



## **Covid Response study (COVRES)**

### **Participant Consent Form**

**NCT XXX**

**09/07/2020**



## Participant Consent Form Phase 1 & 2

**Study Title:** A Northern Ireland population study of SARS-CoV-2 prevalence, predisposing factors and pathology

**Participant Identification no:** \_\_\_\_\_

**Chief Investigator:** Prof Tony Bjourson **Phone:** (028)71 675 661 **Email:** [aj.bjourson@ulster.ac.uk](mailto:aj.bjourson@ulster.ac.uk)

**Please confirm, by marking the boxes provided, that you agree with the following statements:**

1.	I have been given and have read and understood the information sheet dated 09/07/2020 version 6 for the above study and have asked and received answers to any questions raised.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my rights being affected in any way.	
3.	I agree to the collection, processing and use of my biological samples and personal data for this study on the terms outlined in the Participant Information sheet and I understand that genomic data and data will be generated from my biological samples.	
4.	I understand that my paper and electronic medical records (including Northern Ireland Electronic Care Record (NIECR) and other NHS electronic systems) will hold relevant information to this study and I consent for members of the research team to access this information if required for one year to follow the progression of my condition.	
5.	I understand that the researchers will hold all information and data collected during the study securely and in confidence and that all efforts will be made to ensure that I cannot be identified as a participant in the study (except as might be required by law) and I consent for the researchers to hold relevant personal data	
6.	I understand that my pseudonymised data generated as part of this study will be retained indefinitely for scientific research purposes, in accordance with EU data protection laws	
7.	I consent to inclusion of my pseudonymised data in the Northern Ireland Centre for Stratified Medicine database.	
8.	I consent that in the event of loss of capacity on my behalf, any samples and personal information collected prior to this event will remain in the study and consent to continued follow-up of my clinical notes	
9.	I agree and consent to provide blood sample (s) for the purposes of this study and confirm that I have been given details of the amount(s) and time points that they are to be taken and how it will be stored, used and the method of disposal.	



10.	I agree to provide a saliva sample for the purposes of this study and confirm that I have been given details of the amount and time points that samples are to be taken and how it will be stored, used and the method of disposal.	
11.	I consent to the research team sharing a copy of my de-identified health data and genomic data on the European <b>GISAID</b> database (where, researchers will have controlled access to the data for research via a managed data access committee (DAC) as described in the Participant Information Sheet.	
12.	I agree and consent that my donated sample(s), DNA, and associated data could be sent to Ulster University approved research organisations within or outside the UK, and EEA, for secure processing and analysis.	
13.	I agree and consent that approved research organisations can have access to pseudonymised clinical and biological data from my previously donated samples and I understand that the research organisations accessing pseudonymised data could include commercial (for-profit) companies.	
14.	I understand that I will not be paid to take part in this study	
15.	I understand that I will not receive any individual results or feedback	
16.	The potential benefits of keeping my blood or other tissues for future research studies have been explained to me and <b>(Please read carefully and only tick one box):</b>	
	a. I consent to their indefinite storage and use in any future study including genetic studies, <b>OR</b>	a.
	b. I consent to their indefinite storage and use in any future study that does not involve the isolation of my genetic material <b>OR</b>	b.
	c. I do not wish my blood or tissues to be used for any purpose other than this study for which they will be stored for 10 years	c.
17.	I agree and consent to take part in the above study	
18.	I agree and consent to being contacted at a later date and invited to take part in future studies of a similar nature. I understand that I am agreeing only to receive information and I am under no obligation to take part in any future studies.	
19	Would you like your GP to be informed you are taking part in this research study?	<b>YES</b> <b>NO</b>

**Consent form Phase 1 & 2  
Retrospective sample follow up**



Name of Participant (please print)

Signature

Date (dd/mmm/yy)

Name of Researcher

Signature

Date (dd/mmm/yy)