

**Comparison of Protocol Items on Register
Joint Pharma Position, ClinicalTrials.gov, WHO 2005, Ottawa Proposed**

Joint pharma position	Clintrials.gov	WHO #	WHO 27 May 2005¹	Ottawa Statement (OS)	Minimum	Optimum
All CTs other than exploratory	Interventional & observational studies		All prospective trials other than exploratory ²	All trials		
Unique ID	ID assigned by ClinicalTrials.gov	1	Primary Register and Trial ID# (former Unique ID)	Unique ID		
	Date assigned by ClinicalTRials.gov	2	Date of registration in Primary Register			
	6.d Key dates: <ul style="list-style-type: none"> • Record verification • Study start • Last followup • Data entry closure • Study completion 	16	Date of First Enrolment (estimated date of enrolment of the first study participant)	Key trial dates: <ul style="list-style-type: none"> • registration • ethics approval • recruitment start • recruitment end • followup end • trial stopped • trial extended 		
	1.a Organization's unique ID 1.b Secondary IDs	3	Other Trial IDs	Secondary IDs		
	11.h Research contact /PI	8	Lead Principal investigator	Principal investigator (s)		
	1.d Official scientific title	10	Scientific title (including intervention name, condition and primary outcome)	Official scientific title		
Brief title	1.c Brief title	9	Public title	Brief title		
				Acronym		
	12.b Link to study website			Trial website		

¹ Updated wording based on the latest WHO documents (see <http://www.who.int/ictrp/en/> October 3rd 2005)

² The WHO expressed in May 2005 that registration of exploratory trials was strongly encouraged but not mandatory

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Lay description	5.a Brief study description 5.b Detailed study description			Short lay description (text)		
	Included in primary and secondary sponsor fields	4	Funding source	Funding source (s)		
	4.a Primary sponsor	5	Primary sponsor	Primary sponsor		
	4.b Secondary sponsors (including funders)	6	Secondary sponsor(s)	Secondary sponsor(s)		
	11.f Central contact 11.g Central contact backup	7	Responsible contact person (public contact)	Responsible contact person	+	
	3. Board approved? Approval #, board name, affiliation, board chair, oversight	11	Research Ethics Review Board Approval	Ethics approval: REB/ IRB/ IEC: y/n-which body, date of the original approval		
Condition or disease	9.a Conditions	12	Disease or Condition Studied	Disease or condition		
				Trial objectives		
Trial type (eg intervention, drug, vaccine)	6.b Study type			Study type: eg, intervention, drug, device, vaccine, behaviour, complementary		
Trial purpose (eg th, dx, prev)	7.a Study purpose			Trial purpose (eg tx, dx, pvn, device)		
	7.e Design (single group, parallel, crossover, factorial, expanded access)	15	Study type: randomized, controlled (formerly: clintrials.gov list): interventional or observational	Design (single group, parallel, crossover, factorial, expanded access)		
	7.f Overall endpoint (safety, efficacy, bioequiv, bioavail, pharmacokinetics, pharmacodynamics)			Framework (superiority, noninferiority, equivalence, dose ranging)		

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	7.b Randomized or not			Randomized or not		
Trial phase: exploratory, hypothesis testing	6.a Phase 1-4 or NA			Phase of trial: 1-4 or other descriptor		
Key eligibility criteria including gender & age	10. Eligibility criteria (inclusion, exclusion, sex age)	14	(Key) ³ Inclusion & Exclusion Criteria	Eligibility criteria <ul style="list-style-type: none"> • Full list • Lay version (text) 		
	Target number of subjects	17	Target Sample Size	Target sample size		
Location of trial	11.a Location of each facility			Trial locations (recruiting and resource centers)		
Trial status	6.c Overall recruitment status	18	Recruitment Status at Time of CT-UID Request	Recruitment status		
	7.d Nature of control (placebo, historical, dose escalation, std) 8.a Interventions (intervention type: drug, gene transfer, vaccine, behavior, device, procedure) 8.b Intervention name	13	Intervention(s) with duration of intervention	Interventions <ul style="list-style-type: none"> • all interventions • in all trial arms, • both test intervention(s) and comparison(s) with duration 		
	7.g Primary outcome	19	Primary Outcomes + time of measurement or time to completion	All primary outcomes: both variable name and time points measured		
	7.h Secondary outcomes	20	(Key) Secondary Outcomes + time to measurement or	Secondary/additional outcomes		

³ the word Key is eliminated

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			time to completion	<ul style="list-style-type: none"> list all other outcomes to be examined including subgroup analyses and adverse events; list both variable names & time points measured 		
				Study data collection forms PDFs of all study data collection forms		
				Study consent form approved by Ethics boards (IRB/REB)		
	2. IND info (protocol, grantor, number, serial number) – not made public					
	7.c Masking					
	9.b Keywords					
	11.b Recruitment status at each facility 11.c Contact at each facility 11.d Contact backup at each facility 11.e PI at each facility					
	12.aReferences <ul style="list-style-type: none"> MEDLINE ID Citation Results link 					