

TEEN-BESTrial – Procedure Emergency Unblinding

De blinding of the bariatric procedure is reversed in the following cases:

- During the follow-up visit – two months after the surgery (after all the data of this follow-up moment have been collected by a blinded member of the research team);
- In the event of an emergency, for example with an SAE;
- If the DSMB needs blinded data;
- In the event that the PI considers this necessary.

Procedure emergency unblinding

1. The request to unblind the bariatric procedure is received from a parent/GP/responsible clinician/the chair of the DSMC;
 - Verbally, by phone or in person, or
 - by email

In both cases, the Unblinding Request Form (URF) must be sent per email to; bariatrics.resurge@mmc.nl

2. Team member in receipt of the request (if not PI/Delegate) contacts the PI/Delegate to advise. Email correspondence (including URF) received from the requestor should be forwarded to the contacted PI/Delegate for their information.
3. PI/Delegate considers the request
4. If it is agreed that unblinding is not necessary, the PI/Delegate advises the requester and complete a '*note to file*' documenting the exchange.
5. If the PI/Delegate agrees unblinding is appropriate, unblinding will proceed. The PI/Delegate will directly access the webpage of Research Manager.
6. Once unblinding has occurred the PI/Delegate will then advise the requestor.
7. The PI/Delegate will ensure that the Unblinding Request form is added to the Trial Master File.
8. The PI/Delegate will state in the eCRF that there was a request for unblinding and weather this unblinding occurred.
9. The PI/delegate will inform the DSMC about the request for unblinding and weather the unblinding occurred.
10. The PI/delegate will report, in case the reason for unblinding is a SAE, this SAE in ToetsingOnline.