

## Supplement 1. Participant informed consent form

### About this Study

You are being asked to take part in a research study that will help us better understand prescribing behavior for treatment of uncomplicated gonorrhoea among physicians in China. Your participation in this project will allow us to develop better interventions to improve physicians' prescribing behaviors to follow the treatment guidelines.

### What's involved?

Our study participants consist of physicians from eight provinces including Jiangsu, Shanghai, Zhejiang, Fujian, Guangdong, Guangxi, Hainan, and Yunnan. If you participate in this study, you will be asked to complete an online questionnaire. A subset of participants will be asked to complete an additional follow-up questionnaire. The questionnaires will ask you to provide sociodemographic information and information about your comment on the interventions we provided. In addition, your prescriptions for uncomplicated gonorrhoea will be randomly selected and audited. In order to ensure that your privacy is protected, all of your online responses will be encrypted and securely transferred to our data servers.

### Voluntary participation

A decision not to participate or to withdraw from participation will not affect your relationship with the hospital in any way.

### Discomfort and risks

Our study does not introduce any additional risk or discomfort to participants.

### Compensation

No financial incentives are offered for participating in the study.

### Questions

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have any questions about the research or your participation in the study, feel free to contact Ting-Ting Jiang (021-85478901).

### Participant statement

I have been informed about this study and understand what is involved. I also know whom to contact if I need more information. I understand that confidentiality will be preserved. I agree to participate in this study.

## Supplement 2. Hospital information

*This form is used for collecting background information of the eligible hospitals for participating in the cluster randomized controlled trial. By providing this information, neither do you commit to participating in the trial nor is your hospital for sure allocated to a specific arm of the trial. It is guaranteed that confidentiality of this information can be ensured and the data from the information collection will be only used for anonymous analysis.*

*Thank you in advance for your time in providing this information.*

**Province:** \_\_\_\_\_ **City:** \_\_\_\_\_ **Code:** \_\_\_\_\_ (Assigned)

**Hospital name:** \_\_\_\_\_

**Hospital nature:**  General hospital;  Specialized hospital;  Community hospital;  
 Other (Specific \_\_\_\_\_)

**Hospital township:**  Public teaching hospital;  Public non-teaching hospital;  
 Private hospital;  Other (Specific \_\_\_\_\_)

**Hospital category:**  Primary hospital;  Secondary hospital;  
 Tertiary hospital;  Uncategorized or others

**Number of gonorrhoea cases reported in the last year:** \_\_\_\_\_

**Department and staff:** *Does the hospital have the following departments and how many doctors qualified are there in each department for managing patients with sexually transmitted infections?*

- Dermatology (dermatovenerology); Number of doctors: \_\_\_\_\_  
 Urology; Number of doctors: \_\_\_\_\_  
 Andrology; Number of doctors: \_\_\_\_\_  
 Gynaecology; Number of doctors: \_\_\_\_\_

**Availability of antibiotics:** *Does this hospital stock the following antibiotics and what are their dosage forms?*

- Ceftriaxone (injectable):  250mg;  500mg;  1g;  
 2g;  Other (Specific: \_\_\_\_\_)  
Spectinomycin (injectable):  2g;  Other (Specific: \_\_\_\_\_)

**Does the hospital agree to participate in the study?**  Yes;  No

### Supplement 3. Questionnaire survey for the physicians in the participating hospitals

*This form is used for collecting socio-demographic information. You are invited to participate in this questionnaire survey which takes you about less than 5 minutes to answer all questions. By completing this questionnaire, you are not automatically required to commit to participating in the intervention trial later on. Participation in this survey is totally voluntary and you can choose either participation to answer all or some questions or rejection to participate. Any choice does not influence the relationship between you and the investigators.*

*Thank you in advance for your time in completing this questionnaire.*

**1. Your working number:**

- (Assigned)

**2. Your gender:**

- Male  
 Female

**3. Your age:**

- <25  
 25~35  
 35~45  
 45~55  
 55~65  
 >65

**4. What is the highest degree that you have obtained?**

- Post-Doctor  
 Doctor  
 Master  
 Bachelor  
 Other (Specific:\_\_\_\_\_)

**5. What department are you working?**

- Dermatology & STD
- Andrology
- Urology department
- Obstetrics and gynecology
- Other (Specific: \_\_\_\_\_)

**7. How long have you been working in this department?**

- ≤5 years
- 6~10 years
- ≥11 years

**8. Your professional title is:**

- Chief physician
- Associate chief physician
- Physician-in-charge
- Resident physician
- Other (Specific: \_\_\_\_\_)

**9. In the last three months, approximately how many cases of uncomplicated gonorrhoea have you treated?**

- (Number)

**10. In the last three months, have you received relevant trainings on treatment of gonorrhoea?**

- Yes (Specific: \_\_\_\_\_)
- No

## Supplement 4. Questionnaire survey for the physicians in the intervention hospitals

*This form is used for collecting information after a cluster randomized controlled trials (RCT) is conducted at your hospital. You are invited to participate in this questionnaire survey which takes you about 10 minutes to answer all questions. Participation in this survey is totally voluntary and you can choose either participation to answer all or some questions or rejection to participate.*

*Any choice does not influence the relationship between you and the investigators.*

*Thank you in advance for your time in considering this questionnaire survey or completing this questionnaire.*

### 1. Your working number:

- (Assigned)

### 2. Your gender:

- Male  
 Female

### 3. Your age:

- <25  
 25~35  
 35~45  
 45~55  
 55~65  
 >65

### 4. What is the highest education degree that you have obtained?

- Post-Doctor  
 Doctor  
 Master  
 Bachelor  
 Other (Specific: \_\_\_\_\_)

**5. The name of hospital you are working at:**

- \_\_\_\_\_(Text)

**6. What department do you work in the hospital?**

- Dermatology & STD
- Andrology
- Urology department
- Obstetrics and gynecology
- Other (Specific:\_\_\_\_\_)

**7. How long have you been working in this department?**

- ≤5 years
- 6~10 years
- ≥11 years

**8. Your current professional title is:**

- Chief physician
- Associate chief physician
- Physician-in-charge
- Resident physician
- Other (Specific:\_\_\_\_\_)

**9. In the last three months, approximately how many cases of uncomplicated gonorrhoea have you treated?**

- \_\_\_\_\_(Number input) (If answer <1, Skip to End of Survey)

**10. Before participating in the on-line video-based training, do you know about the up-to-dated National STD Treatment Guidelines for treatment of uncomplicated gonorrhoea?**

- Yes
- No

**11. In the last six months, how many times did you access to the on-line training video developed on the WenJuanXing platform?**

- 0
- 1~3
- 4~6
- $\geq 7$

**12. In the last six months, have you received other relevant trainings on treatment of gonorrhoea?**

- Yes (Specific: \_\_\_\_\_)
- No

**13. What do you think about the up-to-dated regimen in the National STD Treatment Guidelines for treatment of uncomplicated gonorrhoea using ceftriaxone 1g as a single dose?**

- Appropriate (enough) dosage
- Dosage is overdose
- Dosage is not enough
- Difference from case to case
- Don't know

**14. Do you think this on-line video-based training programme is helpful for improving your knowledge on management of gonorrhoea?**

- Very helpful
- Helpful
- Not helpful
- Don't know

**15. Do you think the participation in this on-line video-based training programme every two months occupy too much of your time?**

- Yes
- No

**16. Will you continue to use this on-line video-based training programme?**

- Yes
- No

**17. Are you willing to recommend this on-line video-based training programme to other colleagues?**

- Yes
- No

**18. Do you have any suggestions on the on-line training programmes?**

- Yes (Specific: \_\_\_\_\_)
- No



## Supplement 5. Baseline data on prescriptions

*This form is used for retrospectively collecting data derived from the eligible prescriptions PRIOR to the trial in each of departments in each of participating hospitals. It is guaranteed that confidentiality of these data can be ensured, and these data will be only used for anonymous analysis.*

*Thank you in advance for your time in providing these data.*

**Province:** \_\_\_\_\_ **City:** \_\_\_\_\_ **Code:** \_\_\_\_\_ (Assigned)

**Hospital name:** \_\_\_\_\_

**Department:**

- Dermatology (dermatovenerology)
- Urology
- Andrology
- Gynaecology

### Prescription information

No.	Patient' gender	Patient's age	Diagnosis	Treatment			Physician's working number
				Drug	Dosage	Duration	
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## Supplement 6. Endline data on prescriptions

*This form is used for collecting data derived from the eligible prescriptions AFTER the trial in each of department in each of participating hospitals. It is guaranteed that confidentiality of these data can be ensured, and these data will be only used for anonymous analysis.*

*Thank you in advance for your time in providing these data.*

**Province:** \_\_\_\_\_ **City:** \_\_\_\_\_ **Code:** \_\_\_\_\_ (Assigned)

**Hospital name:** \_\_\_\_\_

- Department:**
- Dermatology (dermatovenerology)
  - Urology
  - Andrology
  - Gynaecology

### Prescription information

No.	Patient' gender	Patient's age	Diagnosis	Treatment			Physician's working number
				Drug	Dosage	Duration	
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## **Supplement 7. Data Collection and analysis plans prior to implementing the prospective cluster randomized controlled trial**

The analyses presented in the current manuscript evolved from the following research question and associated data collection and analysis:

### **1. How will we evaluate the appropriateness of randomization?**

- a) We will use questionnaires to collect the background information of participating hospitals (hospital's level, and category) and participating physicians (sex, age, education level, working year, department, and previous training).
- b) We will estimate the differences between the intervention and control arms in cluster (hospital)'s characteristics including level (capital vs. other city), and category (general vs. specialized hospital).
- c) We will compare the differences between the intervention and control arms in participating physician's characteristics including sex, age, education level, working year, department, and previous training.

### **2. How will we evaluate the missing data?**

- a) We will define the physicians who provide informed consent and are willing to participate in the study and then withdraw from the intervention or are unwilling to have their prescriptions audited later on as missing participants.
- b) We will identify the missing participants from the complete dataset and define the data of these participants as missing data.
- c) We will compare the differences between the missing data and the data for analysis in participating physician's characteristics including sex, age, education level, working year, department, and previous training.

### **3. What are the determinants used to describe the adherence rate to the National Guidelines and intervention effect for measuring the primary outcome?**

- a) We will collect the most recent 100 eligible prescriptions from each participating hospital (cluster) prior to intervention implementation period and 6 months after the implementation.

- b) We will define the regimen of 1 g ceftriaxone described by the participating physician for treatment of uncomplicated gonorrhoea as adherence to the National Guidelines (dichotomous outcome).
- c) We will estimate the adherence rate and its 95% confidence intervals (CIs) using the total number of eligible prescriptions and the number of the prescriptions met the criteria of adherence.
- d) We will estimate the intervention effect which is reported as rate ratio (RR) and 95% CIs compared with the control group. The stratum-specific endline adherence rate ratios will be calculated from the stratum-specific endline adherence rates (mean cluster-level outcomes) in each arm. The crude intervention effect as the overall endline adherence rate ratio between the intervention arm and control arm will be estimated from the weighted average of the stratum-specific endline adherence rate ratios, with weights that are inversely proportional to the stratum-specific variances. Formal testing of the null hypothesis that the overall adherence rate ratio is equal to 1 will be conducted using stratified t-test, and 95% confidence interval will be adjusted for between-cluster variance and stratification. To adjust for potentially important covariates, including cluster-level outcome at baseline, and additional patient (age [years], sex [male, female]), linked physician (age [years], sex [male, female], education level [bachelor degree or higher, other], working year [years], department [dermatology or dermatovenerology, other], previous training [yes, no]) and hospital (province located) factors, a two-stage adjusted analyses will be conducted. We will fit a logistic regression model to the individual-level binary outcome data including all covariates of interest as fixed effects, but without adjusting for the treatment effect. The individual-level model predicted values and the individual-level observed values will be used to calculate covariate-adjusted cluster-level ratio residuals. The covariate-adjusted ratio residuals will then be used in place of cluster specific proportions to conduct stratified t-test and calculate 95% confidence interval using the above methods. Statistical significance will be based on the (two-sided) p value estimated for the primary outcome obtained from the covariate-adjusted analyses, considering adjusting increases power and reduces the effect of imbalances between arms with typically minimal risks.

- e) We will calculate the differences over 6 months of the intervention in both intervention and control groups, respectively.
- f) We will also conduct subgroup analyses on primary outcome to indicate the intervention effect across the subgroups in terms of hospitals [hospital's level, and category] and physicians [sex, age, education level, working year, department, and previous training]. The same main analysis approach planned above will be used for the cluster-level subgroup analyses to obtain estimates of the treatment effect, its 95% confidence interval and statistical significance within each subgroup. To estimate the statistical significance of any differences in treatment effect among subgroups, analysis of variance will be used on the cluster-level summary outcome data, with terms for treatment, subgroup and the interaction between treatment and subgroup.

#### **4. How will we measure the barriers to non-adherence to the National Guidelines for measuring the secondary outcome?**

- a) We will collect the physician's information on socio-demographic characteristics, education background, working experience, and perceptions, attitudes, and practices using a questionnaire survey in the intervention hospitals.
- b) We will define the physicians who have at least 25% prescriptions nonadherent to the National Guidelines as the physician with nonadherence.
- c) We will use the nonadherence as dependent variables for the analyses to identify the factors influencing the nonadherence.
- d) We will present descriptive statistics on the physician's socio-demographic characteristics, education background, working experience, and perceptions, attitudes, and practices.
- e) We will use multivariate logistic regression model to explore the associations between key factors (physician's age [years], education level [bachelor degree or higher, other], working year [years], department [dermatology or dermatovenerology, other], on-line training video access times [ $\leq 3$ ,  $> 3$ ], perceptions on the National Guidelines [appropriate (enough) dosage, other], attitude on the training programme [very helpful or helpful, other]) and the nonadherence. These results will be presented as adjusted odds ratio (AOR), associated 95% CIs and p values. The factors included in the model will be determined theoretically, based on the literature and the findings of our qualitative work.



**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**  
Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	<b>BRIEF NAME</b>		
1.	Provide the name or a phrase that describes the intervention.	<u>Page 8</u>	_____
	<b>WHY</b>		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	<u>Page 8</u>	_____
	<b>WHAT</b>		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	<u>Page 8</u>	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	<u>Page 8</u>	_____
	<b>WHO PROVIDED</b>		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	<u>Page 8</u>	_____
	<b>HOW</b>		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. <b>WHERE</b>	<u>Page 8</u>	_____
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. <b>WHEN and HOW MUCH</b>	<u>Page 8</u>	_____
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. <b>TAILORING</b>	<u>Page 8</u>	_____
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. <b>MODIFICATIONS</b>	<u>N/A</u>	_____
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). <b>HOW WELL</b>	<u>N/A</u>	_____
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.		_____
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	<u>Page 8</u>	_____
		<u>N/A</u>	_____

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

\* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

\* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-network.org](http://www.equator-network.org)).





**SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\***

Section/item	ItemNo	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	ChiCTR2000029591
	2b	All items from the World Health Organization Trial Registration Data Set	ChiCTR2000029591
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	12-13
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	13

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	7
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5-6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8

	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7

**Methods: Assignment of interventions (for controlled trials)**

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
<b>Methods: Data collection, management, and analysis</b>			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10-11, Supplement 7
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	11
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11
<b>Methods: Monitoring</b>			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	11
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	7

**Ethics and dissemination**

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	12

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	12
<b>Appendices</b>			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplement 1
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.