For more details on QA within RESPOND, see Work Instructions (WI) R6: QUALITY ASSURANCE PROCESS FOR INCOMING COHORT STUDY DATA.

For more details on on-sit monitoring within RESPOND, see WI R7: RESPOND INTERNAL EXTERNAL ONSITE MONITORING

3.1. QA of submitted data

Data submission from participating cohorts undergoes an extensive QA process based on the following parameters:

- Row count assessments (i.e., comparisons of rows in specific tables in consecutive data submissions)
- Data completeness
- Lists of participants triggering QA queries
- Missing and incomplete e-CRFs

3.2. On-Site Monitoring

For more details, please see WI R7: RESPOND Internal External onsite monitoring

To uphold a high-quality data collection, the RESPOND secretariat performs on-site monitoring. Cohorts are selected for on-site monitoring based on a list of objective criteria, including evaluation of performance-based reimbursement, adherence to submission deadlines, correction of data items upon notice, submission, and quality of RESPOND event and CoDe forms, and adequate communication.

A list of cohorts considered as candidates for on-site monitoring, based on fulfilment of three or more criteria, is assembled by the RESPOND secretariat annually by 1 May.

If selected, the cohort agrees to permit access to its records relating to the RESPOND study, including study subject medical records for monitoring.

4. Reimbursement

For more details on reimbursement within RESPOND, see WI R3: RESPOND REIMBURSEMENT, RATES AND TIMELINES

The RESPOND consortium budgets a defined amount intended for reimbursement each year. Therefore, new cohort enrolments must be coordinated and agreed with the RESPOND secretariat each year before data submission.

4.1. Rates

Current reimbursement rates can be found in the WI R3: RESPOND REIMBURSEMENT, RATES AND TIMELINES

4.2. Performance-based Reimbursement

Performance-based reimbursement is based on the completeness of submitted must-have variables, with the assessment performed on participants under active follow-up only.
Must-have variables are assessed depending on the expected frequency of measurements (i.e., as either ever reported, reported within five years or reported within two years). Each defined must-have variable with less than 80% completeness for all cohort participants will result in a deduction in the total reimbursement rate.

4.3. Timelines

Reimbursement is made in June-July annually, based on data submitted between 1 September and 1 December the previous year.

Reimbursement of RESPOND Event and CoDe forms is based on forms submitted in REDCap 1 April the previous year until 1 April of the reimbursement year.

5. RESPOND Organisation; Committees, Scientific Interest Groups, Working Groups and Writing Groups

For more details on organisation within RESPOND, see WI R10: COMMITTEES AND MEETINGS WITHIN RESPOND

5.1. RESPOND organisation

A schematic illustration of the RESPOND organisation can be found in Figure 1

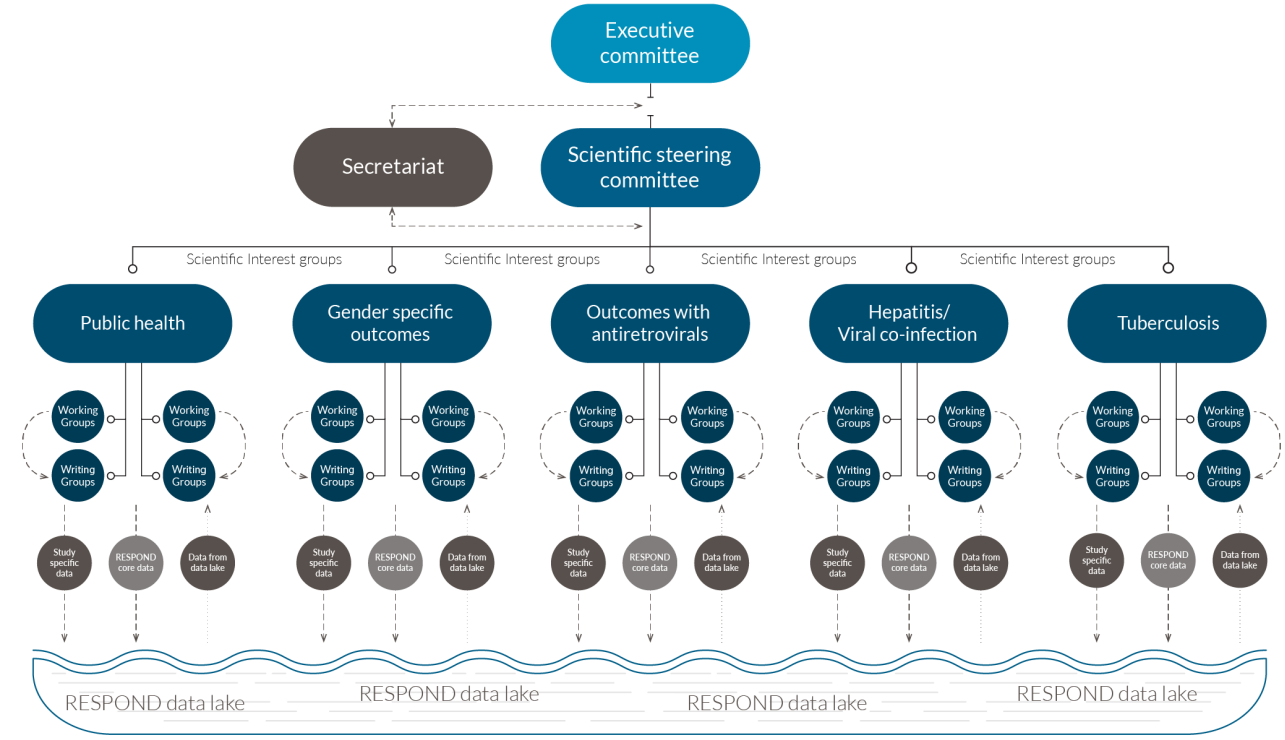

Figure 1. RESPOND organisation

5.2. Executive Committee

The role of the Executive Committee (EC) is to ensure the overall structural integrity of RESPOND and to safeguard that study objectives are being met in a timely manner. However, the EC has no direct involvement in the conduct of the scientific agenda.

The EC is composed of the EC chair(s), representatives from each of the companies funding RESPOND, representative from each of the cohorts who are investing financially in RESPOND), the chair(s) from the Scientific Steering Committee (SSC) and representatives from the three largest RESPOND cohorts.

EC meetings are scheduled twice a year, with the option to call ad hoc meetings in case of important developments. Whenever possible, EC meetings should be held face-to-face in conjunction with conferences or scientific retreats.

5.3. Scientific Steering Committee

The RESPOND SSC oversees RESPOND's scientific agenda across the Scientific Interest Groups (SIGs), while safeguarding the scientific integrity and robustness of RESPOND projects, by reviewing and assessing if the projects are hypothesis driven, answer novel research questions, and are analysed and interpreted appropriately.

The SSC is composed of the SSC chair(s), the EC chair(s), the principal investigators from participating cohorts in the Outcomes study, HIV community representatives, SIG moderators, and members from each of the funding bodies, selected based on their academic credentials.

The SSC officially approves all RESPOND scientific proposals and SAPs, abstracts, conference presentations, manuscripts for publication and the annual report (see section 6). No single member of the SSC, including no representative from a funding body, can veto any project or scientific publication. The SSC members must clearly state any potential conflict of interest (COI) that may occur when assessing scientific proposals, conference abstracts, (oral or poster) presentations, and manuscripts for publication.

The SSC meetings are scheduled every second month, with the option to call in ad hoc meetings if needed. Whenever possible, SSC face-to-face meetings should be held in conjunction with conferences or scientific retreats. Based on the assessment of the SSC chair(s) certain matters may be handled by e-mail instead of a meeting.

5.4. Scientific Interest Groups, working groups and writing groups

The RESPOND SIGs reflect the different scientific research areas within the RESPOND consortium.

The role of the SIGs is to have a forum for generating innovative and pertinent research ideas and discussions of ongoing projects and existing literature.

The RESPOND SIGs are formed and managed by a scientific moderator(s) and are open for individuals associated with RESPOND cohorts, community, funders, and external experts.

There is no fixed number of required SIG meetings, or cap on SIG members.

5.4.1. Working groups and writing groups

Smaller working groups can be formed by SIG members with a special interest within the spectrum of a SIG's research field to focus discussions. Likewise, working groups can be formed when specific scientific projects need additional expertise and discussions, to heighten the scientific output of the analysis.

All working groups have one or two leads to facilitate discussions and liaise with the SIG moderator(s) to ensure consistency and feasibility (see section 6.1). Current RESPOND working groups can be found here.

For more details on working groups and writing groups see sections 7.1 and 7.2.

5.5. RESPOND secretariat and data management

RESPOND's secretariat functions and data management are handled at the Centre of Excellence for Health, Immunity and Infections (CHIP) in Copenhagen, Denmark. The statistical centres, located at CHIP and Kirby Institute, Sydney, Australia, clean data, perform statistical analyses and support cohort-led specific projects.

The RESPOND secretariat is responsible for coordinating effective and minuted committee meetings, circulating operational and scientific documents within the committees see WI R1: Developing New Scientific Proposals and Circulation of Scientific Documents Within the RESPOND Consortium and organising the membership of the committee and writing groups (see section 7.2)

5.6. Scientific Retreats

An annual, scientific retreat is held in conjunction with The International Workshop on HIV and Hepatitis Observational Databases (IWHOD) or EACS conference/Glasgow HIV Conference. The overall aim of the retreat is to generate and discuss novel scientific ideas for the future and direction of the consortium. In addition, the retreat functions as a discussion forum for ongoing projects and data quality assessment. A data manager retreat is preferably held in parallel with the scientific retreat, to discuss and optimise data transfer, collection, and quality.

All individuals affiliated with collaborating cohorts, external experts and funders will be invited to the retreat.

If an in-person retreat is not feasible, it may be substituted with a shorter virtual retreat.

6. Scientific Projects

For more details on development, timelines and circulation of scientific projects within RESPOND including timelines, see: WI R1: Developing New Scientific Proposals and Circulation of Scientific Documents Within the RESPOND Consortium and WI R5 CONSTRUCTION OF WRITING GROUPS WITHIN RESPOND

The RESPOND Secretariate facilitates all scientific communication and circulation of documents. There should be no direct communication between funding bodies and lead authors; all communication regarding scientific projects are managed by the RESPOND Secretariate.

6.1. Proposals for Scientific projects

Scientific proposals are formulated on a RESPOND project proposal template and should always be accompanied by a statistical analysis plan (SAP). The proposals are developed by a proposing core writing group, and the SAP must be developed in close collaboration with one of the affiliated RESPOND statisticians to ensure consistency. These documents serve as the basis for the initial discussions between the core writing group, working group and the moderators of the specific SIG.

The working group lead and the SIG moderator(s) will review suggested proposals to ensure the proposal is 1) scientifically sound, 2) within the scope of the SIG's scientific agenda, 3) feasible within RESPOND, 4) together with the cohort representatives, evaluated for overlapping projects with participating cohorts.

If the working group lead and/or the SIG moderator(s) and/or cohort representatives become aware of potential overlapping agendas, this should be raised to the writing group as soon as possible. If so, it should be discussed in the SSC whether carrying out the analysis within RESPOND is merited and if there are any timing considerations to be made in relation to the project.

6.2. Approval of Scientific Proposals and Circulation and timelines of Scientific Documents

Circulation and timelines vary depending on the type of document, as described below in 6.2.1 - 2

6.2.1. Scientific proposals and SAP

If a proposal and SAP is moved forward, they are shared for review with the respective working group (if formed), respective SIG, community representatives and funders. The proposal and SAP are revised by the core writing group in accordance with comments and suggestions provided from the respective groups. A document with replies to reviewers should be created for circulation.

The revised proposal, SAP and replies to initial comments are then sent by the RESPOND secretariat, for review by randomly selected SSC members, preferably including one biostatistician. This review forms the basis for the SSC's decision on whether the proposal can proceed.

As the final step of circulation, the proposal and SAP, replies to reviewers' comments and the reviews by the selected SSC members, are sent to the SSC, preferably prior to a scheduled bi-monthly meeting (see 5.3). Based on the reviewers' suggestions, the SSC will either accept, request further revision, or dismiss the proposal during the meeting. As an exception and if the SSC chairs agree on a case-by-case basis, the proposal and SAP can in rare instances (e.g., in case of time-sensitive deadlines) be approved via email consensus.

Once a project has officially been approved by the SSC, a final writing group is constructed by the RESPOND secretariat (see 7.2).

- Companies outside the RESPOND collaboration may propose scientific projects within the RESPOND collaboration. As a prerequirement, an external proposing company must provide funding at least equivalent to the annual funding from the lowest paying funder of RESPOND.

- Funding bodies may, similar to other academic collaborators, suggest new projects via a scientific project proposal for discussion (see below and as outlined in section 5.3). Additional funding and hiring of statistical support may be required for these projects and will be decided on a case-by-case basis.

For both subpoints described directly above, such project proposals will be subjected to the same scientific review process as all other scientific proposals within the consortium and will follow the same circulation flow. However, representatives of funding bodies cannot be the scientific lead of the project, i.e., the proposing party may be part of the core writing group but may not feature as first – or last (senior) author of a RESPOND nference presentation or manuscript. If the proposal is considered of general scientific interest to RESPOND and therefore approved by the SSC, the data will be analysed by an affiliated RESPOND statistician. RESPOND data will not be transferred to any 3rd parties not affiliated with the RESPOND consortium.

For specific projects, statistical groups associated with RESPOND, can also perform statistical analysis for specific projects depending of capacities, but always in close collaboration with the affiliated RESPOND statisticians overlooking the process

6.2.2. Manuscripts, conference abstracts, and (oral or poster) presentations

Manuscripts, conference abstracts, and (oral or poster) presentations share the same route of circulation as outlined above for scientific proposals; and are sent for review within the respective writing and working group, respective SIG, community representatives and funders

The abstract, presentation, or manuscript are revised by the core writing group in accordance with comments and suggestions provided from the respective groups. A document with replies to reviewers should be created for circulation.

A process is in place, in case any RESPOND analysis suggests a drug specific findings of sensitive or special interest of the funding bodies, see appendix 1, in WI R1: Developing New Scientific Proposals and Circulation of Scientific Documents Within the RESPOND Consortium

7. Authorships in RESPOND

For more information on constitution of writing groups, please see WI R5: Construction of Writing Groups within RESPOND

7.1. Working Groups

Participation in a specific working group does not automatically guarantee inclusion in a project specific writing group (**see 7.2.**). However, principal investigators (PIs) are encouraged to nominate individuals from their respective cohorts participating in a working group, for a potential writing group. Please also see section 5.4 for more general detail on working groups

7.2. Writing Groups

Once the RESPOND SSC has officially approved a proposal (i.e., when the proposing group have received an official notification of approval), the RESPOND secretariat will construct the writing group for the project in accordance with the scheme outlined in WI R5. Please also see section 5.4 for more general details on writing groups.

The writing group includes members from the (core) proposing group and representatives of RESPOND cohorts that supply data and scientific inputs. In addition, the writing group includes members of the HIV community, members from funding bodies, providing that they provide active scientific contribution and fulfil the ICMJE criteria, and If relevant experts from outside the RESPOND collaboration.

The order of which members of the writing group should be listed is outlined in WI R5. The writing group composition and order also applies when submitting manuscripts under a group authorship, where the writing group should be featured in the acknowledgement section.

Abstracts are to be submitted with the core group on behalf of the RESPOND study, whereas all named authors should figure on oral and poster presentations at conferences and meetings.

7.3. Study Group

The current RESPOND Study group should be featured in the acknowledgement section of all RESPOND presentations and manuscripts.

For poster presentations, where space may be limited, the following link can be inserted with a note of acknowledgement to the study group https://chip.dk/Research/Studies/RESPOND/Study-group

8. Cohort Requirements for being part of RESPOND

For more details on joining RESPOND, please see WI R8.1: Criteria for being part RESPOND

To uphold a high degree of data quality within the RESPOND consortium, cohorts wishing to be part of the collaboration, must fulfill a set of predefined criteria outlined by the SSC. The criteria focus on the number of participants that the cohort can provide data on, the character of the cohort's data collection, the data structure and the cohorts infrastructure including communication.

8.1. Joining RESPOND

Once approached by a cohort aspiring to join the collaboration, the RESPOND secretariat will provide information regarding RESPOND to the cohort and conduct a written feasibility survey to ensure that the cohort can comply with the criteria for joining RESPOND. Initiation of the process must be approved by the RESPOND EC.

The cohort seeking to join RESPOND is responsible for completing the survey truthfully and in accordance with the cohort's actual number of participants under follow-up, data collection (including completeness of data and quality), and staff employed. Further, the cohort is responsible for complying with the answers provided in the survey once part of the collaboration.

8.2. Participation in RESPOND

Cohorts are expected to continually supply and improve the quality of data submitted, have an active dialogue regarding data quality improvements with the Secretariat and engage in the scientific activities. The SSC and EC may decide to temporarily inactivate a cohort in case these expectations are not adequately met, with the prospect of re-activation at later stage.

9. Annual Report

For more details, please see WI R9: annual report

The RESPOND secretariat will annually produce a report of publications and presentation from the previous year, along with a data summary of key demographics, HIV related factors and clinical events, based on the latest available working dataset. The report also provides an executive summary of projects and key findings.

The draft report is reviewed and approved by the RESPOND SSC, before being approved by the EC.

As the report contains information on future research, it is not publicly available. However, it can be utilised by funding bodies when reporting to regulatory agencies. In cases of doubt on whether the report may be utilised for reporting to specific agencies or institutes, the RESPOND secretariat will advise (respond.rigshospitalet@regionh.dk).

10.Funding, Data Sharing, Ethical and Disclaim Statement

When required by journals, the Funding Statement, the Data Sharing Statement, the Ethical Statement, and disclaimer statement can be can be found in WI R1: Developing New Scientific Proposals and Circulation of Scientific Documents Within the RESPOND Consortium