Minutes Research Subgroup of Expert Advisory Group 10 April 2020, 4pm (by telecall)

<u>Present</u>: Colm Bergin (Co-Chair), Cliona O'Farrelly (Co-Chair), Mark Ferguson, Mairéad O'Driscoll, Ana Terres, Teresa Maguire, Siobhán O'Sullivan, Orla Feely

ITEM	Discussion	ACTIONS
1	Draft Minutes from 3 April 2020 and 7 April to be circulated	TM to circulate
	for review and sign-off at next meeting	
2	Conflict of Interest Declarations	
	 TM thanked those that have already submitted their signed CoI forms and reminded others to submit CB noted that he was not aware of or involved in the content of the media release that issued from TCD in 	All to complete and send signed COI forms to TM COI to remain an active
	relation to a planned COVID-19 immunology centre and that he had alerted the CMO and the CCO in the HSE of this (CB and COF will be involved with this centre should it receive funding). Committee members advised they did not identify this as a significant COI at this time	agenda item on all meetings
3	Membership	
	 The subgroup discussed a number of proposals for representation from public health research and it was agreed that the co-chairs would make the final decision and make contact accordingly 	CB/COF to confirm public health member and invite
	 Members were asked to make further suggestions for social sciences and/or community healthcare rep/s 	All to circulate possible names for discussion
4	Clinical Trials	
	TM gave an update on the WHO SOLIDARITY Trial including:	TM to forward this paper to OF and all to review and provide comments
	 Letter of response has issued from Minister Harris to Dr Tedros in WHO confirming Ireland's support and participation; 	MOD to circulate draft process for
	 On-going telecalls between small group (DoH/HRB, CRCI and HPRA) and WHO R&D team to progress all trial logistics; 	assessment/recommendations on national priority trials
	Detailed contract needs to be signed between Minister and WHO as Government agrees to act as trial sponsor and to provide state insurance for all aspects	MoD to develop a second related paper on what the group means by important
	of the trial (this is not an insignificant issue to progress) - Certain sponsor responsibilities to be delegated (in a legal agreement) to UCC; Discussions planned	trials
	between UCC and DOH and State Claims Agency	
	Prof Joe Eustace to serve as National Lead PI;CRCI acting as designated trial coordinator and linking	
	with CRF/CRCs, hospital sites and investigators	
	- CRCI to engage with DoH and HRB about an overall	
	project plan including a resource plan and a trial management plan	
	 Valuable discussions on-going between all parties and HSE Acute Hospital Drug Management in relation to drug availability and distribution process for Redemisvir 	
	- Agile nature of the trial and the nature of drug	

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	provision means that certain GCP labelling/recording practices in trials for hospital pharmacists will not be possible - will require further discussions with HPRA GCP Inspectors and others to find solution, Enquiries being made with other countries - REC and regulatory approval applications are in train. DoH (Minister) provided the necessary signed letter for this process. - TM noted that it is difficult to predict exact date of first recruitment based on all the moving parts above but intention is to progress with available drug even if remdesivir hasn't arrived yet and plan is also to start first wave of recruitment in those sites which have CRF/CRCs and the necessary supports in place.	
	The subgroup discussed the large interest in clinical trials around the system and noted the need to balance agility with some degree of coordination, especially in the context of limited drugs, funds and trial support staff. MOD has circulated a process paper for collating clinical trials proposals and a paper on high level priorities for inclusion in a national portfolio of covid-19 trials. It was agreed that these 2 papers could be combined into one document with a view to submitting to the EAG and NPHET.	MOD to merge both papers and to resubmit for final review
5	 Serology/Immunology CB noted that in follow-up to the discussion on this topic at NPHET, recent developments included: Paul Reid (HSE) has appointed Ms Niamh O Beirne to help develop/progress present testing strategy The Chair of the EAG in discussions with HPSC and Chair of the Evidence Subgroup will take this issue forward. WHO were producing a protocol/guidance for population-based serology testing SOS noted that she had recommended that research membership be considered in whatever mechanism was agreed to take this agenda forward 	The matter of a National Testing Strategy to remain an active agenda item
6	NREC COVID-19 - TM and SOS provided update; DoH has requested permission to soft-launch the NREC this weekend if the Dept Taoiseach announcement is not going to issue	TM to keep all updated
7	today	
7	 Infrastructure (Biobanks/registries/data sharing) To progress this issue, it was agreed that HRB would work with the DoH to produce a paper setting out a framework for biobanking/registries 	MoD to circulate when draft is ready
8	Capturing NPHET priorities for research	
	 SOS noted that she has not yet but will draft a brief communication from our subgroup and send to all of the NPHET subgroups 	SOS to send request to all NPHET subgroups

OF has circulated a paper to the subgroup to review on the issue of coordination of COVID-19 research nationally (including a request for additional funding). It was agreed that such a case is timely and important and would be valuable to submit to EAG/NPHET for endorsement and then to submit to the Dept of the Taoiseach to input to their planned whole-of-Government approach.

All to provide comments on OF paper; to be discussed at next meeting

- MF agreed to draft a complementary paper to support a request for additional funding aligned with the emerging research priorities and national coordination efforts.

MF to draft and circulate

Date of Next Meeting: Tuesday 14 April at 4pm (Telecall)