WEAN SAFE

Statement on Waiver of Informed Consent

The WEAN SAFE Executive committee consider that Ethical Committees should strongly consider approving the conduct of the study in their institution under a waiver of informed consent for the WEAN SAFE Study. We suggest this based on the following grounds:

(1) ***Observational Study****:* This study is entirely observational with no risk to participants. The data collected is data generated as part of routine clinical care, and no additional tests or examinations will be performed.

(2) ***Data is De-Identified****:* The data is de-identified and cannot be traced back to the individual patients once the database is closed[1].

(3) ***Scientific Value****:* To generate truly generalizable scientific insights in a study such as this, a large (several thousand patients) and globally geographically dispersed patient population is required. For example, in LUNG SAFE, the fact that data was collected on over 12,000 patients made this an authoritative and widely generalizable study.
A requirement for informed consent will prejudice the scientific value of the study, by reducing participation and thereby creating biases in the study population. Consequently, it will not be possible to generalize the findings to the entire population at risk if consent is required. This has been previously demonstrated for similar studies[2].

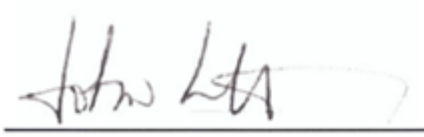
(4) ***Risk of Population Bias****:* There is clear risk of bias where informed consent is required for these types of studies, in that certain populations may be over or under-selected. This results in a study population that does not represent the typical patient weaning from mechanical ventilation. The impact of bias due to consent requirements are highlighted in studies by Kho et al.[3] and Tu et al.[2]. Tu et al. report that requiring informed consent for a stroke registry reduced participation to 39% of the eligible population. Patients that consented had lower mortality rates compared to those that did not, which means that findings were not generalizable, compromising the research programme.

(5) ***Difficulties in Informed Consent in Population****:* Requiring informed consent in a study of this size in this specific patient population is impractical[4]. Patients requiring artificial mechanical ventilation are generally unable to consent due to their illness. Requiring consent from next-of-kin or another third party and/or deferred consent are possibilities, but will serve to reduce participation, further exacerbating bias in the study sample.

(6) ***Cost and Workload****:* Requiring informed consent greatly increases workload in observational studies, due to the study requirement for large patient populations, and this greatly increases the associated cost, as clearly demonstrated in the study by Tu et al.[2]. This would greatly reduce the feasibility of the study.

(7) ***Risk of Geographic Bias****:* The greatly increased workload from requiring informed consent may mean that certain study sites, or even whole countries, may choose not to participate in this study. This means that this research cannot be applied to these countries, which constitutes a significant disadvantage to future critically ill patients from these countries.

(8) ***Public Interest****:* There is significant public interest in the findings of a large study such as WEAN SAFE. Medical advances generated by this study will benefit all people requiring mechanical ventilation. This should also be weighed against any arguments for informed consent.



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References

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2. Tu JV, Willison DJ, Silver FL, et al. Impracticability of informed consent in the Registry of the Canadian Stroke Network. *N Engl J Med* 2004; 350(14): 1414-21.
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4. Williams BF, French JK, White HD, investigators H-cs. Informed consent during the clinical emergency of acute myocardial infarction (HERO-2 consent substudy): a prospective observational study. *Lancet* 2003; 361(9361): 918-22.