Health Research Authority (UK) Emergency Research Consent Guidance Summary

HRA guidance on emergency research consent: https://www.hra.nhs.uk/covid-19-research/seeking-consent-covid-19-research/ (accessed on 15.04.2020)

More specific guidance by country: http://www.hra-decisiontools.org.uk/consent/principles-ALC.html (accessed on 15.04.2020)

General note for emergency research			The consent requirements for adults who are not able to consent for themselves, depends on the type of study and where in the UK the research is taking place.
			For CTIMPs the law is the same across the UK; however the details of who can give consent may vary between nations. If your study is not a CTIMP: The law regulating how and when adults lacking capacity can be included in your research will vary, depending on where in the UK your research takes place.
Area of UK	**Participants**	**Consent setting**	**Requirements**
UK	Adults	No capacity and emergency CTIMPs	Adults not able to consent for themselves in emergency In the UK the law allows adults not able to consent for themselves to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if: - treatment needs to be given urgently - it is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial - it is not reasonably practicable to obtain consent from a legal representative - the procedure is approved by a NHS Research Ethics Committee - **consent is sought from a legal representative as soon as possible**. Please note, adults recruited in such a manner may regain their capacity to give consent. As this is the case you must plan how you are going to involve them in the on-going consent process. In most cases it is appropriate to ask them to give their own consent when and if they are able. If you intend to ask participants who regain capacity for their on-going consent you should: -inform the legal representative (CTIMPs) or consultee (other intrusive research) of this at the outset -prepare an appropriate Participant Information Sheet and consent form for the participants themselves that explains what has happened so far, and what you are seeking their consent for; -plan how you will handle a participant withdrawing consent at

Summary prepared by Hanne Bruhn, University of Aberdeen

			each stage of your study, and tell them what they can expect.
England Wales	Adults	No capacity, and emergency, non-CTIMP	Adults not able to consent for themselves in other intrusive emergency research In England and Wales the law allows adults not able to consent for themselves to be recruited into other intrusive research i.e. research other than CTIMPs, without prior advice from a consultee, in emergency situations if: -treatment needs to be given urgently -it is also necessary to take urgent action to administer a drug for the purposes of the trial -it is not reasonably practicable to seek advice from a consultee -the procedure is approved by a NHS Research Ethics Committee -**a consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings**. A person is not prevented from being a consultee if they are an attorney authorised under a registered Lasting Power of Attorney or are a deputy appointed by the Court of Protection; but that person must not be acting in a professional or paid capacity (for example, person's solicitor). Non-CTIMPs (other intrusive research) You should seek advice from a consultee on whether an adult lacking capacity to consent would wish to be included in your research study or not. Consultees are not asked to give consent on behalf of the adult, but rather to provide an opinion on the views and feelings of the potential participant. Consultees for intrusive research other than Clinical Trials of Investigational Medicinal Products (CTIMPs), in England and Wales are: Personal consultee, i.e. a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity; If not available or unwilling to give advice then a nominated consultee i.e. a professional who is independent of the study can do so. There is further provision for emergency situations, visit 'Emergency research'. The consultee must be: Told that they are being asked to advise on the views and feelings they believe the adult would have towards participation in your study. Told that they are free to decide whether they wish to provide this advice or not. Given sufficient information, in an understandable form, about your study to ensure that they provide you with informed advice. The advice given by consultees should be recorded on a Consultee Declaration form (rather than a consent form). A template is available to download from 'Examples & Templates'. You should also provide the participant themselves with information, according to their capacity of understanding, about your study and its

			risks and benefits.
Scotland	Adults	No capacity, and emergency, non-CTIMP	Adults lacking capacity in other emergency research **The law in Scotland demands that consent be in place before research other than Clinical Trials of Investigational Medicinal Products can begin**. The law does not provide any 'exemptions' or alternatives for the involvement of adults not able to consent for themselves in non-CTIMP research, even in emergency situations. Therefore, to include an adult not able to consent for themselves in emergency non-CTIMP research in Scotland, you must obtain consent before the adult can be involved in your study from: Welfare Attorney / Welfare Guardian, if not appointed Adults nearest relative Adults recruited in such a manner may regain their capacity to give consent. To record consent given by Legal Representatives in non-CTIMP research in Scotland: Welfare Guardian / Welfare Attorney / Nearest relative Participant Information Sheet and Consent form Recovered Capacity Participant Information Sheet and Consent form

Summary prepared by Hanne Bruhn, University of Aberdeen