

5.7 SOP Study Subject Unblinding v4.0

5/11/2022

11/11/2022

The purpose of this document is to provide a clear and concise description of the procedures for unblinding study subjects in the 5.7 SOP Study Subject Unblinding v4.0.

This document is intended for use by all staff members who are involved in the unblinding process, including but not limited to the following:

- Study Site Staff
- Study Site Principal Investigator
- Study Site Sponsor
- Study Site Investigator
- Study Site Research Assistant
- Study Site Research Coordinator
- Study Site Research Nurse
- Study Site Research Technician
- Study Site Research Assistant II
- Study Site Research Assistant III
- Study Site Research Assistant IV
- Study Site Research Assistant V
- Study Site Research Assistant VI
- Study Site Research Assistant VII
- Study Site Research Assistant VIII
- Study Site Research Assistant IX
- Study Site Research Assistant X
- Study Site Research Assistant XI
- Study Site Research Assistant XII
- Study Site Research Assistant XIII
- Study Site Research Assistant XIV
- Study Site Research Assistant XV
- Study Site Research Assistant XVI
- Study Site Research Assistant XVII
- Study Site Research Assistant XVIII
- Study Site Research Assistant XIX
- Study Site Research Assistant XX
- Study Site Research Assistant XXI
- Study Site Research Assistant XXII
- Study Site Research Assistant XXIII
- Study Site Research Assistant XXIV
- Study Site Research Assistant XXV
- Study Site Research Assistant XXVI
- Study Site Research Assistant XXVII
- Study Site Research Assistant XXVIII
- Study Site Research Assistant XXIX
- Study Site Research Assistant XXX

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Investigator (PI) written consent for the PI should be obtained

This SOP does not apply to subjects under

Emergency Unblinding

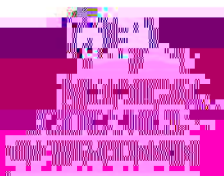
obtained

Emergency Unblinding

setting ph

staff or to the study subject, unless ten annual

deviation



UNA

Documentazione Tecnica

Documentazione di Progetto

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eSignature Addendum

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