

**Participant Information Sheet/Consent Form**

|  |  |
| --- | --- |
| **Title** | **Intubation speed by ‘experts’ in a simulated model of cardiac arrest with continuous chest compressions** |
| **Short Title** | N/A |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr. Simon Ellis |
| **Associate Investigator(s)** | A/Prof Jason Bendall |
| **Location** | John Hunter Hospital – Recovery Unit |

**Part 1 What does my participation involve?**

**1 Introduction and purpose of research**

You are invited to take part in this research project.

The current Cardio-Pulmonary Resuscitation (CPR) guidelines state that intubation should be attempted without interruption to CPR if possible. No studies have looked at the rate or time taken to perform such a task.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. There will be no professional or financial repercussions from participating or not participating in this study.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

You will be given a copy of this Participant Information and Consent Form to keep.

This research has been initiated by the Department of Anaesthetics and Pain Management by A/Prof Jason Bendall, and Dr Simon Ellis from John Hunter Hospital, Newcastle, NSW, Australia.

There are no costs associated with participating in this research project, nor will you be paid.

**2 Do I have to take part in this research project?**

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project up to the point the data is entered and de-identified.

**3 What will happen?**

You will be introduced to the study and have the chance to ask any questions. You will then be asked to intubate a whole body resuscitation manikin with either a traditional or a videolaryngoscope. The amount of attempts and time to successful intubation will be recorded. The participant will then be asked to perform the same task with the other type of laryngoscope. After this, there will be a short survey asking your thoughts on the task.

This information will be de-identified almost immediately. The data will be analysed and will be presented for publication.

**4. What are the possible benefits of taking part?**

We cannot guarantee that you will receive any benefits from this research, however the information collected may result in improving health care for patients in the future.

**5. What are the possible risks and disadvantages of taking part?**

The primary risk to participants is the potential for reputational or psychological harm in the event the manikin cannot be successfully intubated. This is what the study is looking at, and is *expected* to be found in some cases.

Individual results will not be disclosed, and the strictest of confidentiality will be upheld to prevent these risks from materialising. Those who feel they may be distressed by this situation should discuss this with the authors of the study and re-consider their willingness to participate in the study.

**6 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. No personal consequence will result.

**7 Who is organising and funding the research?**

This research project is being conducted by Drs Bendall and Ellis of Hunter New England Health, and being sponsored by the Department of Anaesthesia and Pain Management. No other funding is being sought, and no external influences or conflicts of interest exist.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**8 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor for your hospital on 02 49855153 or any of the following people:

**9 Complaints about this research:**

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2018/ETH000230. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics And Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHED-HREC@hnehealth.nsw.gov.au

**Contact person:**

|  |  |
| --- | --- |
| Name | Dr. Simon Ellis |
| Position | Study Lead |
| Telephone | 02 49213 000 (John Hunter Switch board), extension 67841 |



**Consent Form -** *Adult providing own consent*

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**Declaration by Participant**

I have read the Participant Information Sheet.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

**Declaration by Study Doctor/Senior Researcher†**

All questions asked by the participant of the research project have been answered and/or explained, and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

Note: All parties signing the consent section must date their own signature



PRE-task questionnaire:

Candidate number:

1. Level of Anaesthetic experience:
   1. Specialist b. Fellow
2. Level of task experience – Times intubated during CPR:
   1. 0 b. 1-5 c. >5
3. Which laryngoscope would you use if faced with this situation?
   1. DL b. VL
4. What instrument were you assigned to?
   1. DL b. VL



Candidate number:

POST task questionnaire:

1. How would you rate the fidelity of the manikin?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Very poor | Poor | Acceptable | Good | Very Good |

1. How would you rate the fidelity of the task (intubating under continuous CPR)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Very poor | Poor | Acceptable | Good | Very Good |

1. What was your comfort level during intubation with the direct laryngoscope?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Very low | Low | Acceptable | High | Very high |

1. What was your comfort level during intubation with the video laryngoscope?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Very low | Low | Acceptable | High | Very high |

1. To what extent has this study changed your opinion of which laryngoscope you would use in this situation?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Definitely not | Probably not | About the same | Probably | Definitely |