

Begin forwarded message:

**From:** "IP GROOT BLUEMINK, Marjolein (HEALTH RESEARCH AUTHORITY)"  
**Subject:** RE: DALES 232512  
**Date:** 15 May 2018 at 11:57:04 BST  
**To:** "SAVIC, Louise (LEEDS TEACHING HOSPITALS NHS TRUST)"

Dear Louise

Thank you for your email.

We would not expect the IRAS Form to be updated except under very specific circumstances (e.g. change in radiation, using tissue samples for the first time or a change to CI or Sponsor). The Protocol with the correct wording has already been approved so does not require submission. Please therefore advise sites of the discrepancy to avoid any confusion.

Many thanks

Maeve

Maeve Ip Groot Bluemink  
Assessor  
Health Research Authority

W. [www.hra.nhs.uk](http://www.hra.nhs.uk)

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-----Original Message-----

**From:** SAVIC, Louise (LEEDS TEACHING HOSPITALS NHS TRUST)  
**Sent:** 15 May 2018 11:07  
**To:** IP GROOT BLUEMINK, Marjolein (HEALTH RESEARCH AUTHORITY)  
**Subject:** DALES 232512

Dear Maeve,

We have had a number of queries from sites asking about the timing of data collection. The IRAS form states that the 3 collection days need to be consecutive, but in fact they can be NON-consecutive, as detailed in the approved protocol V3.4. Are you happy with this discrepancy or would you prefer us to amend the IRAs form accordingly?

Best wishes,

Louise